Two-year follow-up after implantation of diffractive aspheric silicone multifocal intraocular lenses

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ABSTRACT

Purpose: To evaluate the stability of visual performance after implantation of a diffractive aspheric silicone multifocal intraocular lens (MIOL).

Methods: Thirty eyes of 15 patients received the Tecnis MIOL ZM900 (*Abbot Medical Optics*) after cataract extraction at Tokyo Dental College Suidobashi Hospital. The uncorrected and best-corrected distance visual acuities (UCDVA, BCDVA); uncorrected, distance-corrected, and best-corrected near VAs (UCNVA, DCNVA, and BCNVA); spherical equivalent refraction, spectacle independence, contrast sensitivity, and posterior capsule opacification (PCO) were measured at 1 week; 1, 3, and 6 months; and 1 and 2 years postoperatively.

Results*:* Two years postoperatively the UCDVA was 0.01 logMAR, BCDVA -0.09 logMAR, UCNVA 0.19 logMAR, DCNVA 0.1 logMAR, and BCNVA 0.04 logMAR. There was no significant change from 1 week through 2 years. The percent of spherical equivalent refraction error within ±0.5 diopter was 63.4% at 2 years. No patient required spectacles for reading; two patients have used spectacles for intermediate vision when necessary. One eye underwent Nd:YAG laser posterior capsulotomy due to PCO.

Conclusion*:* The visual performance after implantation of the Tecnis MIOL was stable for 2 years. A low rate of PCO contributed to the long-term visual performance.

Key words: intraocular lens, multifocal, diffractive

Introduction

Multifocal intraocular lenses (MIOLs) have been designed to provide both distance and near visual acuities (VAs) for reducing spectacle dependence. Because of recent innovations in refractive surgeries, the interest in bifocal vision is increasing among patients with cataracts. Preferable visual function has been reported with new-generation refractive and diffractive MIOLs (Chiam et al. 2007; Alfonso et al. 2007; Cillino et al. 2008).

Two types of multifocal optics, refractive and diffractive, are commercially available. Diffractive MIOLs can provide two distinct focuses at distance and near (around 30 cm) as bifocal spectacles do. ZM900 (*Abbot Medical Optics, formerly Advanced Medical Optics, Santa Ana, CA*) is a silicone MIOL consisting of diffractive optics on the posterior surface and an aspheric surface on the anterior surface. This MIOL provides preferable VA at distance and at 30 cm (Goes 2008). As for the intraocular lens (IOL) material, a higher risk of development of posterior capsule opacity (PCO) has been discussed. However, recent studies have shown that the sharp-edge design in the IOL peripherals have reduced the incidence of PCO for both silicone and acrylic materials. (Nishi et al. 2004; Biber et al. 2009). A slight effect of PCO on visual function has been shown in eyes with a MIOL (Elgohary et al. 2008). The purpose of the current study was to assess the long-term stability of this silicone MIOL and its effect on visual function up to 2 years.

Patients and Methods

This prospective study included 36 eyes of 18 patients who underwent cataract surgery and implantation of the same MIOL bilaterally at Tokyo Dental College Suidobashi Hospital, Tokyo, Japan, between May and October 2005. As for the patient selection, those who wished to reduce the spectacle dependency at distance and near, especially at a reading distance of approximately 30 cm, whose corneal astigmatisms were less than 1.5 diopters, and without any history of ocular pathology except cataract, were included in this study. Fifteen patients completed the 2-year follow-up and were enrolled in this study. Three patients withdrew after randomization and during the postoperative period. This study adhered to the tenets of the Declaration of Helsinki and was approved by the internal review board of the Tokyo Dental College Suidobashi Hospital. All patients provided informed consent. The demographic and preoperative characteristics of the patients are summarized in Table 1.

IOL

The implanted MIOL was ZM900, a three-piece silicone IOL with diffractive multifocal optics and an optical diameter of 6.0 mm. The anterior surface has an aspheric shape to reduce postoperative ocular spherical aberrations. The IOL power was determined by axial

length and corneal refraction measured using the IOL Master (Carl Zeiss Meditec, Jena, Germany) and the SRK/ T formula. Emmetropia was targeted in all patients.

Surgical procedure

All surgeries were performed by one surgeon (HBM). Under topical anesthesia, a 3.0-mm clear corneal temporal incision and a 5.0- to 5.5-mm continuous curvilinear capsulorrhexis were made. After extraction of the crystalline lens during phacoemulsification, the ZM900 MIOL was implanted in the capsular bag using an injector. No intraoperative complications developed. Implantation was performed in the fellow eye 1 week after the first implantation. Postoperative antiinflammatory and antibiotic agents were used for 4 weeks.

Outcome measurements

Postoperative examinations were performed at 1 week; 1, 3, and 6 months; and 1 and 2 years after surgery. The VAs measured were the uncorrected distance visual acuity (UCDVA), the best-corrected distance visual acuity (BCDVA), the uncorrected near visual acuity (UCNVA), the best-corrected near visual acuity (BCNVA), and the distance-corrected near visual acuity (DCNVA). Distance and near VAs were measured using the Landolt decimal VA chart at 5 m and the Landolt near VA charts at 33 cm,

respectively. The VA was converted to logarithm of the minimum angle of resolution (logMAR). The results are expressed in mean ± SD.

The refraction spherical equivalent (SE), the incidence of glare and halo, spectacle independence, and the rate of Nd:YAG laser capsulotomy also were assessed. When patients become conscious of a visual disturbance, and it was caused by central PCO, they were offered Nd:YAG laser capsulotomy. Contrast sensitivity function was measured using the CSV-1000 system (Vector Vision, Inc., Greenville, OH) under background illumination of 85 cd/m^2.

A patient questionnaire addressed visual phenomena such as glare, halos, and spectacle independence.

Statistical analysis

The differences in VA from 1 week postoperatively were compared using Kruskal-Wallis and Steel multiple tests. Changes in contrast sensitivity were compared using the Wilcoxon rank-sum test. Categorical variables were compared using the chi-square test. $P < 0.05$ was considered statistically significant.

Results

Visual outcomes

The mean distance VAs from 1 week to 2 years postoperatively are shown in Fig. 1A. The UCDVA at 1 week was -0.01±0.12 logMAR and at 2 years 0.01±0.10 logMAR. There were no significant differences between 1 week and 2 years (p=0.97). The BCDVA was -0.11±0.08 logMAR at 1 week and -0.09±0.06 logMAR at 2 years; the difference did not reach significance (p=0.98). The UCDVAs and BCDVAs did not change significantly from 1 week through 2 years.

The near VAs are shown in Fig. 1B. At 2 years, the UCNVA was 0.19±0.10 logMAR, the DCNVA 0.10±0.06 logMAR, and the BCNVA 0.04±0.06 logMAR. None changed significantly from 1 week through 2 years.

At 1 week, 90% of patients achieved an UCDVA of 0.10 logMAR (20/25) or better and 93.3% at 2 years (Fig. 2). The UCNVA was 0.30 logMAR or better (20/40) in 93.3% of patients at 1 week and 2 years postoperatively (Fig. 3). The UCDVA of 0.10 logMAR or better and the UCNVA of 0.30 logMAR or better did not change significantly through 2 years. The distance and near VAs did not differ significantly from 1 week though 2 years after cataract surgery.

Refractive error

The SE was less than ± 0.5 D in 70% of patients at 1 week and 63.3% of patients at 2 years. There was no significant difference from 1 week through 2 years (Fig. 4).

Halos and glare

One week postoperatively, 6.7% of patients reported halos and 3.3% reported glare; however, no severe halos and glare were reported that affected the patients' daily activities throughout follow-up (Fig. 5).

Spectacle wear

No patients required distance or near spectacles for 2 years after implantation of this MIOL. Two patients occasionally used spectacles for intermediate vision from 50 cm to 1 m.

Contrast sensitivity

Figure 6 shows the mean contrast sensitivity at 3 months and 2 years postoperatively. The mean contrast sensitivity was within the normal range at low spatial frequencies, however, lower at 12 and 18 cycles per degree. There was no significant difference at each spatial frequency (Wilcoxon signed-rank test).

Nd: YAG laser posterior capsulotomy

Nd:YAG laser capsulotomy for PCO was performed for one eye (3.3%) at 1 year and 8 months postoperatively. The UCVA of this eye decreased to 0.3 logMAR and the UCNVA

was 0.7 logMAR. After Nd:YAG laser capsulotomy, the UCVA improved to 0.15 logMAR and UCNVA improved to 0.10 logMAR.

Discussion

As previously reported, implantation of the ZM900 IOL results in good uncorrected distance and near VAs (Cillino et al. 2008). AcrySof ReSTOR (Alcon Laboratories, Inc. Fort Worth, TX, USA) is another IOL with an apodized diffractive design. de Vries et al. (2008) reported the 3-year follow-up results with this IOL and confirmed stable distance and near VAs and high patient satisfaction. Although the patients in the current study were followed for up to 2 years, similar stable results also were found for the silicone MIOL.

Refractive error and changes should be avoided, especially in cases with a MIOL to obtain spectacle independence. New biometry instrumentation and modifications of IOL power calculations have improved the predictability of IOL powers (Lee et al. 2008; Hoffer 2000; Narváez et al. 2006). The current results showed that the refractive error was small and comparable to those with the AcrySof ReSTOR IOL (de Vries et al. 2008).

Halos and glare with diffractive MIOLs have been reported to be less than with refractive MIOLs (Pieh et al. 1998), however, greater than with monofocal IOLs (Montés-Micó et al. 2004; Sen et al. 2004). Kohnen et al. (2006) reported that the AcrySof ReSTOR IOL induced severe glare in 8.5% of patients and severe halos in 4.2% of patients.

The Tecnis ZM900 IOL performed significantly better than the Array (*Abbot Medical Optics*) MIOL regarding halos and glare (Mester et al. 2007). However, a study that used a model eye under nighttime driving conditions reported that the quality of vision with the ZM900 IOL was lower than with the AcrySof ReSTOR IOL (Blaylock et al. 2006). In the current study, 10% of patients reported halos and glare; however, these symptoms did not disturb their daily activities. The patients in the current study reported glare until 3 months and halo until 6 months postoperatively. Central neuro-adaptation has been discussed; however, proving that this works is a challenge (Pepin 2009).

The aim of MIOLs is to enable patients to be less dependent on spectacles after surgery. Achieving good UCDVA and UCNVAs can provide spectacle independence in most activities. In the current study, the rate of spectacle use was less than with AcrySof ReSTOR IOL (Kohnen et al. 2006; Souza et al. 2006; Chiam et al. 2006). However, two patients in the current study required spectacles for intermediate visual tasks lasting more than 1 hour. Visual adaptation after implantation of a MIOL is expected and the timing of a request for a prescription for spectacles changes according to the patient's needs. One patient requested a prescription for spectacles 1 week after implantation to work on a computer terminal for extended periods of time; another patient requested a prescription more than 1 year after implantation, because the patient tried to adjust to looking at the display for 1 year after surgery but was unsuccessful. Despite the occasional use of

spectacles, these patients were satisfied with their near and distance vision. The problem of intermediate vision has been already reported with AcrySof ReSTOR IOL (de Vries et al. 2008; Blaylock et al. 2006). The characteristics of a defocus curve can well explain the reason for why some patients complain of decreased intermediate vision. Thus, the need for spectacles for intermediate vision is reasonable.

Decreased contrast sensitivity is a major concern with diffractive MIOLs. Several studies reported decreased contrast sensitivity at higher spatial frequency and improvement of bilateral IOL implantations (Fernandez-Vega et al. 2007). The current results showed a normal range of contrast sensitivity at low spatial frequencies, however, lower at 12 and 18 cycles per degree. The aspheric optic design is expected to provide better contrast sensitivity than the spheric design. Awwad et al. (2008) reported that the aspheric design of the AcrySof IQ SN60WF reduces spherical aberration, especially with larger pupils, and improves mesopic contrast sensitivity at higher frequencies with and without glare. Otani et al. (2009) reported that the same type of monofocal silicone aspherical IOL (Z9000, Abbot Medical Optics) improved scotopic contrast sensitivity. Mesopic contrast sensitivity and the benefit of the aspheric design on diffractive optics should be investigated further.

We evaluated the rate of Nd:YAG laser capsulotomy and only one eye required a posterior capsulotomy 20 months postoperatively. Generally, eyes with an MIOL require Nd:YAG laser capsulotomy earlier than those with monofocal IOLs, since the near vision is

affected by the opaque capsule (Elgohary & Beckingsale 2008). Recently, the surgical technique of lens removal and implantation in the bag with continuous curvilinear capsulorrhexis and a sharp-edge design were developed and the incidence of capsular opacity decreased dramatically. Toto et al. (2007) reported no significant difference between the rate of posterior capsule opacity with the ReSTOR IOL and the ZM900 IOL.

In conclusion, our study showed stable visual function including distance and near VAs, contrast sensitivity, and spectacle independence up to 2 years postoperatively.

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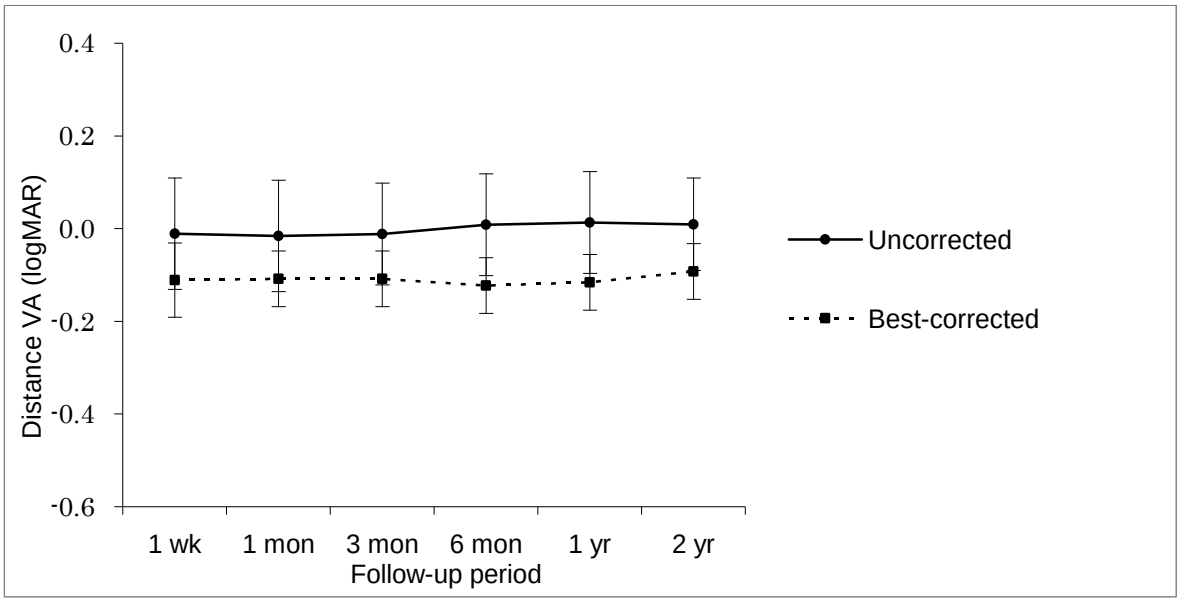
Table 1. Preoperative characteristics of patients.

Parameter	
No. eyes/patients	30/15
Male/female	5/10
Age (y)	
Mean (±SD)	65.8 (8.1)
Range	48-75
UCVA (logMAR）	
Mean (±SD)	0.65 (0.35)
Range	0.22-1.30
BCVA (logMAR）	
Mean (±SD)	0.19 (0.21)
Range	0-0.82
Corneal astigmatism (D)	
Mean (±SD)	0.75 (0.42)
Range	0.22-1.21
Mean spherical equivalent (±SD)	0.35 (2.11)
Range	-5.5-3.0
Mean axial length (mm) (±SD)	23.13 (0.81)
Range	21.49-24.54

UCVA = uncorrected visual acuity; BCVA = best corrected visual acuity; SD = standard deviation.

Fig. 1. Postoperative VA (logMAR, mean±SD) 1 week to 2 years after bilateral IOL implantation. (A) Distance VA, (B) near VA. SD, standard deviation.

A) Distance VA



Near VA

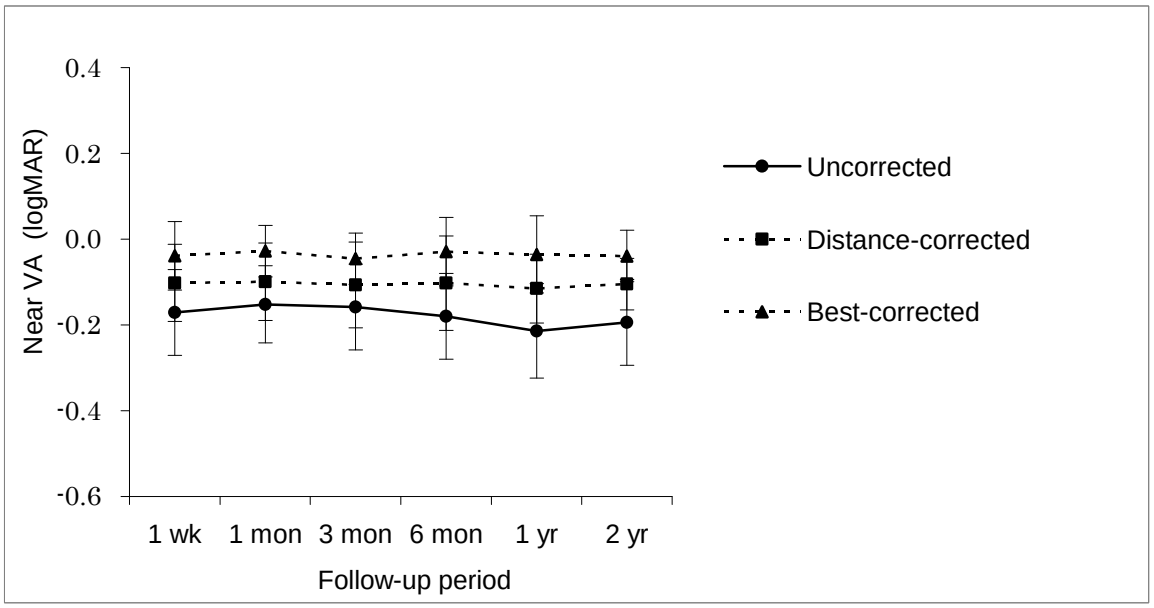


Fig. 2. UCDVA of 0.10 logMAR (=20/25) or better (n=30).

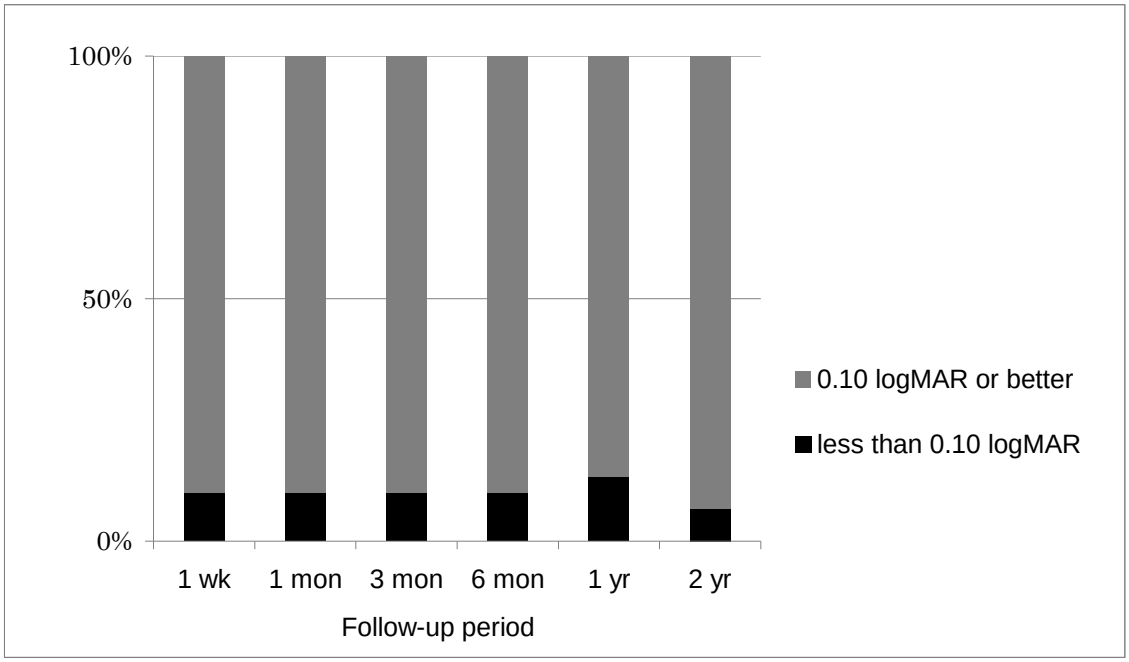


Fig. 3. UCNVA of 0.30 logMAR (=20/40) or better (n=30).

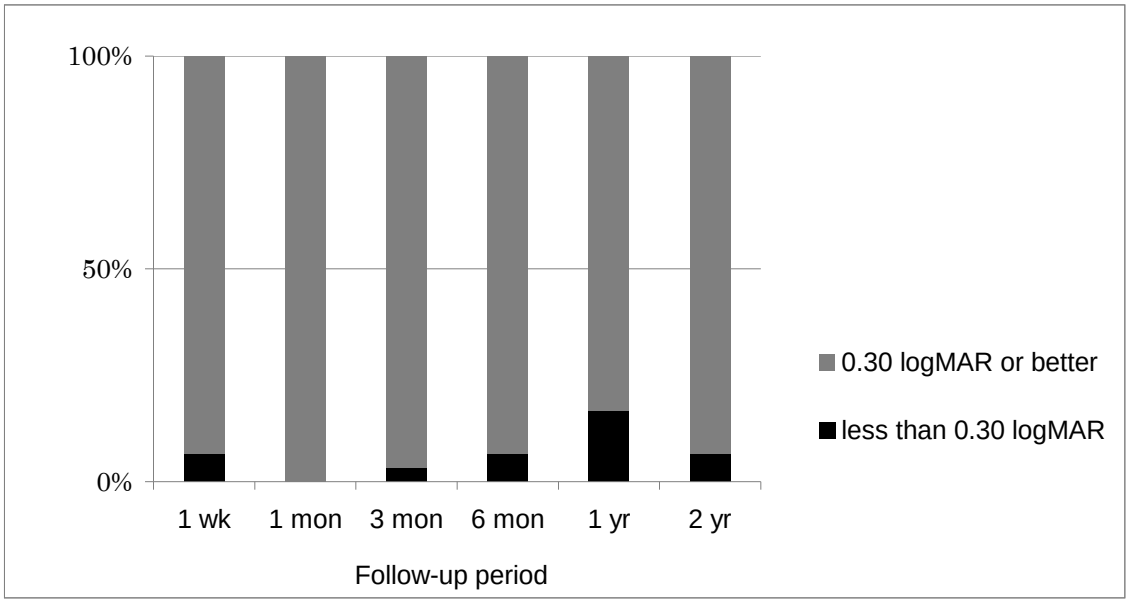


Fig. 4. Postoperative spherical equivalent of ±0.5 diopter or less (n=30).

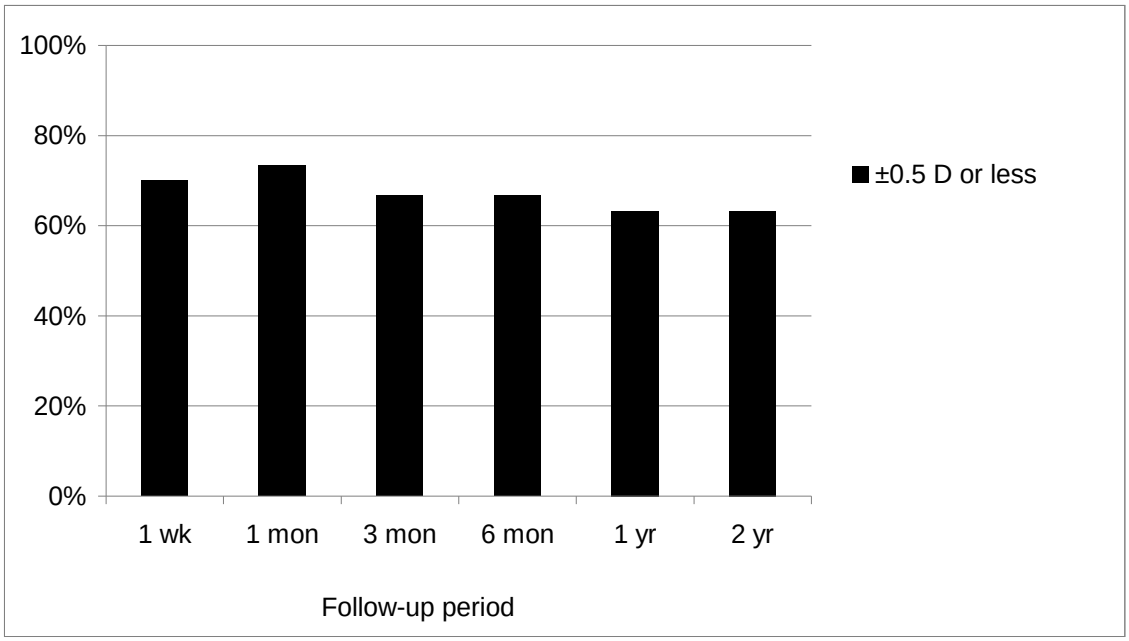


Fig. 5. Incidence of halos and glare (n=30).

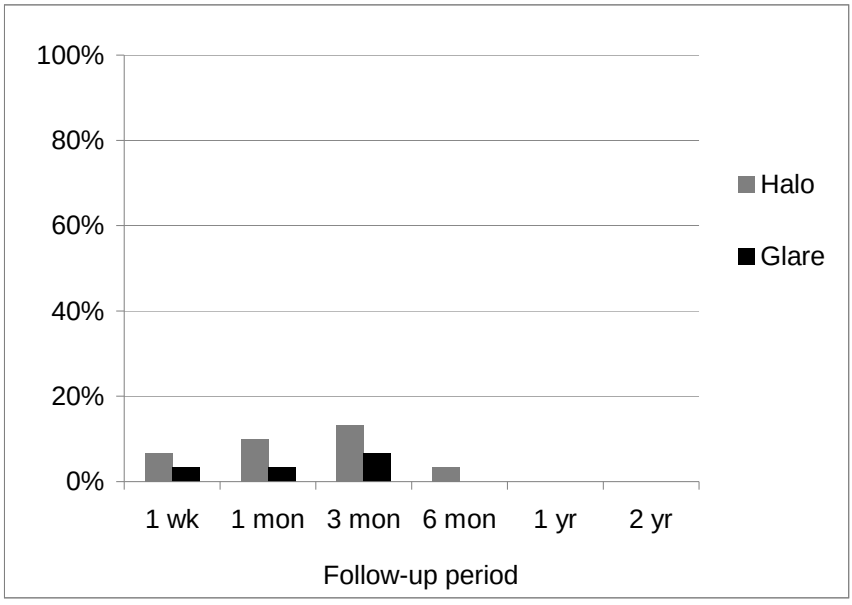


Fig. 6. Contrast sensitivity 3 months and 2 years after IOL implantation (n=18).