ORIGINAL RESEARCH PAPER
Volume - 13 | Issue - 10 | October - 2024 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

PUPIL EXPANSION DEVICE-A BOON IN SMALL PUPIL CATARACT SURGERY

Ophthalmology

Reshma Premanandan Junior Resident, Dept. Of Ophthalmology, Kles Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi. Karnataka, India.

Shivanand C. Bubanale* Professor, Dept. Of Ophthalmology, Kles Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi. Karnataka, India. *Corresponding Author

Bhagyajyothi B. K. Associate Professor, Dept. Of Ophthalmology, Kles Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi. Karnataka, India.

Shivanand B. Patil Professor, Dept. Of Ophthalmology, Kles Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi. Karnataka, India.

Keerti Manjunath Naik Junior Resident, Dept. Of Ophthalmology, Kles Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi. Karnataka, India.

ABSTRACT

Context: Cataract is the leading cause of moderate or severe vision impairment globally. The small, poorly dilated pupil is one of the most common difficulties faced by cataract surgeons. **Aims:** This study emphasises on the efficacy & safety of pupil expanders on small pupil in a phacoemulsification cataract surgery. **Settings and Design:** This prospective interventional non comparative study. **Methods and Material:** This prospective interventional non comparative study was approved by the local institutional ethical committee & written informed consent was obtained from 48 patients with small pupil of < 5mm & undergoing cataract surgery during the period of August 2023 to July 2024. **Results:** The mean patient age was 66.54 ± 9.22 years. The B HEX PED was successfully applied in all eyes. On Post operative day 1 the mean pupil diameter was 4.78 ± 0.44 mmHg and postoperative day 28 it was 3.55 ± 0.43 mmHg. 62.5% of cases had round pupil postoperatively on day 28. Major complication noted with PEDs was corneal edema in 35.42 % followed by iris bleeding and floppy iris while 52.08% had no complications. There was no significant difference in IOP on POD 1 and POD 28 compared to pre operative IOP. **Conclusions:** Small pupil is of the most important causes of intraoperative complications during cataract surgery. The PEDs safely and effectively provided and maintained adequate pupil expansion and surgical visualization in eyes with significantly reduced the chance of complications and increased the success rate of small pupil cataract surgery.

KEYWORDS

small pupil , pupil expansion device, cataract surgery, B hex ring.

INTRODUCTION

Small pupil is a well-known risk factor associated with numerous complications during and after cataract surgery. Literature states that small pupil cataracts accounted for about 11 percent of all cataract operations.[1] Most commonly pupil diameter less than 5 mm is considered as small however, there is a study that considered pupil diameter of 4 mm or less as small pupil.[2]

There are various causes for the small pupil during cataract surgery. The most common and important causes of small pupil include pseudoexfoliation syndrome (PXF), diabetes mellitus (DM), intraoperative floppy iris syndrome (IFIS), and iridoschisis. In PXF, pseudoexfoliative material within the iris stroma causes mechanical obstruction, which along with hypoxia due to vascular abnormalities, causes limited mydriasis.[3] Other causes includes prior trauma or surgery, uveitis, and chronic mitotic therapy for glaucoma.

Small pupil makes the surgery more difficult to perform and causes more postoperative damage response. The complications of small pupil include serious sight-threatening complications such as anterior and posterior capsule tears, iris trauma, dropped nucleus or intraocular lens, cystoid macular edema, and retinal detachment.[1]

Numerous pharmacologic and mechanical strategies have been developed to increase pupil size and optimize surgical visualization. One of the most important inventions in the history of mechanical pupil expansion was introduction of the iris hooks.[5] The sleeve of the hook is adjusted to expand the pupil to the desired size. The drawbacks of iris hook include iris sphincter tears and risk of bleeding. It could provide a pupil expansion over 5.0 mm in size to decrease the chances of iris tissue overstretching producing irregular and atonic pupils postoperatively. Pupil expansion devices(PEDs) are of different materials with advantage of different flexibilities and can be inserted through the main incision. They provide continuous dilatation and also protect the iris sphincter margin and prevent iris tearing or damage.[6]

Prevalence of small pupil in cataract is increasing over years. Lack of proper usage of equipment required for small pupil surgery as well as insufficient guidelines on how to utilize them signifies the need to undertake this study. Studies are also lacking on cataract in small pupil and the pupil expansion devices. This study emphasises on the efficacy & safety of pupil expanders on small pupil in a phacoemulsification cataract surgery.

Methodology

This prospective interventional non comparative study was approved by the institutional ethical committee & written informed consent was obtained from 48 patients with small pupil of < 5mm & undergoing cataract surgery during the period of August 2023 to July 2024. Primary inclusion criteria included eyes undergoing cataract removal that required application of a PED. Excluded were eyes with previous history of iris trauma, iris surgery, or iris laser treatment (i.e., peripheral iridotomy, laser pupilloplasty), prior use of PED or medications that may influence pupil size (i.e., pilocarpine, amphetamine), zonular weakness, and severely shallow anterior chamber depth (<2.0 mm as measured by optical biometry). In addition, eyes that required concomitant ocular surgical procedures (i.e., pars plana vitrectomy, glaucoma surgery, etc.) Phaco were also excluded.

A detailed clinic-demographic history on a predesigned proforma along with comprehensive eye examination was performed at the time of first visit. Eyes with surgical cataracts and non-dilating pupils (<5 mm) are evaluated for preoperative inclusion/exclusion criteria. Intraoperatively, the eyes were enrolled after failure to achieve pupil dilation of 5 mm or more with pharmacologic and mechanical maneuvers such as administration of topical and intracameral mydriatic agents and subsequently PEDs was inserted. Pupil Diameter in the various stages of the surgery and at the 1-month follow-up visit, and the postoperative pupil shape and irregularity were evaluated. Pupil Diameter was measured using Castroviejo calipers at 7 pre-defined time- points: (1) preoperative baseline, (2) after maximal preoperative dilation with topical mydriatics, (3) after intracameral dilation with epinephrine and OVDs, (4) following application of the

pupil expansion ring, (5) at the end of the surgery, following withdrawal of the ring, (6) post of day 1 , (7) at 1month postoperative visit (4 weeks).

In this study B-Hex was used as the pupil expansion device. It is preloaded in a transparent single-use carrier with an ergonomic handle which delivers the device sterile at the incision.

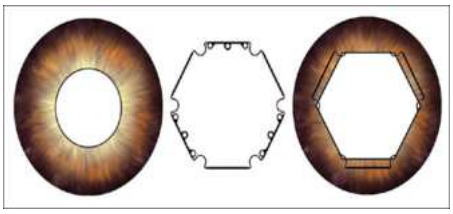

Fig 1: B HEX Ring

Surgical Technique:
All Phaco procedures were performed by one surgeon. A 1.5 mm or larger incision was placed on the steep axis, straddled by two side-port incisions 90 degrees away. Viscoelastic was injected under the pupil margin, and the anterior chamber was kept underfilled. Viscoelastic was also injected into the B-HEX housing. The ring was grasped at the median positioning hole on a flange with 23 G forceps and advanced inside the anterior chamber. Alternate flanges bearing holes were tucked under the iris. The manipulator was engaged in a mid-flange hole and a 23-gauge forceps was used to draw the flange centrally and tuck it under the pupil margin. A 5 mm capsulorhexis and nucleus disassembled into small fragments. The anterior chamber was kept formed with viscoelastic when the phaco or I/A probes exit the eye. A single-piece hydrophobic acrylic IOL was then injected into the bag.

The 23 G forceps were used to disengage a notch, the ring was then grasped and fished out of the main incision. Viscoelastic was removed thoroughly and an intracameral injection of antibiotics was given. The main incisions and side ports were hydrated. Postoperatively, slit lamp assessment was performed next day after surgery and repeated after 1 week and 1 month later. Topical steroids were prescribed starting 6 drops a day and tapered as usual. Intraocular pressure and pupil diameter was also assessed.

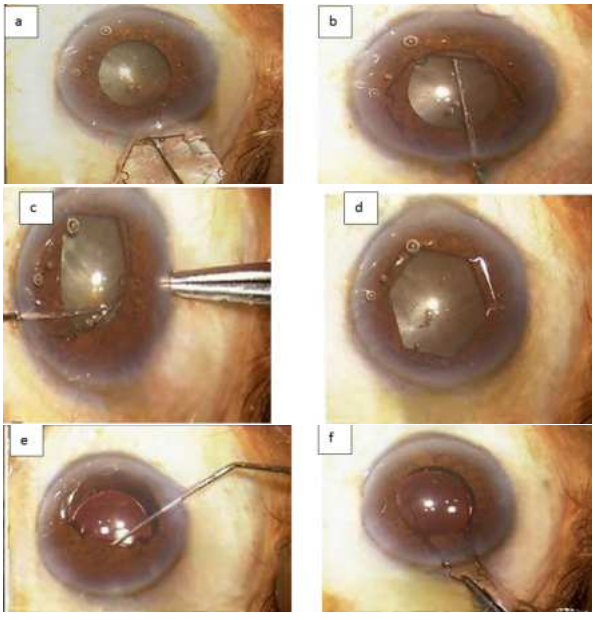

Fig 2 : Implantation of B-Hex ring in a case **Fig 2a :**Insertion of the B-Hex ring into the anterior chamber **Fig 2b :** Engagement of the first flange through the main port **Fig 2c :**Tucking of the second flange through the right side-port **Fig 2d :** B hex in situ **Fig 2e:** Disengaging a flange with notches **Fig 2f:** The B-Hex ring is pulled out from the main incision

Statistical analysis
Data is analysed using statistical software R version 4.3.2 and Microsoft Excel. Categorical variables given in the form of frequency tables. Continuous variables given in Mean ± SD / Median (Min, Max) form. Stuart Maxwell Test is used to compare the distribution of visual acuity over time. Normality of variable is checked by Shapiro Wilk test and QQ plot. Friedman test is used to compare the distribution of variables over time. Pairwise Wilcoxon test with Bonferroni adjustment is used as post hoc analysis. P-value less than or equal to 0.05 indicates statistical significance.

RESULTS
During the study period total 48 patients were enrolled in the study with mean age of 66.54 ± 9.22 years (47-85 years) & 54.17% were male patients. About 20 (41.67%) had diabetes and 24 (50%) had HTN. About 23 (47.92%) had diminution of vision in right eye and 25 (52.08%) had diminution of vision in left eye out of which Senile immature cataract (SIMC) was present in 35 (72.92%) subjects and Senile mature cataract (SMC) in 10 (20.83%) subjects and remaining contributed to 3 cases which included 1 Hypermature cataract (HMC) , 1 Posterior polar cataract (PPC) and 1 posterior subcapsular cataract (PSC). The pupil shape was irregular in 18 (37.5%) subjects and round in 30 (62.5%) subjects. (Table 1) Table 2 shows the visual acuity over time. From Stuart Maxwell Test, it is observed that there is significant difference in the distribution of visual acuity over time. Clearly, there is a noticeable improvement in visual acuity following the treatment. From Friedman test, it is observed that, there is significant difference in the distribution of IOP over time (p-value = 0.0008). Further, from post hoc analysis, it is observed that, there is significant difference in the distribution of pre-op IOP and POD 1 IOP (p-value = 0.0009). However, no significant differences are observed in the distribution of IOP on POD 28 compared to preop IOP (p-value = 0.1148) and POD 1 IOP (p-value = 0.1148). (Table 3) From Friedman test, it is observed that, there is significant difference in the distribution of pupil diameter over time (p-value < 0.0001). Further, from post hoc analysis, it is observed that, there is significant difference in the distribution of all pairs (p-value < 0.001) with the exception of Mydriatics and POD1 (p-value > 0.9999), as well as Device removal and Intracameral epinephrine (p-value > 0.9999). (Table 4)

Table 1: Patients demographics with risk factors & complications associated with small pupil cataract surgery

Socio-demographic Parameter		Frequency	Percentage
Gender	Male	26	54.17
	Female	22	45.83
Diabetes	No	28	58.33
	Yes	20	41.67
HTN	No	24	50.00
	Yes	24	50.00
Diminution of vision	Left Eye	25	52.08
	Right Eye	23	47.92
Pseudo exfoliation	No	34	70.83
	Yes	17	29.17
Diagnosis	SIMC	35	72.92
	SMC	10	20.83
	HMC	1	2.08
	PPC	1	2.08
	PSC	1	2.08
Complications	Corneal edema	17	35.42
	Floppy Iris	2	4.17
	Iris bleeding	4	8.33
Pupil shape	Irregular	18	37.5
	Round	30	62.5

Table 2: Distribution of visual acuity over time

Visual Acuity	Preop	POD 1	p-value
<6/60	35 (72.92%)	3 (6.25%)	**<0.001^{SM}***
6/60-6/36	8 (16.67%)	10 (20.83%)	
6/24-6/18	5 (10.42%)	15 (31.25%)	
6/12-6/9	0 (0.00%)	20 (41.67%)	

Table 3: Comparison of IOP over timepoints

Time	IOP		p-value
	Mean ± SD	Median (Range)	
Pre-op	14.46 ± 4.15	14.6 (7.1 - 23.4)	**0.0008^{F}***
POD 1	16.97 ± 5.28	17.55 (10.2 - 43)	
POD 28	15.79 ± 2.72	15.85 (10.2 - 20.3)	

Table 4: Comparison of pupil diameter at predefined study time points.

Time	Pupil diameter		p-value
	Mean ± SD	Median (Min, Max)	
Pre-op	2.35 ± 0.55	2 (1.5 - 3)	<0.0001[F]*
Mydriatics	4.92 ± 0.21	5 (4 - 5)	
Intracameral epinephrine	5.42 ± 0.3	5.5 (4.5 - 6)	
Device insertion	6.52 ± 0.25	6.5 (6 - 7)	
Device removal	5.4 ± 0.52	5.5 (4 - 6.5)	
POD 1	4.78 ± 0.44	5 (4 - 5.5)	
POD 28	3.55 ± 0.43	3.5 (3 - 4)	

DISCUSSIONS

Achieving the appropriate mydriasis is a cornerstone for successful cataract surgery providing favourable anatomical and functional results. Small pupil is a common challenging situation, and every cataract surgeon should be familiar with strategies to minimize the possible complications and to achieve best outcomes.[6] In cases with inadequate pupil dilation and/or poor capsular support, the potential for complication is significantly increased.[5] Inadequate preoperative mydriasis and/or intraoperative miosis might result in iris trauma and photophobia. Modern-day cataract surgeons have an armamentarium of assistive pupil expansion devices at their disposal. Gone are the days when sphincterotomies and key-hole iridectomy were inevitable for small pupils, as would the consequent glare and unhappiness.[7] The surgical algorithm in managing small pupil cases should include topical and intraocular mydriatics, appropriately selected viscosurgical device and mechanical dilatation with instruments, iris hooks, and/or pupil expanders.[4]

However, the impediment to the surgical manipulations is not the only issue in patients with small pupils. Inadequate pupil dilation is a symptom caused by various systemic and local comorbidities leading to blood-aqueous barrier disruption, degeneration and loss of biomechanical properties of the iris, lens capsule, and zonular fibers.[8] Our study enrolled patients with pupil dilation of 5 mm or less even after dilatation with pharmacologic agents. Akman et al. reported that eyes in which pupil size >3.5mm could not be achieved with pharmacological dilation may require mechanical dilation during cataract surgery.[9] For the past 2 decades, PEDs have become important components of the surgical tool kit for small pupil cataract surgery, especially as alpha-adrenergic antagonist agents have become more prevalent and cause not only inadequate pupillary dilation but also increased iris flaccidity, termed the intraoperative floppy iris syndrome (IFIS).[2] Consequently, multiple PEDs are currently available which includes 5S Iris Ring, Perfect Pupil, Graether Expander, Malyugin Ring, APX 200, Canabrava Ring, Bhattacharjee B-HEX Pupil Expander, I-Ring etc.

A total of 48 patients were enrolled in the study, spanning an age range from 47 to 85 years with mean age of 66.54. Out of 48 subjects, 54.17% were male and 45.83% were females. With a p value of 0.67, there was no statistically significant difference in the male to female ratio.

Although diabetes often causes abnormally small pupil in our study only 41.67 % had diabetic history as their systemic illness whereas patients with history of hypertension constituted for 50 %. The most common etiology of inadequate pupillary dilation was predictably PXF, as it was identified in almost 50% of eyes with small pupil.[10] However, inadequate pupil dilation was not very common in our patient population with PXF and was observed only in 29.17 % of the patients. Contrary to the present study, Drolsum et al. reported that small pupil occurred in 47% of their patient population with PXF and cataract. Nevertheless, they did not specify what size of pupil they count as "small pupil" in their study.[11] In cases with PXF, the pupils are rigid and dilate poorly and as a consequence poor visibility and zonular instability are quite common in them. In a review of literature by Anastasopoulos E et.al PXF is considered to be an absolute contraindication for multifocal lenses and a relative contraindication for the toric lenses due to the prospect of late decentration and tilt which would compromise the visual quality tremendously in multifocal and toric lenses.[12]

The most common complication in our study was post operative corneal edema seen in 35.4 % of patients. Higher incidence of endothelial damage with pupil expansion devices indicated that careful removal of the device should be a focus. When there has been a degree of manipulation of the iris during insertion or removal of pupil expansion device, floppy iris was seen as intraoperative complications. Postoperatively, the PEDs was not observed to have caused significant iris distortion, as pupil shape after surgery remained round in 62.5 % of cases with mean eccentric index approaching that of the perfectly circular pupil. The best corrected visual acuity was more than 6/18 in majority of patients showing there is a noticeable improvement in visual acuity following the treatment. In a case report by Tian et al.[13] small-pupil cataract surgery with the I-Ring resulted in less pupil distortion than when a Malyugin ring was used in the fellow eye of the same patient.[13] Inability of the pupil to return to its preoperative size has been observed after use of PEDs, as other studies utilizing various other PEDs documented postoperative pupil size increases of 0.64 to 1.1 mm in the study conducted by Harvey S Uy et al.[2] According to their study pupil size after surgery was also close to preoperative baseline pupil size, averaging only a 0.5 mm enlargement. Excessive postoperative pupil size is undesirable, leading to glare and negative dysphotopsias.

There is significant difference in the distribution of pre-op IOP and POD 1 IOP with p-value of 0.0009. However, no significant differences were observed in the distribution of IOP on POD 28 compared to preoperative IOP and POD 1 IOP. In this particular study, the average preoperative pupil size after mydriatic agent was 5mm and intraoperatively enlarged to 5.5mm with intracameral epinephrine and 6.5 mm after device insertion. In a study conducted by Salviat et al, B Hex ring was used and pupil size enlarged to 4.8mm following viscoelastic injection and 5.8mm after B hex insertion.[14] With the use of PEDs, there was improvement in best corrected visual acuity with no significant difference in IOP values and less complications noted during the study. This study also evaluated in detail important intraoperative and postoperative factors as well as visual outcomes, finding overall efficacy and safety of the device.

CONCLUSION :

Cataract surgery in small pupil patients presents challenges in the preoperative, intraoperative and postoperative settings. Innovations in surgical instruments and techniques may improve patient safety and suggest new treatment paradigms. Preoperative assessment and identification of patients with small pupils or at risk for miosis is important to take compensatory measures to keep the complication rate as low as possible and to achieve excellent visual outcomes. A variety of newest PEDs are available to cataract surgeons. They differ with the design and easiness of insertion and removal as well as the stability throughout the procedure. Most will provide wide and unobstructed access to the lens facilitating safe and effective cataract surgery.

REFERENCES

1. Flaxman SR, RRA B, Resnikof S, et al. Global causes of blindness and distance vision impairment 1990–2020: a systematic review and metaanalysis. Lancet Glob Health. 2017;5(12):e1221–34
2. Gimbel HV. Nucleofractis phacoemulsification through a small pupil. Can J Ophthalmol. 1992;27:115–9.
3. Hashemi H, Seyedian MA, Mohammadpour M. Small pupil and cataract surgery. Curr Opin Ophthalmol. 2015;26(1):3–9.
4. Malyugin B. Cataract surgery in small pupils. Indian J Ophthalmol 2017;65:1323-8
5. Goldman JM, Karp CL. Adjunct devices for managing challenging cases in cataract surgery: pupil expansion and stabilization of the capsular bag. Curr Opin Ophthalmol. 2007 Feb;18(1):44-51. doi: 10.1097/ICU.0b013e3280121b09. PMID: 17159447.
6. Hashemi H, Seyedian MA, Mohammadpour M. Small pupil and cataract surgery. Curr Opin Ophthalmol. 2015;26(1):3–9.
7. Sarosh R, Rashid O. B-Hex, an ace up the sleeve for small pupil phacoemulsification. Rom J Ophthalmol. 2022 Jan-Mar;66(1):61-68. doi: 10.22336/rjo.2022.13. PMID: 35531448; PMCID: PMC9022140.
8. Malyugin BE. Recent advances in small pupil cataract surgery. Curr Opin Ophthalmol. 2018 Jan;29(1):40-47. doi: 10.1097/ICU.0000000000000443. PMID: 29059105
9. Akman A, Yilmaz G, Oto S, et al. Comparison of various pupil dilatation methods for phacoemulsification in eyes with a small pupil secondary to pseudoexfoliation. Ophthalmology 2004; 111:1693–1698
10. Halkiadakis I, Chatziralli I, Drakos E, Katzakis M, Skouriotis S, Patsea E, Mitropoulos P, Kandarakis A. Causes and management of small pupil in patients with cataract. Oman J Ophthalmol. 2017 Sep-Dec;10(3):220-224. doi: 10.4103/ojo.OJO_102_2016. PMID: 29118499; PMCID: PMC5657166.
11. Drolsum L, Haaskjold E, Davanger M. Pseudoexfoliation syndrome and extracapsular cataract extraction. Acta Ophthalmol. 1993;71:765–70. [PubMed: 8154250]
12. Anastasopoulos E, Founti P, Topouzis F. Update on pseudoexfoliation syndrome pathogenesis and associations with intraocular pressure, glaucoma and systemic diseases. Curr Opin Ophthalmol. 2015;26:82–9. [PubMed: 25594764]
13. Tian JJ, Garcia GA, Karanjia R, Lu KL. Comparison of 2 pupil expansion devices for small-pupil cataract surgery. J Cataract Refract Surg 2016;42:1235-7.
14. Salviat F, Febbraro JL, Zuber K, Yavchitz A, Moran S, Gatinel D. Evaluation of a uniplanar pupil expansion ring in small-pupil cataract surgery: a feasibility study. Int Ophthalmol. 2022 Feb;42(2):489-496. doi: 10.1007/s10792-021-02065-9. Epub 2021 Oct 16. PMID: 34655377