

Use of Malyugin pupil expansion device for intraoperative floppy-iris syndrome: Results in 30 consecutive cases

David F. Chang, MD

PURPOSE: To evaluate a new disposable, small-pupil expansion device in tamsulosin patients with intraoperative floppy-iris syndrome (IFIS) having cataract surgery.

SETTING: Private practice, Los Altos, California, USA.

METHODS: The 5-0 polypropylene Malyugin pupil expansion device (MicroSurgical Technology) was used in 30 eyes from 21 tamsulosin patients having routine cataract surgery. The pupil diameter was measured at the beginning and end of surgery, and the severity of IFIS was graded. Intraoperative and postoperative complications were recorded.

RESULTS: The device maintained a constant 6.0 mm pupil diameter throughout surgery. Although iris prolapse was still possible, there were no significant intraoperative or postoperative complications despite the fact that 93% of the eyes had moderate to severe IFIS. All eyes achieved a best corrected visual acuity of at least 20/25. There was a tendency for ring deformation if flash sterilization was used without sufficient cooling time.

CONCLUSIONS: The disposable Malyugin pupil expansion device was highly effective at maintaining an adequate pupil opening in eyes with IFIS. It is easier and faster to use than iris retractors and other pupil expansion rings and represents an excellent small-pupil strategy.

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Intraoperative floppy-iris syndrome (IFIS) is associated with the use of systemic α -antagonists in general and tamsulosin in particular.¹ Severe IFIS is characterized by billowing and prolapse of the iris and progressive intraoperative miosis.¹ Several retrospective studies have shown that if IFIS is not anticipated or expected, the risk for complications such as posterior capsule rupture is increased.^{1–4} Since IFIS was first reported in 2005, many strategies for managing the iris

intraoperatively to reduce the surgical complication rate have been proposed.^{1–10}

The new disposable Malyugin pupil expansion device¹¹ (MicroSurgical Technology [MST]) is inserted with a single-use injector system. The device was evaluated in a series of tamsulosin patients having cataract surgery.

PATIENTS AND METHODS

The disposable Malyugin ring was used for cataract surgery in a series of patients taking tamsulosin who presented with a preoperative pupil diameter of 6.0 mm or less between August 2007 and December 2007. Tamsulosin was not discontinued before surgery, and all eyes received a standard preoperative dilating regimen of cyclopentolate 1%, phenylephrine 2.5%, and nepafenac 0.1%. The disposable ring was inserted as described below, and phacoemulsification and insertion of a foldable posterior chamber IOL were performed through a 2.6 mm temporal clear corneal incision under topical anesthesia using sodium hyaluronate 1.6% (Amvisc Plus). All surgery was performed using a phaco-chop technique with aspiration parameters up to 38 mL/min flow and 400 mm Hg vacuum.

External calipers were used to measure the pupil diameter at the start of surgery and after the ophthalmic viscosurgical

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From a private practice, Los Altos, California, USA.

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MicroSurgical Technologies provided the devices used in the study.

Corresponding author: David F. Chang, MD, 762 Altos Oaks Drive, Suite 1, Los Altos, California 94024, USA. E-mail: dceye@earthlink.net.

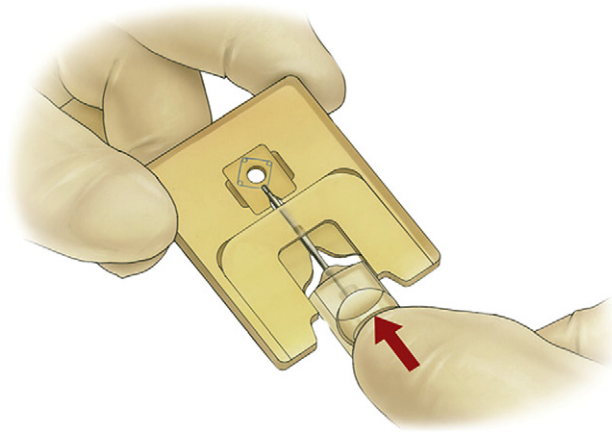


Figure 1. Injector docks into ring holder and the tab on the handle is advanced to extend the hook.

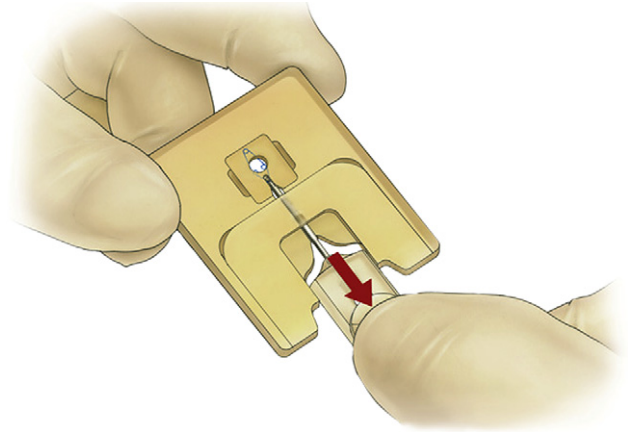


Figure 2. Moving the tab back retracts the hook, which has grasped 1 scroll of the Malyugin device.

device (OVD) had been removed. The IFIS severity was graded according to the following scale: none = no iris billowing, prolapse, or miosis; mild = iris billowing without intraoperative miosis or prolapse; moderate = iris billowing and miosis, without prolapse; severe = iris billowing and miosis, with a tendency to iris prolapse. The presence or absence of these IFIS signs was evaluated after the ring was removed and while the OVD was removed with the irrigation/aspiration handpiece.

Intraoperative complications such as posterior capsule rupture, vitreous loss, and hyphema were recorded. Patients were seen on postoperative day 1 and at 3 to 6 weeks. The final best corrected visual acuity (BCVA) was recorded, along with any postoperative complications or iris abnormalities.

Malyugin Pupil Expansion Device

The disposable Malyugin pupil expansion device is a foldable square made of 5-0 polypropylene with a coiled scroll at each of the 4 corners (B.E. Malyugin, MD, "Russian Solution to Small-Pupil Phaco and Tamsulosin Floppy-Iris Syndrome," video presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, San Francisco,

California, USA, March 2006). A single-use injector system that was developed in conjunction with MST is used to insert and remove the device from the anterior chamber (Figures 1 and 2).

A special holding platform contains the unfolded square-shaped Malyugin device. The injector tip fits into the docking port of the holding platform and a sliding tab on the injector handle is used to manually extend a blunt hook from the distal tip (Figure 1). As the hook is retracted, it grasps the proximal scroll and pulls the flexible device into the injector shaft (Figure 2). The tip of the injector is then introduced through a phaco incision measuring at least 2.2 mm and, in the presence of sufficient OVD, is positioned over the anterior lens capsule in the center of the pupil.

As the Malyugin device is expelled with the sliding tab and the injector tip is retracted proximally, it expands into a square configuration. The lead scroll is directed to capture the contra-incisional pupil margin, and the rest of the expanding device is deposited into the anterior chamber (Figures 3 and 4). A blunt Lester-type positioning hook is used to sequentially engage the pupil margin with each of the remaining 3 scrolls, resulting in a rounded pupil diameter of approximately 6.0 mm (Figures 5 to 7). It is frequently

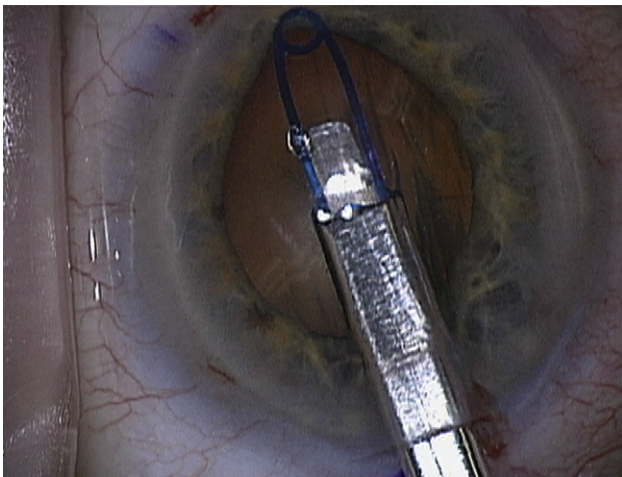


Figure 3. Advancing the tab on the handle expels the device into the anterior chamber, where the lead scroll engages the pupil margin.

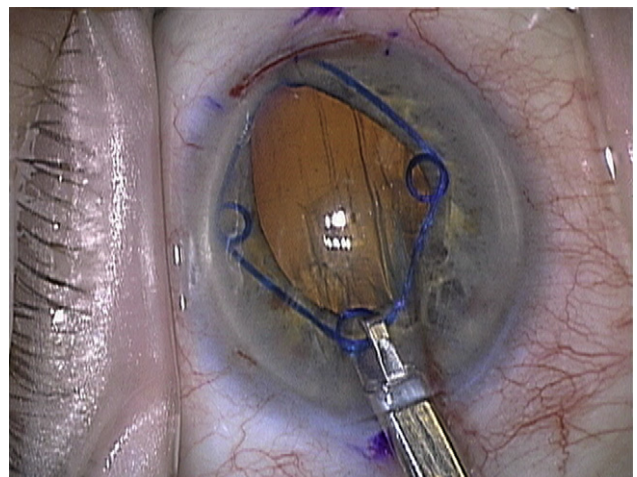


Figure 4. When the tab has been maximally advanced, the device is fully released into the anterior chamber.

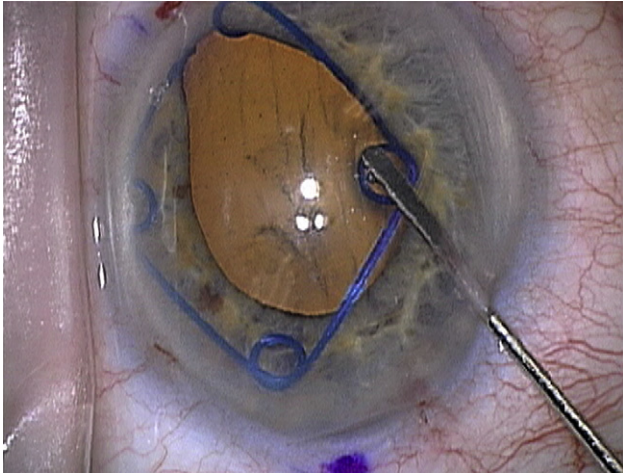


Figure 5. A Lester hook is used to engage the pupil margin with 1 lateral scroll.

possible (but not necessary) to engage the iris margin with 1 or both lateral scrolls as the device is injected.

Surgery is performed in the usual fashion. Following implantation of a foldable intraocular lens (IOL) but before removal of the OVD, the proximal scroll of the device is disengaged from the pupil margin using the Lester positioning hook (Figure 8). With the sliding tab in the proximal position, the injector device is reinserted into the anterior chamber. The sliding tab is then moved to the full distal position and the tip platform is placed beneath the proximal scroll, with the retractable hook located above it. The sliding tab on the injector handle is moved proximally until the retractable hook grasps the freely exposed scroll (Figure 9). The Malyugin device is then partially retracted into the injector tip, resulting in a linear profile that is easily extracted through the clear corneal incision (Figures 10 to 12).

RESULTS

The study comprised 30 consecutive eyes in 21 patients taking tamsulosin. All patients were male, with a mean

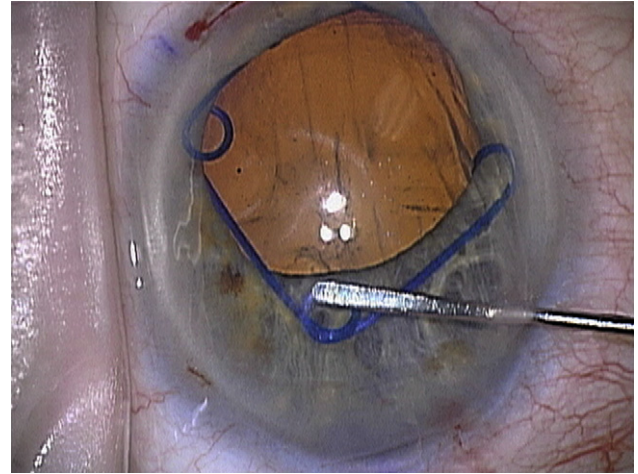


Figure 6. The fourth and final scroll is positioned.

age of 76.8 years (range 66 to 87 years). The patients' ages and preoperative pupil diameters are shown in Table 1, along with the IFIS severity rating and the pupil diameter measured at the end of surgery. The mean preoperative pupil diameter was 5.1 mm (range 2.5 to 6.5 mm) and the mean final intraoperative pupil diameter, 3.0 mm (range 2.5 to 4.0 mm). There were no instances of posterior capsule rupture. Minor bleeding from the pupil margin occurred in 1 case but was not significant. Postoperatively, there was minimal evidence of iris trauma from the ring. Minor sphincter tears were observed at the slitlamp in 5 patients, but these had no effect on pupil size or reactivity. There were 8 cases of minor iris stromal atrophy or transillumination defects, which were associated with intraoperative iris prolapse. All pupils returned to a physiologic size without permanent mydriasis or distortion. Three eyes experienced intraocular

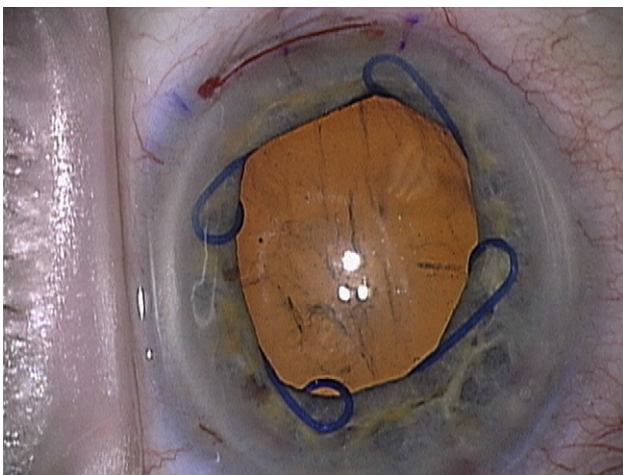


Figure 7. The iris drapes over the straight edges of the Malyugin device to achieve a 6.0 diameter rounded pupil.

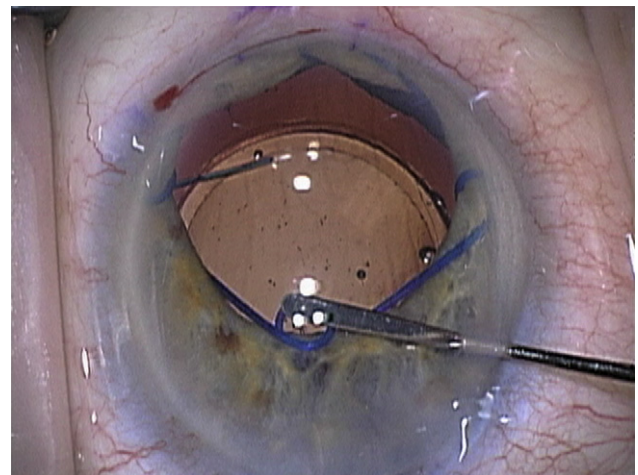


Figure 8. To remove the device, the proximal scroll is released from the pupil margin with the Lester hook.

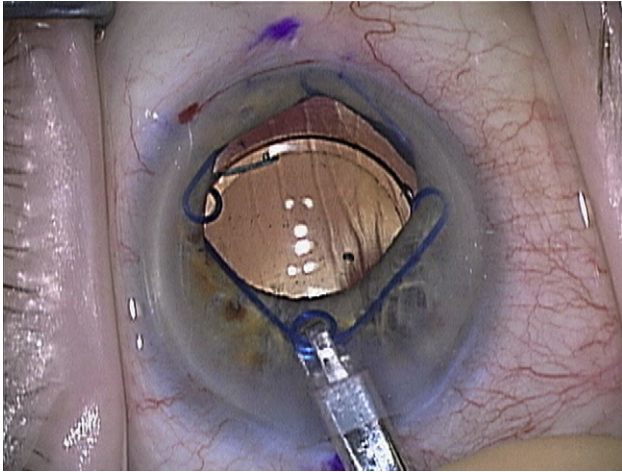


Figure 9. The extended hook grasps the proximal scroll.

pressure spikes greater than 22 mm Hg on postoperative day 1 that responded to topical medications and did not persist. There were no instances of prolonged or excessive iridocyclitis, pigment dispersion, or clinical cystoid macular edema. At 1 month, the BCVA was 20/25 or better in all 30 eyes.

Three of the first 6 rings used became partially deformed during the loading/injection process. In 2 cases, the expelled device assumed a diamond rather than a square configuration and at least 1 of the scrolls was stretched apart. This made proper placement along the pupil margin difficult but possible. In a third case, the 2 lateral scrolls of the device became entangled as they were expelled, which prevented the device from re-expanding. The device was removed and another Malyugin ring inserted.

Subsequent to the first 6 cases, the sterilization method was changed. Instead of flash sterilizing the

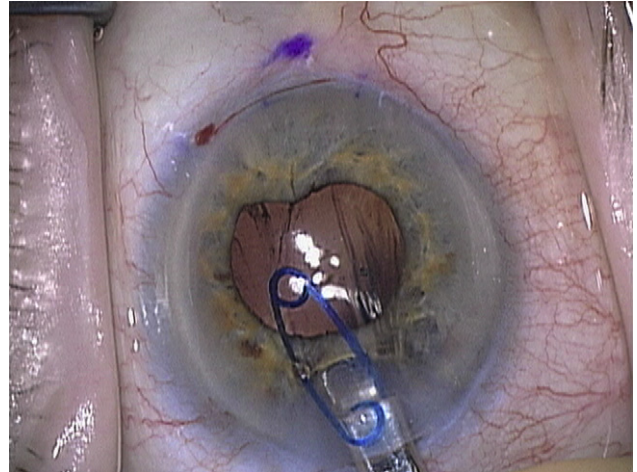


Figure 10. The device is removed after it partially telescopes into the injector.

device immediately before surgery, the system was autoclaved and then wrapped in a sterile peel pack for storage until it was needed. Only 3 of the next 24 rings used were partially deformed during the loading/injection process. In each instance, the deformed ring was removed and replaced with a new disposable ring.

Measurements using external calipers showed that a consistent intraoperative pupil diameter of 6.0 mm was achieved with the device. In one case with a 6.0 mm × 7.0 mm oval pupil diameter, the Malyugin ring could not fully engage the widest part of the pupil. As a result, the lateral scroll slipped off during surgery, requiring repositioning with a Lester hook. Aside from this case, once the ring was properly positioned, the iris did not become disengaged during surgery. In several instances, the peripheral iris prolapsed momentarily to the side port and phaco incision. The degree of iris prolapse was minor, it was easy to reposit, and miosis

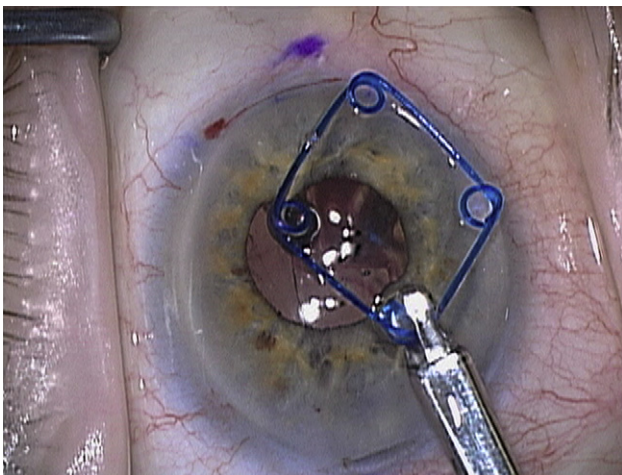


Figure 11. View of the extracted device and the injector with the extended hook.

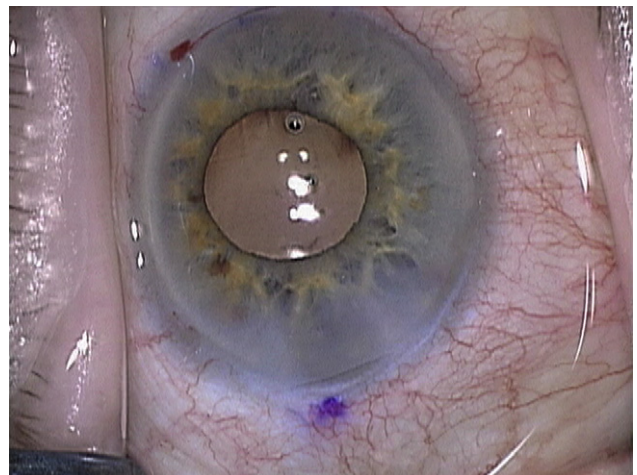


Figure 12. The pupil immediately constricts following removal of the Malyugin device.

Table 1. Patients and findings.

| Case | Patient | Eye | Age (Y) | Pupil (mm) | | IFIS Severity | Final BCVA | Intraoperative Complications | Postoperative Complications |
|------|---------|-----|---------|------------|---------------|---------------|------------|------------------------------|-----------------------------|
| | | | | Preop | Final Intraop | | | | |
| 1 | 1 | L | 80 | 5.5 | 3.0 | Moderate | 20/20 | — | — |
| 2 | | R | | 5.5 | 3.0 | Moderate | 20/20 | — | — |
| 3 | 2 | L | 73 | 6.0 | 2.5 | Severe | 20/20 | Iris prolapse | — |
| 4 | | R | | 6.0 | 2.5 | Severe | 20/20 | Iris prolapse | — |
| 5 | 3 | L | 79 | 5.5 | 3.0 | Severe | 20/25 | — | — |
| 6 | 4 | L | 74 | 5.0 | 2.5 | Severe | 20/25 | — | — |
| 7 | | R | | 5.0 | 3.0 | Severe | 20/25 | — | — |
| 8 | 5 | L | 70 | 5.5 | 3.0 | Severe | 20/20 | Iris prolapse | TD |
| 9 | 6 | L | 78 | 5.0 | 3.0 | Severe | 20/20 | — | — |
| 10 | 7 | L | 87 | 6.0 | 3.0 | Severe | 20/20 | — | — |
| 11 | | R | | 5.5 | 3.0 | Severe | 20/25 | Iris prolapse | Minor ST |
| 12 | 8 | R | 80 | 6.0 | 3.5 | Severe | 20/20 | Iris prolapse | — |
| 13 | 9 | R | 66 | 4.5 | 3.0 | Severe | 20/25 | Iris prolapse | ST |
| 14 | | L | | 4.0 | 3.0 | Mild | 20/20 | — | ST |
| 15 | 10 | L | 77 | 4.5 | 3.0 | Severe | 20/20 | Iris prolapse | POD1 IOP 30; TD |
| 16 | | R | | 4.0 | 3.0 | Severe | 20/20 | Iris prolapse | POD1 IOP 26 |
| 17 | 11 | R | 85 | 4.5 | 2.5 | Severe | 20/25 | Iris prolapse | — |
| 18 | 12 | R | 78 | 2.5 | 3.0 | Severe | 20/25 | Iris prolapse | TD; ST |
| 19 | 13 | R | 86 | 3.5 | 2.5 | Severe | 20/25 | — | — |
| 20 | | L | | 4.0 | 2.5 | Severe | 20/20 | Iris prolapse | TD |
| 21 | 14 | L | 79 | 5.0 | 3.5 | Moderate | 20/25 | — | POD1 IOP 26; ST |
| 22 | 15 | | 79 | 6.5 | 3.5 | Moderate | 20/20 | Ring slipped | TD |
| 23 | 16 | L | 72 | 6.5 | 4.0 | Mild | 20/25 | — | — |
| 24 | 17 | R | 80 | 6.0 | 3.0 | Moderate | 20/20 | — | — |
| 25 | | L | | 5.5 | 3.0 | Severe | 20/20 | Iris prolapse | TD |
| 26 | 18 | L | 69 | 5.5 | 2.5 | Severe | 20/20 | Iris prolapse, microbleed | TD |
| 27 | | R | | 6.0 | 3.0 | Severe | 20/25 | Iris prolapse | — |
| 28 | 19 | R | 73 | 6.0 | 2.5 | Moderate | 20/20 | — | — |
| 29 | 20 | L | 72 | 6.0 | 3.0 | Severe | 20/20 | Iris prolapse | TD |
| 30 | 21 | L | 76 | 5.5 | 4.0 | Moderate | 20/20 | — | — |

IFIS = intraoperative floppy-iris syndrome; IOP = intraocular pressure (mm Hg); POD1 = postoperative day 1; ST = sphincter tear; TD = transillumination defect

did not occur because of the presence of the ring. In each instance, the Malyugin device was removed by disengaging the proximal coil after IOL placement and retracting the device into the injector.

DISCUSSION

The use of mechanical expansion devices, such as iris retractors or pupil expansion rings, represents an important strategy for the management of IFIS. Alternative methods include pharmacologic strategies, such as preoperative topical atropine or intracameral epinephrine, and the use of a viscoadaptive OVD, such as sodium hyaluronate 2.3% (Healon5).⁵⁻¹⁰ Off-label intracameral injection of α -agonists, such as epinephrine or phenylephrine, increases iris dilator muscle tone and iris rigidity. Incremental mydriasis from

intracameral α -agonists can occur in some, but not all, IFIS cases. By virtue of its maximal viscosity, Healon5 produces viscomydrisis and restrains the iris from prolapsing. However, using Healon5 entails a separate surgical learning curve and the use of lower aspiration flow and vacuum parameters to prolong its presence within the anterior chamber. In my experience, both these techniques are less effective in severe IFIS cases and the resulting pupil diameter can be quite variable.

Mechanical devices incur additional surgical time and expense but achieve a consistently large pupil diameter that will not constrict regardless of the IFIS severity or the type of OVD or fluidic parameters used. No alteration of the surgeon's phaco technique is necessary. Three other pupil expansion rings are currently available for use in the United States. The 5S Pupil

Ring (Morcher GmbH; distributed by FCI Ophthalmics, Inc.) and the Perfect Pupil (Milvella Ltd.) are disposable poly(methyl methacrylate) and polyurethane, respectively, pupil expansion rings.¹² They are inserted with the use of a reusable metal injector but have a higher vertical profile within the anterior chamber than the Malyugin ring. Because of their girth and rigidity, plastic rings incur a greater risk for corneal endothelial touch as they are manipulated in the anterior chamber.

The Graether silicone pupil expansion ring (Eagle Vision, Inc.) is inserted with a disposable injector.¹³ The device is more cumbersome to insert because a modified Sheet's glide must be used. In my experience, the Malyugin device was easier to insert, manipulate, position, and remove than any of the other commercially available pupil expansion rings.

Iris retractors allow the surgeon to manually adjust how widely the pupil is expanded. However, excessive pupil stretching incurs a risk for tearing the iris sphincter muscle, which can result in permanent atonic mydriasis. This is less likely to occur with the elastic pupil characteristic of IFIS than the fibrotic pupils associated with pseudoexfoliation or prior miotic use. Unless used in a diamond configuration, the retractors can tent the iris up in front of the phaco tip, creating a physical obstacle to entry.¹⁴

Overall, the Malyugin device was faster and easier to insert and remove than iris retractors and there was no need to make 4 additional paracentesis openings. Because of the way the iris drapes over the straight sides of the square device, it produces a round rather than a square pupil configuration. Because of the proximal scroll, the Malyugin device also provides excellent access to the subincisional cortex. However, the Malyugin device is not able to engage a pupil margin whose diameter is 7.0 mm or larger.

The expansion device does not place the iris on maximum stretch. This fact and the mobility of the lightweight ring allowed the iris to prolapse to the side port and phaco incisions in some eyes. This resulted in slight decentration of the ring but did not decrease the pupil diameter, which was stabilized by the device. Although not allowed for the purposes of this study, intracameral epinephrine or phenylephrine would be expected to increase iris rigidity and prevent prolapse when used in conjunction with the Malyugin ring. In a few cases, the ring remained slightly decentered after the iris was repositioned because 1 lateral scroll had become hooked over the capsulorhexis edge. A Lester hook was able to disengage the scroll from the capsulorhexis edge easily each time.

Initial experience demonstrated a tendency for the ring to become slightly deformed if it was used immediately following flash sterilization. The frequency of this problem was dramatically reduced by autoclaving

the product and wrapping it in a sterile peel pack. Experiments subsequently performed by the manufacturer confirmed that if the ring was not allowed sufficient time to cool following flash sterilization, the deformation problems could be duplicated. A minimum cooling period of 5 minutes usually prevented these deformation problems in vitro. As a result of this discovery, the directions for use were changed to reflect the required cooling time following flash sterilization and to add validated instructions for sterilizing and wrapping the device in a peel pouch. By early 2008, the device was provided in a sterile package.

Ninety-three percent (28/30) of the eyes in this series had moderate to severe IFIS. This is consistent with the fact that the device was used only in patients with small pupils, which is often associated with moderate to severe IFIS.^{1,3} Despite this, there were no instances of posterior capsule rupture, large iris tears, excessive iridocyclitis, or clinical cystoid macular edema. Several eyes had mild stromal iris transillumination defects and minor sphincter tears that could be identified at the slitlamp. Sphincter tears tended to occur with smaller preoperative pupils, as would be expected with their need to be stretched further by the device. These findings were asymptomatic, and there were no instances of an atonic, mydriatic, or misshapen pupil postoperatively.

In conclusion, in a small series of eyes with IFIS in patients on tamsulosin, insertion of the Malyugin ring with the disposable MST injector system was easier and quicker to use than other mechanical pupil expansion devices. It was a reliable and stable method of maintaining an adequate surgical pupil diameter and was associated with minimal trauma to the iris. Slight ring deformation may result if the device is used immediately following flash sterilization.

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First author:

David F. Chang, MD

*Private practice, Los Altos, California,
USA*