

Analysis of glistenings in hydrophobic acrylic intraocular lenses on visual performance

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Abstract

• **AIM:** To assess patients' visual performance with glistenings in one piece soft hydrophobic acrylic intraocular lenses (IOLs) (Alcon) 2y postoperatively.

• **METHODS:** This cross section trial included 120 eyes with one piece IOL at 2y postoperatively. Glistening was classified in 4 groups, ranging from 0 (none) to 3 (most evident) according to their severity in IOLs optics observed under a slit lamp. All eyes underwent a uncorrected and best-corrected visual acuity evaluation (UCVA and BCVA, LogMAR scale), a complete clinical examination, a contrast sensitivity (CS) evaluation by F. A.C.T chart, and a visual field test by Humphrey Field Analyzer II (HFA). One-way ANOVA was used for quantitative data, while Pearson χ^2 test was used for qualitative data to analyze the visual function of 4 glistening groups.

• **RESULTS:** Totally 120 eyes were enrolled with 30 eyes in each glistening group. There was no statistical correlation between glistening grades and patients' age, IOLs power, postoperative UCVA and BCVA ($P > 0.05$). Quantificationally, CS values among each group were not statistically different. However, qualitative analysis showed there were more eyes in grade 3 group than in grade 0 group having abnormally declined CS at high spatial frequency (10% vs 36.7% at 18 cpd, $P = 0.029$; 6.7% vs 26.7% at 12 cpd, $P = 0.013$). Mean deviation (MD) of the visual field test was -2.14 ± 2.31 , -1.97 ± 2.23 , -3.02 ± 3.17 , -4.12 ± 3.38 in group 0 to 3 respectively. There was a significant decrease in the most serious glistenings group ($P = 0.018$).

• **CONCLUSION:** Glistenings may potentially have an impact on contrast sensitivity at high spatial frequency and MD in visual field test.

• **KEYWORDS:** cataract; intraocular lens; hydrophobic acrylic; contrast sensitivity; mean deviation

INTRODUCTION

Since hydrophobic acrylic intraocular lenses (IOLs) have been used since mid-1990s, it has become the most popular one because it could provide better postoperative visual acuity (VA), low incidence of posterior capsular opacification and lighter postoperative inflammatory reaction^[1]. However, various problems, especially glistenings were identified in the process of postoperative follow up. "Glistening" represents a reduction in the transparency of the IOLs caused by bright spots in the internal optic matrix. According to several observations, almost all IOL materials may allow for the formation of glistenings, including silicone, polymethyl methacrylate (PMMA), hydrogel, hydrophobic and hydrophilic acrylic lenses, with incidence ranging from 40% to 100%^[2-6]. However, the frequency of glistenings in one-piece hydrophobic acrylic IOLs, appears to be the greatest^[6-8].

The specific mechanisms of the development of glistening have not yet been identified clearly. It has been proposed that the underlying pathology is fluid-filled micro-vacuoles^[9]. Suggested etiologies include AcryPak and Wagon Wheel packaging, rise of temperature when placed in the eye, change in the equilibrium water content, osmotic pressure from the aqueous and spinodal decomposition of the polymer network^[7,9-12].

Whether the density of glistenings in the IOL impacts visual functions is a matter of debate. Though, visual complaints such as glare and abnormal reflections have been reported, most studies indicate that glistenings do not affect postoperative visual acuity^[4,5,13-16]. However, for postoperative contrast sensitivity (CS), especially in high spatial density, contradictory data exists in literatures^[8,12,14,15,17,18]. Meanwhile, few relationships have been reported in other visual function tests, such as visual field.

The purpose of this study was to identify the correlation between the level of glistening and contrast sensitivity, as well as visual field disturbances in eyes with one-piece acrylic IOLs at two years postoperatively.

SUBJECTS AND METHODS

Subjects This study presents a randomized observational study performed at Zhongshan Ophthalmic Centre, Guangzhou, China, between October 2009 and August 2011. 120 eyes that had undergone small-incision phacoemulsification with AcrySof IOL (Alcon Laboratories, Ft Worth, USA) implantation between September 2008 and April 2010 were planned to be enrolled. The patients were randomly identified from medical records with no complications reported during the procedure, contacted by telephone and invited to participate in the study. The study followed the tenets of the Declaration of Helsinki and was approved by the local ethics committee. The purpose and methods of the study, including rare complications of cyclopentolate eyedrops, were explained to the parents before written informed consent was obtained.

Exclusion criteria included: Patients with postoperative best-corrected visual acuity (BCVA) over 0.1 logMAR (logarithm of the minimum angle of resolution), intraoperative or postoperative complications (*e.g.* anterior capsule opacification (ACO), posterior capsule opacification (PCO), growth of lens epithelial cells (LEC) on the IOL's anterior surface, systemic or ocular pathology (*i.e.* glaucoma, proliferative diabetic retinopathy, corneal pathology, uveitis or systemic medication therapy with anti-inflammatory agents), and previous intraocular surgery.

Methods

Surgical procedure All patients had a 3.2 mm cornea incision followed with a 5.0×5.0-mm² continuous curvilinear capsulorhexis created under sodium hyaluronate (1% Healon), and had phacoemulsification by the same experienced surgeon (C.B). All eyes received a single-piece hydrophobic acrylic IOL (AcrySof SA60AT, Alcon Inc, USA) implanted in the capsular bag, which has a 6.0 mm spherical optic and a 13.0 mm overall length. Tobradex (0.3%, Alcon, USA) eye drops were used four times daily for three days preoperatively and four weeks postoperatively.

Examinations All eyes underwent a complete clinical examination, which include uncorrected visual acuity (UCVA) and BCVA, by using an Early Treatment Diabetic Retinopathy Study (ETDRS) chart with a chart luminance of 160 cd/m², and a working distance of 4 m^[16], refraction test by non-cycloplegic autorefractometer (Topcon AR 8800, Tokyo, Japan), a slit-lamp examination, a measure of the intraocular pressure (IOP) with non-contact tonometer and an ocular fundus examination after pupil dilation for retinal and optic nerve pathology. Past neodymium: yttrium aluminum garnet (Nd: YAG) laser capsulotomy history was recorded. Then, they were separated into four groups on the basis of the amount of glistenings present.

The incidence and severity of glistenings were evaluated by examining the center of the IOL optic after pupil dilation using a slit lamp beam which was set at 10×2 mm² with an angle of 30 degrees. A single investigator who was masked to the visual testing results graded all glistenings (C.B). The intensity of glistenings was graded according to the classification of Tognetto *et al*^[19] as the number of glistenings in central visual axis on the following scale: 0= absent, 1 = trace (countable vacuoles), 2 = moderate (low density of uncountable vacuoles), and 3=severe (high density of uncountable vacuoles). The data was recorded and photographed at 16 × and 25 × magnifications with a six-megapixel digital camera (Nikon D-200, Nikon, Japan) mounted on a photo slit-lamp (TOPCON, Japan).

CS was tested with the Functional Acuity Contrast Test, a hand-held chart (F.A.C.T., Stereo Optical, Chicago, IL, USA) using the manufacturer's recommended testing procedure. The F.A.C.T. chart, which is arranged in five rows (of spatial frequencies 1.5, 3, 6, 12 and 18 cycles per degree (cpd)) and nine columns (representing various contrast levels), is a simple, fast and effective test that could provide not only the CS values, but also the number of eyes with abnormal results^[20]. All of the tests were measured monocularly, with optimal refractive correction and an un-dilated pupil, with a chart luminance ranging between 68 and 239 cd/m² (representing normal office lighting), at a constant viewing distance of 45 cm^[20, 21]. An examiner tested the patients in random sequence on three occasions, with each response being recorded. The final score was transformed to logMAR units by the faintest contrast patch, which the patient was able to identify correctly at least twice^[21].

Visual field was performed by the standard 30-2 test to delineate the impact of glistenings on the change in mean deviation (MD), using the full threshold testing strategy (HFA II 750, Carl Zeiss, Leandro, CA, USA). We recorded MD value which is the index for light sensitivity deviation of the threshold stimulus intensity between the measured entity and the age-adjusted normal entities^[22]. Visual field results were only accepted when false responses and fixation losses were < 33%.

Statistical Analysis Statistical differences of VA and MD value among different glistening severity grades were evaluated by one-way ANOVA test. Least significant difference (LSD) method was used for post-hoc comparison of glistening grades when the ANOVA test was significant. The difference of CS among glistening grades was analyzed for each spatial frequency respectively, using Pearson χ^2 test. A probability index (*P*) less than 5% was accepted as statistically significant. All analyses were performed using SPSS 16.0 (SPSS Inc., Chicago, IL, USA).

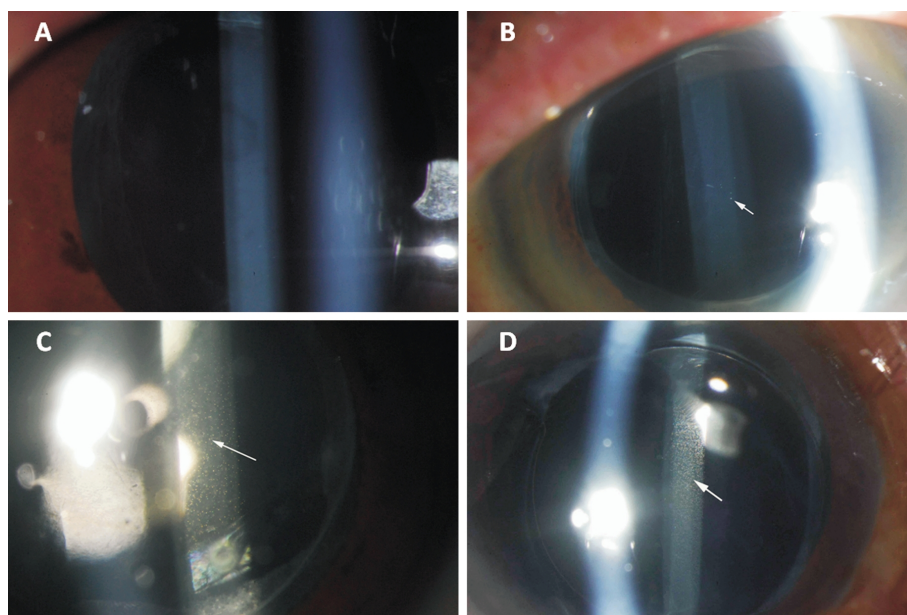


Figure 1 Examples of glistening grading. It was graded according to the number of glistenings per field (25×) A: Grade 0 (absent); B: Grade 1 (trace); C: Grade 2 (moderate); D: Grade 3 (severe).

Table 1 Basic characteristics of patients

| Parameters | Glistening Severity | | | | <i>P</i> |
|--------------------------------------|---------------------|------------|------------|------------|--------------------|
| | Grade 0 | Grade 1 | Grade 2 | Grade 3 | |
| Number (male) | 30(13) | 30(11) | 30(15) | 30(13) | ¹ 0.59 |
| Age (a) | 67.35±7.16 | 70.67±9.63 | 62.05±7.70 | 67.44±7.83 | ¹ 0.56 |
| Follow up time (M) | 23.93±1.72 | 24.09±2.02 | 24.18±1.91 | 24.25±2.03 | ² 0.525 |
| Preoperative BCVA ³ | 0.54±0.14 | 0.50±0.09 | 0.49±0.08 | 0.49±0.07 | ² 0.145 |
| Postoperative BCVA ³ | 0.03±0.05 | 0.06±0.05 | 0.03±0.04 | 0.03±0.04 | ² 0.075 |
| Refraction (D) | -1.44±0.33 | -1.44±0.45 | -1.41±0.45 | -1.50±0.44 | ² 0.924 |
| Mean IOL power | 20.77±3.20 | 20.45±5.40 | 21.20±2.55 | 20.66±4.05 | ² 0.902 |
| Past Nd:YAG laser capsulotomy no (%) | 8(26.7) | 9(30) | 8(26.7) | 6(20) | ¹ 0.843 |

¹Chi-square; ²One-way ANOVA; ³Logarithm of the minimum angle of resolution.

RESULTS

Patient Characteristics This study presented patients' visual function corresponding to glistening grade after two years implantation of Acrysof model SA60AT IOL. The topical photos in each group were presented in Figure 1.

The study subjects were comprised of 120 eyes from 97 patients, 23 of whom underwent bilateral IOL implantation and 43.3% of who were male. 71 patients had IOL implantation in the right eye. The mean postoperative UCVA among 120 eyes was 0.15±0.10. No obvious visual discomfort was announced from patients.

Table 1 shows the basic characteristics of patients. Among 4 glistening groups, patients' age were 67.35±7.16, 70.67±9.63, 62.05±7.70 and 67.44±7.83 separately without significant difference ($P=0.56$). So was the gender rate of the 4 groups ($P=0.59$). Besides, the follow up time were 23.93±1.72, 24.09±2.02, 24.18±1.91 and 24.25±2.03 respectively, showing no significant difference ($P=0.525$).

Before IOL implantation, patients' BCVA were 0.54±0.14,

0.50±0.09, 0.49±0.08 and 0.49±0.07 respectively with no significant difference ($P=0.145$). At 2y postoperative visit, patients' BCVA were 0.03±0.05, 0.06±0.05, 0.03±0.04 and 0.03±0.04 with corresponding spherical equivalent (SE) refraction of -1.44±0.33, -1.44±0.45, -1.41±0.45 and -1.50±0.44, respectively among 4 glistening groups. There were no significant difference in BCVA ($P=0.075$) and SE ($P=0.924$). IOL power in 4 glistening groups were 20.77±3.20, 20.45±5.40, 21.20±2.55 and 20.66±4.05 respectively, without significant difference (one-way ANOVA, $P=0.902$). Meanwhile scatter in Figure 2 shows no correlation between patients IOL power and glistening grades ($R^2=0.0001$).

Thirty-one eyes had already undergone an Nd:YAG laser posterior capsulotomy before enrolled in study, and no extensive pits or cracks were found in the optic of all past posterior IOLs and the laser surgery rate of the 4 glistening groups showed no difference ($P=0.843$).

Postoperative Contrast Sensitivity By using one-way ANOVA test, there was no statistically significant difference

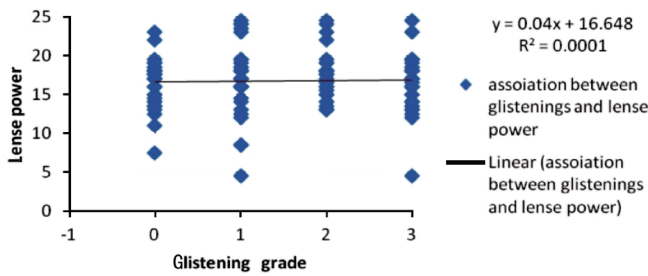


Figure 2 Association between glistening grade and IOL power.

in CS values among all glistening groups at any spatial frequency ($P=0.343$ at 1.5 cpd, $P=0.087$ at 3 cpd, $P=0.215$ at 6cpd $P=0.475$ at 12 cpd, $P=0.818$ at 18cpd) (Figure 3). However, by calculating the number of eyes with abnormal result in each group, it was found that more eyes in glistening grade 3 had a declined CS value. There were 8 (26.7%) and 11 (36.7%) at contrast frequency of 12 and 18 cpd in grade 3 group respectively. Besides that, all 8 eyes that had failed in CS at 12cpd also had a decreased CS in 18cpd. It is suggested that subjects with glistening grades 3 had a higher proportion of falling trend of contrast value than those with other grades in cycle 12 and 18 (adjusted χ^2 test, $P=0.013$ and 0.029, respectively) (Figure 4). No difference of CS was observed between groups at spatial frequency 1.5, 3 or 6 cpd.

Postoperative Visual Field Mean Deviation At 2y postoperative visit, patients' MD were -2.14 ± 2.31 , -1.97 ± 2.23 , -3.02 ± 3.17 and -4.12 ± 3.38 respectively for 4 glistening groups graded from 0 to 3, which showed a statistically significant difference (one-way ANOVA, $P=0.018$). After multiple comparisons by LSD, we found mean MD value in patients of grade 3 was significantly higher than that in grade 0 and 1 ($P_{3,0}=0.008$; $P_{3,1}=0.005$), although it was not higher than that in grade 2 ($P_{2,3}=0.138$). Except that, no more significant difference was shown between any other two groups.

DISCUSSION

With growing knowledge of glistening, the impacts on visual function have attracted more attentions. This study of AcrySof IOLs using 120 eyes, two years postoperatively, divided into four groups according to the grade of glistenings observed from slit lamp, illustrates that two commonly-used tests of visual function have some relation to the intensity of glistenings. Generally, patients with more severe glistening (grades 2 and 3), have a trend of decrement in contrast sensitivity and visual field. And the MD of visual field, usually an indicator in glaucoma, may also be used as an indicator for visual performance of glistenings after cataract surgery.

We found that glistening grades were potentially associated

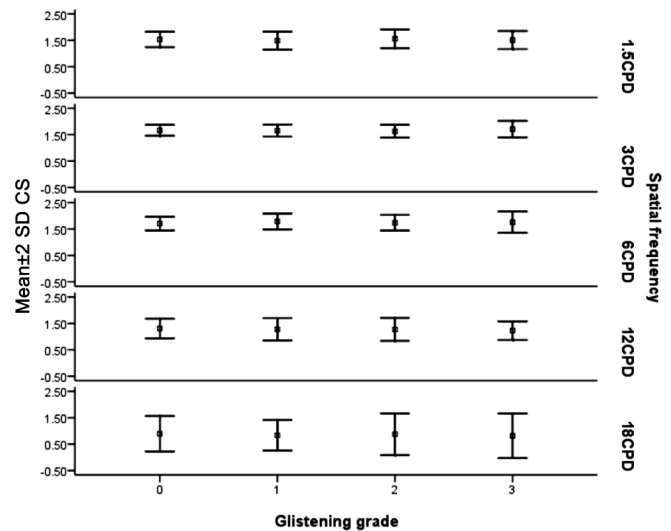


Figure 3 Contrast sensitivity values among glistening grade groups Error bars represent 95% confidence intervals. Glistening grade was not associated with contrast sensitivity (analysis of variance, $P>0.1$ at all spatial frequencies). Data were available for 120 eyes.

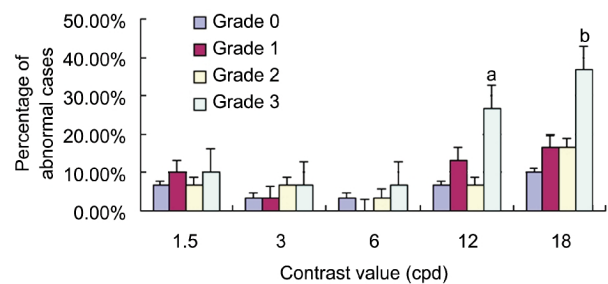


Figure 4 Percentage of cases with declined contrast sensitivity in each group at different frequency Data were available for 120 eyes (Chi-square test) ^a There are significant differences of cases with declined cs in group grade 3 and other groups at 12 cpd (cycle per degree). ^b There are significant more cases with cs decreased in group grade 3 than the other groups at 18 cpd.

with contrast sensitivity at high spatial frequency in some degree. F.A.C.T. chart is a simple, fast and effective way to detect the changes of CS in a broad spatial frequency spectrum with minimum equipment requirement [20]. In our study, we used two methods to assess the correlation between glistening grades and contrast sensitivity. By using quantitative one-way ANOVA analysis which the results were converted into logMAR units, there was no significant decrease in contrast sensitivity value at each spatial within each group. These are consistent with other studies, showing no relationship was found between glistenings and contrast sensitivity [8, 15, 19, 23]. However, after adjust for qualitative χ^2 analysis, there were significant more patients suffering decreased CS at 12 cpd and 18 cpd in the most serious glistening group. These are in concordance with other studies which reported an opposite conclusion that glistenings deteriorate CS at high spatial frequencies for eyes with

higher grade of glistening severity [12, 14, 24]. We presume that the target in high spatial frequency is smaller and concentrated than low and intermediate spatial frequencies have; it is more sensitive and easily being influenced. But the adjustment ability of eye may reduce these influences, which leads the controversial results being reported.

By considering few patients with server glistenings in our study suffered a noticeable decline in CS at high density, we performed Visual Field Test which is a light sensitivity test usually for screening glaucoma patients. To our knowledge, the impact of glistening on MD value had never been explored, except for glaucomatous eyes [24]. They found a significant increase in loss variance index value rather than MD value for glaucoma patients with server glistenings. Though, MD value in glaucomatous eyes may differ from normal eyes.

We analyzed the correlation between MD value of visual field and the glistening severity in normal eyes after IOL implantation. In this study, compared with no glistening eyes, we observed a decrease in MD value for eyes with most serious glistenings. However, no difference was found between mild and severe groups. Theoretically, glistenings particles which usually have a diameter ranged from 10 to 20 μm might induce light diffraction [25]. We predict that light scattering effect induced by glistening particles within the IOL optic may cause diffused reduction in light sensitivities. The higher the intensity that glistening reaches, the worse light sensitivities patients may get. That may be the reason a few patients experienced obvious visual discomfort such as glare, ultimately resulting in IOL replacement in some extreme cases [13, 26]. This finding requires further exploration to be confirmed.

Furthermore, glistenings has no relationship with IOL dioptric power in our study. Although, two reports [16, 27] showed the thickness of IOL may influence the density of the glistenings.

In this study, all the patients have a good BCVA two years after surgery with no difference between each group. Even in patients with the worst glistening (grade 3). This is in agreement of many current reports that have found similar results [3, 4, 6, 14, 15] varied from a few months to over 10 years, only one literature identified a one-half line lower in the Snellen chart on AcrySof IOLs [23]. While, due to the small difference (20/22.1 versus 20/25.5) and low incidence rate of patients with sever glistenings, it is generally acknowledged that the visual significance of glistenings may be somewhat limited.

At present, as no other potential causes of the decreased function were identified, we proposed that glistening size and

density might have direct relation on visual function. Fortunately, we believe the impaction would not be obvious until a certain degree.

The limitations of our study are that the patients in this study were selected carefully to avoid pathology, which may have an influence on visual performance. Additionally, we should notice that these two visual function tests are psychological tests and the outcomes are vulnerable by opacification in the visual axis of optical structure. Furthermore, we used limited grading of the glistenings. Despite the limitations, we consider this study to be a valuable contribution to the research of visual function that is possibly affected by glistenings.

In conclusion, although glistenings found in single piece monofocal IOLs have no impact on visual acuity, severe glistenings may have influence on high spatial frequency contrast sensitivity and reduce light sensitivity. Most importantly, we should pay more attention on the impaction of glistenings on functional IOLs, such as multifocal and accommodating IOLs, which aim to afford excellent optical quality. A prospective study is much needed.

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