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Long-Term Stability of Diffractive Multifocal Intraocular Lenses: Contralateral Comparison between Silicone and Acrylic Materials

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Abstract

Objective: To compare visual function stability between silicone and hydrophobic acrylic materials of diffractive multifocal intraocular lenses (MF-IOLs).

Methods: This retrospective study reviewed clinical records of 10 patients who received a silicone MF-IOL in the first eye and hydrophobic acrylic lens in the fellow eye. Intra-individual differences in logMAR corrected distance visual acuity (CDVA) and distance-corrected near visual acuity (DCNVA) were evaluated until 2 years postoperatively. Contrast sensitivity at 1 year was also compared.

Results: Age of the patients ranged from 39 to 77 years. There was no statistical difference in the uncorrected distance visual acuities at 2 years, while the uncorrected near visual acuity of the silicone IOL was better (P=0.046). The medians of the CDVA and DCNVA with the silicone MF-IOLs were -0.13 and 0.10 logMAR, respectively, while those with hydrophobic acrylic MF-IOLs were -0.09 and 0.12 logMAR, respectively. No significant difference was found between the two materials (P>0.17). There was no difference in the contrast sensitivity (P>0.11). One eye with the silicone MF-IOL underwent Nd:YAG laser capsulotomy.

Conclusions: The differences in the material and fabrication of diffractive MF-IOLs did not influence the long-term visual performance.

Keywords: Multifocal intraocular lens; Silicone; Hydrophobic acrylic; Long-term stability

Introduction

Multifocal intraocular lenses (MF-IOLs) are safe and efficient in restoring distance and near visual acuities after cataract removal [1], and numerous reports demonstrated the postoperative outcomes [2-4]. The majority of MF-IOLs are designed with diffractive grating optics which requires precise fabrication technology [5]. The Tecnis® multifocal platform (Abbott Medical Optics, Santa Ana, CA) is produced with a silicone material using cast-molding fabrication and a hydrophobic acrylic material using lathe-cutting fabrication. The effect of the MF-IOL material on the postoperative visual performance was assessed up to 6 months postoperatively without significant difference [6].

Compared with monofocal IOL, performances of the diffractive MF-IOL has been shown to be more sensitive under postoperative conditions, such as posterior capsular opacification (PCO) [7,8] glistenings, and surface light scattering [9]. Development of mild PCO, which does not influence the patient's visual acuity when implanted with monofocal IOLs, could degrade the near visual acuity when implanted with MF-IOLs [4,7]. Laser capsulotomy is normally performed earlier after MF-IOL implantations [10]. Hence, long-term observation is also important to compare the postoperative degradations. This study aimed to compare long-term contralateral outcomes in the use of silicone (ZM900) and hydrophobic acrylic (ZMA00) MF-IOLs for minimizing variations between patient groups [6,11].

Patients and Methods

This retrospective study reviewed clinical records of patients who underwent bilateral cataract surgery with implantations of the silicone ZM900 in the first eye, and followed by implantation of the acrylic ZMA00 in the fellow eye. The contralateral implantation occurred due to approval of the ZMA00 lens in Japan. The first eye was assigned based on the severity of the cataract only, without consideration of the ocular dominance. The preoperative corneal astigmatism was limited to 2.0 diopters (D) or less, otherwise an enhancement with laser in situ keratomileusis (LASIK) was planned. Patients with any pathology except cataract were excluded. This study adhered to the tenets of the Declaration of Helsinki.

The implanted ZM900 and ZMA00 were three-piece silicone and hydrophobic acrylic diffractive MF-IOLs, respectively, with an optical diameter of 6.0 mm. The MF-IOLs had the same diffractive grating optics on the posterior surface, while the ZM900 had a sharp edge and the ZMA00 had a modified edge profile (OptiEdge®) to prevent development of PCO [12]. The anterior surface was aspheric to reduce postoperative ocular spherical aberrations. The power of the MF-IOL was determined by measuring the axial length and corneal refraction with an IOL Master (Carl Zeiss Meditec, Jena, Germany) and the SRK/T formula. Emmetropia was targeted for all patients. One surgeon (H.B-M.) performed all cataract surgeries and used identical surgical

methods for each eye. The cataracts were removed by phacoemulsification through a 2.75 mm corneal incision at the temporal position, followed by implantation of MF-IOLs using an injector into the capsular bags. No intraoperative complications developed.

Postoperative visual acuities at 1 and 6 months, and 1 and 2 years postoperatively were recorded. Visual acuities included the uncorrected and corrected distance visual acuities (UDVA and CDVA) at a distance of 5 m, and uncorrected and distance-corrected near visual acuities (UNVA and DCNVA) at 30 cm. The visual acuity was measured using a Landolt ring chart that has been comprehensively used in Japan, and converted from decimal notation to logarithm of the minimum angle of resolution (logMAR) for statistical analysis. The monocular contrast sensitivity was also measured using the CSV-1000 test (Vector Vision, Greenville, OH, USA) at 2.5 m under distance spectacle correction.

One patient with development of PCO and degradation in the visual acuity underwent YAG laser capsulotomy. The rate and postoperative duration of the Nd:YAG laser capsulotomy were also recorded. To avoid the influence of refractive change, corrected visual acuities (CDVA and DCNVA) of each MF-IOL were examined. Statistical change during the observation period was tested using the Friedman test with the Scheffe paired comparison. The difference in the CDVA and DCNVA were compared between the ZM900 and ZMA00 using the Wilcoxon signed-rank test with the Holm multiple corrections. Contrast sensitivity at 1 year postoperatively was also compared using the Wilcoxon signed-rank test. $P<0.05$ was considered significant.

Results

The case series comprised 10 patients (2 men, 8 women), and the demographic data of the patients are shown in Table 1. There was no significant difference in preoperative corneal astigmatism (P=0.68, Wilcoxon signed-rank test). Two patients underwent bilateral LASIK 3 and 5 months after MF-IOL implantation due to high corneal astigmatisms. After the 2-year observations, the laser capsulotomy was performed on 2 eyes with ZM900 at 2.2 and 2.7 years postoperatively, and for 3 eyes with ZMA00 during 2.6 to 3.0 years. For UDVA, there was no difference between the two MF-IOLs from 1 month (P=0.21) to 2 years (P=0.50) postoperatively. Whereas, there was no difference between the two MF-IOLs for UNVA, except for those with ZM900 were significantly better than ZMA00 at 2 years postoperatively (P=0.046).

The corrected visual acuities from 1 month to 2 years postoperatively were analyzed (Table 2). The CDVA with the ZM900 did not change (P=0.33, Friedman test), while there was a significant change between 1 month and 2 years in the ZMA00 (P=0.029, Scheffe paired comparison). The DCNVA with each MF-IOL did not change (P=0.64 and 0.17 respectively). For CDVA and DCNVA, there was no difference between ZM900 and ZMA00 (P>0.72 and 0.17 respectively. The Wilcoxon signed-rank tests with the Holm multiple corrections). The contrast sensitivities of the two MF-IOLs at 12 months postoperatively (Figure 1) were within the normal range and did not differ significantly at any spatial frequencies (P>0.11). Up to 2 years postoperatively, YAG laser capsulotomy was performed on one eye with ZM900.

Patient	Age	Sex	Preoperative corneal astigmatism (D)		Axial length (mm)		Intraocular lens power (D)	
			ZM900	ZMA00	ZM900	ZMA00	ZM900	ZMA00
1	77	Female	1.15	0.49	23.83	23.82	23.5	23.0
2*	65	Female	1.31	0.80	24.19	24.52	17.0	15.0
3+	64	Female	0.51	0.78	26.32	26.26	12.0+	13.0
4	61	Female	0.27	0.37	27.73	27.31	10.0	12.0
5	64	Female	1.51	0.07	21.70	21.73	26.0	25.5
6	56	Female	0.53	0.27	24.00	23.98	22.0	21.5
7	58	Female	1.32	1.05	26.06	26.06	12.5	12.0
8	39	Male	0.32	0.43	26.95	27.18	12.0	11.0
9*	58	Female	3.31	2.82	27.47	27.57	7.5	6.5
10	58	Male	0.48	0.15	26.45	26.27	16.5	16.5

D: diopter

* : Laser in-situ keratomileusis after MF-IOL implantation

+: Laser capsulotomy performed in one eye with ZM900 22 months postoperatively

Table 1. Patient demographic data.

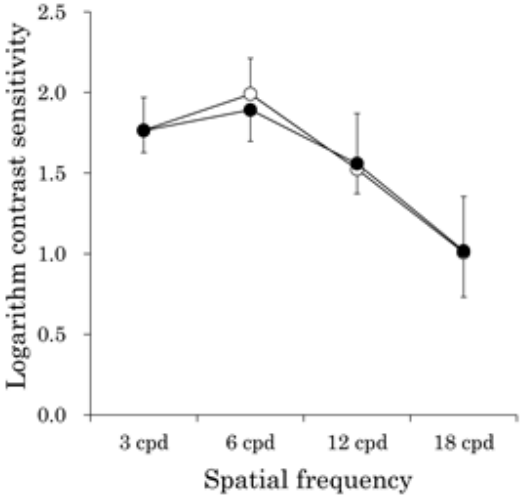

Figure 1: Contrast sensitivities of eyes with the silicone ZM900 and hydrophobic acrylic ZMA00 at 1 year postoperatively.

		1 month	6 months	1 year	2 years	P value*2
UDVA	ZM900	-0.18 (0.16)	-0.08 (0.25)	-0.08 (0.19)	-0.08 (0.10)	
	ZMA00	-0.04 (0.23)	-0.04 (0.22)	-0.04 (0.25)	0.00 (0.19)	
CDVA	ZM900	-0.18 (0.10)	-0.11 ± 0.11	-0.18 (0.15)	-0.18 (0.10)	0.33
	ZMA00	-0.18 (0.02)†	-0.18 (0.16)	-0.18 (0.10)	-0.13(0.18)†	0.028
	P value*1	1	0.72	1	1	
UNVA	ZM900	0.07 (0.27)	0.13 (0.26)	0.10 (0.29)	0.05 (0.23)	
	ZMA00	0.10 (0.29)	0.02 (0.48)	0.19 (0.23)	0.07 (0.40)	
DCNVA	ZM900	0.05 (0.19)	0.07 (0.21)	0.02 (0.21)	0.05 (0.15)	0.64
	ZMA00	0.05 (0.13)	0.02 (0.19)	0.07 (0.11)	0.05 (0.17)	0.17
	P value*	0.79	0.66	0.17	0.72	

Median (interquartile range)

*1: Difference between two IOLs using the Wilcoxon signed-rank test with the Holm multiple corrections.

*2: Difference throughout the follow-up period using the Friedman test.

†: P = .029, Scheffe's paired comparison.

Table 2. Postoperative distance visual acuities with ZM900 and ZMA00 MF-IOLs.

Discussion

The intra-individual comparison between a silicone and a hydrophobic acrylic diffractive MF-IOL for 2 years postoperatively showed no differences in the visual acuity or contrast sensitivity. Comparison of MF-IOL material on visual performance has rarely been evaluated. The previous contralateral study evaluating until 6 months postoperatively [6] shows the results concurring with the current results. These comparisons between ZM900 and ZMA00 were attributed to not only to the material but also the technology in fabricating the diffractive gratings. The silicone ZM900 was manufactured by the cast molding, while the hydrophobic acrylic ZMA00 was fabricated by lathe cutting the polymer material under cryogenic temperature (lathe cutting) [13]. These studies confirmed that the differences in the material and fabrication technology did not influence the clinical outcomes.

Factors that degrade the near visual acuity include PCO [7,8] increased roughness of the grading surface [5] and/or an increase of internal scattering [14]. Development of PCO varies with the material and edge shape of the intraocular lens (IOL). The previous comparison between the hydrophobic acrylic and the silicone IOLs showed a higher incidence of YAG laser capsulotomy in the hydrophobic acrylic IOL [12]. On contrast, diffractive MF-IOLs with a hydrophobic acrylic material that were manufactured with the cast-molding fabrication show stable distance and near visual acuities for 3 years [15]. Both IOLs had sharp edges that could prevent migration of the lens epithelial cells onto the posterior capsular bag [16,17]. In the current results, there was no difference in the Nd:YAG laser capsulotomy rate and most of them were performed in 2 to 3 years postoperatively. These findings demonstrated that there would be no difference in development of PCO between the ZM900 and ZMA00 IOLs.

Producing diffractive optics requires precise fabrication, so that the cast-molding fabrication is fundamentally more beneficial and the surface roughness could be further reduced rather than utilizing lathe-cutting [5]. Smooth IOL surfaces reduce cell adherences [10] and the silicone material prevents cell adherence more than the hydrophobic acrylic material [18]. These findings lead to speculations that the rougher surface of the ZMA00 could induce the cell migration on the diffractive gratings and decrease efficiency of the bifocality. However, we could not identify that theory with the observation up to 2 years. Longer observation would be necessary to identify the differences between the two MF-IOLs.

There were limitations in the current study. First, the sample size was small. In addition, the intra-individual comparisons were possible when the diffractive MF-IOL approval transitioned from the silicon ZM900 to the hydrophobic acrylic ZMA00. Although a greater sample size was desired, it was difficult to increase it. Next, there was a lack of quantitative analysis of PCO, the MF-IOL surface, and internal scattering. A slit-lamp examination could easily diagnose substantial PCO and cell adhesion on the MF-IOL surface; however, quantitative measurement using a Scheimpflug camera is required for further investigation [19]. The internal scattering could be evaluated using forward scattering measurement [20]. In conclusion, differences in the material and the fabrication technology of diffractive MF-IOLs did not affect the long-term visual performance.

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