

Clinical Profile and Refractive Outcomes of Medennium Phakic Intraocular Lens (MPL) Implantation: A Prospective Case Series

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ABSTRACT

Background: This study aims to report the clinical profile and refractive results of Medennium Phakic Intraocular Lens (MPL) in patients with mild to high myopia who are not suitable for laser refractive correction. **Methods:** This prospective, single-centre case series included patients who underwent MPL implantation at IIUM Eye Specialist Clinic from February to August 2024. Manifest refraction, uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), intraocular pressure, and endothelial cell density were analysed at 1 month after surgery. Complications during the intraoperative and postoperative periods were also recorded. **Results:** This study included 30 eyes from 15 patients, with a mean age of 30.2 ± 5.23 years. The spherical equivalent of manifest refraction was -10.01 ± 3.99 diopters (D) (range: -3.63 to -18) preoperatively and 0.02 ± 0.57 D (range from +1.25 to -1.13) at 1 month. Postoperative uncorrected visual acuity (UCVA) of logMAR 0.5 achieved in 1 eye (3%), 0.2 in 5 eyes (17%), 0.1 in 6 eyes (20%) and 0.0 in 18 eyes (60%). Factors contributing to suboptimal outcomes included residual astigmatism, amblyopia and monovision correction. No intraoperative complications occurred. Postoperative complications include high intraocular pressure (2 eyes), glare (2 eyes) and a statistically significant reduction in mean endothelial cell counts at 1 month ($p=0.045$). **Conclusion:** MPL implantation demonstrates effective refractive outcomes in the treatment of myopia at one month. However, due to a small sample size and short follow up, further studies is required to assess its long-term safety and efficacy.

Keywords:

phakic intraocular lens; refractive outcomes; high myopia; case series

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INTRODUCTION

Myopia is the most common refractive error affecting both children and adults worldwide (Durajczyk et al., 2021). It is the second leading cause of blindness worldwide (Holden et al., 2015). The prevalence of myopia has risen steadily over recent decades and is projected to affect nearly 50% of the world population by 2050, including in Southeast Asia (Holden et al., 2016). Myopia is generally classified as mild (-0.50 D to -3.00 D), moderate (-3.00 D to -6.00 D), and high myopia (≥ -6.00 D). The conventional non-surgical correction of myopia includes spectacles and contact lenses, which remain the standard treatment options (Ang & Wong, 2020). For patients with stable refractive error seeking long term correction, surgical management may be considered.

There are three principal surgical approaches, including

laser refractive surgery, phakic intraocular lens (IOL) implantation, and refractive lens exchange. Among these three options, phakic intraocular lens has emerged as an effective alternative, particularly for patients with moderate to high myopia who may not be suitable for corneal refractive surgery due to thin corneas, high refractive error or risk of postoperative ectasia (Jonker et al., 2020). Unlike refractive lens exchange and laser refractive surgery, phakic IOL implantation is a reversible procedure. It also preserves the natural crystalline lens and patient's accommodation. Hence, for younger patients, implanting phakic IOL is a reasonable option.

Phakic intraocular lens implantation for correction of myopia has been started since 1953 by Strampelli (Jonker et al., 2020). Although the refractive outcome was promising, there were reported complications including cataract formation, endothelial cell loss, elevated

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intraocular pressure, pigment dispersion, pupillary block, and vault-related complications (Jonker et al., 2020). These concerns have driven the development of newer generation phakic intraocular lens to improve intraocular biocompatibility and long-term safety such as the Medennium Phakic Intraocular Lens (MPL; Medennium Inc, California, United States, CE 0459, GC4247923-154518).

Medennium phakic intraocular lens is the newly available phakic lens in Malaysia, featuring plate haptics for sulcus support. Its self-centering and self-buoyant design allow it to float within aqueous humour. This feature is intended to optimise vault predictability and reduce the risk of touching with surrounding structures such as crystalline lens and iris. It is made from hydrophobic silicone to minimize mechanical irritation. Unlike other phakic lens, MPL is available in only two sizes, MPL 100 and MPL 101, which simplifies the selection process using standard white-to-white measurements. Despite increasing interest in this newer phakic intraocular lens in our market, evidence regarding the safety, efficacy and long-term stability of the MPL remains scanty.

This prospective, interventional case series represents the early clinical experience in Malaysia. We aim to report on the clinical profile and refractive outcomes of Medennium Phakic Intraocular Lens (MPL) that were implanted in our patients, specifically focusing on patient's demographic, visual outcomes, refractive predictability, and its safety.

MATERIALS AND METHODS

Study design

A prospective case series of patients who underwent MPL implantation at IIUM Eye Specialist Clinic from February to August 2024 was undertaken. Patient demographic data, preoperative and postoperative uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), subjective refraction, optical biometry, intraocular pressure, and corneal endothelial cell density were collected.

Inclusion and exclusion criteria

Patient who included in the study met the following criteria: age ≥ 18 years old, stable refractive error (refractive change ≤ 0.50 D in past year), cylinder power ≤ 2.0 diopters, anterior chamber depth ≥ 3.0 mm, endothelial cells count ≥ 2000 , intraocular pressure < 20 mmHg and keen for MPL implantation for refractive correction. Exclusion criteria were previous intraocular surgery, glaucoma, cataract, active ocular infection and anterior chamber depth < 3.0 mm.

Clinical examination

All patients had a complete preoperative ophthalmic examination, including slit lamp microscopy for anterior segment assessment, applanation tonometry for intraocular pressure measurement, indirect ophthalmoscopy for posterior segment status, corneal topography, pachymetry, optical biometry and specular microscopy. Manifest and cycloplegic refraction was performed by optometrist. Uncorrected and spectacle-corrected visual acuity was performed using MS Smart System 20/20 (M&S Technologies, USA). The optical biometry was performed using IOL Master 700 (Zeiss, Germany). Endothelial cell count was taken using Konan Specular Microscopy (Konan medical, Japan).

The MPL with appropriate power was calculated by furnishing the required parameters from IOL Master data to the company. The lens power was calculated based on formula which included data of patient's axial length, anterior chamber depth, manifest refraction and keratometry value. The type of MPL implanted will be determined by patient's white-to-white parameter measured, either MPL 100 (WTW < 11.3 mm) or MPL 101 (WTW ≥ 11.3 mm) measured from IOL Master 700 (Zeiss, Germany).

Post operatively, patients will be reviewed at day 1, 1 week and 1 months. Patient safety and tolerability were evaluated at each follow up through objective clinical examinations including slit lamp examination, intraocular pressure, endothelial count, measurement of manifest refraction, UCVA and BCVA as well as active elicitation of patient-reported symptoms.

Surgical technique

All operations were performed by a single surgeon (K.K). Prior to the surgery, cyclopentolate 1% and phenylephrine 2.5% were used to dilate the pupil. MPL was implanted under intracameral anesthesia through a 3 mm clear temporal corneal incision. The anterior chamber was filled with a viscoelastic agent.

The lenses were manually loaded into the cartridge and implanted via injector. Both lens haptics were placed under the iris. Viscoelastic materials were removed from anterior chamber and exchanged with balanced salt solution. The corneal wound was self-sealing.

Postoperatively, the patient was given topical antibiotic and corticosteroid drops (Fluomethalone 0.1% and Moxifloxacin 0.5%) prescribed four times daily for 1 week and dose was tapered for another 4 weeks.

Statistical analysis

Statistical analysis was performed using SPSS software version 30.0 (SPSS Inc, Chicago, Illinois). Normality of data distribution was assessed using the Shapiro–Wilk test and analysed using paired *t*-test or Pearson correlation, when appropriate to assess differences in visual and adverse outcomes. Results were presented as mean $\pm$ standard deviation. *P* value <0.05 were considered statistically significant.

RESULTS

Patient demographics

A total of 30 eyes from 15 patients were included in the study. All patients were implanted with MPL lens. Preoperative ocular characteristics are summarized in Table 1. The patient's mean preoperative UCVA and postoperative UCVA were measured in logMAR.

Table 1: Demographic characteristics of patients

Characteristics	Result
Age (years)	30.2 $\pm$ 5.23
Gender	Male: 7 (46.7%) Female: 8 (53.3%)
Laterality	Right eye: 15 (50%) Left eye: 15 (50%)
Preoperative UCVA (logMAR)	1.39 $\pm$ 0.30 (range: 0.8-2.10)
Preoperative BCVA (logMAR)	0: 21 (70%) 0.1: 4 (13.3%) 0.2: 2 (6.7%) 0.3: 3 (10%)
Spherical equivalent (D)	- 10.01 $\pm$ 3.99 (range SE: -3.63 to -18.0) (range sphere: -3.0 to -18.0)
Astigmatism (D)	- 0.80 $\pm$ 0.54 (range: 0-1.75)
AXL at baseline (mm)	27.36 $\pm$ 2.47 (range: 23.62-32.37)
ACD at baseline (mm)	3.65 $\pm$ 0.25
CCT at baseline (μ m)	511 $\pm$ 39.78
WTW at baseline (mm)	12.0 $\pm$ 0.38 (range: 10.9-12.4)
Indication	
High myopia	10
Steep cornea	1
Low pachymetry	4

Refractive outcomes

Visual outcome

Postoperatively at 1 month, UCVA improved from 1.39 $\pm$ 0.30 logMAR preoperatively to 0.06 $\pm$ 0.08 logMAR. The BCVA of patient's at 1 month was summarised in Table 2.

Overall, at 1 month, 20 eyes (67%) maintained preoperative best corrected visual acuity, 5 eyes (17%) gained at least ≥ 1 line, 3 eyes (10%) reduce 1 line, 2 eyes (7%) reduce ≥ 2 lines. The patient who had reduce ≥ 2 lines was due to having minimal inflammation (1 eye) and received monovision treatment of 1.5 D (1 eye). Despite this, the above data indicates that MPL phakic IOL implantation not only effectively corrected refractive error but also maintained and improved visual function in majority of patients.

Table 2: UCVA and BCVA at baseline and 1 month

Characteristics (logMAR)	Number of eyes		
	BCVA at baseline	UCVA at 1 month	BCVA at 1 month
0	21 (70%)	18 (60%)	22 (73%)
0.1	4 (13.3%)	6 (20%)	5 (17%)
0.2	2 (6.7%)	5 (17%)	3 (10%)
0.3	3 (10%)	-	-
0.5	-	1 (3%)	-

Refractive accuracy

The mean spherical equivalent improved from -10.0 $\pm$ 3.99 Diopter (D) preoperatively to 0.02 $\pm$ 0.57 Diopter (D), *p* value <0.001 . The predictability of the procedure was high, with 16 (53%) of eyes within ± 0.50 D and 11 (37%) within ± 1.00 D of the target refraction. However, 3 (10%) eyes were within ± 2.00 D target. The mean residual astigmatism remained 0.71 $\pm$ 0.50 Diopter (D) (range: 0 to -1.75), *p* = 0.291.

Complications

Endothelial count

The mean endothelial count preoperatively was 2855 $\pm$ 220 (cells/mm²) and 1 week was 2739 $\pm$ 363 (cells/mm²) with correlation (*r* = 0.358), 4% reduction, *p* = 0.084. While mean endothelial count at 1 month was 2708 $\pm$ 368 (cells/mm²) with correlation (*r* = 0.229), 5.1% reduction, *p* = 0.045.

Table 3: Endothelial count at baseline and 1 month

Characteristics	Result	
	Baseline	1 month
Mean endothelial count (cells/mm ²)	2855 ± 220	2706 ± 387

Intraocular pressure

The mean intraocular pressure preoperatively was 11.9 ± 2.3 mmHg and 1 week was 15.9 ± 2.7 mmHg, $p < 0.001$. While mean intraocular pressure at 1 month was 16.79 ± 2.9 mmHg, $p < 0.001$. A transient rise in IOP (>21 mmHg) was observed in both eyes of similar patient (6.7%), which was controlled with topical medication. No cases of persistent ocular hypertension or secondary glaucoma were noted.

Other complications

No intraoperative complications were reported. Post operatively, 2 eyes experienced glare which was tolerable, 1 eye had mild anterior chamber inflammation during early postoperative period, which resolved with topical corticosteroid. At 1 week and 1 month, no eyes reported experienced cataract formation, IOL decentration, rotation or pupil ovalization.

DISCUSSION

In this study, we evaluated the refractive outcomes and safety profile of MPL phakic intraocular lens implantation. Our results suggest that MPL implantation is suitable for patients with mild to high myopia, providing predictable refractive correction and visual improvement. We observed that 90% of eyes achieved a postoperative spherical equivalent within ±1.00 D of the intended target refraction, which is consistent with outcomes reported in previous studies (Jongsareejit, 2006). Residual astigmatism, monovision correction and existing amblyopia were identified as contributing factors to suboptimal outcomes. This is an important limitation to current lens design, as the absence of a toric option prevents direct correction of pre-existing corneal astigmatism. These factors may limit functional visual improvement despite accurate refractive correction. Thus, meticulous preoperative counseling is essential, including clear addressing of patient expectations and potential visual limitations, alongside careful patient selection.

Previous reports have described complications associated with phakic IOLs, including elevated intraocular pressure,

halos, cataract formation, endothelial cell loss, and pigmentary dispersion (Jonker et al., 2020; Stein & Stein, 2023; Jongsareejit A, 2006; Verdeet al., 2007; Hoyoset al., 2002; Pérez-Cambrodíet al., 2013). In our study, we observe clinically significant endothelial cell changes and slightly increase in intraocular pressure at 1 month. This is consistent with previous finding by Subudhi et al. They found a significant reduction in the endothelial cell count at the end of 1 month. However, the endothelial cell count was found to remain stable with no significant reduction at the end of 12 months. Nevertheless, the observed early endothelial cell loss should be interpreted with caution as postoperative corneal changes, measurement variability, and transient surgical trauma may have contributed to the apparent reduction. Further studies with longer follow up are warranted. As for high intraocular changes, Jongsareejit also reported similar finding at 1 month and the pressure returned to preoperative level at 3 months. Hence, close monitoring is important.

In this study, we did not encounter cataract formation or pigmentary dispersion. This difference is likely attributable to the relatively short duration of follow-up, as such complications often develop over longer periods. In addition, vault assessment and anterior segment imaging were not performed, limiting our ability to evaluate lens position, vault and cornea-lens-iris relationship which are important factors associated with cataract formation, pigment dispersion and other phakic IOL related complications. Therefore, although the short-term safety profile of MPL phakic IOLs appears favourable, these findings should be interpreted with caution. A continuous long-term monitoring is essential to detect delayed complications and to confirm the sustained efficacy of the lens. Future studies with extended follow-up will be necessary to fully establish the long-term safety, particularly regarding endothelial health, lens vault stability, and the potential for cataract development.

CONCLUSION

In summary, MPL phakic IOL implantation demonstrated acceptable early refractive accuracy with generally favourable short-term visual outcomes in the majority of eyes. However, endothelial cell loss, transient IOP elevation and reduction in best corrected visual acuity in a subset of eyes, together with methodological limitations including potential inter-eye dependence, require further evaluation. Longer-term follow-up is required to ensure continued safety and are needed before definitive comparisons with corneal refractive surgery can be made.

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