Dilation devices in cataract surgery

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Purpose of review
Cataract surgery in the setting of small pupil represent a major challenge and it is associated with a higher risk of complications. When pharmacologic pupil dilation fails, mechanical pupil expansion devices are needed to obtain and maintain sufficient intraoperative mydriasis. The purpose of this review is to assess the pupil expansion devices currently available.

Recent findings
A variety of pupil expansion devices are offered on the market. They differ for design, material, shape, size, cost, and easiness of insertion/removal, nonetheless they all seem to be effective in improving the pupil size and easing the cataract surgery.

Summary
Mechanical pupil expansion can be effectively achieved with a variety of devices, which are well tolerated and can facilitate cataract surgery in the setting of poor mydriasis.

Keywords
Assia Pupil Expander Devices, B-HEX Pupil Expander, Canabrava ring, cataract surgery, I-Ring pupil expander, iris hooks, Malyugin ring, mechanical pupil dilation, Oasis iris expander, pupil expansion devices, small pupil, Xpand iris speculum

INTRODUCTION

Cataract continues to be a leading public-health issue, counting as the second commonest cause of reversible loss of useful vision worldwide [1]. With the advancement of surgical technology and techniques, cataract surgery has evolved to small-incisional surgery with rapid visual recovery, providing good visual outcomes and minimal complications in most patients. Thanks to the development of advanced technology in intraocular lenses (IOL), the combined treatment of cataract and astigmatism or presbyopia, or both, is now possible, making the aspirations of patients undergoing cataract surgery gradually shifting from simply being able to see towards achieving clear vision in the distant, intermediate, and near range without glasses [2].

Adequate pupil dilation and maintenance of dilation are necessary for well tolerated and efficient cataract surgery. The small pupil is a common and significant challenge, especially for beginning cataract surgeons. The visualization of the lens can be greatly diminished, which will make every step of the surgery more difficult, and each step can become even more difficult if the previous ones where not perfect. For example, a diminished red reflex can make the capsulorrhexis formation more difficult and interferes with visual cues used to judge sculpting depth; a very small capsulorrhexis has a higher risk of capsular blow out during hydrodissection, and it could make the lens prolapse difficult. Moreover, the space where to perform the surgical maneuvers is reduced and inadvertent iris trauma could cause even further miosis, bleeding, iris dialysis, and so on. As a result, cataract surgery in small pupil is associated with a higher risk of complications, including posterior capsular rupture, vitreous loss, dropped nuclear fragments, retained lens fragments, iris damage, increased inflammation, cystoid macular edema, and inflammation. Iris damages and improper IOL placement can result in visual disturbances postoperatively and reduced refractive outcomes, especially with Premium IOL [3–10,11▪▪].

There are several methods to overcome inadequate mydriasis during cataract surgery and the purpose of this review is to review the available surgical devices to mechanically enlarge poorly dilating pupils.

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KEY POINTS

- Small pupil cataract surgery has higher rate of complications.
- Among the armamentarium available to achieve sufficient intraoperative mydriasis, a stepwise approach, starting with pharmacological options, is advisable and usually effective. When the result is insufficient, mechanical pupil expansion is needed.
- The most used pupil expansion devices, iris hooks and Malyugin ring, have comparable visual and safety outcomes.
- A variety of new pupil expander devices is available to cataract surgeons.

RISK FACTORS FOR SMALL PUPIL

A small pupil is a relatively common occurrence that may result from a variety of causes (Table 1); one study reported an incidence of 11% in uncomplicated cataract surgery [12].

INDICATIONS FOR PUPIL DILATION DEVICES

Despite many preoperative and intraoperative pharmacologic pupil expansion strategies have proven to be successful in achieving an appropriate mydriasis for cataract surgery, they cannot always guarantee the result and the use mechanical iris expansion devices may be needed.

There is no consensus in the current literature about what pupil size should be considered unacceptable to proceed with cataract surgery; however, the diameter of the pupil to be considered small may start at 6 mm [13]. Nevertheless, the threshold of pupil size to perform phacoemulsification without seeking for further dilation with mechanical dilations devices is subjective and can vary based on the level of the surgeon's experience. However, pupil expansion devices can be very valuable not only in small pupil cases but also in the setting of iris prolapse, intraoperative floppy iris syndrome (IFIS), iridoschisis, and for capsular support in cases with zonular dehiscence or subluxed crystalline lens [14–18].

DEVICES FOR INTRAOPERATIVE MECHANICAL ENLARGMENT OF SMALL PUPIL

Ophthalmic viscosurgical devices

Viscomydriasis, or viscodilation, may enlarge a borderline pupil to an acceptable size. When injecting the OVD into the anterior chamber, the anterior chamber, deepens, and the pupil becomes larger. OVD with high viscosity are preferred; however, repeated injection may be needed during surgery because of the OVD leak from the AC during various surgical steps. Some authors suggest a combination of viscoadaptive and dispersive OVD, combining the advantages: the viscoadaptive OVD mechanically stretches the pupil, while the dispersive OVD will better resist aspiration and delay the evacuation. Despite this technique may be useful only in borderline cases, it has the advantage of being the less invasive [19–22].

Iris hooks/retractors

Iris hooks are one of the first pupil mechanical dilation devices that have been used since the early 90s and never lost popularity [11▪▪,23]. Today, there is a wide availability of flexible iris hooks, produced by multiple manufacturers, disposable or reusable, made in different sizes, materials, and designs [24]. Nylon retractors are more flexible and usually smaller; therefore, they might be more difficult to handle but have less potential to injure the iris [25].

Iris hooks can be valuable not only in small pupil cases but also in the setting of iris prolapse, IFIS, iridoschisis, and even for capsular support in

Table 1. Risk factors associated with poor mydriasis

Risk factors for poor mydriasis		
Medical conditions	**Surgical conditions**	**Medications**
Pseudoexfoliation syndrome (PEX)	Femtosecond laser-assisted cataract surgery (FLACS)	Systemic α-adrenergic blockers
Diabetes	Previous ocular surgery	Chronic use of topical miotic
Intraoperative floppy iris syndrome (IFIS)	Prolonged duration of surgery	Opioids
Uveitis		Antipsychotics
Elderly age		Nicotine
Previous ocular trauma		Clonidine
Horner syndrome		Prostaglandins

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cases with zonular dehiscence or subluxed crystalline lens [14–18].

Flexible iris hooks are well tolerated and have a relatively easy learning curve. Traditionally, four or five iris hooks are introduced trough evenly spaced paracentesis, to catch the iris edge and retract the pupil in a square or pentagonal opening. One of the four hooks (diamond shaped pattern), or a fifth additional hook, can be placed subincisionally, to minimize iris prolapse through the main incision. Proper positioning of the iris hooks is crucial to prevent possible complications such as raised iris platform between the hooks and iris prolapse. To ensure proper placement, the paracentesis should be placed parallel to the iris plane and as posteriorly as possible. Using tying forceps in each hand, the hooks are inserted parallel to the incision, then rotated into position using the plastic donut-shaped sleeve. Injecting OVD under the iris to elevate the iris from the capsule can ease the positioning of the hooks. Once the iris edge has been hooked, the iris hooks is gently retracted to expand the pupil to the desired size and secured adjusting the position of the sleeve. In order to minimize trauma and reduce the risk of complications, iris hooks should be placed symmetrically, and excessive retraction should be avoided. It is generally recommended not to extend the pupil over 5.0 mm in size to decrease the chances of iris tissue overstretching, which could cause iris tears, bleeding, chronic inflammation, and irregular or atonic pupils postoperatively [24,26–31]. The iris hooks are removed after the implantation of the intraocular lens (IOL). For removal, the sleeve is loosened, the iris hook is first pushed inside to disengage the pupil, and then it is drawn outwards. The affordable cost is an important advantage of iris hooks. Challenges of iris hooks include the need for multiple paracenteses which may be disadvantageous in the presence of pterygium, bleb, and radial keratotomy incisions.

Pupil expansion rings

Various type of ring expanders has been developed over the years, aiming to dilate the pupil minimizing the iris-sphincter damage by inducing a circumferential expansion in the physiologic iris plane, without elevating or tenting the iris. Also, once in position, they not only retract the iris but also stabilize and protect the pupil margin, which is particularly helpful in cases with IFIS.

Perfect pupil injectable

It is a grooved polyurethane incomplete ring with an internal diameter of 7 mm, described by Dr John Milverton, from Australia. The iris is held firmly in position by a 315° flanged groove. Attached at one end of the ring, there is an integral arm, which is kept to one side of the corneal incision and aids in the removal of the device. The ring opening (45°) is positioned at the wound to accommodate the passage of instruments. The ring can be inserted both with forceps and with an injector, through a 2.8 mm clear corneal incision. The device is first inserted into the anterior chamber, which has been previously filled with OVD. It is preferable not to inject the device directly into the pupil, as that tends to torque the iris. Instead, once inside the AC, the surgeon can manipulate the device to engage the pupil with a Sinskey hook or a Lester manipulator. The proximal-most area of the ring is first engaged, then adjacent areas are progressively engaged in the pupillary margin [24,32,33]. Kershner evaluated the Perfect Pupil expansion system in 30 cataract patients with a mean preoperative pupil of 3.2 mm. The mean pupil size after device insertion was 7.8 mm and the mean pupil size after device removal was about 1 mm larger than the preoperative mean. There were no cases of iris sphincter tear, bleeding, ruptured capsule, or irregular pupil following the operation [33] (video: https://www.youtube.com/watch?v=TCj8bAL2QTQ).

Morcher pupil-dilator ring

The Morcher pupil-dilator ring is a semi-circular, incomplete, disposable ring made by polymethyl methacrylate (PMMA). The length of the device is 7.50 mm. Insertion of the ring can be performed manually or facilitated with an injector, through a 2.5 mm incision. After insertion in the anterior chamber, the central segment of the device is manipulated to engage the distal pupillary margin. Then, the ends of the device are engaged in the pupillary margin with the help of the eyelets featured on the ring. For the removal of the device, first, the ends are disengaged, then the ring is removed with the use of forceps. Given its highly rigid PMMA structure, some consider this device more difficult to handle and to insert through a small incision [29,32,33]. According to a study by Akman *et al.* [34] the mean pupil size achievable with this device is about 6.0 mm(video: https://www.youtube.com/watch?v=hjxAZkNo-7w).

Graether 2000 pupil expander

This is a clear soft silicone ring with a circumferential groove for engaging the pupillary margin. The internal diameter of the ring is 7.0 mm and the outer circumference is grooved to engage the iris sphincter. The ring is incomplete; the gap is bridged by a 3.7 mm slender strap that provides access to the pupillary space. The device is inserted inside the eye using a preloaded sterile disposable device and an iris glide-retractor. Unlike for the other two

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above-mentioned rings, the insertion tool is critical because the Graether ring lacks adequate annular rigidity to allow for forward advancement of the ring along the pupil margin without the insertion tool. It dilates the pupil to about 6.3 mm [32,35] (video: https://www.youtube.com/watch?v=9co0tlOPt3M).

Compared with newer ring devices, the above-mentioned rings are relatively difficult to handle during the surgery, they are not very stable in the eye, and it may require significant time and efforts to implant and remove them. These are the reasons why these devices are currently obsolete [28].

Malyugin ring

This single-use and disposable ring is devised by Dr Boris Malyugin from Moscow, Russia. Of all the pupil expansion rings, this is probably the most popular. It is a square foldable device made of polypropylene. The one-piece planar design features four circular eyelets, located at equidistant points on the ring, which engage the iris. However, it has eight points of fixation with the pupillary margin (at four coils and points located at the middle between the coils) and creates a round and dilated pupil. The profile is thinner when compared with preexisting rings, making it easier to manipulate inside the eye. The device is injected into the anterior chamber and removed from the eye with a disposable injection system, with an anterior chamber filled with viscoelastic. The device is manufactured in two sizes, 6.25 and 7.0 mm in diameter, the latter being particularly useful for IFIS cases [36,37,38▪]. The current version of the device is called Malyugin ring 2.0, which is made with even thinner material (5-0 polypropylene instead of 4-0) and, being softer and more elastic, it can be inserted through a 2 mm incision. Insertion and removal of this ring is considered by many to be easier and faster than with other pupil expander devices [29,37,39]. The inventor recommends using high-viscosity OVD to create a space between the anterior lens capsule and the pupil. Three curls (distal coil first and then the two side coils) may be used to engage the pupillary margin automatically during the device insertion, leaving the proximal/sub-incisional curl the only one to be manipulated to hold the iris margin. For the device removal, once the ring has been disengaged from the iris, it can be removed from the AC by using the injector; the inserter has prongs that can be used to grasp the ring and fully retract it inside the inserter.

The Malyugin ring may be helpful in various complicated cataract surgery scenarios. It has been reported that it could be utilized to achieve both capsular stabilization and pupil expansion simultaneously. Zarei-Ghanavati and Bagherian suggested to insert the pupil expansion ring in the usual fashion first. After a capsulorhexis has been created, lateral scrolls of the pupil expansion device are released and repositioned to entrap both the anterior capsulorhexis and the pupil margin by two contralateral scrolls of the devices, placed in the against-the-wound meridian, to fixate the unstable capsular bag to the iris. Phacoemulsification is then performed and the ring is removed after intraocular lens implantation [40]. The Malyugin ring has also been found to be a useful intraoperative tool to assist the surgeon in cases of cataract surgery in the presence of iridoschisis and both anterior and posterior synechiae, to avoid intraoperative positive vitreous pressure during triple procedures, to manage small pupil in the setting of femtosecond laser-assisted cataract surgery (FLACS), and pediatric cataract surgery [41–49] (video: https://www.youtube.com/watch?v=_LisTIDv2OA and https://www.youtube.com/watch?v=2K0fsuZWktA).

I-Ring pupil expander

This is a single-use, circular, soft, green ring made of polyurethane, which causes a circular dilation of the pupil to 6.3 mm. The ring has four outward projecting triangular pockets with a fixed channel height that engage the iris without compressing or pinching it. In each triangular portion, there is a hole that help to position the device properly with the help of a Sinskey Hook. The device is assembled with an injector used to insert and remove it, through a 2.4 mm incision, after injecting OVD into the AC. The ring is injected into the AC first, and then secured to the iris with the help of a Sinskey Hook, starting from the distal channel, moving to the sub-incisional channel, and only then to the lateral channels. The same maneuvers can be used to disengage the device from the iris at the end of the surgery. Similarly to the Malyugn ring, once the ring has been disengaged from the iris, it can be removed from the AC by using the injector; the inserter has prongs that can be used to grasp the ring and fully retract it inside the inserter. The device has a green color to provide contrast and increase its visibility [28,50] (video: https://www.youtube.com/watch?v=FQ857gZKW4).

B-HEX pupil expander

The B-HEX Pupil Expander, invented by Dr Suven Bhattacharjee from India, is the third-generation Bhattacharjee Ring [51,52]. This device is disposable, 6.5 mm, flexible, jointless, hexagonal ring, with six notches at corners and six flanges at sides. Three of the flanges have holes, and the other three do not, and they are alternately placed. The flanges with holes are tucked under the iris so that the notches of both sides of the flange engage the pupil, and the flanges without holes remain above the iris, providing a 5.5 mm dilation. The B-HEX is made in

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plastic (ethylene oxide), with a very thin profile and a uniplanar design that allow for insertion and removal through a 1 mm, or larger, incision, using a manipulator or 23-gauge micro-forceps. The use of the forceps makes both the insertion and the positioning of the device easier. The tabs of the flanges should be held with the tips of the jaws of the forceps, in a manner that no part of the jaw extends beyond the flange. Holding the central tab of the leading flange in this way during insertion allows the B-HEX to be carried to the maximum extent into the AC in a single pass. Because of the device thin profile and flexibility, in case of rigid fibrotic pupil smaller than 4 mm, it is advisable to perform a limited bimanual stretch to easier the B-HEX insertion and obtain proper pupil dilation. The B-HEX could be safely used even after capsulorhexis as the thin uniplanar notches are directly visualized to avoid the capsule margin. This ring can be useful also in FLACS, small pupil pars plana vitrectomy, and shallow anterior chamber eyes [51–54] (video: https://www.youtube.com/watch?v=OCsDqFW887k and https://www.youtube.com/watch?v=o82hHFBwILY).

Xpand^{NT} iris speculum-X1

This preloaded device is a flexible, smooth, with 6.7 mm internal diameter, memory metal (nitinol) ring. The device acts like an iris speculum, with eight points of contact with the iris and an even number of alternating side elements connected by arches. The speculum is available in both single-use and multiuse versions, and it can be injected and removed from the AC through a 2.4 mm incision, by using a special injector. A manipulator is used to engage the iris [29]. This pupil expander device has been suggested for the management of small pupil during cataract surgery but also to stabilize the bag, with a technique called 'iridocapsular capture' (video: https://www.youtube.com/watch?v=lZUFSZcjc9A and https://www.youtube.com/watch?v=rwc-fWM81CU&t=20s).

Oasis iris expander

This pupillary ring expansion device is made in polypropylene and has four pockets that gently cradle the iris rim, without pinching or clamping. The device is foldable, it comes with its own disposable injector, and it is available in two sizes (6.25 and 7.0 mm). There are four pockets at corners to lodge the iris margin. Initially, the expander needs to be loaded into the inserter, then the technique used for placement of the OASIS iris expander is similar to the Malyugin ring [24,55]

(video: https://www.youtube.com/watch?v=gI4UlESwDkw&t=46 s).

Canabrava ring

The Canabrava ring is a PMMA incomplete ring, with a 60° opening and a 6.3 mm internal diameter. The device has seven alternating indents (one is above the iris, surrounded by two indents, which are below iris) and two ends of the device that are shaped-like hooks that go under the iris. Each indent has a hole for help in positioning the device using a Sinskey Hook. The device can be inserted with forceps through a 1.5 mm incision and has a vertical thickness of only 0.4 mm. This was developed by Dr Sergio Canabrava from Brazil, and it could be helpful for cataract surgery in the setting of small pupil, especially in eyes with iris defect/coloboma [56] (video: https://www.youtube.com/watch?v=VH6LDTLOFts and https://www.aao.org/clinical-video/tips-using-canabrava-ring).

Other pupil dilation devices

Assia Pupil Expander Devices

The Assia Pupil Expander Devices (APX) is a relatively new tool developed by Dr Ehud Assia from Israel. The initial version (introduced in 2013), APX-100, was made of metal and was reusable. The second generation of the device, APX-200 (introduced in 2015) is disposable and is made of plastic with a blue color. The APX consist in a pair of devices that have a scissor-like appearance but with blunt rounded tips and with a spring. Each device is inserted into the AC via 19G paracentesis incisions, made parallel to the iris, created opposite to each other, and placed at 90° to the main wound. The closed devices are inserted into the AC by using specially designated forceps to maneuver the device. Once the tip of the device has been introduced into the AC and moved centrally, the device is partially open, so that the terminal tips are positioned behind the iris sphincter. Once the iris margin has been engaged, the APX is slowly further opened and released. At the end of the surgery, the devices can be removed by simply closing the devices with the designated forceps and by pulling out the device from the AC. The APX provide a square pupil very similar to the four iris hooks; however, the number of incisions necessary to achieve pupil expansion is limited to two rather than four. Among potential advantages over expansion ring devices, no intracameral maneuvers are needed and the smaller profile might make this device more suitable for crowded anterior chamber [29,57,58]. A recent study has reported the outcomes of the first 50 consecutive eyes where APX-200 was used to enlarge small pupils, with mean preoperative pupil diameter of 3.7 mm. According to the authors, the APX

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effectively dilated the pupils in all cases and a central and round pupil was restored in all eyes at 1 month postoperatively. Fourteen eyes (28%) had mild sphincter tears that did not require pupilloplasty. No complication related to the use of the APX such as hyphema, iridodialysis, or Descemet membrane detachment were noted in this series [57] (video: https://www.aao.org/clinical-video/apx-novel-pupil-expander and https://www.youtube.com/watch?v=3OvxfcjqrZQ).

CONCLUSION

The selection of the pupil expansion device can be the result of several factors, including expenses, familiarity with the device, pupil condition, and personal preference. Some comparative studies have investigated the outcomes of different pupil expansion devices; however there is lack of significant evidence in favor of one specific device over the others. Iris hooks and the Malyugin ring are probably the most popular; however, a variety of different devices have been introduced into the clinical practice over the past years. In general, iris hooks have the advantage to be less expensive and they can be effectively used even in very small pupils. They are well tolerated and have a relatively easy learning curve. However, the technique is more time-consuming, and it requires multiple limbal incisions and careful planning because it can cause a tenting of the iris towards the cornea, thus reducing the AC depth. On the other hand, the use of thin, foldable, and flexible ring devices makes the surgery shorter, keeps the iris on the same plane, and it creates a rounder pupillary opening, potentially reducing the iris trauma [24,29,34,59–61].

In a recent publication, possibly the largest comparative study on this matter, Balal *et al.* investigated the outcomes of cataract surgery in the setting of small pupil, comparing iris hooks (194 eyes), Malyugin ring (469 eyes), and intracameral phenylephrine (447 eyes). All the techniques were well tolerated and effective, as visual improvement and complications between the three different pupil expansion groups had no significant difference, except for a greater rate of iris tears in the Malyugin group [11▪▪].

In conclusion, several mechanical pupil expander devices are available in the market, most of which are well tolerated and effective to ease cataract surgery in patients with insufficient pharmacological mydriasis.

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Conflicts of interest

VS received honoraria from Janach.

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- ▪ of special interest
- ▪▪ of outstanding interest

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