Management and outcomes of the small pupil in cataract surgery: iris hooks, Malyugin ring or phenylephrine?

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Abstract

Purpose: to investigate outcomes for small versus large pupils in cataract surgery using different pupil expansion techniques.

Methods: retrospective case-series reviewing 20,175 patients' cataract surgery electronic medical records at Moorfields Eye Clinic in Bedford Hospital NHS Trust from January 2010 to April 2020. Outcomes such as visual acuity (VA), intraocular pressure, intraoperative, post-operative complications were recorded and small pupil expansion device outcome.

Results: 1,426 patients were identified as having small pupil (SP). Of these, 1,110 patients (77.8%) had interventions to expand the pupil including 447 (31.3%) with intracameral phenylephrine (IC PE) alone, 194 (13.6%) with iris hooks and 469 (32.9%) with a Malyugin ring. The large pupil (LP) group had a statistically significant greater gain in VA than the SP group ($p<0.05$). SPs had a significantly higher rate of intraocular complications including posterior capsular rupture (PCR) with vitreous loss (OR 2.75, $p<.001$). There was also a significantly higher rate of post-operative complications such as corneal oedema (OR 2.64, $p<.001$) and anterior uveitis (OR 2.11, $p<.001$) in the SP group. However, VA improvement and complications between the different pupil expansion groups showed no significant differences ($p>0.05$) except for a greater rate of iris tears in the Malyugin group ($p<0.05$).

Conclusion: To date, this is the largest reported case series comparing Malyugin rings and iris hooks with other pupil expansion techniques. The various techniques to expand pupil size appear to be safe and equally effective in improving VA with a similar rate of complications except for a greater rate of iris tears with Malyugin ring.

Introduction

In cataract surgery, the presence of small pupils presents a major challenge.[1] It is estimated that 1-3% of cataract surgeries are associated with a small pupil. A small pupil restricts the area that the surgeon is able to work within and increases the chance of damaging the pupillary or capsular edge with surgical instruments. Visibility is also limited in smaller pupils as is the intensity of the red reflex, making it more difficult to perform capsulorrhexis and to crack and remove the nucleus. Thus, small pupils are associated with increased complications including posterior capsule rupture (PCR).[1,2] _ENREF_2 Other possible complications arising from these limitations include damage to the iris and corneal endothelium. Common comorbidities described in patients with small pupil include intraoperative floppy iris syndrome (IFIS), mitotic topical therapy and pseudoexfoliation syndrome (PXF).

IFIS is characterised by poor pupillary response and increased propensity for iris billowing and prolapse.[3] IFIS can occur with the current use of systemic alpha-1 antagonists which are used to treat benign prostatic hyperplasia (BPH). Tamsulosin has been identified as the most likely α -blocker causing IFIS, with risks increased up to forty times more compared to other alpha-1 antagonists and causing more severe IFIS.[4] IFIS can also occur with the use of other non-selective alpha-1 antagonists such as alfuzosin and terazosin. [4]

Pupil dilation techniques have therefore been used to address smaller pupils and/or patients with IFIS or PXF. These techniques range from topical and intracameral mydriatics, iris hooks/retractors, Malyugin dilator rings and viscomydriasis. Topical mydriatics can act as sympathomimetics (phenylephrine), and anticholinergic agents (tropicamide or cyclopentolate). A combination of

phenylephrine and tropicamide produces a stronger mydriatic effect than when used individually.[5] Mechanical dilation techniques such as hooks and rings work by direct mechanical manipulation to increase pupillary size intraoperatively. Viscoamydriasis is also used to increase pupil diameter, without the need of further pupil expansion devices.[3]

There is a paucity of data available concerning visual outcome measures and complication rates in cataract surgery using pupil expansion devices in particular when comparing Malyugin rings and iris hooks with other techniques. We therefore investigated the outcomes and complication rates of pupil dilation techniques at our centre.

Methods

All patients who had cataract surgery without additional procedures between January 2010 and April 2020 were included. A retrospective study on cataract surgery electronic medical records at Moorfields Eye Clinic in Bedford Hospital NHS Trust was undertaken. Only consultants, senior fellows and senior staff grade surgeons were included. This research followed the principles in the Helsinki declaration and internal ethics approval was obtained.

Phacoemulsification was performed using the Infiniti machine (Alcon Laboratories, Switzerland). A 6.25 or 7.0 mm, 5-0 Malyugin ring or 5 flexible iris hooks were used. The choice of pupil expansion

technique was determined by the operating surgeon. The pupil size was subjectively determined by the operating surgeon.

Data was collected from the electronic medical records system (Medisoft, Ltd., UK). This included baseline demographics, operated eye, comorbidities (α -blocker use, corneal pathology, glaucoma, diabetes, age-related macular degeneration (AMD), PXF, dense cataract, retinal pathology, high myopia, amblyopia), biometry measurements, surgeon, intraoperative (IFIS, descemet membrane (DM) tear, iris prolapse, iris tear, PCR, vitreous loss, zonule dialysis) and postoperative complications (cystoid macular oedema (CMO), anterior uveitis, atonic pupil, retinal tear or detachment) visual acuity (VA), intraocular pressure (IOP) and pupil expansion technique if small pupil. Visual acuity was recorded as best corrected logMAR pre-operatively and then at 4 weeks post-operative. The data was accurate and complete because the system employs a forced manual entry mechanism which must be completed before a letter can be generated. Each free text entry box was also analysed to ensure that the correct data was extracted.

Statistical analysis

Multivariate analysis using repeated measures were conducted to compare the effects of group (large vs small pupil) on IOP and VA. Where significant, post hoc testing was completed with covariates accounted for. Covariates of interest included: corneal pathology, AMD, diabetes, retinal pathology, glaucoma, amblyopia, IFIS, α -blocker, dense cataract, PXF and high myopia.

Explanatory models were tested using logistical regression analysis to determine predictors of complications for both large and small pupils. Separate analysis was carried out for each complication. Pupil size was entered at the first step of analysis with the second step of analysis demographics (age, gender, ethnicity) and co-morbidities entered as explanatory models.

Multivariate analysis using repeated measures was also conducted to compare the effects of the intervention (intracameral phenylephrine (IC PE), Malyugin ring, iris hooks, no intervention) on IOP

and VA. Post hoc tests used the Bonferroni correction. All statistical analyses was conducted using IBM Statistical Package for Social Sciences (SPSS) v26.

Results

A total of 20,175 patients were included, of which 1,426 had small pupils. In the small pupil group, 1,110 patients (77.8%) had interventions to expand the pupil including 447 (31.3%) with intracameral phenylephrine (IC PE) alone, 194 (13.6%) with iris hooks and 469 (32.9%) with a Malyugin ring. The mean patient age was 78.6 in the small pupil group and 74.9 in the large pupil group. The small pupil group had more males (58%) whereas the large pupil group had more females (59%). Table 1 shows baseline clinical parameters and pre-operative versus post-operative logMAR visual acuity outcomes between small and large pupils. Mean duration of follow-up was 367.3 days in the small pupil group and 323.6 in the large pupil group.

Small pupil vs large pupil outcomes

Intraoperative complications

The small pupil group, whilst controlling for other independent variables (corneal pathology, AMD, diabetes, retinal pathology, glaucoma, amblyopia, IFIS, α-blocker, dense cataract, PXF and high

myopia), had a significantly higher rate of intraocular complications including PCR with vitreous loss (OR 2.75 (CI 1.69-4.46, p<.001)), DM tear (OR 8.42 (CI 3.32-21.35, p<.001)), Iris tear (OR 8.40 (CI 3.07-22.97, p<.001)), and zonular dialysis (OR 4.74 (CI 2.40-9.40, p<.001)). No significant increase risk was found for the small pupil group for retinal tears or detachments (p>0.05).

Within these complications, specific risk factors were identified after controlling for other independent variables. There was a significantly higher rate of PCR in patients with dense cataracts (OR 4.71 (CI 2.68-8.29, p<.001)). Dense cataracts (OR 4.60 CI 1.84-11.51, p=.001)) and PXF (OR 17.82 (CI .49-5.48, p<.001)) also increased the rate of zonular dialysis. Whereas IFIS (OR 5.49 (CI 1.59-18.89, p=0.007)) was the only significant risk factor for iris tears.

Postoperative complications

There was a significantly higher rate of atonic pupil (OR 50.26 (CI 18.16-139.12, p<.001)), corneal oedema (OR 2.64 (CI 1.99-3.50, p<.001)), CMO (OR 1.77(CI 1.15-2.71, p<.01)) and anterior uveitis (OR 2.11 (CI 1.35-3.31, p<.001)) in the small pupil group after controlling for other independent variables. The risk of CMO was also independently increased by comorbidities including diabetes (p=.03), corneal pathology (p<0.001), and having a dense cataract (p<0.001). The risk of corneal oedema was also independently increased by comorbidities including glaucoma, corneal pathology and dense cataracts (p<0.001).

Small pupil expansion technique outcomes

Pre-operative versus post-operative logMAR visual acuity improvement between the different pupil expansion strategies showed no significant difference when all other independent variables were controlled (p>0.05). There were also no significant differences in post-operative IOP outcomes

between the groups (p>0.05). Table 2 shows intraoperative and post-operative complications between the different pupil expansion techniques. The proportion of patients with iris tears was significantly higher in the Malyugin ring group than in those cases requiring no intervention, IC PE alone or iris hooks. The proportion of endothelial damage with DM tears was also higher in the Malyugin ring group although post-operative corneal oedema was greater in the iris hooks group, however, neither of these were statistically significant. Although the proportion of patients who had a loss of ≥3 logMAR lines was highest in the small pupil group which had no intervention, this did not reach significance.

Discussion

This study comprehensively examines both the intra-operative and post-operative outcomes indicators for the most commonly employed pupil expanding techniques. Baseline characteristics were similarly matched in terms of age, gender, and ethnicity. The primary outcome of VA improvement was encouragingly improved in both small and large pupil groups but the difference was significantly greater for large pupils. The small pupil group also had a significantly greater proportion of patients who lost 3 or more logMAR lines of vision reflecting the increased risk to these patients.

Complications were noted to be increased in both the intra-operative and post-operative phases with small pupils. Small pupils had higher rates of PCR, DM tears, iris tears, atonic pupil, corneal oedema, CMO, anterior uveitis and zonular dialysis. This is unsurprising as small pupil cataract surgery often have other co-morbidities and anatomical challenges which require additional surgical manipulation.[6] _ENREF_11 In our study, PXF was associated with a higher incidence of small pupils and dense cataract. Furthermore, as this study highlights, additional steps are necessary which in itself induces risks and complications.

Previous groups have shown a low rate of intraoperative complications for Malyugin ring and iris hooks.[7-9] Similarly in our study, we found a low overall rate of intraoperative complications for both

techniques except for a higher rate of iris tears in the Malyugin ring group. It was also reassuring to see equivalent VA gains regardless of pupil expansion technique and no differences in significant loss of vision (loss of 3 or more logMAR lines) between them. Additionally, we report a low rate of post-operative complications with a long duration of follow-up for which there is limited data. Nderitu and colleagues[9] found higher rates of post-operative corneal oedema and anterior uveitis with Malyugin rings. However, at our centre, after controlling for covariables in our multivariate analysis we did not confirm this. In their study they did not use a multivariate analysis and therefore it is possible other covariables may have led to these increases in the Malyugin ring group.

It may not be surprising that the Malyugin ring has a higher rate of iris tears. When the Malyugin ring is deformed during retraction, the scrolls can unpredictably crush or release the pupil margin. This is because the scrolls behave like a torsional spring and compression spring with narrowing of the gap as the arms are moved towards each other and vice versa.[10]. The new Malyugin ring 2.0 has tried to eliminate some of these issues by having a new smaller gauge material thereby reducing the amount of force required to compress the ring by 70%. Furthermore, larger spacing in between anterior and posterior scrolls allows for easier engagement and disengagement from the iris.[6]

To date, this is the largest study of its kind comparing iris hooks and Malyugin rings to other pupil expansion techniques; demonstrating equivalent overall safety and VA outcomes. Another advantage of our study was that all cataract surgeries were performed by senior independent surgeons, reducing the risk posed by the learning curved of trainee surgeons which will induce further data bias. Furthermore, this study's data was derived from a single centre where widespread electronic patient records exists. There is also forced entry whereby the record cannot be completed without specific options being selected, ensuring high completion rates, consecutive cases and accuracy. Each surgical record was also reviewed for their free text comments as surgeons often include information in other areas including devices used or complications. This reduced the risk of

transcriptional or recall bias. We ensured that other independent co-variables were adequately controlled for in the multivariate analysis.

Limitations include that over the period of the study, a new iteration of the ring had emerged but it was only used at our centre from mid-2019. The actual size of the pupil was not measured directly but rather categorised for the electronic medical record system and determined by the surgeon. Furthermore, we did not have a reason for why a particular technique was used, although it appears many of the surgeons had a particular preference. It is likely that the ring was used in more complicated cases which may influence the results. Additionally, we are not aware at what threshold the technique was employed, or the decision making process behind it. It is often based on their experience of management of a small pupil or their surgical experience to successfully complete a case with a small pupil, in addition to their handling of the first eye cataract case; this may have introduced systematic bias which could have their influenced the results in this study. Whilst there was excellent digital recording, the study design was retrospective in nature and all the data was derived from a single centre. In particular, post-operative VA outcomes were missing for a proportion of patients as well as the aetiology of the cataract not being available because of the retrospective collection.

In conclusion, to date, this is the largest observational study exploring the outcomes of iris hooks and Malyugin rings to other pupil expansion techniques in cataract surgery. The use of all the different small pupil management techniques led to successful and safe management of small pupils with no significant difference in post-operative VA or IOP between techniques. However, extra care when using the Malyugin rings may be warranted to reduce the risk of iris trauma.

Conflicts of interest

There are no conflicts of interest to declare.

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References

1. Sparrow, J.*, et al.* The Cataract National Dataset electronic multi-centre audit of 55 567 operations: risk indicators for monocular visual acuity outcomes. *Eye* **26**, 821-826 (2012).
2. Narendran, N.*, et al.* The Cataract National Dataset electronic multicentre audit of 55 567 operations: risk stratification for posterior capsule rupture and vitreous loss. *Eye* **23**, 31-37 (2009).
3. Chang, D.F., Osher, R.H., Wang, L. & Koch, D.D. Prospective multicenter evaluation of cataract surgery in patients taking tamsulosin (Flomax). *Ophthalmology* **114**, 957-964 (2007).
4. Chatziralli, I.P. & Sergentanis, T.N. Risk factors for intraoperative floppy iris syndrome: a meta-analysis. *Ophthalmology* **118**, 730-735 (2011).
5. Park, J.-H., Lee, Y.-C. & Lee, S.-Y. The comparison of mydriatic effect between two drugs of different mechanism. *Korean Journal of Ophthalmology* **23**, 40-42 (2009).
6. Grzybowski, A. & Kanclerz, P. Methods for achieving adequate pupil size in cataract surgery. *Current opinion in ophthalmology* **31**, 33-42 (2020).
7. Akman, A., Yilmaz, G., Oto, S. & Akova, Y.A. Comparison of various pupil dilatation methods for phacoemulsification in eyes with a small pupil secondary to pseudoexfoliation. *Ophthalmology* **111**, 1693-1698 (2004).
8. Chang, D.F. Use of Malyugin pupil expansion device for intraoperative floppy-iris syndrome: results in 30 consecutive cases. *Journal of Cataract & Refractive Surgery* **34**, 835-841 (2008).
9. Nderitu, P. & Ursell, P. Iris hooks versus a pupil expansion ring: Operating times, complications, and visual acuity outcomes in small pupil cases. *Journal of Cataract & Refractive Surgery* **45**, 167-173 (2019).
10. Bhattacharjee, S. Pupil-expansion ring implantation through a 0.9 mm incision. *Journal of Cataract & Refractive Surgery* **40**, 1061-1067 (2014).