CHAPTER 40

Small Pupil Clear Corneal Phacoemulsification Surgery

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INTRODUCTION

The increased acceptance of topical anesthesia, phacoemulsification and foldable intraocular lenses (IOLs), have advanced the techniques of microincision clear corneal cataract surgery.[1] Operating through these small (less than 3.0 mm), corneal incisions have placed new demands on surgeons to effectively and safely remove the cataract and implant the IOL without increasing the risk of corneal, iris or capsular damage. The causes of small pupil include atrophy or iris sphincter sclerosis as a result of aging, synechiae, previous trauma, surgery, diabetes, iridoschisis, uveitis, chronic miotic therapy, or pseudoexfoliation. The small pupil (less than 3.0 mm) can impede visualization and makes maneuverability of the instrumentation into the eye more difficult (Fig. 40.1). Capsulorrhexis may be difficult to perform in a small pupil. Hydrodissection and phacoemulsification of the lens nucleus can lead to an increased risk of iris sphincter tear, bleeding, iris emulsification, ruptured posterior capsule and loss of the nucleus. Small pupil is associated with increased operative time, risk of complications, discomfort for the patient and surgeon apprehension. Postoperatively, these may lead to an irregular or atonic pupil, photophobia and an unacceptable cosmetic and functional result.

PHARMACOLOGICAL AGENTS

Present methods of dealing with a small pupil at the time of cataract surgery have limitations. Pharmacological therapy with the use of non-steroidal eye drops, or strong mydriatics such as 10% phenylephrine, preoperatively are often associated with untoward ocular and systemic side effects. Drug therapy may be ineffective in dilating bound-down and scarred pupils. The surgeon is then left with the unappealing anticipation of dealing with these difficult pupils during surgery. The surgeon can simply ignore pupil size and perform the maneuvers of small incision surgery through an unenlarged incision, but this may result in a cascade of undesirable complications.

VISCOMYDRIASIS

Recently, the introduction of a new ophthalmic viscosurgical device (OVD-formally known as the viscoelastics), 2.4% Hyaluronate, a viscoadaptive, (Healon®5-Pfizer Ophthalmics, New York, NY USA) has made mechanical dilation of the pupil at surgery more efficacious. By simply injecting the OVD into

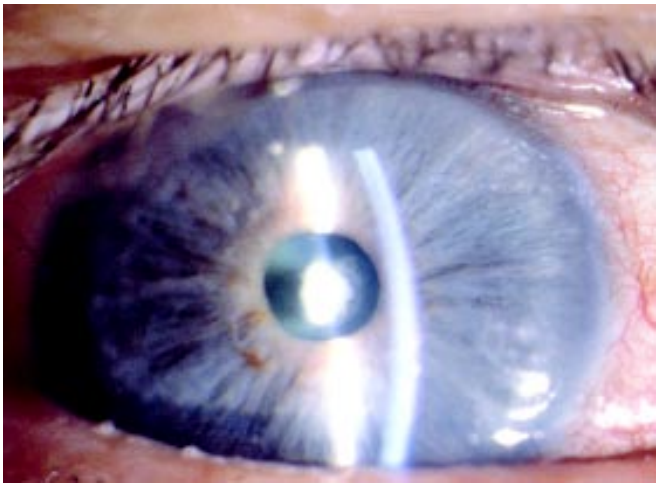

Fig. 40.1: A small pupil prior to cataract surgery

the center of the pupil at the commencement of surgery, the surgeon can mechanically dissect the pupil sphincter from any underlying synechiae, and stretch the sphincter creating a more physiologic pupil. (Fig. 40.2). The only potential pitfall of this technique is that it is not always possible to loosen the pupil with viscodissection alone, requiring subsequent mechanical intervention. It is also important to completely remove the OVD at the conclusion of the procedure to avoid postoperative pressure rises.

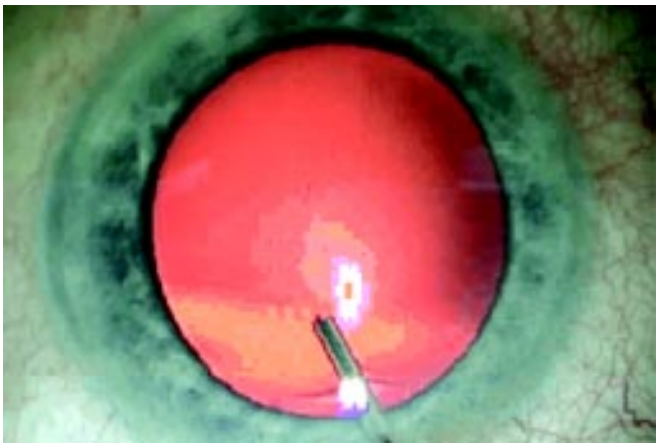

Fig. 40.2: Healon®5 can be used to dilate the pupil

MECHANICAL DEVICES

Many surgeons have turned to many other mechanical methods and innovative devices to enlarge the pupil at cataract surgery. These devices have varying degrees of success and are limited by the need to acquire and have a handy unique instrument, the additional cost and training involved, and the almost invariable result of permanently damaging the pupil structure. These devices include a blade, needle or scissors to make multiple iris sphincter tears, iris hooks to retract the iris tissue through four or more corneal stab incisions,[2] or mechanical stretching devices to pull on the sphincter margin. All of these methods are cumbersome, require specialized instruments, difficult intraocular maneuvers, and are associated with bleeding, permanent loss of iris sphincter function, and abnormal pupil shape postoperatively.

Accordingly, most surgeons will attempt to mechanically dilate the pupil at the time of cataract surgery if pharmacological agents fail to enlarge the pupil by themselves. There have been numerous techniques and instruments utilized for this task. I classify pupil dilation methods into three types. The first is the *mechanical stretching method*. The second is the *cutting method*. The third is the *iris retainer method*.

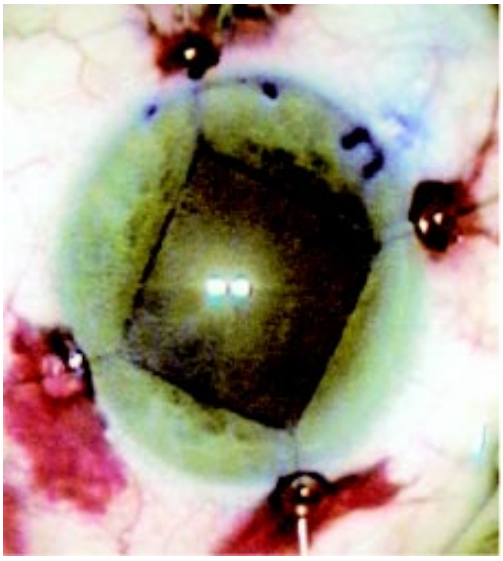

Fig. 40.3: Iris hooks or retractors can hold the pupil

MECHANICAL STRETCHING METHOD

In the first method, the iris is mechanically stretched. The instruments of choice to perform this can be a pair of hooks introduced through two stab incisions in the cornea (Fig. 40.3). The hooks engage the iris sphincter and are pulled in opposite directions. This results in one or more tears of the sphincter, which leads to an enlargement of the pupil aperture. Alternatively, the iris sphincter can be stretched with an instrument designed specifically for this purpose (Fig. 40.4). The advantages of this procedure is that it is simple, and requires no special instruments. The disadvantage is that the iris sphincter is permanently damaged and

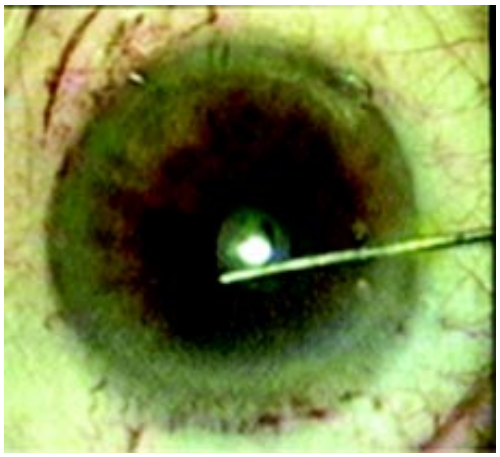

Fig. 40.4: Iris sphincter can be stretched with an instrument

the tear cannot be controlled, resulting in bleeding, pigment dispersion, and an abnormal and non-functional pupil postoperatively.

CUTTING METHOD

In the second method, sharp instruments are used to cut the iris sphincter. The instruments of choice can be a bent needle or intraocular scissors (Fig. 40.5). The cutting method is more controlled but requires the use of a large instrument in the eye that can result in corneal endothelial damage. The advantages of the method are that the purposeful tears can be made small and controlled with less effect on the appearance and function of the pupil. The disadvantages are the same as the stretching method. The additional disadvantage is permanent cosmetic defect that may or may not be noticeable to the patient.

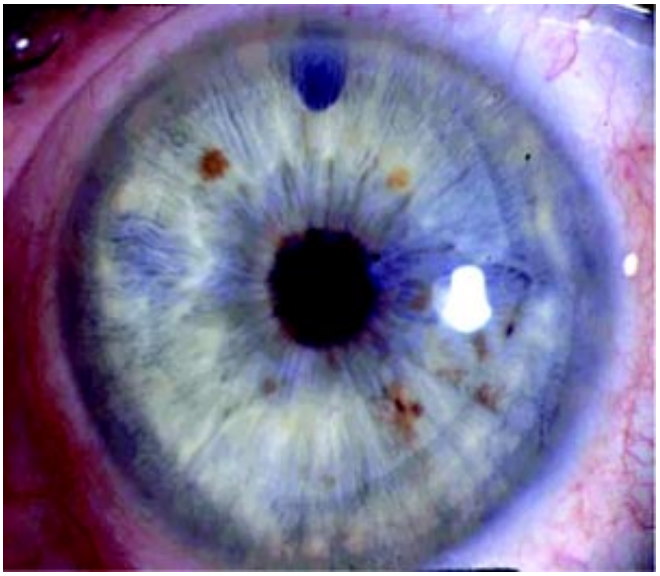

Fig. 40.5: Multiple sphincterotomies can be performed with a microscissor

IRIS RETAINER METHOD

The third method is the iris retainer method. There have been several devices fabricated for holding the pupil in the enlarged state.[7] The effect of these devices is to stretch the pupil around a ring and allow the ring to keep the pupil dilated (Fig. 40.6). The advantages are these devices are sterile, and hold the pupil in the enlarged state. The disadvantages with these iris retainers are they are fixed, rigid and difficult to insert into the eye through a small incision, cumbersome to manipulate when engaging the sphincter, and they may interfere with the instrumentation needed to enter the eye for the cataract procedure.

To better determine which of the various methods have the best potential for success, reproducibility and ease of use I undertook a study to assess the protective effect and dilating potential of the new reusable and disposable devices for small pupil cataract surgery. I found that a device, aptly named the Perfect Pupil®, developed by John Milverton, MD of Sydney, Australia, seemed to fit the requirements I established. The device is a sterile, disposable, polyurethane ring with an integrated arm that allows for easy insertion into the eye and removal at the conclusion of surgery. It is inserted (and can be injected through a clever loading device), through an unenlarged clear corneal incision. The integrated arm remains outside the eye to aid in easy removal. This makes this device superior to the one-piece retaining rings which are often difficult to position and even more difficult to remove. The procedures of capsulorrhexis, hydrodissection,

Fig. 40.6: Iris Sphincter Retainer to hold open the pupil

phacoemulsification and IOL insertion can all be safely carried out with the device in place. The Perfect Pupil® is then removed at the end of the surgery by reversing the steps used for its insertion.

Thirty patients were selected for inclusion in the study.[8] These patients had pupils that failed to dilate as measured at the slit lamp beyond 4.0mm with topical 1% tropicamide and 2.5% phenylephrine. All cataract patients with visually significant cataracts and

a desire for surgical correction underwent a comprehensive examination, preoperative ultrasonic biometry, topography, and measurement of pupil diameter at the slit lamp. All patients signed an informed consent which included surgical intervention for pupil size. Institutional Review approval was not required as the device was approved for use in the United States by the Food and Drug Administration and the surgery did not require a new or different protocol than that which was routinely used for cataract surgery. All procedures were performed by a single surgeon (RMK).

Preoperatively, the patients received one drop each of topical 1% tropicamide and 2.5% phenylephrine every five minutes for fifteen minutes prior to surgery. They were transported to the operating room where a drop of 4% topical povidone iodine was instilled and surgical prep performed. The patient's eye was draped with a sterile adhesive disposable drape (Kershner Cataract Drape II- Kimberly Clark Corporation) and the Kershner reversible eyelid speculum (Rhein Medical, Tampa, Florida USA) was inserted. All procedures were performed under topical anesthesia.[3] Several drops of 0.5% tetracaine hydrochloride were instilled. The pupil, as seen through the cornea, was measured through the ocular of the operating microscope and compared to a known standard pupil gauge chart in millimeters (mm).

A 2.8 mm clear corneal incision was created with either a diamond keratome or the BD disposable clear cornea incision system (Atomic Edge-Becton Dickinson Ophthalmic Surgical, Waltham, Massachusetts, USA). Astigmatism was corrected with an arcuate keratotomy incision (1, 4) or a toric intraocular lens (IOL). Intracameral sodium hyaluronate (Healon®, Healon GV® or Healon® 5-Pfizer, New York, NY USA) was injected into the anterior chamber.

The Perfect Pupil® (Fig. 40.7) is a sterile, disposable polyurethane ring with an internal diameter of 7.0 mm. The ring is open for 45 degrees to allow for the passage of instruments. There is one 1.6m tab at the top of the device and five 4mm fenestrations in the ring for positioning. The iris is firmly held for 315 degrees by an integrated 0.24 mm flanged groove throughout the length of the ring. The material is biocompatible and flexible allowing it to be passed easily through an unenlarged corneal incision. Once in place, the device automatically expands the pupil aperture to 7 to 8 mm. It can be left in place throughout the procedure. The integral arm can be kept to the side of the corneal incision as a buttress to protect the incision, keep the device in place within the pupillary space, and to aid in removal at the conclusion of the surgical procedure. As the ring captures the entire iris sphincter, it acts not only to dilate the pupil, but it provides unparalleled protection of the iris sphincter margin avoiding the complications of iris tearing, bleeding, inadvertent sphincter damage or emulsification.

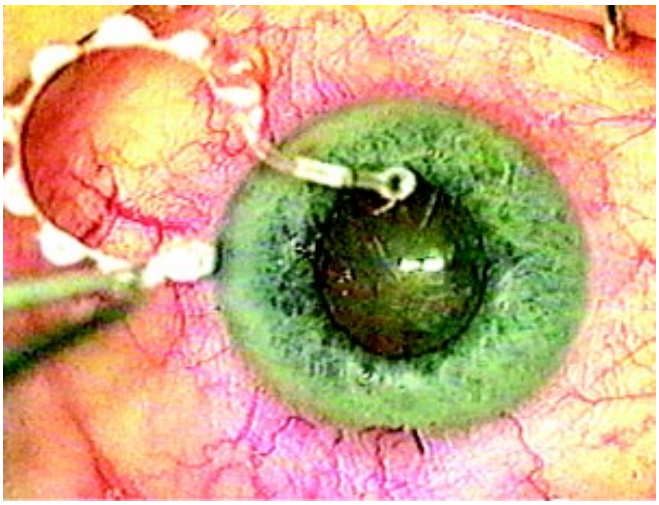

Fig. 40.7: Perfect Pupil® is an open 315¼ polyurethane ring with 5 positioning holes and one tab, used to insert into the anterior chamber

The Perfect Pupil® is removed from it's sterile tray with forceps and delivered to the incision. The distal end is coated with a minimal amount of hyaluronate. The leading edge is then dialed counterclockwise into the anterior chamber). A Sinsky style hook is introduced either through the corneal incision or through a sideport incision and used to engage the superior tab. The iris is engaged and the positioning holes are each used in turn until the entire pupil is captured inside the flange of the device. The pupil size is then measured again.

Capsulorrhexis is performed with the Kershner One-Step capsulorrhexis cystotome / forceps[5] or microcapsulorrhexor (Rhein Medical, Tampa, Florida USA). Hydrodissection is performed with a Binkhorst cannula and balanced salt solution by injecting a fluid wave from beneath the sub-incisional cortex to the opposite side of the capsule until a complete wave is created loosening the cortical attachments of the lens to the capsule. Phacoemulsification is performed using a single-instrument, single-incision technique,[6] with

a 30 degree tip, 20% phaco power, vacuum level at 100 mm, and aspiration rate at 20 cc/minute with the Bausch and Lomb Millennium phacoemulsification machine (Bausch and Lomb, Rochester, New York, USA). Irrigation and aspiration (I&A) of residual cortex is completed with the clear cornea I&A tip (Rhein Medical, Tampa, Florida USA). The capsular bag is reinflated partially with viscoelastic and the Anterior Modified Prolate IOL (Tecnis¨ Z-9000, Pfizer Ophthalmics, New York, NY, USA) is loaded into the microinjection cartridge and inserted into the capsular bag and centered in one motion.

The residual OVD is removed with gentle I&A. The Perfect Pupil® (Fig. 40.8) is then engaged at the tab with a hook and the pupil released. The device is backed out of the incision in the reverse procedure of it's insertion by grasping the arm with a forceps and gently dialing clockwise until removed. The pupil is again measured. Subtenons injection of 0.1 cc of cefazolin (Ancef, Smith Kline Beecham Pharmaceuticals) and dexamethasone (Celestone, Schering Corporation), is injected and the patient is discharged for examination the following day.

All patients underwent the procedure without complication. There were no instances of inadvertent iris sphincter damage, bleeding, or capsular rupture. Pupil size as measured preoperatively at the operating microscope, was 3.2 mm (range 2.0 mm to 4.0 mm), which expanded to 7.8 mm (range 7.0 mm to 8.0 mm) after insertion of the device, returning to 4.3 mm (range 3.0 mm to 5.0 mm) after removal.

The ease of removal of the device from it's tray, insertion of the device into the eye, and removal of the device at the end of the procedure, as determined by the surgeon, was similar to insertion of an intraocular lens. No special instrumentation or surgical techniques were required. All devices functioned as expected and there were no defects noted in the manufacture or packaging of the devices used in the study.

The patients, all of whom underwent the procedures under topical anesthesia, were comfortable during the insertion and removal of the device. There were no reported adverse effects experienced by the patients with the use of the Perfect Pupil®.

This instrument is unique when compared to others I have used, in that it does not share the disadvantages with existing pupil dilating methods. In fact, I have not found any downside to it's use. The device is sterile, disposable, flexible and can be easily

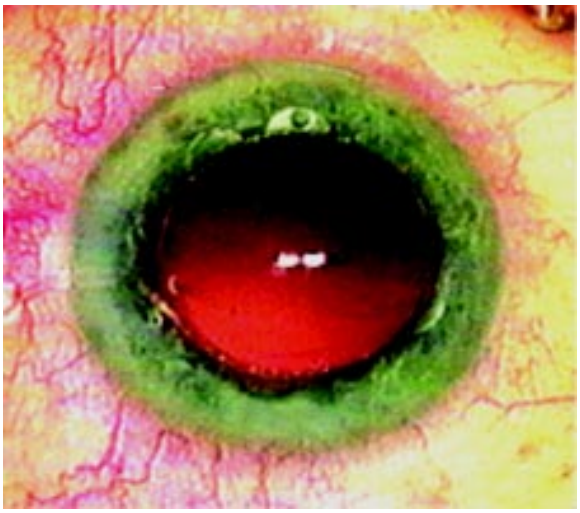

Fig. 40.8: Perfect Pupil® dilates and protects the pupil to 8 mm through the clear corneal incision

inserted through the smallest of incisions (less than 100 microns). Because of it's unique design, the device captures the pupillary margin, protects the sphincter, does not cause tears or stretching of the iris, bleeding or pigment dispersion. Because of the open ring design of the Perfect Pupil®, there is no interference with instrumentation of the eye. The device can be left in place for the entire procedure and following completion of the surgery, the device is just as easy to remove as it is to insert.

I am not aware of a single study that demonstrates the advantages of a pupillary dilation method that also affords the protection of the iris and pupillary margin that this device does. Indeed, one of the distinct benefits of the Perfect Pupil® is it's ability to fully protect the pupil it expands. In fact, this device may be of benefit to the posterior segment surgeon who must often view the retina and vitreous cavity through small, bound down pupils during surgery.

The results of this study demonstrate that when small pupils of less than 4.0 mm are encountered, the Perfect Pupil® effectively and consistently dilates the pupil to almost 8.0 mm. When removed, the pupil quickly returns to a size approximating the pre-operative state (4.3 mm). The resulting surgery leaves the patient with an iris that is indistinguishable from the appearance prior to surgery, and does not affect the iris function postoperatively.

Clear cornea cataract surgery offers distinct advantages over conventional cataract surgical techniques. The procedure is more efficient, requires

less cutting and less instrumentation and results in faster and superior visual outcomes.[1] The techniques of operating through a small, corneal incision places demands on the surgeon who must have an unobstructed view of the intraocular instruments and maneuvers to successfully complete the surgery. A small pupil (less than 4.0 mm), that fails to adequately dilate, can provide an obstruction to visualization that makes the techniques of cataract removal more difficult with added risk.

A method that adequately dilates the pupil, prevents iris sphincter damage, protects the pupil margin, and is easily performed has decided advantages for the clear corneal cataract surgeon. The Perfect Pupil® is just this superior device, and an excellent addition to small incision cataract surgery. When encountering pupils that do not adequately dilate, the surgeon will find the Perfect Pupil® on the shelf, ready to use, and easy to insert and remove. The Perfect Pupil® expands the pupil to 8 mm, protects the iris sphincter during surgery, and allows the pupil to return to normal size, shape and function following the clear cornea cataract procedure. It is an excellent adjunct in the armamentarium of every clear cornea cataract surgeon. Try other methods, I am convinced that every surgeon will find this an excellent solution to a difficult problem.

The Perfect Pupil® injectable was designed and developed by E. John Milverton, MD of Sydney, Australia and is manufactured and distributed by Milvella Pty. Ltd, Sydney, Australia. Perfect Pupil® injectable is a registered trademark of Milvella Pty. Ltd. Dr Kershner has no proprietary or financial interest in the techniques or instruments described in this chapter.

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