"DIY" technique of self retaining disposable iris retractors for non-dilating pupils in cataract surgery

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Abstract

Aim: To explore a simple and low-cost self made disposable iris retractors and study its clinical efficacy and safety for non-dilating pupils in cataract surgery **Methodology**: Polypropylene suture (5-0) and silicone tube are used to make iris retractors. A prospective study was carried on 25 patients (25 eyes) with a maximally dilated pupil size 2.5-4 mm which underwent SICS/phacoemulsification using self made iris retractors. Another 25 cases with normal size pupil serve as a control group. **Results**: Pupils could be expanded to approximately 4.5-5.5 mm with our self made iris retractors during surgery. No serious post-operative complication was found. Most 22 (88%) of the pupils returned round to oval shape, light reflex returned to varying degree of the 1st day after surgery. BCVA stabilized in 18 eyes (72%) at 1st week, 21 eyes (84%) in 1st month and 22 eyes (88%) after 1 and half month. Compared with the control group, more time was needed to complete the surgery in non-dilating pupil. **Conclusion:** Our self made (DIY technique) disposable self retaining iris retractors could be easily obtained pre-operatively and intra-operatively. It performed both safety and efficacy in our study. The simple self made device has shown economic and practical values especially in Govt Hospitals/Tertiary care hospitals.

Keywords: DIY technique, non-dilating pupil, iris retractors, cataract surgery.

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INTRODUCTION

A Small pupil presents a considerable challenge for cataract surgeons. Such cases carry a fairly high risk of complications such as failed capsulorhexis, posterior capsule rupture, vitreous loss, dropped nucleus, endothelial cell loss and asymmetrical IOL fixation¹. Small pupils are commonly caused by a lot of reasons such as central posterior synechias, related to anterior uveitis, trauma, previous surgery, advance age, diabetes and pseudoexfoliation syndrome etc²⁻⁴. Previously, various methods have been devised to enlarge the pupil for increased safety; Graether developed a useful device to expand the pupil⁵. Mackool⁶ described iris retractors

that have small hooks connected to small blocks of titanium that can be used without assistance to retract the iris. Chang and Campbell⁷ reported their usage of iris hooks in small pupils associated with Intraoperative floppy iris syndrome. Getting and Omphroy⁸ modified techniques in using iris retractors to reduce the possibility of iris prolapsed as well as damage. Malyugin has proposed a new injectable iris ring useful for cataract cases with small pupils. (B. Malyugin, MD, "New Iris Ring Useful for Cataract Cases with Small Pupils and Weak Zonules," Eurotimes. Accessed December 28th, 2012). Meanwhile, the device we have found most useful and commonly used, is the flexible iris retractor made from modified suture material with a silicone sleeve. This type of iris retractor has long been commercialized and been sold by ophthalmic instrument companies universally 10,11. The modified and some self-made flexible iris retractor has been reported occasionally 12-14. However, neither of them was both economic and practical enough to make them generally acceptable. Here we develop a cheap, self-made, self retaining disposable flexible iris retractor which can be easily obtained preoperatively or intraoperatively. This simple self-made device has shown economic and practical values especially in primary care hospital of the less developed districts. In addition, trials have shown that it performs as well as, if not better than conventional pupil stretching in terms of both safety and efficacy.

MATERIALS AND METHODS

This prospective study was performed at General Hospital, Sangli from November 2014and October 2015. Twenty five cases (14 males and 11 females) with pupils (between 2.5 and 4.0 mm) unresponsive to conventional pupil dilation techniques were involved as experimental group (small pupil group) in our study. The mean age was 59.7±15.3 (SD) years old. These cases had various nucleus density (II-IV) and different ocular comorbidities, which included anterior uveitis (16%). previous anti-glaucoma surgery (8%), diabetes (20%) and retinal detachment (4%). The best corrected visual acuity (BCVA) was between Light Perfection and 6/18. Control group (normal pupil group): 25 normal age-matched (62.3±18.2y) cases of SICS with normal pupil size were included; Nucleus density was between II to IV; the included cases had no history of other ophthalmic disease (Table 1).

Table	1:	Backs	round	demog	raphics
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Parameters	Experimental group	Control	Р
N	25	25	
Gender (M/F)	14/11	13/12	
Age (a)	59.7±15.3	62.3±18.2	0.21
Nucleus density (II)	6	4	
Nucleus density (III)	14	15	
Nucleus density (IV)	5	6	

Polypropylene suture (ETHICON, INC. PROLENE 5-0), disposable silicone tube, icense stick, microscopic needle holder, scalpel. **Preparation of iris retractor** l) We cut the suture prolene, "U" shape bended prolene was roasted by incense stick fire temperately. The tension of prolene and its distance from fire was critical. After heating, the prolene was taken away for natural cooling. Then, a fixed "U" shape polypropylene hook was formed: 2) The silicone tube was cut into 1 mm small piece which was used as holder. Each piece of holder was punctured by the needle of the prepared "U" shape suture prolene. The holder was moved and placed 6 mm from the prolenen hook; 3) Suture prolene was cut by scalpel at 12 mm from the prolene hook and an iris retractor is







Figure 3

Figure 1

Figure 2

The retractor is 12 mm in length (we call it retractor rod) and has a 1 mm hook at the end as shown in Fig.3.The small silicone holder holds the retractor in place. Scissors should not be used to cut the suture prolene, since the sharp end of the scissors cut suture prolene has a higher likelihood to break the posterior capsule rupture.

Simple process to make a disposable flexible iris retractor

After packaging, they were disinfected by autoclave/ethylene oxide sterilization. We usually made dozens of retractors and sub-packaged 4 retractors as a group in small permeable plastic bag for sterilization. Domestic horizontal autoclave was employed in our hospital. The main sterilization parameter as follows: Autoclave – 121°C for 20 mins with 20 pounds pressure. Surgical techniques

One percent of tropicamide, 10% phenylephrine, and 0.1% diclofenac drops were given 4 times in the hour before surgery to dilate the pupil and stabilize the blood-aqueous barrier. Four areas for the wound which on the

peripheral cornea were marked 90 degrees; from each other. A paracentesis was made in a comfortable position for insertion of the second instrument. Two to four additional \$tab incisions were made by a 26 no needle at the marked sites for the ins hooks, The self-made ins retractors were then placed. Once the retractor has been inserted into the anterior chamber, the needle holder was then turned so that the retractor can hook the edge of the iris and pull it toward the entry site. The silicone holder then be adjusted to the appropriate length and tension. With the iris retractors in position, viscoelastic material used to displace aqueous from the anterior chamber and stiffen the eve before the corneal incision/tunnel was made.. The hooks were adjusted in position again if necessary, creating a square, triangle or "D"-shaped pupil which afford enough space for CCC/capsulotomy. The remainder of the procedure was performed in a standard fashion. At the conclusion of the case, there were two ways to remove the retractor. The first one was that retractor were pulled out directly. When the hooked

portion of the retractor came close to the tunnel, it would bend and slip out; the other one was that we could remove the silicone holder first, and cut the extraocular portion of retractor rod. Then the intraocular portion was dragged out though the tunnel. Sometimes, viscoelastic material was needed in this procedure to prevent posterior capsular rupture.





Figure 4 and 5: Clinical application ot sell-made ins retractor in small pupil cataract surgery

Generally, as to how many iris retractors should be used in an operation, the decisions were made on a 'case by basis by surgeon according to their experience as shown in the above picture. The mean operation time, was documented intraoperatively. Postoperative care and follow-up Postoperatively, a topical mixture of antibiotic and steroid eye drops for 2wk were prescribed. Follow-up reviews were 1 d, 1 wk, 1 mth and 1 and half mth after operation. The visual acuity, pupil size and complication were observed.

Statistical Analysis

All data are presented as mean $\pm SD$. Statistical analysis was performed by independent sample Student's /-test, P<0.05 was considered as statistically significant in all tests.

RESULTS

In experimental group, pupils could be expanded to approximately 4.5-5.5 mm with 2-4 self-made iris retractors in operation. The mean time for placement of self-made iris retractor was 5 min, the mean operation time was 27.5min.Compared with the control group, only the mean operation time significantly increased (r=2.38, P < 0.05, Table 2). No serious postoperative complication was found. There were only a few minor surgical complications included minute sphincter tears in 2 eyes (8%), a transitory increase in intraocular pressure in four eyes (16%), and micro-hyphacma in one eye (8%). Frequently, some mild increase in inflammation manifested by increased flare and cells in the anterior chamber, was observed on the first postoperative day as conventional management of small pupils (16 eyes, 64%). The inflammatory response was related to iris manipulation and responded promptly to topical steroids. Most (22 eyes, 88%) of the pupils size 3-4 mm (round or oval shape) at the first day after surgery and remained stable in follow-up. Light reflex restored to varying degrees. Visual rehabilitation was also rapid in most eyes.

BCVA stabilized in 18 eyes (72%) at one week, in 21 eyes (84%) at one month and 22 eyes (88%) in 1 and half month.

DISCUSSION

A small pupil is undesirable for cataract and vitreoretinal surgery. Several methods have been developed to enlarge a small pupil intraoperatively. Flexible iris hooks has been introduced by de Juan E and Hickingbotham and Nichamin^{9,15}. The use of flexible iris hooks for cataract surgery continues to be refined and commercialized. In our study, we develop a simple and low-cost self-made iris retractor by DIY i.e. Do in Yourself technique. We have used our self-made iris retractor in 25 case; with small pupils unresponsive to conventional pupil dilation techniques. No Serious postoperative complications were found. There were only minor surgical complications included minute sphinceter tears, a transitory IOP increase, and one case of micro-hyphaema. Compared with the control, the operation time of small pupil group seemed longer. But the extension of operation time mainly related to the placement of iris retractor rather than operation itself. Mild increase in inflammation related to iris manipulation responded promptly to topical steroids. Visual rehabilitation was also rapid in most eyes. We didn't present the exact postoperative BCVA of both groups but the stabilisation time of it. Actually, the postoperative average BCVA of small pupil group was relatively lower than that of the control group. This was reasonable since postoperative BCVA of eyes in small pupil group was affected by other ocular co-morbidities such as anterior uveitis, previous anti-glaucoma surgery, diabetes etc. Pupil size of 22 eyes (88%) returned to 3-4 mm at the first day after surgery and 2 eyes (8%) had minute sphincter tears. The rest 1 eye (4%) could not recover its round shape, showing irregularities in pupil border without visible damage or abnormality. Indeed, iris retractors cause damage to the iris structure at the point at which the iris retractors are positioned. These could explain why other 4% pupils could not return to normal size even though no visible abnormality was found. Most likely, their inner structures were slightly damaged and the function of sphincter pupillae was decreased. However, in our experience, regular recover of the pupil size could result from the devices more gently stretching of the iris tissues. In a word, our self-made self retaining iris retractor showed a good safety in cataract surgery. In addition, to achieve optimal pupil size, the number of self-made iris retractor employed in a surgery should be decided by the surgeon regarding the particular condition and his/her experiences. Frankly, the aim of the study at first was to prove this self-made retractor rod is practicable and safe. We have not conducted a wellcontrolled study to comparing the commercially available retractor with our self-made retractor rod about their clinical parameters such as complication rates, surgery and implantation time etc. Since its mechanism and usage are similar to the previously reported mainstream iris retractor, the clinical parameters mentioned above couldn't be far from each other. And this has been manifested by our observation in daily medical practice. However, based on rigorous attitude, a better controlled research is needed in the future. Just like those commercialized product, our self-made iris retractor is strong enough to break even firmly adherent synechiae and enlarge pupil size vet flexible and self retaining enough to prevent damage to the anterior capsule in phakic eyes. However, our self-made iris retractor can be easily and quickly made preoperatively. Furthermore, this kind of retractor can be quickly made intraoperatively if necessary in some emergency. According to our experience, one polypopylene suture can be cut into 40-45 retractors which cost roughly Rs-12-15 per retractor. When compare with the commercially available ins retractor, which cost between Rs- 550-600 per retractor. Our self-made iris retractor is much cheaper This lowcost retractor is especially suitable for the primary care hospital of the less developed districts such as those densely populated rural area in India. In addition, the procedure to retractor has shown easy acceptability and simplicity. Meanwhile, our trials have performs both safety and efficacy. In conclusion, this simple self retaining self-made disposable flexible iris retractor is practical and low-cost ophthalmic surgical instrument which would benefits primary hospital in some undeveloped areas. It can be easy obtained preoperatively and intraoperatively if necessary.

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