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Comparison of Visual Outcome in Phacoemulsification Surgery with and Without Intra-Operative Use of Pupil Dilating Device

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Abstract: Background: It may be challenging to perform phacoemulsification in cataract patients who have small or poorly dilated pupils. Objective: We conducted this cross-sectional analysis of secondary data to compare the visual outcomes, contrast sensitivity, and higher order aberrations in eyes in with and without the use of pupil dilating technique during phacoemulsification. Methods: We compared the best corrected distance visual acuity (BCDVA), pupil size and contrast sensitivity (photopic and scotopic conditions), higher order aberrations, and satisfaction in 20 eyes (18 patients) in whom no pupil dilating device was used (Group A) with 19 eyes (17 patients) in the 'Pupil dilating device group' (Group B). In small pupil patients, the surgeon used one of the pupil dilating technique (stretch pupilloplasty, iris-hook, or malyugin rings) for intra-operative pupil dilatation. Results: In the post-operative examination, the median (IQR) logMAR values for BCDVA was significantly lower in Group A compared with Group B (0.00 [0.00, 0.09] vs. 0.18 [0.00, 0.18], p = 0.03). However, there were no significant differences in the near vision. The mean change in pupil size was significantly more in Group A compared with Group B (0.85 [0.46] vs 0.53 [0.31]; p = 0.01). After adjusting for age, gender, and time since surgery, mean contrast sensitivity (photopic) was significantly lower in whom Iris Hooks were used compared with those in whom pupil dilating device was used (-0.270, 95% confidence intervals [CI]: -0.464, -0.076, p < 0.001). The satisfaction with vision was very high (97%). Conclusion: Pupil dilating devices are often used in small pupils. However, visual acuity and pupillary reaction may be reduced post-operatively in these patients. Thus, they should be adequately counselled about these potential side effects during the pre-surgical period.

Keywords: Pupil Dilating Devices, Visual Outcomes, Higher Order Aberrations, Contrast Sensitivity, Phacoemulsification

1. Introduction

It may be challenging to perform phacoemulsification in cataract patients who have small or poorly dilated pupils.. Some of the reasons for miotic pupil are aging, diabetes, pseudo-exfoliation syndrome, posterior synechiae, glaucoma surgery and chronic iritis [1, 2]. It has been demonstrated that the systemic α-1 antagonist (tamsulosin hydrochloride) which is useful for treatment of benign prostatic hypertrophy may also result in miosis and poor pupil dilation [3]. Sometimes this may be accompanied with intraoperative floppy-iris syndrome (IFIS) [3]. A moderately dilated pupil allows the surgeon to perform phacoemulsification easily resulting in good clinical outcomes [4].

There is limited consensus in the existing literature on the size of the pupil that is insufficient to proceed with cataract surgery; it may start from a pupil diameter of 6.00 mm [5]. Small pupil is a risk factor for various intraoperative and postoperative complications in cataract surgery. Insufficient preoperative dilatation and/or intraoperative pupil constriction may result in iris injury and subsequently photophobia [6]. Preoperative mydriatic drops augmented

with intracameral mydriatic injections is often the first choice in the management of small pupil and provides adequate dilatation in most eyes [7, 8]. Four important surgical maneuvers help us successfully perform phacoemulsification when pharmacomydriasis and viscomydriasis [9] fail to achieve adequate pupil dilation. They are synechiolysis, stretch pupilloplasty, sphincterotomy, and the use of mechanical pupil expanders [10]. Often when other strategies fail, mechanical pupil dilation helps in achieving good and sustained mydriasis [11].

Though surgical manipulation for pupil enlargement is possible, it can lead to complications such as higher risks of pupillary sphincter tear, iris bleeding, iris tissue damage, and intense postoperative anterior chamber fibrinoid reaction [12, 13]. These complications could affect visual outcomes post operatively. Some methods developed for enlarging miotic pupils during phacoemulsification are stretch pupilloplasty, malyugin ring, iris-hook, nylon iris retractors, and Graether pupil expander [12, 14-18].

As a surgeon conducting phacoemulsification surgeries in miotic pupils, the goal is to have adequate pupil to perform uneventful surgeries. However, at the same time one would like to have adequate reactivity of the pupil, pupil contour that is near normal, and good post operative vision. Though pupil dilating techniques can achieve adequate and stable pupil diameter during cataract surgery, inappropriate use of these devices can cause chronically dilated atonic postoperative pupil [12, 13, 19]. With this background, we conducted the present study to compare the visual outcomes, contrast sensitivity, and higher order aberrations in eyes in whom the pupil dilating device was not used with eyes in whom pupil dilating technique was used during phacoemulsification.

2. Methods

We have conducted a cross-sectional analysis of secondary clinical data collected from 39 eyes of 35 patients.

Study site

The study was conducted at Laxmi Eye Institute (LEI). LEI is a private tertiary eye care center located at about 50 kilometres from Mumbai (India).

2.1. Study Participants

All the participants were operated by same surgeon and in all these patients an aspheric intra ocular lens was implanted. These participants were evaluated 3 weeks to 9 months after their surgery. The inclusion criteria were: 1) Age 30-75 years; 2) Diameter of the dilated pupil (pre-surgery) ≥ 4.5 mm – Normal pupil participant; 3) Diameter of the dilated pupil (< 4.5 mm) – Small pupil participant; and 4) Use of a pupil dilating device in small pupil participants. The exclusion criteria were: 1) No ophthalmic pathology other than cataract; 2) Media opacity during follow-up evaluation; 3) Amblyopia; 4) History of ocular trauma; and 5) Intraocular inflammation at the time of follow-up evaluation. Based on the above criteria, we included 20 eyes of 18 patients in the 'No Pupil dilating device group' (Group A) and 19 eyes of 17 patients in the 'Pupil dilating device group' (Group B).

2.2. Study Procedures

2.2.1. Surgical Procedure Used

The phacoemulsification procedure was done using the Alcon INFINITI ® Vision System (Alcon Laboratories Inc.) by a single surgeon. A clear corneal 2.8 mm temporal incision was made and IOL was inserted using a standard injector. In small pupil patients, the surgeon used one of the pupil dilating technique (stretch pupilloplasty, iris-hook, or malyugin rings) for intra-operative pupil dilatation as described elsewhere [12, 14, 16].

2.2.2. Study Variables

We abstracted the following data for analysis from the charts: 1) age; 2) sex; 3) date of surgery; 4) distance visual acuity (Snellen's chart and corresponding LogMAR values); 5) near visual acuity (N-notation chart); 6) contrast sensitivity (Pelli-Robson chart [20] with best corrected visual acuity in photopic and mesopic conditions); 7) Post-surgical pupil size (photopic and mesopic conditions) with Topcon autorefractometer (Topcon Medical Systems, Inc, NJ, USA); 8) type of pupil stretching device used in Group B; 9) Higher order aberrations (Total Higher order aberration [HOA], internal HOA, corneal HOA, Trefoil, Coma) using Hoya I-Trace (Tracey Technologies, Houston, TX); and 10) Satisfaction with current vision.

2.3. Statistical Analysis

The means and standard deviations (SDs), or median and inter-quartile range (IQR) were estimated for continuous variables, and proportion were estimated for categorical variables. We used the t-test to compare means across two groups using the t-test, or Mann-Whitney test was used for non-parametric data. We used the chi square test or Fisher's exact test for low expected cell counts to compare the proportions across groups. For more than two groups, we used Analysis of Variance (ANOVA) to compare the means and Kruskal-Wallis test for equality of medians across different data points for data that were not normally distributed. We also used linear regression models for multivariate analysis. The main explanatory variable in these models was the type of pupil stretching device used. The potential confounders were age, gender, and time after surgery.

For each test, a p value of < 0.05 a statistically significant result.

The study was approved by the local ethics committee.

3. Results

The mean (SD) age of patients was 62.4 (9.3) and 63.8 (11.9) in Groups A and B respectively. There were no significant differences in the gender distribution or laterality of the eye included in the study. Detailed information on the baseline characteristics have been shown in Table 1.

Table 1. *Comparison Demographic and baseline characteristics in patients.*

	No pupil dilating device used	Pupil dilating device used	P value
Eyes	20	19	
Age			
Mean (SD)	62.4 (9.3)	63.8 (11.9)	0.67
Gender			
Male (%)	12 (60)	14 (74)	0.37
Female (%)	8 (40)	5 (26)	
Laterality			
RE	10 (50)	12 (63)	0.41
LE	10 (50)	7 (37)	

BCDVA = Best corrected distance visual acuity, BCNVA = Best corrected near visual acuity.

In the post-operative examination, the median (IQR) logMAR values for best corrected distal visual acuity was significantly lower in the group in whom no pupil dilatation device (Group A) was used compared with those in whom the device (Group B) was used (0.00 [0.00, 0.09] vs. 0.18 [0.00, 0.18], p=0.03). However, there were no significant differences in the near vision (Table 2). The mean photopic pupil size was lower in Group A whereas the mean scotopic pupil size was lower in Group B; the differences were not statistically significant. However, the mean change in pupil size was significantly more in Group A compared with Group B (0.85 [0.46] vs 0.53 [0.31]; p=0.01). There were no significant differences in the contrast sensitivity (photopic or scotopic) between both these groups. The mean change in contrast sensitivity in both these groups was not statistically significant (0.34 [0.13] vs 0.43 [0.20]; p=0.11). Furthermore, aberrations were not significantly different in both these groups. We have presented all the values in Table 2.

Table 2. *Post-surgical comparison of photopic and scotopic pupil sizes, contrast sensitivity, and higher order aberrations in patients with phacoemulsification with and without pupil dilating devices.*

Parameters	No pupil dilating device used (Group A) Mean (SD)	Pupil dilating device used (Group B) Mean (SD)	P value
Vision			
BCDVA Median (IQR)	0 (0, 0.09)	0.18 (0, 0.18)	0.03
BCNVA n (%)			
N 6	19 (95)	17 (89)	0.74
N 8	1 (5)	1 (5)	
N 18	0 (0)	1 (5)	
Pupillary size			
Photopic pupil size	3.17 (0.47)	3.44 (0.71)	0.16
Scotopic pupil size	4.02 (0.06)	3.97 (0.59)	0.79
Change in pupil size	0.85 (0.46)	0.53 (0.31)	0.01
Contrast sensitivity			
Photopic contrast sensitivity	1.38 (0.17)	1.35 (0.21)	0.57
Scotopic contrast sensitivity	1.04 (0.18)	0.92 (0.27)	0.10
Change in contrast sensitivity	0.34 (0.13)	0.43 (0.20)	0.11
Aberrations			
Spherical aberration	0.28 (0.08)	0.24 (0.12)	0.20
Total HOA	0.12 (0.07)	0.13 (0.10)	0.69
Internal HOA	0.11 (0.07)	0.11 (0.08)	0.96
Corneal HOA	0.06 (0.03)	0.08 (0.05)	0.35
Trefoil	0.06 (0.03)	0.08 (0.07)	0.35
Coma	0.06 (0.06)	0.06 (0.04)	0.43
Secondary astigmatism	0.02 (0.02)	0.03 (0.03)	0.32

BCDVA = Best Corrected Distant Visual Acuity
BCNVA = Best Corrected Near Visual Acuity
HOA = Higher Order Aberrations

In the multivariate analysis, after adjusting for age, gender, and time since surgery, we found that mean contrast sensitivity (photopic) was significantly lower in those individuals in whom Iris Hooks were used compared with those in whom pupil dilating device was not used (-0.270, 95% confidence intervals [CI]: -0.464, -0.076, p<0.001). However, this was not significantly different in those in whom 'Stretched pupilloplasty' or 'Malyugin rings' were used. Even though the mean contrast sensitivity (scotopic) was also lower in individuals in whom Iris Hooks were used, the difference was not statistically significant (-0.229, 95% CI: -0.497, 0.038; p=0.09). Age was significantly associated with a lower contrast sensitivity in both the photopic (-0.011, 95% CI: -0.017, -0.006; p<0.001) and scotopic (-0.010, 95% CI: -0.018, -0.002; p=0.008) conditions. We have presented these models in Table 3.

Table 3. *Table showing the estimates and 95% confidence intervals from linear regression models for changes in contrast sensitivity.*

	Contrast sensitivity (photopic)	Contrast sensitivity (scotopic)
	Estimate (95% confidence intervals)	**Estimate (95% confidence intervals)**
Type of device		
None	Reference	
Stretched Pupilloplasty	0.085 (-0.058, 0.229)	-0.017 (-0.215, 0.180)
Iris Hooks	-0.270 (-0.464, -0.0765)*	-0.229 (-0.497, 0.038)
Malyugin Ring	-0.001 (-0.194, 0.191)	-0.230 (-0.495, 0.353)
Age	-0.011 (-0.017, -0.006)*	-0.010 (-0.018, -0.002)*
Sex		
Female	Reference	
Male	0.146 (0.315, 0.260)	0.112 (-0.046, 0.270)
Time since surgery (in months)	-0.003 (-0.140, 0.007)	0.001 (-0.014, 0.016)

Among higher order aberrations, we found that the mean corneal higher order aberrations were significantly higher in individuals in whom stretched pupilloplasty was used compared with those in whom not pupil stretching devices were used (0.042, 95% CI: 0.004, 0.081; p=0.03). Similarly, even though mean trefoil was higher in this group, the difference was not statistically significant (0.048, 95% CI: -0.004, 0.101; p=0.07). We have presented data on multivariate models for aberrations in Table 4.

Table 4. *Table showing the estimates and 95% confidence intervals (CI) from linear regression models for higher order aberrations (HOA).*

	Total HOA	**Internal HOA**	**Corneal HOA**	**Trefoil**	**Spherical Aberration**	**Total Coma**	**Secondary Astigmatism**
	Estimate (95% CI)	**Estimate (95% CI)**	**Estimate (95% CI)**	**Estimate (95% CI)**	**Estimate (95% CI)**	**Estimate (95% CI)**	**Estimate (95% CI)**
Type of device							
None	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Stretched Pupilloplasty	0.036 (-0.045, 0.117)	0.112 (-0.064, 0.087)	0.042 (0.004, 0.081)*	0.05 (-0.004, 0.101)	-0.075 (-0.158, 0.008)	0.003 (-0.045, 0.051)	0.007 (-0.013, 0.028)
Iris Hooks	-0.037 (-0.148, 0.072)	-0.044 (-0.146, 0.057)	0.001 (-0.051, 0.053)	0.011 (-0.06, 0.082)	0.081 (-0.032, 0.193	-0.043 (-0.108, 0.023)	-0.000 (-0.029, 0.029
Malyugin Ring	-0.015 (-0.124, 0.094)	-0.030 (-0.013, 0.071)	-0.002 (-0.054, 0.049)	0.030 (-0.040, 0.101)	0.033 (-0.078, 0.145)	-0.029 (-0.094, 0.036)	-0.001 (-0.030, 0.026)
Age	0.000 (-0.003, 0.004)	0.001 (-0.002, 0.004)	0.000 (-0.001, 0.002)	0.001 (-0.001, 0.003)	0.0050 0.0020, 0.0080)*	0.000 (-0.002, 0.002)	0.000 (-0.000, 0.001)
Sex							
Female	Reference						
Male	-0.024 (-0.089, 0.041)	0.027 (-0.087, 0.033)	0.008 (-0.022, 0.039)	-0.021 (-0.063, 0.021)	-0.036 (-0.102, 0.030)	-0.007 (-0.046, 0.032)	-0.003 (-0.019, 0.013)
Time since surgery (in months)	0.001 (-0.005, 0.008)	0.027 (-0.003, 0.008)	-0.001 (-0.004, 0.002)	-0.002 (-0.006, 0.002)	-0.005 (-0.012, 0.001)	0.003 (-0.001, 0.006)	0.001 (-0.001, 0.002)

About 97% of total individuals were extremely satisfied/satisfied with their current vision, the proportion was slightly higher in individuals in whom no pupil dilating device was used compared with the other group (100% vs 97%; p=0.49). Only one individual was not satisfied with current vision – a pupil dilating device was used in this case (Malyugin rings). We did not record any other complications in these patients.

4. Discussion

In this study, we compared the visual outcomes between eyes undergoing phacoemulsification with and without pupil dilating device. Our main finding was that the best corrected distance visual acuity is better in subjects with phacoemulsification without pupil dilating devices. Furthermore, we also found that that pupillary reactions were affected in subjects who had undergone phacoemulsification with pupil dilating procedures. Individuals in whom Iris hooks were used had lower contrast sensitivity (photopic) compared with individuals in whom no pupil dilating procedure was done. The overall satisfaction with current vision was not significantly in both the groups.

Pupil dilating techniques were introduced to avoid complications encountered during phacoemulsification surgery in eyes with inadequate pupil dilatation. These methods can facilitate intraoperative visualization and thereby reduce intraoperative complications. However, it is equally important that post-surgical vision is good, and the patient is satisfied with the procedure. As shown earlier, we found that the best corrected distance visual acuity was better in individuals who underwent emulsification without pupil dilating devices. Shingleton and colleagues [21], however, did not report any significant differences in best corrected visual acuity in pupil stretch phacoemulsification group and the control group. In our study population, we did not find any other pathology including macular pathology which may account for reduced BCDVA in this our study group. It is quite likely that a higher corneal aberration may help explain this.

The other important finding was the significant difference in the change in pupil size between these two groups. We found that photopic pupil size was higher in individuals in the pupil dilatation group and the scotopic pupillary size was higher in the group with no dilatation. The change in pupillary size (difference between photopic and scotopic), however, was significantly higher in the group in which no pupil dilatation procedure was used. Yuguchi and coworkers [19] also found that pupillary contraction reduced significantly in the group in whom pupil stretching was done. Though large pupillary areas may be associated with glares [22], nearly all the patients were satisfied with their post-operative vision. Though age may be associated with changes in pupillary reactions [23], the age groups were comparable in our population. Thus, it is quite likely pupillary reaction has been reduced in patients who underwent cataract surgery with pupil dilatation devices. This should be considered as one of the potential complications of this procedure and should be monitored regularly.

The unadjusted photopic and scotopic contrast sensitivity was slightly higher (though not statistically significant) in the group in which no pupil dilatation device was used. However, after adjusting for age, gender, and time since surgery, we found that the photopic contrast sensitivity to be significantly lower in the group in which Iris hooks were used. There may be an association between some of the higher order aberrations and contrast sensitivity; coma-aberrations are associated with contrast sensitivity whereas spherical aberrations are not [24]. Another study found that in the eyes with larger photopic pupil diameter (≥4.0mm), spherical aberrations affects contrast sensitivity; however, in those eyes with smaller pupil size (<4.0mm), coma-like aberration affects contrast sensitivity [25]. In general, we did not find any significant differences in the higher order aberrations between the two groups. We also found that age was significantly associated with a reduction in the photopic and scotopic contrast sensitivity.

We were limited by the secondary nature of our analysis. Pupillary size may have effect on ocular aberration and there is a need to control it during measurements. However, in the present study we were not able to control fixed pupil size during ocular aberration measurements.

Nonetheless, the study provides useful information on the role of pupil dilatation devices. Surgical technique should be safe, consistently reproducible, and induce the least intra and post-operative complications. Careful approach, surgeon's skills and minimum iris manipulations while performing cataract surgery in small pupils are helpful. However, these manipulations may also result in complications such as anterior chamber reaction, iris bruises, cortex residuals, or increased intra ocular pressure in early postoperative period to name some [2].

5. Conclusion

Iris hook technique is time consuming; it ensures stable pupil throughout surgery. [12] The Malyugin pupil expansion device is simpler and quicker to use compared with iris retractors or other pupil expansion rings, and is often used in small-pupils. [14] However, visual acuity and pupillary reaction may be reduced post-operatively in these patients. Thus, they should be adequately counselled about these potential side effects during the pre-surgical period.

Conflict of Interest

The authors have no conflict of interest to declare.

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