The Next Gen. Pupil Dilating Device

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The pupil may not dilate resulting in poor visualization despite the use of pharmacological agents in diabetes, miotic use, pseudoexfoliation syndrome, uveitis, posterior synechiae, prior intraocular surgery etc.\textsuperscript{1,2,3} A small pupil can compromise visualisation during phacoemulsification and pars plana vitrectomy surgery.\textsuperscript{1-4} Phacoemulsification in eyes with small pupil is associated with increased incidence of iris trauma, capsule rupture, vitreous loss, nucleus drop, endothelial loss and zonular dehiscence.\textsuperscript{2,3,5}

A small pupil may also be due to Intraoperative floppy-iris syndrome (IFIS), characterised by billowing of iris, iris prolapse and progressive Intraoperative pupil constriction.\textsuperscript{6,7} Poor preoperative pupil dilation and elasticity of the pupil margin are often present.\textsuperscript{6} Strong relation has been found with α-1 adrenergic receptor antagonist (α-1 ARA) medications like Tamsulosin.\textsuperscript{6,7} Eyes with preoperative dilated pupil diameter of 7.0 mm or smaller, are at risk for IFIS regardless of α-1 adrenergic receptor antagonist (α-1 ARA) treatment.\textsuperscript{8,9}

The new design pupil dilating devices, referred to as ‘Bhattacharjee Ring’ in this study, available as a square and a hexagon (Madhu Instruments, New Delhi, India), were evaluated in a series of small pupil eyes.

MATERIALS AND METHODS

Ethical committee approval was obtained from Institutional board and informed consent was obtained from patients. The new device was used in 33 consecutive eyes with small pupil from January 2013 to August 2013. All eyes received a standard regimen of Tropicamide and Phenylephrine to dilate the pupils. Preoperative and postoperative pupil diameter was measured with the beam of the slit lamp placed horizontally. Eyes with preoperative dilated pupil diameter of 5.0 mm or smaller were included. When history of α-1 ARA intake was present or the other eye had Intra operative miosis or IFIS, eyes with 6.0 mm or smaller pupil, were also included.
The Bhattacharjee ring is a flexible closed ring made from a strand of 5-0 Nylon (Off label use, Ethilon, Johnson and Johnson Ltd.). It has notches at corners and flanges at sides, and is disposed entirely within a single plane. Alternate flanges are tucked under the pupillary margin so that the notches engage the pupillary margin at different parts, pushing them apart, resulting in sustained enlargement of the pupil. The device is available as a 6.5 mm and 7 mm Square and 6 mm and 7 mm Hexagon. The disposable ring is provided in an ETO sterilized pack. Square and Hexagon devices were used alternatively in consecutive eyes.

No Pupil stretching manoeuvres or sphincterotomies were performed. All surgeries were performed under topical anaesthesia. The horizontal white to white corneal diameter was measured with Castroviejo calipers. 6.5 mm Square and 6 mm Hexagon were used when the corneal diameter was less than or equal to 10 mm. Two 0.9 mm (20G) side – port incisions were made in all eyes. In the first 10 eyes the 2.2 mm clear corneal phaco incision was used to insert the device. In the next 10 eyes a 1.5 mm incision was used. In the remaining 13 eyes a 0.9 mm (20G) incision was used. These incisions were enlarged to 2.2 or 2.6 mm for phaco and further to 2.8 mm if required for IOL implantation. The anterior chamber was filled with viscoelastic. The device was held at the middle of a flange with a 23G straight forceps with serrated platforms (Joja Surgicals, Kolkata, India) and carried through the incision, and placed on the iris. The device took an elongated shape and notches straightened as they passed through and did not snag the incision. The flexible device regained its square or hexagon shape as soon as it was entirely in the anterior chamber. Alternate flanges were tucked under the iris bimanually, using the 23G forceps through one side port and an Iris hook or Kuglen hook through the other side port. The pupillary margin was thus engaged at the notches and it passed above and below alternate flanges. Phaco was performed using standard techniques using the chopper and second instrument wherever required. Bimanual irrigation aspiration was performed through the side-ports. Foldable IOLs were implanted under viscoelastic in all eyes. With the anterior chamber still filled with viscoelastic, a 23G forceps was inserted through the phaco incision or a side port, the flange anterior to the iris and closest, was held and moved towards the centre of the pupil and anteriorly to disengage the two notches at the ends of the flange, and the device was gently pulled out of the incision. The flexible device once again deformed easily and the notches straightened without snagging the incision during exit. Viscoelastic was removed and the incisions were hydrated.

The enlarged pupil’s size and capsulorhexis diameter was measured with an anterior chamber millimetre ruler inserted through an incision. The square or hexagon pupil was measured from side to side. Pupil shape after removing the
device and viscoelastic was noted. Accurate measurements were made later from stills obtained from videos using an on-screen digital calipers. Videos were analyzed to note ease of device insertion, engagement and removal. Videos were also used to note stability of the device, hindrance to passage of chopper and second instrument and IOL implantation. Intraoperative complications such as hyphema, posterior capsule tears, vitreous loss and sphincter tears were recorded. The IFIS severity was graded after removal of the device and during viscoelastic removal according to a scale proposed by Chang. Patients were examined on Postoperative day 1, day 7 and day 30. Postoperative pupil shape, size and transillumination defects were recorded to determine pupil and iris trauma.

**RESULTS**

The study included 33 consecutive eyes of 27 patients with small pupil and cataract where the Bhattacharjee ring was used to enlarge the pupil for phacoemulsification. The Square device was used in 17 eyes; 6.5 mm in 2 eyes and 7 mm in 15 eyes. The Hexagon was used in 16 eyes; 6 mm in 3 eyes and 7 mm in 13 eyes. Average preoperative dilated pupil diameter was 4.0 mm (range 2.5 to 6.0 mm). Incision size used was 2.2 mm in 10 eyes, 1.5 mm in 10 eyes and 0.9 mm (20G) in 13 eyes. The insertion of the device was smooth, easy and without snagging of the incision in all eyes. A small bleeding occurred as the flanges were being tucked in one eye with uveitis and posterior synechiae. This was controlled by injecting viscoelastic and raising the IOP. Phaco was uneventful in all eyes. The device did not obstruct the passage of the chopper, second instrument, phaco probe, IOL Cartridge nozzle or IOL. There was no incidence of posterior capsule tear or vitreous loss. The device remained stable throughout the surgery in all eyes and there was no incidence of spontaneous disengagement from the pupil. A small Iridodialysis and bleeding occurred in one eye as the iris was held inadvertently by the forceps during removal of the device. The bleed was controlled but a small hyphema persisted for 2 days. The device was removed through the phaco incision in 28 eyes and through the 0.9 mm (20G) side port in 5 eyes. Removal of the device was smooth and easy in all eyes. Severe IFIS with Iris prolapse was noted in 1 eye, Moderate IFIS - 2 eyes and mild IFIS - 2 eyes. Small iris sphincter tears with mildly distorted pupils were seen in 2 eyes which had preoperative pupil size of 2.5 mm. Microscopic sphincter tears were seen on the slit lamp in 8 eyes but there was no distortion of pupil or loss of function. Average pupil diameter was 3.5 mm and all eyes except two had round pupils and normal reactions at 7th postoperative day. Transillumination defects suggestive of iris trauma, were seen postoperatively in 4 eyes.
**Conclusion**

The Bhattacharjee Ring (square and hexagon) safely and effectively dilates pupil, is easily inserted through a 0.9 mm (20G) incision and can be used for sub 2 mm MICS also. It overcomes limitations of Malyugin ring which has bulky two plane structures at corners with gaps which snag the incision and cannot be inserted through sub 2.2 mm incisions. For pars plana vitrectomy in eyes with small pupil, where a 2.2 mm incision is not desirable, this device is invaluable. Pupil shape and function is retained. Since no special injectors, manoeuvres or skills are required for the new device, the learning curve is short.

**DISCUSSION**

Viscomydriasis, stretching, pupilloplasty and sphincterotomy have been used to enlarge a small pupil for phacoemulsification. However, these techniques fail to expand the pupil in eyes with IFIS. Diabetes, miotic use, posterior synechiae or pseudoexfoliation, result in nonelastic miotic pupils which may dilate with stretching. Unlike with nonelastic miotic pupils, the IFIS pupil immediately snaps back to its original size following attempts at stretching it. Self retaining Iris retractors and hooks provide adequate dilation but at least four additional corneal incisions are required. Pupil stretching, Pupilloplasty and Iris retractors are all associated with increased postoperative pupil size and distortion of the pupil. Pupil enlargement is associated with increased glare disability and it is necessary to maintain normal pupil size and function after cataract surgery, especially with multifocal lenses.

Pupil Expansion Rings mechanically dilate the pupil, prevent it from constricting, and restrain the iris from prolapsing. The 5S Pupil Ring (Morcher GmbH), the Perfect Pupil (Milvella Ltd.) and the Graether silicone pupil expansion ring (Eagle Vision, Inc) are difficult to position if the pupil is less than 4.0 mm wide or if the anterior chamber is shallow.

Malyugin ring (Micro- Surgical Technology, Redmond, USA) was found to be highly effective in eyes with IFIS and other small pupil conditions, and also easier and faster to use than iris retractors and other pupil expansion rings. The Malyugin ring is made of 5-0 polypropylene, has four coiled scrolls (helical coils) that engage the pupil edge to expand it. It has to be carefully loaded into a single-use injector system which is used to insert and remove the device.

The Malyugin ring has limitations. It requires a 2.2 mm incision and a special injector. The side facing gaps are difficult to visualize from a top view. It snags the incision because of the gap in the biplanar helical coil. Occasionally, intra operative behaviour like unpredictable twisting and disengagement of the Malyugin ring can limit safe usage. The Helical coils act as torsional...
and compression springs as the device is deformed and can unpredictably crush or release the pupillary margin. Polypropylene floats in water. BSS has a higher specific gravity than water. Malyugin ring may float and touch the endothelium if it disengages and there is inadequate viscoelastic.

The Bhattacharjee ring being made of Nylon, does not float in water. It does not snag the incision because the notches can straighten and the device is entirely in a single plane. It holds on to the pupillary margin, without crushing, due to a paper clip effect. The configuration and flexibility allows the device to be inserted and removed through a 0.9 (20G) incision.

Progressively decreasing incision sizes were used in this study, to find the safest and smallest size required. Though both the square and hexagon can effectively dilate the pupil, the hexagon has geometric advantages. For a given incircle (capsulorhexis), hexagon requires a smaller circumcircle than square. Thus, a larger hexagon can be accommodated in the anterior chamber resulting in a larger pupil. But, tucking another flange requires additional time.

REFERENCES


