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Safety and efficacy of poly(methyl methacrylate), hydrophobic acrylic and hydrophilic acrylic intraocular lenses: A comparative clinical investigation

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ABSTRACT

Objectives: Cataract surgery is a prevalent procedure for restoring vision in patients with cataracts. Intraocular lens (IOL) material selection significantly impacts outcomes. This study aimed to assess the safety and efficacy of poly(methyl methacrylate) (PMMA), hydrophilic, and hydrophobic IOLs in cataract surgery. The primary objective was to assess intraoperative safety and IOL performance. The secondary objective was to determine lens-related adverse events and visual acuity.

Materials and Methods: This prospective clinical study included adult cataract patients undergoing IOL implantation at a single centre in India. Exclusion criteria included patients unwilling to participate, with previous intraocular or corneal surgery, traumatic cataract, pregnancy or lactation, concurrent participation in other drug or device investigations, unstable keratometry or biometry measurements, or irregular astigmatism. Patients with glaucoma and retinal disorders were also excluded. The study duration was one year with five follow-up visits. For the PMMA, hydrophilic, or hydrophobic IOLs 331, 340 and 330 eyes from 331, 340 and 330 patients were included respectively for the study. Intraoperative safety and performance were assessed through documented adverse events. Visual outcomes were evaluated at each visit using visual acuity measurements, slit-lamp examination, and intraocular pressure measurement.

Results: No significant intraoperative complications or safety concerns were reported. There were no observed cases of IOL decentration, tilt, dislocation, discoloration, or opacity. Both distance uncorrected and distance best-corrected visual acuity (BCVA) showed significant improvement from baseline to the final visit in all groups.

Conclusion: PMMA, hydrophilic, and hydrophobic IOLs demonstrated good safety and efficacy in cataract surgery, with significant improvement in visual acuity and no lens-related adverse events reported in this study.

Keywords: Cataract surgery, Intraocular lens, Poly(methyl methacrylate), Hydrophilic intraocular lens, Hydrophobic intraocular lens, Visual acuity

INTRODUCTION

Cataracts, which involve the clouding of the eye's natural lens, lead to substantial visual impairment and often require surgical treatment. Cataract surgery entails the replacement of the clouded lens with an intraocular lens (IOL), thereby restoring vision and enhancing the patient's quality of life. Choosing the optimal IOL material is vital for achieving successful outcomes, considering factors such as biocompatibility, intraoperative safety and long-term visual function.[1-3]

Modern cataract surgery typically employs phacoemulsification and the implantation of an IOL into the capsular bag. Surgeons have access to a range of IOL types, including monofocal, multifocal, accommodating and toric lenses. Efforts are focussed on minimising potential post-surgical complications such as posterior capsule opacification (PCO), lens dislocation, cystoid macular oedema, and endophthalmitis to address the growing demands of an ageing population.[3-6]

At present, various IOL materials and designs are available, including hydrophobic acrylic, hydrophilic acrylic, silicone and poly(methyl methacrylate) (PMMA). These IOLs can have aspheric or non-aspheric designs and can be positioned in either the anterior or posterior chamber. They can also be

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one-piece or three-piece designs and can be placed either in the capsular bag or fixed in the sulcus. Hydrophobic acrylic IOLs are designed to prevent hydration from affecting the lens post-implantation and are the most widely used material. Their stability within the eye is attributed to this hydration resistance. Early concerns about calcification and opacification limited the acceptance of hydrophilic acrylic IOLs. Silicone IOLs are known for their resistance to PCO but have a three-fold higher risk of serious infection compared to acrylic IOLs.[6] In addition, they are not recommended for high myopia due to an increased risk of vitreoretinal pathology and the potential need for silicone oil.[2,3,5,7,8]

PCO is the most prevalent complication of cataract surgery and can impair vision. IOLs with sharp-edged designs have a lower incidence, with continuous 360° square edges being more effective than square edges interrupted at the optic-haptic junction. PMMA IOLs exhibit higher rates compared to acrylic or silicone IOLs.[1,8,9]

MATERIALS AND METHODS

Objectives

Primary objective: The primary objective of the study is to assess the intraoperative safety and performance of the IOL. Secondary Objective: The secondary objective of the study is to determine the presence of lens-related adverse events/ residual risks in the individuals on whom the device was implanted.

This prospective clinical study evaluated the safety and efficacy of PMMA, hydrophilic and hydrophobic IOLs implanted in adult cataract patients. For the PMMA lens implantation, manual small incision cataract surgery (MSICS) was performed. The hydrophilic and hydrophobic IOLs were implanted after phacoemulsification. The study was conducted in an eye hospital run by a trust. The study duration was 1 year with five follow-up visits. The Institutional Ethics committee approved the study.

PMMA lens consists of aspheric, spheric, and 360° square edge designs. The square edge design can arrest lens epithelial cell growth and migration of cells. The aspheric design suits the majority of the global population, enhancing contrast sensitivity and reducing the chances of PCO. In this clinical investigation, PMMA spherical with model no: 10380, Optic Diameter: 6.00 mm, Overall Length: 12.50 mm and with 2 dialling holes were used.

Hydrophilic IOL similarly consists of aspheric, spheric and 360° square edge designs. In this clinical investigation, hydrophilic IOL spherical with model no: 20380, optic diameter: 6.00 mm, overall length: 12.50 mm and double haptic design were used.

Hydrophobic IOL also consists of aspheric, spheric and 360° square edge designs. In this clinical investigation, hydrophobic IOL spherical with model no: 40492, optic diameter: 6.00 mm, overall length: 13.00 mm and muscle haptic were used.

There were five follow-up visits after the implantation of IOL: 1st visit - after 2 days of surgery, 2nd visit - after 2 weeks of surgery, 3rd visit - after 2 months of surgery, 4th visit - after 6 months of surgery and 5th visit – after 1 year of surgery.

Inclusion criteria

1. Adult subjects who have already undergone cataract surgery using IOL
2. Calculated IOL power is within the range of the investigational IOL (6.0–35.0 Dioptre)
3. Subjects are available after contact and willing to come for follow-up during the clinical study.

Exclusion criteria

1. Patients who decline to participate in the study
2. Subject with previous intraocular or corneal surgery
3. Subject having traumatic cataract
4. Pregnancy or lactation
5. Simultaneous involvement in another drug or device trial
6. Instability of keratometry or biometry measurements
7. Irregular astigmatism.
8. Glaucoma
9. Retinal disorders.

Methods

The IOLs were implanted by the MSICS for the PMMA lens and phacoemulsification for the hydrophobic and hydrophilic lens. Different surgeons performed the surgeries.

The MSICS was performed as follows:

1. Exposure and Preparation: Peritomy was performed, followed by cautery.
2. Access Creation: A superior scleral tunnel was created, and a side port was established. Paracentesis was performed, and the anterior chamber was filled with viscoelastic material after trypan blue staining.
3. Capsule Management: An anterior continuous curvilinear capsulorhexis (CCC) was created.
4. Nucleus Removal: Hydrodissection was performed, and the cataract nucleus was extracted using a vectis.
5. Lens Implantation: Irrigation and aspiration were performed to remove cortical matter. An IOL was implanted.
6. Closure and antibiotic prophylaxis: The anterior chamber was washed with a balanced salt solution (BSS), and the wound and side port were hydrated. Subconjunctival injection of gentamicin and dexamethasone was administered.

The phacoemulsification was performed with the following steps:

Phacoemulsification steps

1. Incision and access: A temporal clear corneal incision was created with a tunnel and a side port. Paracentesis was performed, and the anterior chamber was filled with viscoelastic material.
2. Capsule management: An anterior CCC was created.
3. Nucleus removal: Hydrodissection was performed, and the cataract nucleus was emulsified using phacoemulsification.
4. Lens implantation: Cortical matter was removed through irrigation and aspiration using a bimanual technique. The IOL was implanted.
5. Closure and antibiotic prophylaxis: The anterior chamber was washed with BSS, and the tunnel and side port were hydrated. Subconjunctival injection of gentamicin and dexamethasone was administered. Intraoperative Safety and Performance: It was assessed through case report forms (CRFs) documenting any adverse events during surgery.
    - Visual Outcome and Performance: Evaluated at each visit using CRFs, including:
        - UNDVA (Uncorrected distance visual acuity)
        - BCDVA (Best corrected distance visual acuity)
        - Subjective Refraction
        - IOL Tilt and Decentration
        - Slit Lamp Examination
        - Fundus examination with dilated pupil
        - Keratometry
        - Intraocular pressure (IOP).

Subjects

For the PMMA, hydrophilic or hydrophobic IOLs, 331, 340 and 330 eyes from 331, 340 and 330 patients were included, respectively, for the study.

RESULTS

Table 1 depicts the number of eyes that were studied under each group for their safety and efficacy.

Primary endpoint (intraoperative safety and performance)

There were no significant intraoperative complications or safety concerns reported. The corneal status was normal in all the subjects. There was no inflammation, cystoid macular oedema, endophthalmitis, pupillary block or retinal detachment in any of the subjects. The posterior capsule was intact in all the subjects. No new risks, safety-related issues or adverse events were reported.

Table 1: Study population.

IOL material	Study population	Screen failure	Drop out	Number studied
PMMA	350	-	19	331
Hydrophilic	343	3	-	340
Hydrophobic	340	10	-	330

IOL: Intraocular lens, PMMA: Poly (methyl methacrylate)

With respect to the performance, there was no IOL decentration, tilt, dislocation, discolouration or opacity in any of the study subjects.

Secondary endpoint (visual acuity and lens-related adverse events)

Both UNDVA and BCDVA showed significant improvement from baseline to the final visit. These are depicted in Tables 2 and 3.

Mean IOP remained within the normal range throughout the study, as depicted in Table 4.

Keratometry readings indicated no significant changes in corneal curvature post-implantation, as seen in Table 5.

DISCUSSION

Cataracts are the leading cause of blindness globally., affecting a significant number of individuals. The IOL material has the greatest impact on adverse events such as PCO, anterior capsule opacification, and glistening formation following cataract surgery.[2,5,10,11]

IOLs have advanced over time, and the gold standard for an ideal lens is defined by its biocompatibility, compatibility with surgical techniques and freedom from optical defects. Modern IOLs have made advancements in terms of material chemistry and design, leading to improved performance and outcomes.[3,5]

PCO is a frequent complication following cataract extraction, occurring in up to 50% of cases. The study by Mudhol *et al*. aimed to compare the effectiveness of square-edge and conventional round-edge IOLs in preventing PCO and enhancing visual outcomes in MSICS. While the incidence of PCO was similar between the two groups, incomplete cortical cleanup was linked to a higher rate of severe PCO. However, the square-edge IOL group demonstrated better visual outcomes, with a greater percentage of patients achieving good visual acuity.[12] None of the subjects had a PCO in this study in the follow-up period.

The study by Cochener *et al*. assessed the progressive contraction of the anterior capsule opening following in-the-bag implantation of two types of IOLs – PMMA and silicone. Both silicone and PMMA IOLs exhibited capsule contraction, but the contraction rate was statistically

Table 2: UNDVA and BCDVA mean values amongst the study groups.

IOL material	VAS	Pre-visit	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
PMMA	UNDVA (mean value)	24.33	63.78	70.43	73.63	75.04	76.25
	BCDVA (mean value)	30.33	75.6	91.46	95.22	97.5	98.08
Hydrophilic	UNDVA (mean value)	41.1	67.54	77.13	82.72	83.53	83.81
	BCDVA (mean value)	56.71	79.96	95.69	97.93	99.22	99.36
Hydrophobic	UNDVA (mean value)	40.98	68	79.38	82.5	83.5	83.84
	BCDVA (mean value)	56.31	80.86	95.35	98.42	99.39	99.45

IOL: Intraocular lens, PMMA: Poly (methyl methacrylate), UNDVA: Uncorrected distance visual acuity, BCDVA: Best corrected distance visual acuity, VAS: Visual acuity score

Table 3: LogMar values of UNDVA and BCDVA amongst the study groups.

Material	VAS	Pre-visit	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
PMMA	UNDVA LogMar	1.51	0.72	0.59	0.53	0.5	0.48
	BCDVA LogMar	1.39	0.49	0.17	0.1	0.05	0.04
Hydrophilic	UNDVA LogMar	1.18	0.65	0.46	0.35	0.33	0.32
	BCDVA LogMar	0.86	0.4	0.09	0.04	0.08	0.01
Hydrophobic	UNDVA LogMar	1.18	0.64	0.41	0.35	0.33	0.32
	BCDVA LogMar	0.87	0.38	0.09	0.03	0.01	0.01

PMMA: Poly (methyl methacrylate), UNDVA: Uncorrected distance visual acuity, BCDVA: Best corrected distance visual acuity, VAS: Visual acuity score

Table 4: Mean intraocular pressure amongst the study groups.

IOL material	Pre-visit	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
PMMA	13.58	16.56	12.42	12.15	11.67	13.28
Hydrophilic	13.36	15.34	12.3	12.07	11.86	13.39
Hydrophobic	13.24	15.23	12.27	12.55	12.42	13.04

IOL: Intraocular lens, PMMA: Poly (methyl methacrylate)

Table 5: Keratometry readings amongst the study groups.

IOL material	Pre-visit	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
PMMA						
K1	45.25	45.57	45.98	45.89	45.76	45.8
K2	44.61	57.06	44.3	44.57	44.5	44.54
K Mean	44.93	51.29	45.14	45.23	45.13	45.17
Hydrophilic						
K1	44.98	44.73	45.04	45.02	44.72	45.19
K2	44.52	44.21	44.41	44.28	44.58	44.67
K Mean	44.75	44.42	44.72	44.65	44.65	44.93
Hydrophobic						
K1	44.87	44.51	44.83	44.92	46.11	44.88
K2	44.44	44.51	44.42	44.4	44.43	44.59
K Mean	44.65	44.51	44.63	44.66	45.27	44.74

IOL: Intraocular lens, PMMA: Poly (methyl methacrylate), K stands for keratometry value

higher in the silicone group. The study found no significant difference in fibrosis or cellular response between the two groups. It underscores the need to evaluate factors such as biomaterial, size, IOL design and biocompatibility in comparative studies of single-piece IOLs to understand their impact on capsule contraction better. The findings provide valuable insights for clinicians in selecting the appropriate IOLs and surgical techniques to minimise the risk of anterior capsule contraction and PCO.[13]

Snowflake degeneration refers to the gradual opacification of PMMA IOLs, which can develop a decade or more after

implantation. This condition involves the central aggregation of deposits composed of IOL material. Al-Otaibi case report details a patient with late-onset optical opacification of a PMMA IOL, which was successfully diagnosed and treated, leading to improved best-corrected vision.[14] No case of such degeneration was evident in the present study.

The study by Kim and Shyn included 137 cataractous eyes from 108 patients who underwent phacoemulsification and IOL implantation. The eyes were randomly assigned to three groups based on IOL type: PMMA, silicone and soft acrylic. Biometric analysis and best corrected visual acuity (BCVA) measurements were conducted at 1, 3 and 6 months post-surgery. There are no statistically significant differences in BCVA amongst the three IOL types. In addition, there was no significant decentration or tilt of the IOLs, and anterior chamber depth (ACD) did not differ significantly amongst the IOL types. The study concluded that a well-constructed CCC and precise IOL implantation in normal capsular bags resulted in comparable ACD changes, IOL decentration and tilt and BCVA across silicone, PMMA and soft acrylic IOLs.[15]

The study by Hayashi *et al*. compared decentration and tilt between one-piece and three-piece PMMA IOLs implanted in the capsular bag after CCC. The one-piece IOL group exhibited significantly less decentration than the three-piece IOL group at 1 week, 1 month, 3 months and 6 months postoperatively. However, there was no significant difference in tilt between the two IOL types throughout the observation periods.[16] None of the eyes with the IOLs demonstrated any IOL decentration or tilt in the current study.

Panahi-Bazaz *et al*. compared the use of hydrophilic acrylic and PMMA IOLs in paediatric cataract surgery and found that hydrophilic acrylic IOLs had comparable biocompatibility and visual outcomes to PMMA IOLs but had fewer post-operative complications.[17]

The study by Gozum *et al*. compared visual functions following cataract surgery and IOL implantation using different lens materials (acrylic and PMMA) with those of age-matched subjects with clear phakic eyes. Acrylic IOLs demonstrated superior visual quality in pseudophakic eyes compared to PMMA IOLs.[8] The present study showed similar improvements in visual quality.

The meta-analysis by Zhao *et al*. comparing hydrophobic and hydrophilic IOLs in preventing PCO after cataract surgery found that hydrophobic IOLs were linked to lower neodymium-doped yttrium aluminium garnet laser capsulotomy rates compared to hydrophilic lenses. In addition, hydrophobic IOLs were associated with lower subjective and estimated PCO scores.[18]

The study by Johansson *et al*. assessed the visual, refractive and safety outcomes of a hydrophilic acrylic IOL in cataract patients with or without pre-existing ocular pathologies. After 12 months, 95% of eyes achieved monocular corrected distance visual acuity (CDVA) of 0.3 logMAR or better, with a mean post-operative CDVA of 0.06 ± 0.17 logMAR and a mean UNDVA of 0.31 ± 0.29 logMAR. Visual acuity outcomes significantly improved post-surgery compared to pre-operative values, and the IOL remained stable in the capsular bag.[19] The findings are similar to the current study.

The study by Zacharopoulos *et al*. evaluated the safety and efficacy of a hydrophilic acrylic IOL over a 2-year follow-up period. The results demonstrated excellent optical performance, good centration and a low rate of intra- and post-operative complications. However, the incidence of PCO increased significantly over time, with 77% of eyes exhibiting some degree of PCO by the end of the 2nd post-operative year.[20] Although there was no follow-up for 2 years, the present study showed no intra and post-operative complications and no PCO development in the follow-up period.

The study by Van Der Linden *et al*. compared the outcomes of a new apodised diffractive hydrophilic multifocal IOL with a well-established apodised diffractive hydrophobic multifocal IOL. It found that the mean UNDVA was not significantly different between the two groups, but the CDVA was significantly better with the new study lens.[21]

The study by Koshy *et al*. found that both hydrophilic and hydrophobic IOLs performed comparably in terms of capsular bag performance and PCO development, with no significant differences between the two groups. Both IOL types demonstrated good capsular bag performance and low PCO rates within the first 2-year post-surgery, and there was no statistically significant difference in PCO scoring between the groups. Intraoperative complications included a capsular tear in the hydrophobic IOL group and damage to the haptics of the IOL in the hydrophilic IOL group.[22]

The PMMA design used in this study is more prone to risk compared to other designs, making it the bottom design in the PMMA product line. However, the clinical investigation conducted for the product PMMA lens spherical did not pose any risk or side effects such as vision loss, wound leakage, corneal oedema, blurred vision, inflammation, posterior capsule rent during the surgery and post-surgery in any subjects participating in this study. Even though being the bottom-design product, the PMMA lens spherical model demonstrated the expected safety and performance through the clinical investigation performed, which in turn substantiated the same outcomes for aspheric and 360° square edge designs.

Although double haptic design in hydrophilic lens offers better stability and centration, it is more prone to risk compared to other designs, making it the bottom design

in the hydrophilic product line. However, the clinical investigation conducted for the product hydrophilic IOL-spherical did not pose any risk or side effects during the surgery and post-surgery in all the subjects participating in this study. Even though being the bottom-design product, hydrophilic IOL spherically demonstrated the safety and performance through the clinical investigation performed which in turn substantiate the same outcomes for aspheric and 360° square edge designs.

The design for the hydrophobic lens in this study was chosen as it is comparatively produced and sold in larger numbers compared to others. Even though being the bottom-design product, hydrophobic IOL spherically demonstrated the safety and performance through the clinical investigation performed which in turn substantiate the same outcomes for aspheric and 360° square edge designs.

The current clinical investigation undertaken demonstrates the safety and efficacy of PMMA, hydrophilic and hydrophobic IOLs in improving vision in cataract patients. The findings are consistent with established literature regarding their biocompatibility and durability. While various studies have had episodes of intra and post-operative complications, the current clinical evaluation performed has no such events recorded. There was significant improvement in the visual outcomes without any adverse events.

Study limitations

While the study provides valuable insights into the safety and efficacy of different IOL materials, several limitations need to be considered:

Study design limitations

- Limited IOL Designs: The study focussed on spherical designs for PMMA, hydrophilic and hydrophobic IOLs, limiting the generalisability of findings to other designs such as aspheric and square-edge
- Short Follow-up Period: The 1-year follow-up period might not be sufficient to assess long-term outcomes and complications, such as late-onset PCO or IOL-related complications.

Methodological limitations

- Different surgical techniques: The use of MSICS for PMMA and phacoemulsification for hydrophilic and hydrophobic IOLs introduces a potential confounding factor, as surgical techniques can influence outcomes
- Subjective Assessments: Reliance on subjective assessments such as visual acuity and patient satisfaction can introduce bias and variability in the results.

Generalisability concerns

- Patient population: The study population may not be representative of the entire cataract surgery patient population, limiting the generalisability of the findings
- IOL material focus: The study primarily focussed on IOL materials and designs, with limited information on other factors influencing outcomes, such as surgeon experience and patient characteristics.

Addressing these limitations in future research would strengthen the evidence base for IOL selection and optimisation of cataract surgery outcomes.

CONCLUSION

Modern IOLs aim to be defect-free, with materials and designs that minimise potential complications during and after surgery. The continuous evolution of IOLs has led to a wide variety of options, allowing surgeons to select lenses that are best suited to individual patient needs. This study contributes valuable data on the safety and efficacy of PMMA, hydrophilic and hydrophobic IOLs in cataract surgery. Choosing the optimal IOL material requires a comprehensive understanding of individual patient needs, preferences and risk factors. Continued research is crucial to evaluate emerging IOL materials further.

The purpose of conducting a clinical study is crucial for ensuring the safety and efficacy of medical devices in accordance with current regulations and standards. A well-executed clinical evaluation provides essential information for decision-making. Manufacturers must systematically collect, analyse and report safety and performance data from real-world use of the device in humans. In this context, the clinical investigation contributes valuable real-life data for the IOLs assessed in this study.

Ethical approval

The research/study was approved by the Institutional Review Board at Divyajyoti Trust Tejas Eye Hospital, number ECR/942/Inst/GJ/2017, dated November 15, 2021.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Vatva, Ahmedabad, Gujarat 382445, India. SHARPVIEW® brand of PMMA IOL, CLEARVIEW™ brand of Hydrophilic IOL and HEXAPHOB® brand of Hydrophobic IOL of the sponsors were used in this clinical investigation.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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