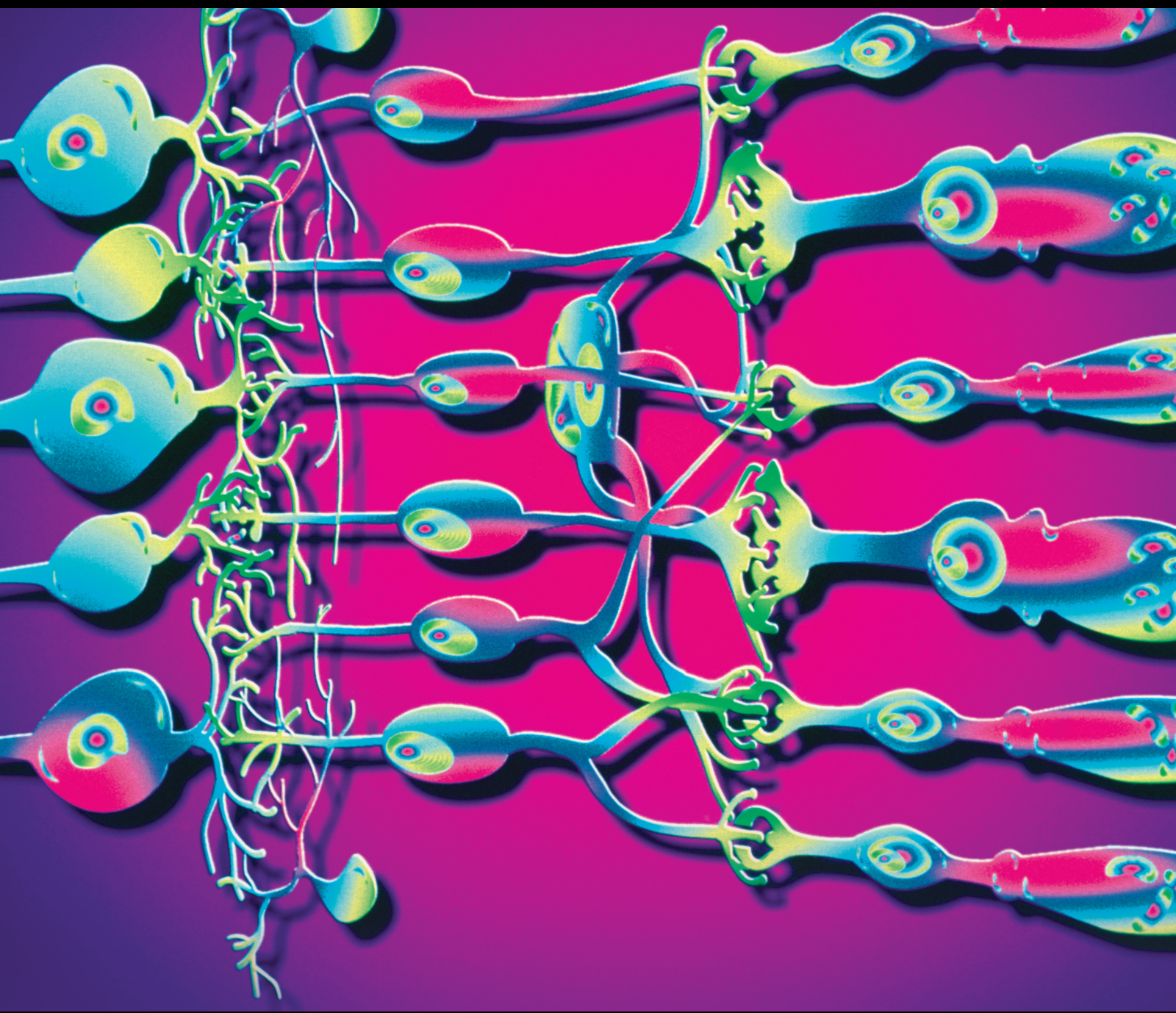
Journal of Ophthalmology

Optical and Material Properties of Intraocular Lenses

Lead Guest Editor: Ramin Khoramnia
Guest Editors: Chul Young Choi and Gerd Auffarth



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Review Article

Posterior Capsule Opacification after Cataract Surgery via Implantation with Hydrophobic Acrylic Lens Compared with Silicone Intraocular Lens: A Systematic Review and Meta-Analysis

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Hydrophobic acrylic intraocular lens (IOL) is the most popular material in cataract surgery. Posterior capsule opacification (PCO) is a long-term complication of cataract surgery. It can impair vision and adversely affect the prognosis of IOL delamination. The objective of this study was to perform a systematic review and meta-analysis to provide an updated evaluation of long-term complications and visual function after implantation with hydrophobic acrylic and silicone intraocular lenses. PubMed, Embase, and Cochrane Library were searched from January 2000 until March 2021. Randomized controlled trials (RCTs) and retrospective studies were finally included. The main outcomes were PCO value and neodymium-doped yttrium aluminum garnet (Nd : YAG) capsulotomy rate. Subgroup analysis was performed to compare hydrophobic acrylic and silicone IOLs during the follow-up period. Sensitivity analysis was also performed. The meta-analysis included a total of 17 studies. When the follow-up period was considered, the results of the analysis revealed higher PCO value (Group 3: standardized mean difference (SMD), −0.59; 95% confidence interval (CI), −0.90 to −0.28) and Nd : YAG capsulotomy rate (Group 3: risk ratio (RR), 0.60; 95% CI, 0.40–0.89) for hydrophobic acrylic IOLs than silicone IOLs during a long-term (≥6 years) follow-up. In conclusion, both the PCO value and the Nd : YAG capsulotomy rates were higher in hydrophobic acrylic IOLs group than the silicone IOLs group at long-term use (more than 6 years) after implantation.

1. Introduction

Cataract surgery is frequently performed worldwide primarily due to aging [1, 2]. Cataract is prevalent in adults aged between 45 and 50 years [3]. Statistical data pertaining to cataracts in the United States have reported a prevalence of nearly 32% among adults below the age of 65 years and 50% among those in their 40s and 50s [4]. Age-related cataract surgery is also being performed earlier than before [5]. As a result, long-term safety and efficacy of intraocular lens (IOL) implantation have been established [6–8].

Materials of IOLs can be distinguished by their moisture content, chemical composition, refractive index, and tensile strength. Differences in these properties can determine complications and vision [9]. Posterior capsule opacification (PCO) value and neodymium-doped yttrium aluminum garnet (Nd : YAG) capsulotomy rate are typical indicators of the incidence of complications after cataract surgeries [10]. In particular, PCO is a representative long-term complication following cataract surgery. It is caused by fibrosis around the posterior capsule [11–13]. This PCO can lead to impaired vision, contrast sensitivity, and glare [11, 13]. PCO can be easily treated via Nd : YAG capsulotomy [10, 12]. However, Nd : YAG capsulotomy can increase the risk of IOL instability, dislocation, or further complications such as increased intraocular pressure, glaucoma, retinal detachment, and cystic macular edema [10, 14, 15].

Hydrophobic acrylic IOLs are widely used because they can reduce complications such as PCO and optimize vision [10, 16]. Theoretically, hydrophobic acrylic IOLs in bioactive

materials are known to prevent serious PCO compared to IOLs in polymethyl methacrylate (PMMA) or silicone materials [17–19]. Several studies [18, 19] have reported that hydrophobic acrylic IOLs can yield a lower PCO value than hydrophilic acrylic IOLs. However, clinical studies [7, 8], including long-term follow-up (over six years), have demonstrated that hydrophobic acrylic IOLs are associated with a relatively higher PCO value or Nd : YAG capsulotomy rate than silicone IOLs. In particular, Rønbeck and Kugelberg [7] have reported a higher degree of survival without Nd : YAG capsulotomy in a 12-year follow-up analysis of silicone IOLs compared with hydrophobic acrylic IOLs at more than 6 to 7 years after cataract surgery. Cheng et al. [20] have stated that clinical trials lasting at least five years are needed to further evaluate the impact of IOL materials on PCO reduction and the use of Nd : YAG capsulotomy. Therefore, we conducted a systematic review and meta-analysis to determine whether hydrophobic acrylic IOLs after cataract surgery might be more effective than silicone IOLs in reducing postsurgical complications during a long-term follow-up.

2. Methods

2.1. Literature Search. This review was conducted following the updated Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) 2020 statement [21] (PRISMA 2020 checklist is detailed in Supplementary File 1). This study was registered with the International Prospective Register of Systematic Reviews (PROSPERO) database (identifier: CRD42021242394). Reports of randomized controlled trials (RCTs) and retrospective studies comparing hydrophobic acrylic IOLs with silicone IOLs in patients with age-related cataracts were identified via a systematic search of PubMed, Embase, and Cochrane Library. The search period was extended from January 2000 to March 2021 to cover long-term follow-up studies. Search terms used a combination of MeSH/Emtree terms and "natural language terminology," including cataract, intraocular lens, lens implantation, capsule opacification, hydrophobic acrylic, and silicone (search strategy is detailed in Supplementary File 2). In case of duplicate studies with data extracted from the same population group, only the most recent studies were included. Any disagreements regarding the search strategy were resolved via consensus based on discussion.

2.2. Selection Criteria. Studies fulfilling the following selection criteria were included: (1) patients >45 years of age who had age-related cataract and treated with cataract surgery; (2) interventions using hydrophobic acrylic IOLs; (3) comparison with silicone IOLs; (4) outcomes included at least one of the following outcome variables: PCO value, Nd : YAG capsulotomy rate, visual acuity, anterior capsule opacification (ACO) value, tilt, and decentration; (5) RCTs and retrospective studies. Case studies, pilot studies, grey literature, studies published in languages other than English, patients with congenital or traumatic cataracts, and diabetes requiring medical control were excluded from this study. Studies were selected by two reviewers (Y.R. and Y.N.). The first reviewer (Y.R.) reviewed all titles, abstracts, and full texts. The second reviewer (Y.N.) analyzed studies excluded from the review.

2.3. Data Extraction and Quality Assessment. The following data were extracted from each study: author's name, year of publication, study design, number of eyes, patient's age and gender, follow-up period, IOL materials and designs, and individual study outcomes. Primary outcomes were set at the quantitative PCO value represented by score or grade using evaluative software and Nd : YAG capsulotomy rate to compare the degree of postsurgical complications during the long-term follow-up after cataract surgery. Secondary outcomes were ACO value represented by score or grade or area, visual acuity (best-corrected visual acuity, BCVA) represented by the logarithm of the minimum angle of resolution (log MAR), degree of tilt, and decentration in relation to complications immediately following cataract surgery or visual function. PCO values and Nd : YAG capsulotomy rates were determined and categorized according to the follow-up period. In the case of multiple values, all values that could be included in a subgroup were extracted. In other cases, only the most recent values were extracted. Quality assessment of included RCT studies was performed using the Cochrane group's Risk of Bias (ROB) tool [22]. Retrospective studies were assessed using the Risk of Bias In Nonrandomized Studies–of Interventions (ROBINS-I) tool [22]. All controversies were resolved via consensus based on discussion among reviewers.

2.4. Data Analysis. Sensitivity analysis was performed except for studies with missing SD data. According to Cochrane's handbook [22], missing SDs were replaced with the mean value of SD based on values determined using the same evaluative system. PCO and ACO values with various measurement scales as continuous variables were pooled using standardized mean differences (SMDs) with 95% confidence intervals (CIs). Dichotomous variables of Nd : YAG capsulotomy rate were calculated using relative risks (RRs) with 95% CIs. Outcomes of visual acuity, tilt, and decentration were pooled using mean differences (MDs) with 95% CIs. Meta-analysis was considered statistically significant if P-value was less than 0.05. For heterogeneity, I^2 values greater than 75% represented high heterogeneity [23] using a random-effects model. Publication bias was visually evaluated via funnel plots. All data analyses for the meta-analysis were performed using RevMan (version 5.4.1, Cochrane Library).

2.5. Subgroup Analysis. Subgroup analysis was performed to confirm results according to the follow-up period. Based on the study of Rønbeck and Kugelberg [7], the following three groups were created according to the length of the follow-up period: (1) Group 1 (G1), short term, 0 years ≤ follow-up period < 3 years; (2) Group 2 (G2), medium term, 3 years ≤ follow-up period < 6 years; (3) Group 3 (G3), long term, follow-up period ≥ 6 years.

3. Results

3.1. Included Studies. A total of 483 articles were identified in the initial analysis. Of them, 122 duplicated articles were excluded. Based on titles and abstracts, 39 potential studies were screened. Finally, 17 eligible studies [6–8, 24–37] were included in this analysis (excluded studies and reasons for exclusion are detailed in Supplementary File 3). The flow diagram of the selection process is presented in Figure 1.

3.2. Characteristics of the Included Studies. Characteristics of included studies are listed in Table 1. This meta-analysis included 14 RCTs [7, 8, 25, 27–37] and three retrospective studies [6, 24, 26]. The average age of patients ranged from 61.3 to 78 years. The follow-up period varied from one week to 12 years. A subgroup analysis was performed to determine PCO values and Nd : YAG capsulotomy rates. These subgroups were separated by follow-up periods. Based on PCO values, four studies [8, 27, 28, 34] were included in the short-term group (G1), seven studies [8, 24, 26, 27, 31, 36, 37] were included in the medium-term group (G2), and two studies [6, 8] were included in the long-term group (G3). Based on Nd : YAG capsulotomy rates, the short-term group (G1) included four studies [24, 28, 33, 34], the medium-term group (G2) comprised six studies [24, 27, 29, 31, 32, 37], and the long-term group (G3) had three studies [6–8]. These included studies were conducted in the Netherlands, Germany, United States, Austria, Japan, South Korea, Finland, Italy, Sweden, and Lithuania (characteristics of IOLs included in the meta-analysis are detailed in Supplementary File 4).

3.3. Assessment of Risk of Bias. Figure 2 summarizes the risk of bias in 14 RCTs using the ROB tool. Investigators used an envelope [28, 30], a randomization scheme [25], or a computerized random number generator [7, 8, 27, 29, 31] for random assignment of the 14 RCTs included in the present meta-analysis. Of these 14 RCTs, five [8, 27–29, 35] were double-blind, one study [25] was single-blind, and two studies [31, 37] were impossible to blind. In the case of single-blind or nonblinded trials, the risk of performance bias was deemed high. When random assignment and blinding methods were not specified, they were considered to have an unclear risk. Figure 3 summarizes the risk of bias in three retrospective studies using the ROBINS-I tool. Patients were recruited by follow-up visits [24, 26] or invitations [6] of patients conducted by the same surgeon. The risk of participant selection bias was deemed high when only patients who met the preliminary criteria were recruited by the same surgeon retrospectively [26]. All studies reported the number and reason of dropout patients (bias of each study is detailed in Supplementary Files 5 and 6).

3.4. Comparison of the Degree of Complications Based on Long-Term Follow-Up after Cataract Surgery

3.4.1. PCO Value. PCO values of hydrophobic acrylic and silicone IOLs were comparatively analyzed in 10 studies [6, 8, 24, 26–28, 31, 34, 36, 37] comprising 1,138 eyes. A

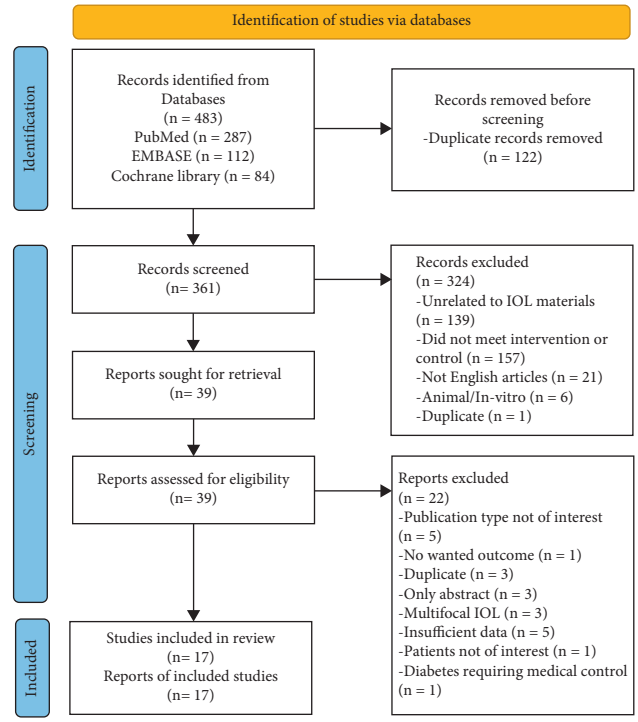

Figure 1: PRISMA flow diagram outlining study selection.

random-effects model was used due to the high heterogeneity ($I^2 = 80\%$) of studies. The overall effect on PCO value showed no statistically significant difference between hydrophobic acrylic and silicone IOLs when the follow-up period was not considered ([SMD], −0.23; 95% CI, −0.50 to 0.05; $P = 0.11$). The forest plot is detailed in Supplementary File 7. Subgroup analysis during the follow-up period revealed a high heterogeneity ($I^2 = 79\%$). Therefore, the random-effects model was used. Short-term (G1, 0 years ≤ follow-up period < 3 years) and medium-term (G2, 3 years ≤ follow-up period < 6 years) groups showed no significant difference in PCO value between hydrophobic acrylic and silicone IOLs (G1, [SMD], −0.15; 95% CI, −0.61 to −0.30; $P = 0.51$; G2, [SMD], 0.08; 95% CI, −0.22 to 0.39; $P = 0.60$). However, in the long term (G3, follow-up period ≥6 years), hydrophobic acrylic IOLs were associated with relatively higher PCO values than silicone IOLs, showing a statistically significant difference (G3 [SMD], −0.59; 95% CI, −0.90 to −0.28; $P = 0.001$, Figure 4).

3.4.2. Nd : YAG Capsulotomy Rate. The meta-analysis included 12 studies [6–8, 24, 27–29, 31–34, 37] involving 1,541 eyes. The overall effect showed an intermediate degree of heterogeneity ($I^2 = 70\%$). Therefore, the fixed-effects model was used. The overall effect without considering the follow-up period showed no statistically significant difference in the Nd : YAG capsulotomy rate between hydrophobic acrylic and silicone IOLs ([RR], 1.21; 95% CI, 0.9–1.56; $P = 0.14$). The forest plot is detailed in Supplementary File 7. Subgroup analysis during the follow-up period revealed an intermediate degree of heterogeneity ($I^2 = 74\%$). Thus, a fixed-effects model was applied. Short-

Table 1: Characteristics of RCTs or retrospective studies included in the meta-analysis.

Study	Study design	Country	IOL group	Eyes	Age	Follow-up
Abhilakh Missier et al. [24]	Retrospective study	Netherlands	Hydrophobic acrylic Silicone	107 107	74 ± 14	3 years
Baumeister et al. [25]	RCT	Germany	Hydrophobic acrylic Silicone	28 28	74 ± 7	1 week 6, 12 months
Daynes et al. [26]	Retrospective study	USA	Hydrophobic acrylic Silicone	60 51	70 77	3 years
Findl et al. [27]	RCT	Austria	Hydrophobic acrylic Silicone	53 53	78 ± 4	1 year 3 years
Hayashi et al. [28]	RCT	Japan	Hydrophobic acrylic Silicone	96 83	68.8 ± 10.5 71.0 ± 8.9	1 week 3, 6, 12, 18 months 2 years
Hayashi et al. [29]	RCT	Japan	Hydrophobic acrylic Silicone	100 100	71.4 ± 6.5	3 years
Kim et al. [30]	RCT	Korea	Hydrophobic acrylic Silicone	25 47	63.7 ± 9.2 61.3 ± 10.4	1, 3, 6 months
Kohnen et al. [31]	RCT	Germany	Hydrophobic acrylic Silicone	60 60	73.9	3 years
Ernest et al. [32]	RCT	USA	Hydrophobic acrylic Silicone	83 73	74	3 years
Pohjalainen et al. [33]	RCT	Finland	Hydrophobic acrylic Silicone	40 40	67.1 ± 14.1 67.2 ± 13.9	2.4 years
Prosdocimo et al. [34]	RCT	Italy	Hydrophobic acrylic Silicone	38 40	71	18 months
Rønbeck et al. [7]	RCT	Sweden	Hydrophobic acrylic Silicone	62 64	73.1	12 years
Sacu et al. [35]	RCT	Austria	Hydrophobic acrylic Silicone	53 53	78 ± 4	1 year
Vock et al. [6]	Retrospective study	Austria	Hydrophobic acrylic Silicone	98 44	M: 66.4 ± 10.1 F: 68.1 ± 10.1 M: 65.6 ± 7.8 F: 69.8 ± 6.5	10 years
Vock, Crnej et al. [8]	RCT	Austria	Hydrophobic acrylic Silicone	53 53	75 ± 9 75	6 years
Wejde et al. [36]	RCT	Sweden	Hydrophobic acrylic Silicone	59 60	75 73	3 years
Zemaitiene et al. [37]	RCT	Lithuania	Hydrophobic acrylic Silicone	34 30	67.6 ± 7.7	3 years

All included patients had age-related cataract; age is reported in years. F = female; IOL = intraocular lens; M = male; RCT = randomized controlled trial.

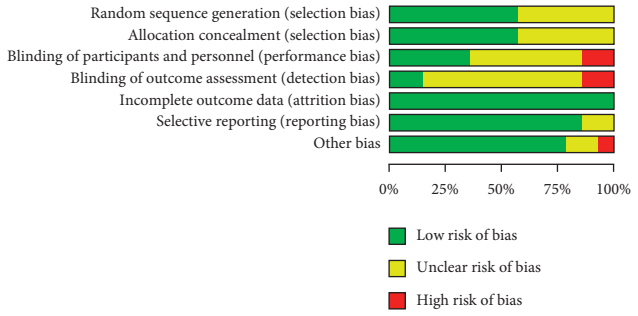

Figure 2: Risk of bias assessment of RCTs.

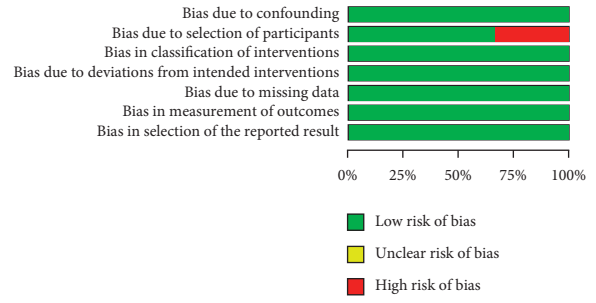

Figure 3: Risk of bias assessment of non-RCTs.

term (G1, 0 years ≤ follow-up period < 3 years) and medium-term (G2, 3 years ≤ follow-up period < 6 years) groups with hydrophobic acrylic IOLs showed lower Nd : YAG capsulotomy rates than those with silicone IOLs (G1, [RR], 3.08; 95% CI, 1.57–6.07; $P = 0.001$, G2, [RR], 2.12; 95% CI, 1.45–3.12; $P < 0.001$). However, in the long-term group (G3, follow-up period ≥6 years), hydrophobic acrylic IOLs resulted in higher Nd : YAG capsulotomy rates than

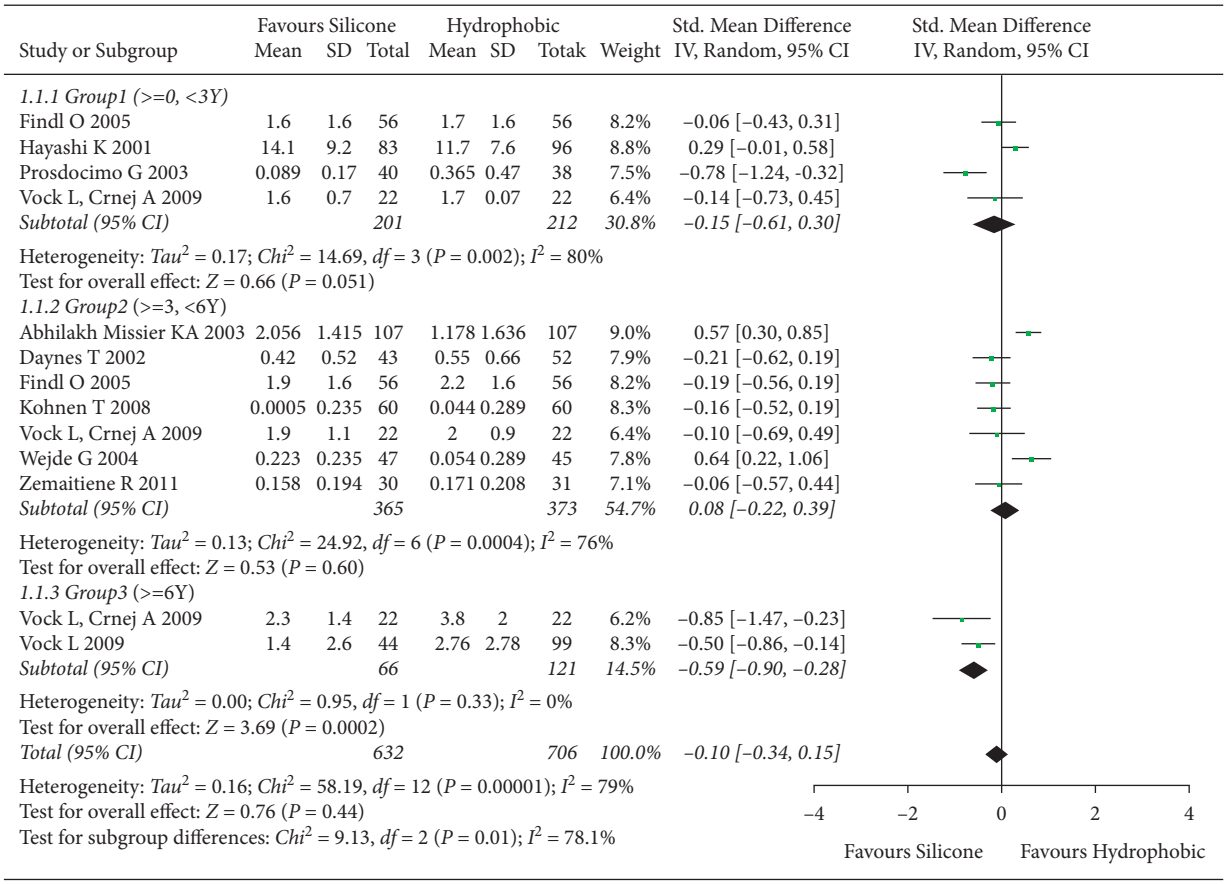

Figure 4: Comparison of subgroup effects on PCO value between hydrophobic acrylic and silicone IOLs. In the long-term group (G3, follow-up period ≥6 years), hydrophobic acrylic IOLs showed significantly high PCO values than silicone IOLs. Chi^2 = chi-square statistic; CI = confidence interval; df = degrees of freedom; I^2 = I-squared, heterogeneity statistic; IOL = intraocular lens; IV = inverse variance; PCO = posterior capsule opacification; SMD = standard mean difference; Z = Z-statistic.

silicone IOLs, showing a statistically significant difference between these two IOLs (G3 [RR], 0.60; 95% CI, 0.40–0.89; $P = 0.01$, Figure 5).

3.5. Complications Immediately following Cataract Surgery and Visual Function

3.5.1. ACO Value. The meta-analysis included four studies [26, 27, 35, 37] with 384 eyes to determine the ACO value. The overall effect showed a high heterogeneity ($I^2 = 81\%$). Therefore, the random-effects model was applied. In the forest plot, ACO values of hydrophobic acrylic IOLs were relatively lower than those of silicone IOLs, showing no statistically significant difference ([SMD], 0.34; 95% CI, −0.14 to 0.83; $P = 0.17$, Figure 6).

3.5.2. Visual Acuity (BCVA). The meta-analysis included five studies [6, 26, 30, 31, 37] with 481 eyes to determine visual acuity. No statistically significant heterogeneity ($I^2 = 0\%$) was observed between included studies. Therefore, the fixed-effects model was used. The overall effect showed no statistically significant difference in visual acuity between hydrophobic acrylic and silicone IOLs ([MD], −0.00; 95% CI, −0.02 to 0.01; $P = 0.92$, Figure 7).

3.5.3. Tilt and Decentration. Two studies [25, 30] with 128 eyes were included to analyze tilt and decentration, respectively. Both outcomes showed no statistically significant heterogeneity between studies (tilt, $I^2 = 0\%$; decentration, $I^2 = 0\%$). Thus, fixed-effects models were applied. Overall effects showed no statistically significant differences between hydrophobic acrylic and silicone IOLs (tilt, [MD], −0.06; 95% CI, −0.43 to 0.31; $P = 0.75$, Figure 8; decentration [MD], 0.02; 95% CI, −0.04 to 0.08; $P = 0.50$, Figure 9).

3.6. Sensitivity Analysis. Sensitivity analysis was performed except for three [27, 31, 36] that did not report SDs. Analysis revealed no significant change in overall results (Supplementary File 8).

3.7. Publication Bias. Publication bias was evaluated by visually examining the funnel plot. The funnel plot showed asymmetry in Nd : YAG capsulotomy rate, suggesting some degree of publication bias (Supplementary File 9).

4. Discussion

In the present study, systematic review and meta-analysis were conducted to evaluate complications during long-term

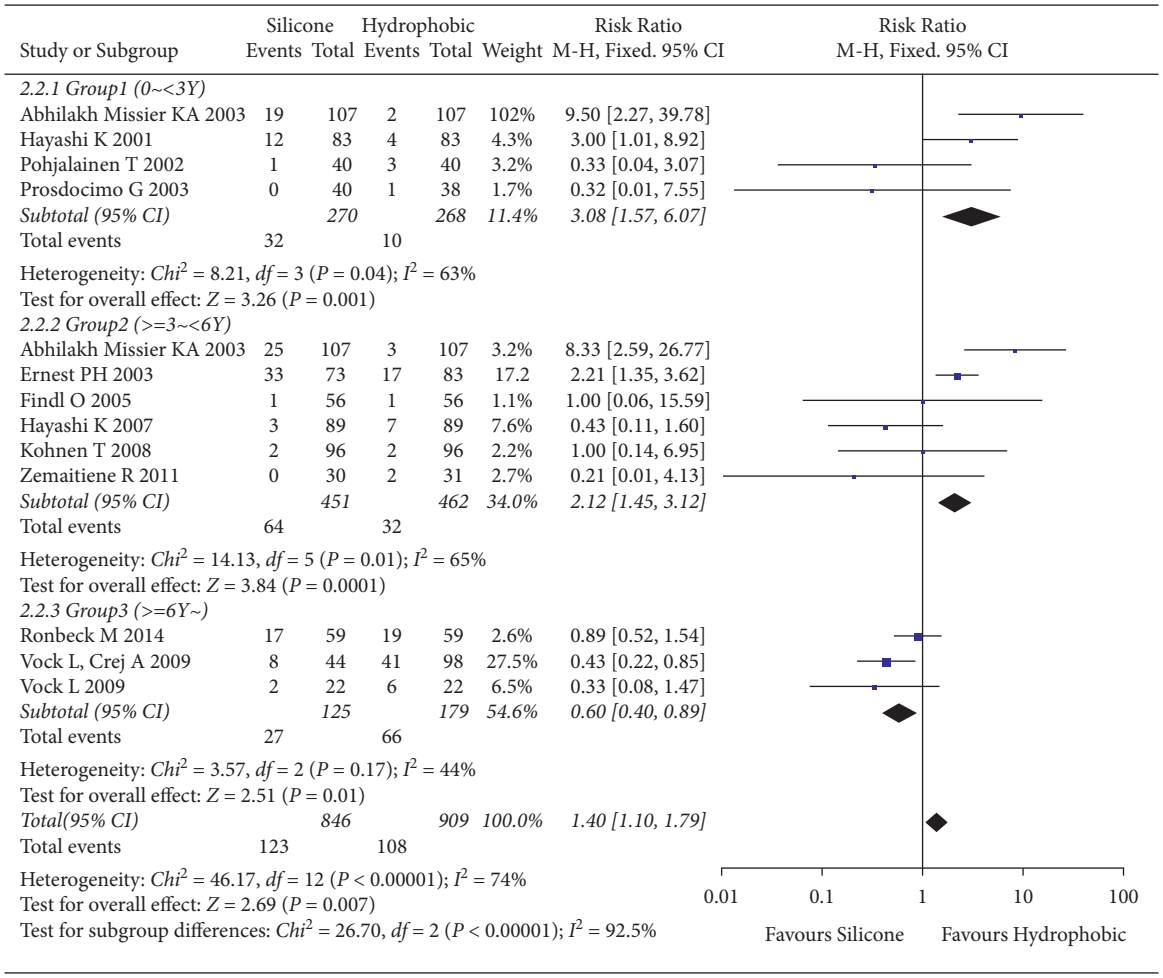

Figure 5: Comparison of subgroup effects on Nd : YAG capsulotomy rates between hydrophobic acrylic and silicone IOLs. In the long-term group (G3, follow-up period ≥6 years), hydrophobic acrylic IOLs were associated with significantly higher Nd : YAG capsulotomy rates than silicone IOLs. Chi² = chi-square statistic; CI = confidence interval; df = degrees of freedom; I^2 = I-squared, heterogeneity statistic; IOL = intraocular lens; M-H = Mantel-Haenszel estimate; RR = risk ratio; Z = Z-statistic.

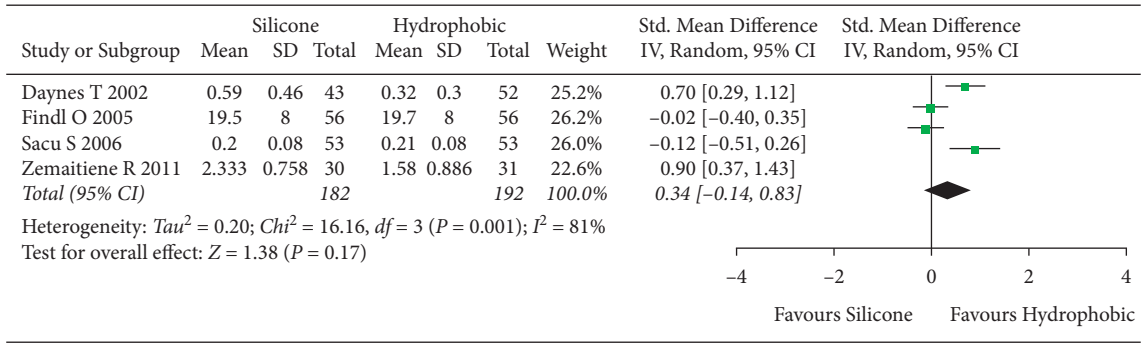

Figure 6: Comparison of ACO values between hydrophobic acrylic and silicone IOLs, showing no statistically significant differences between the two IOLs. Chi² = chi-square statistic; CI = confidence interval; df = degrees of freedom, I^2 = I-squared, heterogeneity statistic; IOL = intraocular lens; IV = inverse variance; SMD = standard mean difference; Z = Z-statistic.

follow-up and visual function of hydrophobic acrylic IOLs compared with silicone IOLs. The contribution of this study can be summarized as follows. We evaluated the effects of complications and visual function, including long-term clinical studies with follow-up of more than six years after implantation of hydrophobic acrylic or silicone IOLs. We also found that compared with silicone IOLs, hydrophobic acrylic IOLs were better in terms of the degree of PCO [17–19]. However, hydrophobic acrylic IOLs were associated with higher PCO values and Nd : YAG capsulotomy rates

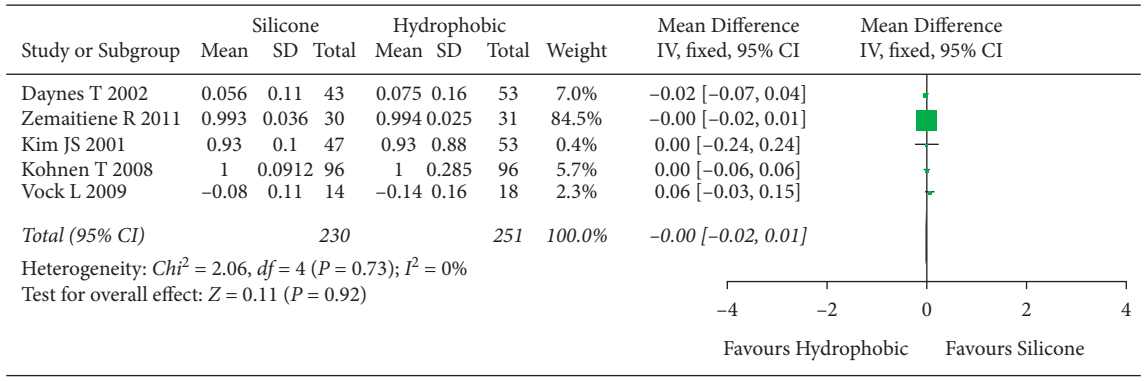

Figure 7: Comparison of visual acuity (BCVA) between hydrophobic acrylic and silicone IOLs, showing no statistically significant differences between the two IOLs. BCVA = best-corrected visual acuity; Chi^2 = chi-square statistic; CI = confidence interval; df = degrees of freedom; I^2 = I-squared, heterogeneity statistic; IOL = intraocular lens; IV = inverse variance; MD = mean difference; Z = Z-statistic.

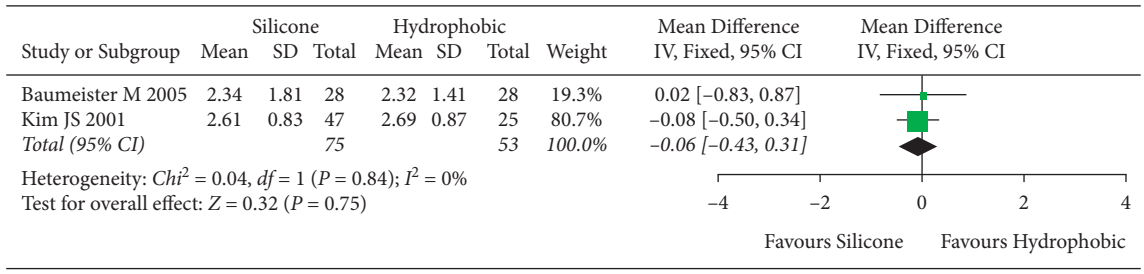

Figure 8: Comparison of tilt between hydrophobic acrylic and silicone IOLs, showing no statistically significant differences between the two IOLs. Chi^2 = chi-square statistic; CI = confidence interval; df = degrees of freedom; I^2 = I-squared, heterogeneity statistic; IOL = intraocular lens; IV = inverse variance; MD = mean difference; Z = Z-statistic.

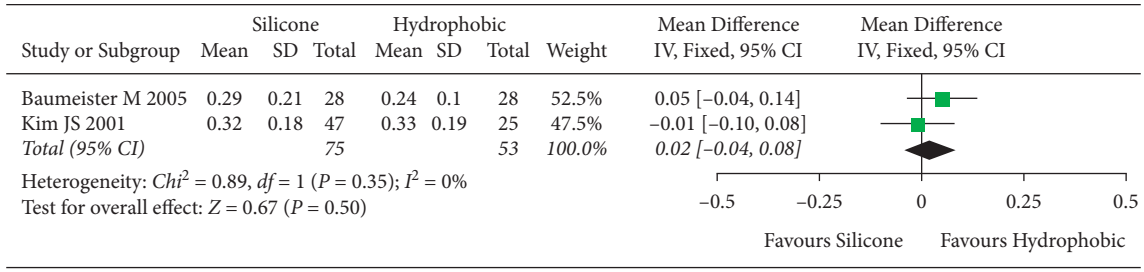

Figure 9: Comparison of decentration between hydrophobic acrylic and silicone IOLs, showing no statistically significant differences between the two IOLs. Chi^2 = chi-square statistic; CI = confidence interval; df = degrees of freedom; I^2 = I-squared, heterogeneity statistic; IOL = intraocular lens; IV = inverse variance; MD = mean difference; Z = Z-statistic.

over a 6-year follow-up. Therefore, a long-term (≥6 years) use of hydrophobic acrylic IOLs could affect PCO and Nd : YAG capsulotomy more than such use of silicone IOLs.

Subgroup analysis during the follow-up period revealed higher PCO value and Nd : YAG capsulotomy rates in the group carrying long-term (≥6 years) hydrophobic acrylic IOLs compared with those bearing silicone IOLs. This finding was inconsistent with previous studies [17–19] reporting a lower PCO value with hydrophobic acrylic IOLs than that with silicone IOLs. The barrier effect on PCO is generated by a stably formed capsule bending inhibiting the movement of lens epithelial cells (LECs) to the posterior capsule, which is primarily superior in sharp-edge IOLs [38, 39]. However, if the continuous proliferation of LECs is delayed over a specific duration, a Soemmering's Ring is formed, which abrades the barrier effect of the sharp edge [39]. The hydrophobic acrylic IOLs in this study all had sharp edges. In contrast, silicone IOLs partially exhibited round edges. Nonetheless, compared with silicone IOLs, hydrophobic acrylic IOLs exhibited higher PCO values and Nd : YAG capsulotomy rates, implying that the barrier effect of sharp-edge hydrophobic acrylic IOL was lost due to a long-term (≥6 years) use. Thus, from a long-term perspective, it can be interpreted that the properties of the material itself had a greater impact on the PCO than the effects of the edge design. Compared with hydrophobic acrylic, silicone can mediate the adhesion between IOL and capsule by combining collagen IV and vitronectin attachment proteins [40]. Silicone can also resist the formation of Soemmering's Ring [39]. Therefore, it could help prevent

PCO longer during the long-term use than hydrophobic acrylic.

The PCO value did not vary significantly between hydrophobic acrylic and silicone IOLs in the short-term (G1) or the medium-term (G2) follow-up. However, the incidence of Nd : YAG capsulotomy rate was lower in the case of hydrophobic acrylic IOLs during short-term (G1) and medium-term (G2) follow-ups. Although Nd : YAG capsulotomy is the only treatment for PCO, the PCO value and the Nd : YAG capsulotomy rate did not show consistency, which was contrary to other studies [7, 41]. This result might be attributed to differences in reaching Nd : YAG capsulotomy diagnosis depending on the degree of PCO. According to Ling et al. [41], the diagnosis of PCO prior to performing Nd : YAG capsulotomy is not always established. It may vary depending on the assessment. Clinical studies analyzed in this meta-analysis used a variety of evaluation systems, including subjective methods for evaluating PCO levels. Unfortunately, no standardized method is currently available to evaluate the PCO value before Nd : YAG capsulotomy in clinical practice [41]. Therefore, advanced methods of PCO standardization and clinical trials with subsequent Nd : YAG capsulotomy are needed.

There was no significant difference in ACO value between hydrophobic acrylic and silicone IOLs. Hydrophobic acrylic IOLs had relatively lower ACO values than silicone IOLs ([SMD] = 0.34), indicating an intermediate effect size ($0.2 \leq [SMD] < 0.5$) [42]. This might be due to a more pronounced effect of similar properties between haptic materials of the two IOLs on ACO than optic materials of the IOLs. Silicone IOLs included in our ACO analysis all had three pieces made of polyvinylidene fluoride (PVDF) or PMMA haptics. Loop memory in PVDF has properties similar to PMMA haptic of hydrophobic acrylic IOLs [43]. However, a high heterogeneity ($I^2 = 81\%$) between ACO studies included in the meta-analysis was found. This interpretation is marginal due to the small number of studies. No further analysis of heterogeneity has been made. However, the high heterogeneity might be attributed to a combination of factors and scales that affect ACO.

Comparing the effect size of hydrophobic acrylic and silicone IOLs in terms of visual function after cataract surgery, visual acuity was statistically similar between the two groups. Previous meta-analyses [11, 44, 45] comparing typical IOL materials (PMMA, silicone, and acrylic) have revealed no significant differences in visual acuity. Our study results are consistent with these prior studies, suggesting the absence of a significant effect on the visual acuity of these two IOL materials. There were no significant differences in tilt or decentration between hydrophobic acrylic and silicone IOL materials either. Forward and backward movement of IOL due to tilt and decentration can affect refraction and aberration of eyes [25]. This effect depends on the spherical degree of IOLs, which has recently been complemented by the emergence of aspherical IOLs [46]. All hydrophobic acrylic and silicone IOLs included in this study were spherical, suggesting no difference in optical performance [25, 47].

This meta-analysis has some limitations. Since most clinical studies related to IOL materials mainly reported results of PCO and Nd : YAG capsulotomy, a subgroup analysis was feasible only for PCO value and Nd : YAG capsulotomy rate during the follow-up period. Therefore, an adequate number of clinical trials related to visual function and complications other than PCO are needed in the future. Furthermore, results of ACO suggested a high heterogeneity ($I^2 = 81\%$). No further analysis has been made to decrease the heterogeneity. Another subgroup or sensitivity analysis, such as an additional analysis based on edge design, haptic material, optical size, presence of aspheric lens, and surgical technique used [48, 49], will be necessary in the future. Nd : YAG capsulotomy irradiated with low energy laser affects the morphology of IOL. Thus, further meta-analysis studies should be done to determine damage and structure changes of IOL after being hit by the laser [50].

5. Conclusion

Hydrophobic acrylic IOLs are associated with higher PCO values and Nd : YAG capsulotomy rates than silicone IOLs when they are used for a long term (more than 6 years). However, both hydrophobic acrylic and silicone IOLs can lead to similar visual functions.

Data Availability

All data are included within this article and its supplementary files.

Disclosure

The organization had no role in the design or conduct of this research.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this article.

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Supplementary Materials

Supplementary File 1. PRISMA 2020 checklist. *Supplementary File 2.* Details of the search strategy. *Supplementary File 3.* Details of excluded studies and reasons. *Supplementary File 4.* Characteristics of IOLs included studies. *Supplementary File 5.* Risk of bias assessment of randomized controlled trials. *Supplementary File 6.* Risk of bias assessment of nonrandomized controlled trials. *Supplementary File 7.* Forest plots of the overall effect of PCO value and Nd : YAG capsulotomy rate. *Supplementary File 8.* Sensitivity

analysis except the studies missing SDs. *Supplementary File 9*. Funnel plots of publication bias. (*Supplementary Materials*)

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Research Article

First Results after Implantation of Hydrophilic and Hydrophobic Trifocal Intraocular Lenses: Visual and Optical Performance

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Purpose. To compare postcataract surgery visual and optical performance between two trifocal intraocular lenses (IOLs) with the same optical design: a hydrophobic acrylic glistening-free IOL and a hydrophilic acrylic IOL. *Methods*. Patients were bilaterally implanted with either the hydrophobic or the hydrophilic IOL. The data of the patients' right eyes were evaluated. Visual quality assessments included refractive outcomes, monocular visual acuity (VA) at far, intermediate, and near distances, defocus curve, aberrations (spherical aberration (SA)), root mean square (RMS) of corneal, internal, and total higher-order aberrations (HOAs)), and tilt of IOL. *Results*. Fifty-one patients were included in the analysis: 26 patients implanted with the hydrophobic IOL and 25 patients implanted with the hydrophilic IOL. At 1 month, no statistically significant differences were found for monocular uncorrected and corrected VA at distance, distance-corrected VA at intermediate and near, defocus curve, manifest spherical equivalent, total SA, and RMS of the total, internal, and corneal HOA. The defocus curve of both groups showed a visual acuity of 0.3 logMAR or better in the intermediate range from 0.5 to −2.5 D of vergence level with no significant differences between the groups. Compared to the hydrophilic group, *y*-direction tilt was significantly higher in the hydrophobic group ($p = 0.027$). The total tilt and *x*-axis tilt did not differ between the groups. *Conclusion*. Both IOLs demonstrated an excellent quality of vision and provided the patient with a wide range of vision.

1. Introduction

Monofocal intraocular lenses (IOLs) achieve excellent visual acuity (VA) results, but as the name suggests, only at one distance—usually far. As patients can no longer accommodate after IOL implantation, they need to use spectacles to see other distances in focus. The first-generation "bifocal" IOLs provided two focal points, one for far and the other for near vision, but thanks to an upsurge in computer, tablet, and smartphone use over recent years, there has been an upsurge in demand for IOLs that offer good intermediate vision too—something that bifocal IOLs cannot achieve [1]. In 2010, the first trifocal IOL (FineVision Micro F, PhysIOL, Liège, Belgium) was introduced [2], and numerous studies have shown that this IOL provides good far, intermediate, and near visual acuities (VA) and results in high levels of patient satisfaction [3–8].

The study reported here used two PhysIOL trifocal IOLs; both are based on the optical design of the FineVision Micro F IOL but differ in the material they are made from, which results in significant differences in the thickness of the IOLs. The POD F GF IOL is made from a hydrophobic acrylic glistening-free material, which should overcome the known disadvantages of conventional acrylic materials—both hydrophobic [9] and hydrophilic [10, 11].

This study compares the hydrophobic glistening-free POD F GF IOL with the hydrophilic POD F IOL in terms of optical quality after implantation in cataract patients.

2. Materials and Methods

This prospective, randomized, and controlled clinical study was performed to compare the quality of vision outcomes including monocular VA at far, intermediate, and near

distances, refractive outcomes, defocus curve, aberrations, and IOL tilt in patients undergoing cataract surgery and bilateral implantation of either the FineVision POD F GF or FineVision POD F trifocal IOLs. The IOL model used for implantation was randomly chosen for each patient.

The clinical trial (NCT03347981) followed the provisions of the Declaration of Helsinki and was approved by the local ethics committee (CEIC Hospital Clínico San Carlos, Madrid, Spain).

2.1. IOL Models. Both IOL models used in this study are single-piece diffractive trifocal lenses, providing three focal points by combining two superimposed diffractive profiles, one with +1.75 D add power at the IOL plane for intermediate vision and another +3.50 D add power for near vision (the far focal point is created by nondiffracted light). The POD F GF and POD F IOLs both have an optic diameter of 6 mm and an overall diameter of 11.4 mm. Both IOLs have a 360° square edge around the optic in order to minimize posterior capsular opacification (PCO). The biconvex aspheric optic of the IOLs partly compensates for the positive corneal spherical aberrations (SAs). The main difference between the IOLs is the material they are manufactured with. The POD F GF IOL is made of glistening-free hydrophobic acrylate with a refractive index of 1.52. The POD F IOL is a 26% hydrophilic acrylic ultraviolet and blue light filtering lens with a refractive index of 1.46. Another minor difference between both IOL models is the design of the lens haptics. Both IOLs have double C-loop haptics with 5° angulation. The haptics of the POD F GF IOL have an additional wave-shaped structure that is intended to reduce the risk of adhesion between the haptics and the capsular bag during implantation.

2.2. Patients. A total of 51 patients were recruited for this study and were divided into two groups: the POD F GF group ($n = 26$) bilaterally implanted with the POD F GF IOL and the POD F group ($n = 25$) with the POD F IOL. A calculation of the sample size showed that this number of subjects per group was adequate to compare the optical quality between groups.

The focus of this paper is the presentation of the monocular visual quality of the patients. To avoid bias, the 1-month outcomes of patients' right eyes (OD) are presented here.

Cataractous patients with an age of 50 years or older were included after uneventful cataract surgery if they had no comorbidities, the desire for spectacle independence after surgery, realistic expectations, availability, willingness, and sufficient cognitive awareness to comply with examination procedures. Exclusion criteria were irregular astigmatism, regular astigmatism >1.0 D measured by automated keratometry or biometry or >1.25 D if the steep axis of the cylinder was between 90° and 120° in one or both eyes, acute or chronic disease or illness that would increase risk or confound study results, history of ocular trauma or prior ocular surgery including refractive procedures, capsule or zonular abnormalities that may affect postoperative centration or tilt of the IOL, pupil abnormalities, and AMD suspicious eyes.

2.3. Surgery. Cataract surgery was performed by one experienced surgeon (FP) using standard phacoemulsification and a 2.2 mm incision. All but four patients received a CTR in both eyes to increase the placement stability of the IOL and to avoid postoperative myopization. The Accujet 2.1 injector (Medicel, Thal, Switzerland) was used for all implantations to standardize surgically induced astigmatism.

2.4. Methods of Evaluation. Preoperative assessment included manifest refraction, corrected distance VA (CDVA), intraocular pressure, and corneal keratometry and biometry (IOLMaster 700, Carl Zeiss Meditec AG, Germany).

The main outcome measures at 1 month postoperatively included manifest refraction, prediction error, monocular uncorrected and corrected VA at far (UDVA and CDVA), distance-corrected intermediate VA (DCIVA), distance-corrected near VA (DCNVA), monocular defocus curve, and aberrometry.

Visual acuities at distance, intermediate, and near were measured at 4 m, 70 cm, and 35 cm, respectively, and were performed using Early Treatment Diabetic Retinopathy Study (ETDRS) charts (Precision Vision, USA). Distance-corrected visual acuities (CDVA, DCIVA, and DCNVA) were measured using subjective refraction for far distance.

Monocular defocus curves were generated by adding a defocus lens to the best-corrected refraction from +2.0 D to −4.0 D in steps of 0.5 D. With each defocus lens, VA was tested at 4 m using ETDRS charts.

The OPD-Scan III (Nidek Inc., Japan) was used to measure photopic and mesopic pupil sizes and aberrometry measurements including spherical aberrations (SA), root mean square (RMS) of the total, corneal, and internal higher-order aberrations (HOAs), and tilt.

2.5. Statistical Analysis. Data analysis was performed using Microsoft Excel (version 16.0) and the WinSTAT (version 2012.1.0.96) plug-in. Descriptive statistics were expressed as mean (±standard deviation (SD), median, and range). The Mann–Whitney U test was used to assess the significance of differences between groups. The Wilcoxon rank-sum test for paired data was performed to assess the significance of differences between examinations. A p value of less than 0.05 was considered statistically significant. The refractive prediction error was defined as the difference in achieved postoperative manifest SE and predicted SE.

Sample size was determined using the sealed envelope power calculator. To show no difference between the two study cohorts and with a drop out of 15%, the sample size calculation results in 25 patients per study group.

3. Results

Fifty-one right eyes were included in the study analysis: 26 eyes in the POD F GF group and 25 eyes in the POD F group. All patients had uneventful cataract surgery with IOL implantation and completed 1-month of follow-up. The demographics and IOL power are summarized in Table 1.

There were no significant differences in patients' age, gender, or IOL power between the study groups ($p > 0.05$).

As shown in Figure 1, the manifest refraction spherical equivalent (MRSE) at 1 month postoperatively did not differ statistically significantly between the groups ($p = 0.299$). Mean MRSE was 0.09 ± 0.47 D in the POD F GF group and 0.03 ± 0.38 D in the POD F group after 1 month; compared with preoperative values (POD F GF: 0.66 ± 2.35 D; POD F: 0.83 ± 2.24 D), there was a numerical improvement, but not a statistically significant one ($p = 0.112$ in the POD F GF group and $p = 0.058$ in the POD F group).

At 1 month postoperatively, both study groups turned out slightly hyperopic (0.11 ± 0.44 D in the POD F GF group and 0.07 ± 0.38 D in the POD F group) with no significant differences between the groups ($p = 0.418$). Figure 2 shows the distribution of prediction error: 86% of eyes in the POD F GF group and 80% of eyes in the POD F group were within ±0.5 D of the targeted MRSE.

Visual acuities at 1 month postoperatively are shown in Table 2. No significant differences were observed between the POD F GF and POD F groups.

Figure 3 shows the cumulative distribution of UDVA, CDVA, DCIVA, and DCNVA for both groups.

Almost 85% of eyes in the POD F GF group and 88% of eyes in the POD F group had a UDVA of 20/25 or better, and 100% of eyes in both groups had a UDVA of 20/50. CDVA was 20/25 or better in about 96% of eyes in the POD F GF group and in all eyes (100%) in the POD F group. DCIVA and DCNVA were better than 20/40 in 96% and 92% of eyes in the POD F GF group and all eyes (100%) of the POD F group, respectively.

The mean monocular defocus curves with the standard deviations are shown in Figure 4.

Maximal VA values were obtained in both groups at a vergence level of 0.0 D, corresponding to the distance vision. Between distance and near visions (i.e., defocus levels between 0.5 and −2.5 D), all eyes of both groups displayed a VA of 0.3 logMAR or better. Eyes that received the POD F IOL had significantly better VA at the vergence levels −4.0 D, −3.5 D, and −3.0 D ($p = 0.013$, $p = 0.014$, and $p = 0.042$) compared to eyes in the POD F GF group. For all other vergence levels, there were no significant differences between both groups ($p > 0.05$).

The photopic and mesopic pupil sizes did not significantly differ between the groups ($p = 0.510$ and $p = 0.279$, respectively). The SA, RMS of the total, internal, and corneal HOA, and x-axis, *y*-axis, and total tilt of the lens, as measured by the OPD-Scan III, are shown in Table 3. The tilt in *y*-direction was significantly higher in the POD F GF group than in the POD F group ($p = 0.027$). Spherical aberrations, HOAs, *x*-axis tilt, and total tilt did not differ between the groups.

In the course of the study, three adverse events (AEs) and one serious adverse event (SAE) occurred within 1 month. All of them were classified as "recovered" after study completion.

In the course of the detailed slit-lamp examination after 1 month, one eye of the POD F GF group showed "mild" PCO (i.e., no need for Nd : YAG treatment). In three eyes, dry eye was diagnosed (two of the eyes were in the POD F group and the remaining one in the POD F GF group). Two eyes (both from the POD F group) developed uveitis (anterior uveitis and slight uveitis, respectively) 1 month after surgery. No anterior capsular fibrosis was detected in any case.

4. Discussion

The present clinical trial demonstrated that eyes implanted with either POD F GF IOL or the POD F IOL achieved a very good postoperative quality of vision. Both IOLs provided similarly good monocular UDVA outcomes, with 85% of the POD F GF group and 88% of the POD F group achieving VA of 20/25 or better. A DCIVA of 20/40 or better was achieved in 96% of the POD F GF group and 100% of the POD F group. The DCNVA was 20/40 or better in 92% of the POD F GF group and 100% of the POD F group. The distance VA results for both the POD F GF IOL and POD F IOL achieved in this study are comparable to those of other studies that examined trifocal IOL models [5, 6, 12–16]. Regarding intermediate and near VAs, the results observed with trifocal IOLs in the literature vary and range from 0.1 logMAR or better for DCIVA and DCNVA [6, 12, 15, 17] to visual acuities considerably below 0.1 logMAR [5, 17, 18]. The DCIVA and DCNVA of our study are within the given ranges of the literature data. However, direct comparisons are difficult due to different measurement methods (VA charts and distances) and different sizes of the study populations. The performance at intermediate and near distances in this study is slightly below that of other studies with the same or similar IOLs. Studies with the same or similar IOL models have shown that intermediate visual acuity improved between 1 and 3 months, and near visual acuity increased until 6 months [12].

There were no significant differences in the visual results of the eyes that received the POD F GF and POD F IOLs in this study. So we are confident in concluding that the different materials do not affect the optical performance of the IOLs. No glistenings were observed in either the POD F GF group or the POD F group during the 1-month follow-up period, although this is a short follow-up period, and much longer-term follow-up would be required for the long-term behavior of this material.

The defocus curves in the POD F GF and POD F groups showed two peaks: one at the vergence level 0.0 D (corresponding to distance vision) and one at −2.5 D (corresponding to 40 cm). There was no considerable decrease in intermediate VA, in the defocus curve range between −2.5 D and 0.0 D, reflecting the clear advantage trifocal IOLs have over bifocal IOLs, which are associated with a V-shaped defocus curve, decreasing considerably in the intermediate range between about −0.5 D and −1.5 D [17, 19–21].

In the intermediate range, both groups achieved VA values between 0.1 and 0.17 logMAR. For the POD F group, significantly better VA at near distance between −4.0 D and −3.0 D of defocus was observed relative to the POD F GF group, although there is the possibility that this can be attributed to the (numerically, but not significantly) slightly

Table 1: Patient demographics and IOL power per group.

	POD F GF	POD F	p value[ǂ]
Gender (n)			
Female	23	21	0.703
Male	3	4	
Age (years)			
Mean ± SD	66.0 ± 6.9	65.0 ± 6.3	
Median	67.5	66.0	0.553
Min/max	52.7/83.7	47.1/75.2	
IOL power (D)			
Mean ± SD	22.6 ± 2.0	21.8 ± 2.3	
Median	23.0	22.0	0.094
Min/max	17.0/25.5	16.0/27.5	
Target MRSE (D)			
Mean ± SD	0.00 ± 0.10	0.00 ± 0.20	
Median	0.0	0.0	0.992
Min/max	−0.20/0.20	−0.60/0.20	

[ǂ]POD G GF IOL vs. POD F IOL. SD = standard deviation; min = minimum; max = maximum; IOL = intraocular lens; MRSE = mean refraction spherical equivalent.

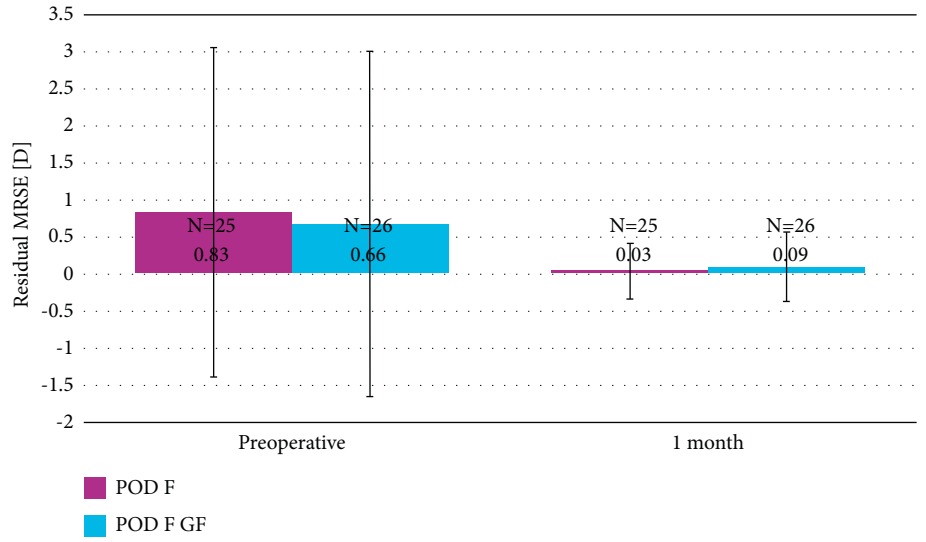

Figure 1: Mean refractive spherical equivalent preoperatively and 1 month (D).

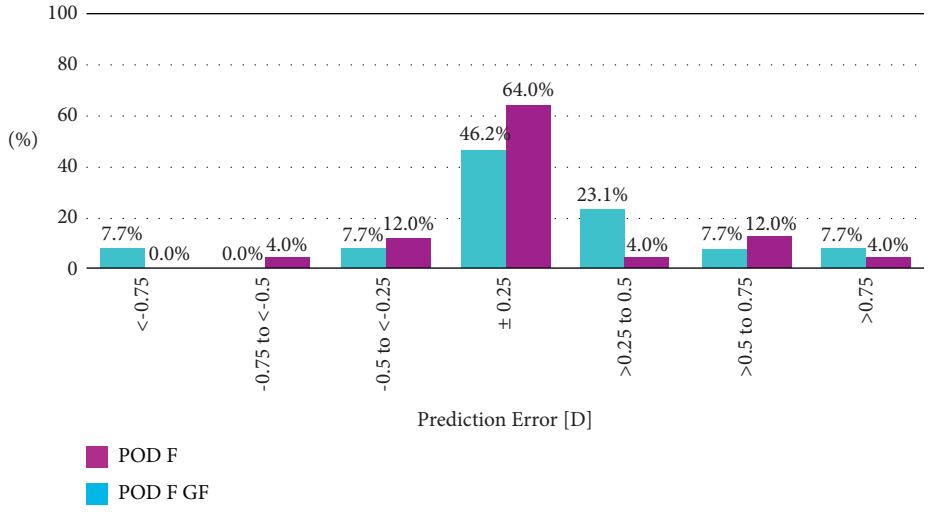

Figure 2: Distribution of prediction error 1 month postoperatively (% of eyes).

Table 2: Monocular postoperative visual acuities (logMAR) at 1 month per group.

	POD F GF	POD F	p value[ǂ]
UDVA			
Mean ± SD	0.08 ± 0.10	0.05 ± 0.10	
Median	0.10	0.00	0.097
Min/max	0.40/0.00	0.40/0.00	
CDVA			
Mean ± SD	0.01 ± 0.04	0.00 ± 0.04	
Median	0.00	0.00	0.661
Min/max	0.20/0.00	0.10/-0.10	
DCIVA			
Mean ± SD	0.12 ± 0.08	0.12 ± 0.09	
Median	0.10	0.10	0.887
Min/max	0.40/0.00	0.30/0.00	
DCNVA			
Mean ± SD	0.12 ± 0.12	0.12 ± 0.10	
Median	0.10	0.10	0.877
Min/max	0.40/0.00	0.30/-0.10	

[ǂ]POD G GF IOL vs. POD F IOL. UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; SD = standard deviation; min = minimum; max = maximum.

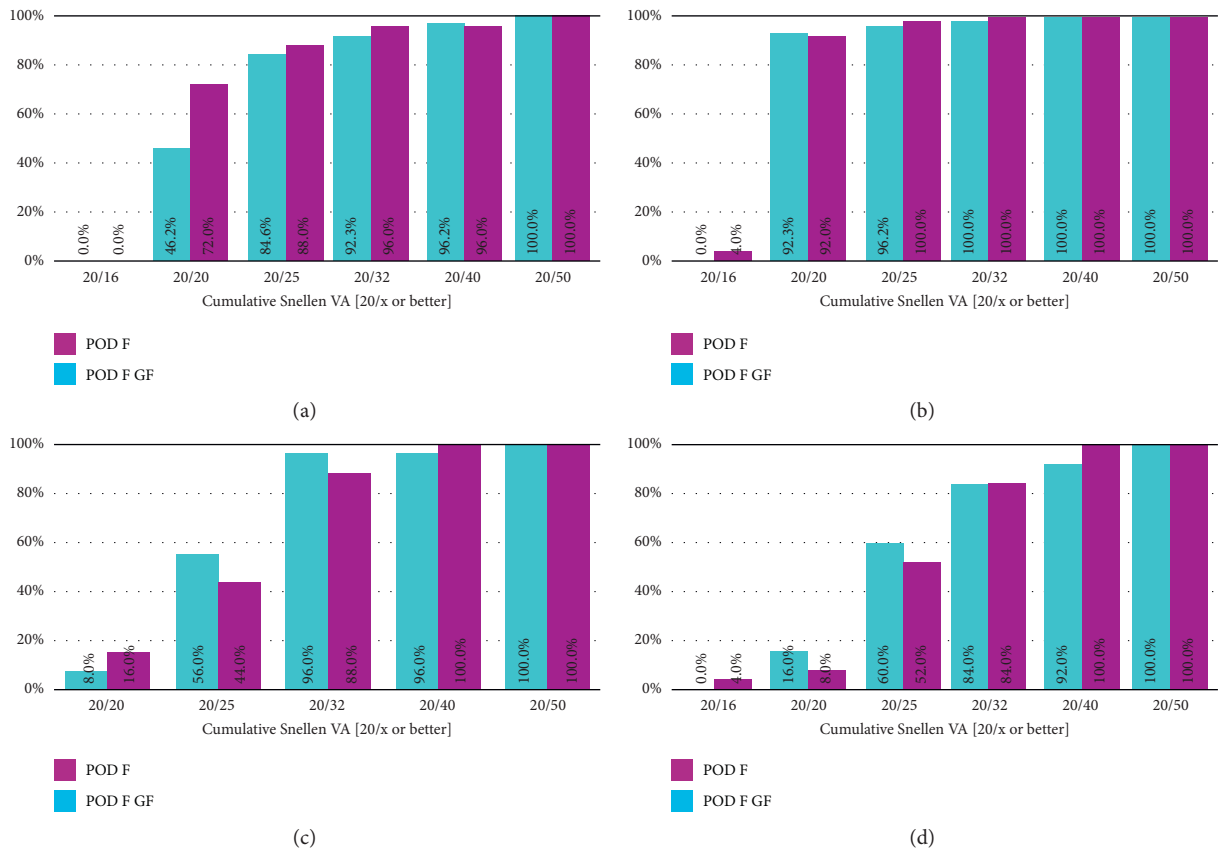

Figure 3: Cumulative distribution of uncorrected distance visual acuity (UDVA) (a), corrected distance visual acuity (CDVA) (b), distance-corrected intermediate visual acuity at 70 cm (DCIVA) (c), and distance-corrected near visual acuity at 35 cm (DCNVA) (d). Monocular visual acuities are shown 1 month postoperatively for eyes implanted with a POD F GF IOL or a POD F IOL.

smaller pupil sizes in the POD F group which may have led to improved performance at close range [21].

The mean total HOA RMS is an important parameter to measure when assessing the optical performance of an IOL; this was also comparable between the groups: 0.29 ± 0.13 μm in the POD F GF group and 0.26 ± 0.12 μm in the POD F group. Whether or not HOAs need to be corrected in cataract surgery is a challenge for which no final answer has

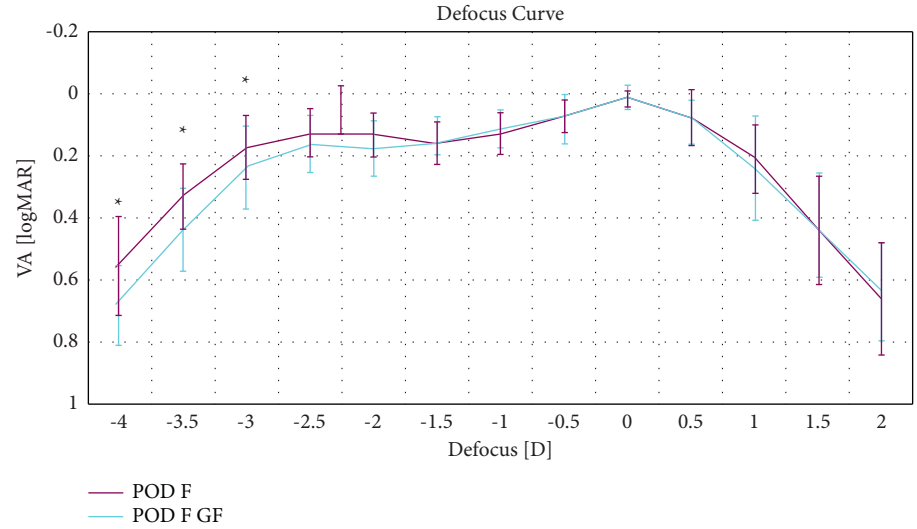

Figure 4: Monocular defocus curves 1 month postoperatively for eyes implanted with a POD F GF IOL or a POD F IOL.

Table 3: Corneal spherical aberration, higher-order aberrations, and IOL tilt at 1 month per group.

	POD F GF	POD F	p value[ǂ]
SA (μm)			
Mean ± SD	0.23 ± 0.19	0.27 ± 0.14	
Median	0.25	0.27	0.451
Min/max	−0.08/0.57	−0.10/0.56	
RMS of total HOA (μm)			
Mean ± SD	0.29 ± 0.13	0.26 ± 0.12	
Median	0.30	0.25	0.300
Min/max	0.08/0.66	0.09/0.54	
RMS of corneal HOA (μm)			
Mean ± SD	0.35 ± 0.31	0.27 ± 0.16	
Median	0.27	0.24	0.451
Min/max	0.09/1.48	0.10/0.87	
RMS of internal HOA (μm)			
Mean ± SD	0.36 ± 0.33	0.27 ± 0.15	
Median	0.29	0.21	0.155
Min/max	0.10/1.56	0.14/0.73	
x-axis tilt (μm)			
Mean ± SD	−0.11 ± 0.29	−0.15 ± 0.29	
Median	−0.12	−0.15	0.806
Min/max	−0.54/0.91	−0.52/0.13	
y-axis tilt (μm)			
Mean ± SD	0.10 ± 0.20	−0.01 ± 0.14	
Median	0.09	−0.01	0.027*
Min/max	−0.35/0.67	−0.34/0.20	
Total tilt (μm)			
Mean ± SD	0.31 ± 0.21	0.24 ± 0.13	
Median	0.25	0.22	0.337
Min/max	0.05/0.98	0.08/0.56	

[ǂ]POD G GF IOL vs. POD F IOL. *Significant at level $\alpha < 0.05$. SA = spherical aberrations; HOA = higher-order aberrations; RMS = root mean square; SD = standard deviation; min = minimum; max = maximum.

yet been found, since the required accuracy of centration of these wavefront-corrected IOLs is an obvious concern. In most cases, they degrade the quality of vision. Otherwise, they may have a beneficial effect. In the case of presbyopia, certain amounts of HOAs (above all SAs) have the potential to increase the depth of field without having a negative impact on visual acuity. If the natural lens is removed during cataract surgery and replaced by an artificial lens, the internal aberrations and accordingly the aberrations of the entire optical system change. Both IOL models used in this

study partly compensate for the positive SA of the cornea by providing a SA of −0.11 μm at a 5 mm pupil. Thus, the IOLs are close to being "aberration-free" IOLs, which also means less sensitivity to decentration and tilt, but does not necessarily lead to any disadvantage in imaging quality compared to the extended depth of focus or bifocal IOLs [22]. No statistically significant differences in SA between the study groups were found.

This study focused on the assessment of monocular visual performance after the implantation of trifocal IOLs. Binocular evaluation was omitted to avoid bias but will be part of a future analysis in connection with a longer follow-up.

In the current study, the POD F and the POD F GF IOLs both demonstrated very good visual results and good refractive predictability, with only small deviations towards hyperopia over a 1-month follow-up period. During this short follow-up period, no disadvantages associated with the hydrophobic GF biomaterial were observed in the POD F GF IOL, compared with the hydrophilic material-containing POD F IOL. All surgeries were uneventful, which is an indication of easy handling and implantation of both IOL models.

5. Conclusion

Based on the clinical and safety data shown in this study, it can be concluded that the implantation of both trifocal lenses within their intended use seems to be a safe and effective option to compensate for presbyopia in the course of cataract surgery. However, future long-term postmarket clinical follow-up studies and postmarket surveillance activities are necessary to confirm these outcomes and to evaluate postoperative spectacle independence and patient satisfaction.

Data Availability

The authors do not intend to share individual patient raw data for reasons of data protection.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this study.

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Research Article

Silicone Oil Adhesion to Hydrophobic Acrylic Intraocular Lenses: A Comparative Laboratory Study of a New versus an Established Hydrophobic Acrylic Intraocular Lens Material

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Background. In vitro assessment of silicone oil adhesion to a new hydrophobic acrylic intraocular lens (IOL) material, the Clareon model CNA0T0, compared with the established AcrySof model SN60WF was carried out. *Methods*. Silicone oil adhesion was assessed for two types of IOLs, Clareon CNA0T0 ($n = 10$) and AcrySof SN60WF ($n = 10$). Lenses were immersed in an aqueous sodium chloride solution for 12 hours and then incubated at room temperature in silicone oil for 12 hours. The lenses were washed with distilled water and photographed at 25x magnification using a microscope. The percent coverage was calculated by dividing the area of oil coverage by the total surface area of the lens. *Results*. Silicone oil adhesion to the surface of the CNA0T0 lens ranged from 4% to 22%, with a mean ± SD coverage of 8% ± 4%. Silicone oil adhesion to the surface of the SN60WF lens ranged from 1% to 17%, with a mean coverage of 9% ± 4%. The silicone oil adhesion of CNA0T0 was equivalent to that of SN60WF ($P > 0.05$). *Conclusions*. The new Clareon model CNA0T0 IOL has silicone oil adhesion and interaction that are equivalent to the established AcrySof IOL.

1. Introduction

Silicone oil is used as an intraocular tamponade in vitreoretinal surgery to reduce fluid flow through retinal tears, preventing recurrent detachment [1, 2]. Patients with IOLs who require vitreoretinal surgery may experience additional postoperative complications from silicone oil tamponades [3]. Silicone oil can adhere to the surface of the IOL, leading to visual disturbances and deterioration of visual quality [4–7]. Removal of silicone oil from certain lens types can be accomplished with mechanical methods; however, these require additional invasive procedures [3].

Oil adhesion is a relatively rare surgical complication, first reported in case studies of explanted silicone IOLs in the 1990s [3, 5, 7]. Subsequent in vitro studies demonstrated that the degree of silicone oil adhesion depended on the biomaterial properties of the IOL, primarily the hydrophobicity of the lens material [3, 8]. Acrylic polymer lenses have been shown to have less silicone oil adhesion than silicone-based models as adhesion is proportional to hydrophobicity and silicone is more hydrophobic than acrylic material [8].

As new IOL materials are developed, in vitro assessment of silicone oil adhesion can evaluate its clinical impact. Interaction of silicone oil with IOL material is a particularly important consideration for pseudophakic patients at risk of retinal tears or proliferative vitreoretinopathy [3, 7].

An innovative hydrophobic acrylic IOL, the Clareon CNA0T0 (Alcon Laboratories, Inc., Fort Worth, TX, USA),

has recently gained CE mark approval. The Clareon CNA0T0 lens is made of a novel hydrophobic acrylic polymer with a water content of 1.5% at 35°C and a refractive index of 1.55. BCNA0T0 has a full 6.0 mm functional biconvex aspheric optic with an overall length of 13.0 mm [9]. The CNA0T0 lens is a single-piece design with STABLEFORCE haptics that is based on the AcrySof SN60WF IOL design and provides predictable mechanical stability [9–11]. This study evaluated the silicone oil adhesion properties of the Clareon CNA0T0 IOL compared with the adhesion properties of the AcrySof SN60WF IOL.

2. Materials and Methods

2.1. Silicone Oil Adhesion Procedure. Intraocular lenses of each model ($n = 10 + 20$ D CNA0T0; $n = 10 + 20$ D SN60WF) were immersed in microcentrifuge vials containing 0.9% aqueous sodium chloride (NaCl) solution (Braun, Melsungen, Germany) at room temperature for 12 hours to simulate aqueous in vivo conditions [3]. The lenses were removed from the sodium chloride solution and then immersed in 5000 centistoke silicone oil [3, 4], Siluron 5000 (Ultrapurified Silicone Oil, Geuder AG, Heidelberg, Germany, Figure 1), for 12 hours at room temperature.

After immersion in silicone oil, the lenses were rinsed and immersed in distilled water to aid visualization of the silicone oil coverage as shown in Figure 2 [3].

2.2. Coverage Calculations. Silicone oil coverage was evaluated by photographing each lens with an INFINITY 1-2CB camera (Lumenera Corporation, Ottawa, ON, Canada) at 25x magnification under an EMZ-8TR Trinocular Zoom Stereo Microscope (Meiji Techno, Saitama, Japan). Quantitative measurements of silicone oil coverage of the IOLs were made using image analysis software (ImageJ, US National Institutes of Health, Bethesda, Maryland, USA, https://imagej.nih.gov). The evaluation procedure is shown in Figure 3.

The percent coverage was calculated by dividing the area covered by oil by the area of the lens. This analysis was performed separately for the anterior and posterior sides of each lens.

2.3. Statistics. One-way ANOVA was conducted to compare the total anterior and posterior silicone adhesion of the CNA0T0 to SN60WF IOL model and to also compare the anterior or posterior of CNA0T0 to that of the corresponding surface of the SN60WF IOL (Minitab 17, State College, PA, USA).

3. Results

3.1. Silicone Oil Adhesion. The CNA0T0 lens silicone oil adhesion ranged from 4% to 22%, with a mean ± SD coverage of 8% ± 4%. Silicone oil adhesion to the surface of the SN60WF lens ranged from 1% to 17%, with a mean ± SD coverage of 9% ± 4%.

The results for each IOL are summarized in Table 1.

Representative digital images depicting the lowest, highest, and mean percent oil coverage for each of the 2 IOLs tested are shown in Figure 4.

The silicone oil adhesion of CNA0T0 was equivalent to that of SN60WF ($P > 0.05$). Additionally, silicone oil adhesion on the anterior surfaces and posterior surfaces of CNA0T0 and SN60WF was equivalent ($P > 0.05$). Most of the silicone oil was removed after 2 minutes of irrigation/aspiration following the postimmersion observations.

4. Discussion

Vitreoretinal surgery is performed to address complex conditions such as retinal tears and detachment, proliferative vitreoretinopathy, and diabetic retinopathy; it is often facilitated by a tamponade agent injected to replace the vitreous fluid [7, 12, 13]. Tamponades help prevent further damage by reducing the flow of fluid through open tears, while the repaired or reattached retina heals [1, 2]. Gas or silicone oil can be used as retinal tamponades; the benefits and disadvantages of these materials have been discussed in a recent review of comparative studies [1]. The major benefit of the gas tamponade is that it spontaneously dissipates, while silicone oil removal requires an additional surgical intervention [1]. Although some studies have shown higher surgical success rates and significantly better visual outcomes with the use of silicone oil compared with a gas tamponade, the choice of tamponade agent ultimately depends on individual factors, such as the classification of retinal detachment [2].

In the 1990s, a rare clinical complication from the use of silicone oil was reported in several case studies [5, 7]. Pseudophakic subjects with implanted silicone IOLs required vitreoretinal surgery with a silicone oil tamponade and subsequently experienced decreased visual acuity and visual aberrations. Surgeons observed silicone oil droplets adhered to the lenses; attempts to remove oil with vitrectomy instruments and aspiration were unsuccessful [5]. Evaluation of the explanted lenses in aqueous solution showed a thick coating of silicone oil that was not removable by mechanical pressure with an injected viscoelastic device [7]. Scanning electron microscopy demonstrated the extent of oil adherence to silicone IOLs. One of the explanted IOLs showed approximately 80% oil coverage of the lens surface [7]. The complications of silicone oil adherence, including visual disturbances in patients and difficulty for the operating surgeon in visualization of the surgical field during vitreoretinal procedures, led to recommendations against implanting silicone IOLs in patients at high risk of vitreoretinal disease [3, 7].

Following the clinical case reports, in vitro studies were performed to assess silicone oil adherence to various IOL materials and to crystalline lenses from human cadaver eyes [4, 14]. Adhesion to human crystalline lenses was not previously reported to cause clinically significant visual problems, and the in vitro study of crystalline lenses showed a mean ± SD adhesion of 11% ± 6% [4]. Oil was easily removed from human lenses by injection of a viscoelastic device. Four IOL biomaterials that showed comparable

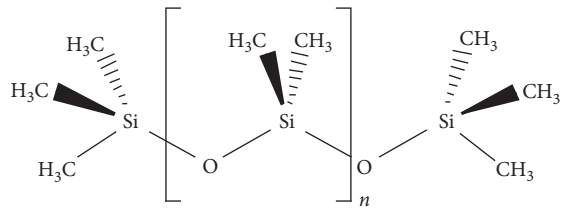


Figure 1: Structure of Siluron 5000.

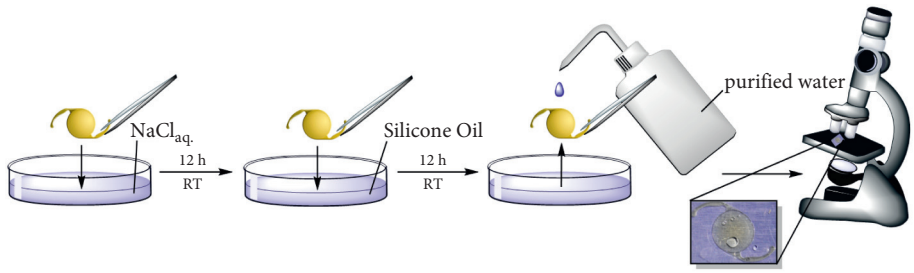


Figure 2: Investigation process of the silicone oil adhesion procedure.

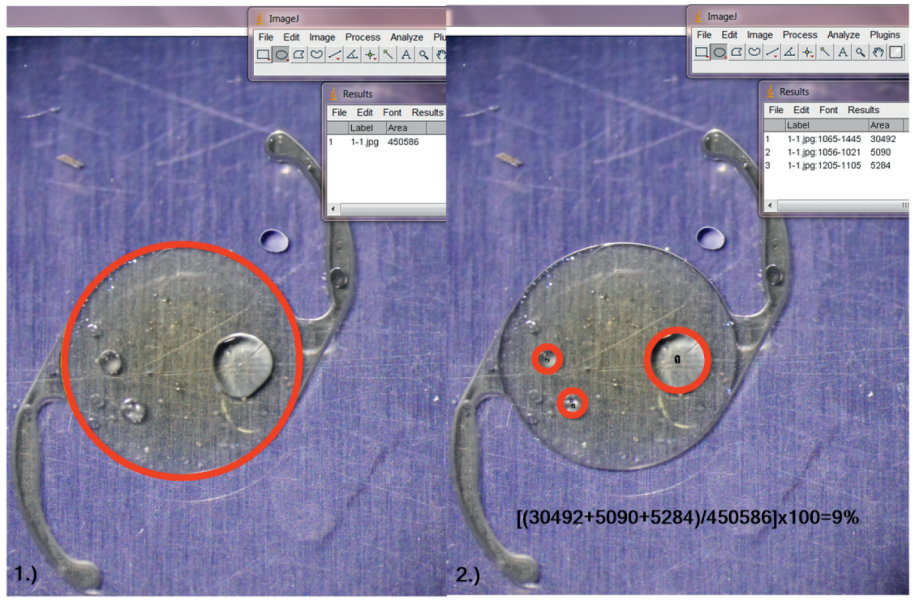
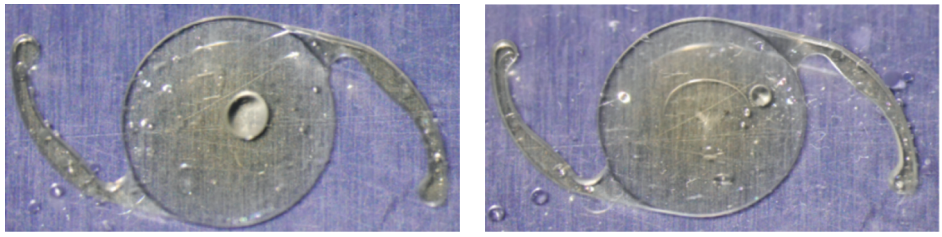


Figure 3: Evaluation with ImageJ for silicone oil adhesion. (a) The whole area of the central optic is given by 450586 pixel^2. (b) The silicone oil adhesion on the IOL is given by (1) 30492 pixel^2; (2) 5090 pixel^2; (3) 5284 pixel^2. The result is the difference between the area wetted with silicone oil and the total area of the optic.

Table 1: Percentage of silicone oil coverage on the intraocular lens (IOL).

IOL no.	AcrySof		Clareon	
	Anterior* (%)	Posterior* (%)	Anterior* (%)	Posterior* (%)
1	10	11	8	7
2	17	11	11	9
3	6	6	22	6
4	5	8	8	5
5	6	6	7	4
6	14	15	4	10
7	6	1	4	7
8	8	17	6	12
9	9	7	11	9
10	10	9	12	4
Mean ± SD†	9 ± 4		8 ± 4	

IOL: intraocular lens. *Results for each surface of a lens; adhesion was measured by looking first at 1 side and turning the lens over to measure the adhesion on the opposing surface. There was no expectation of a difference in adhesion between the 2 sides. †Based on all assessments (10 anterior and 10 posterior).



CNA0T0 Posterior Surface Coverage = 4%

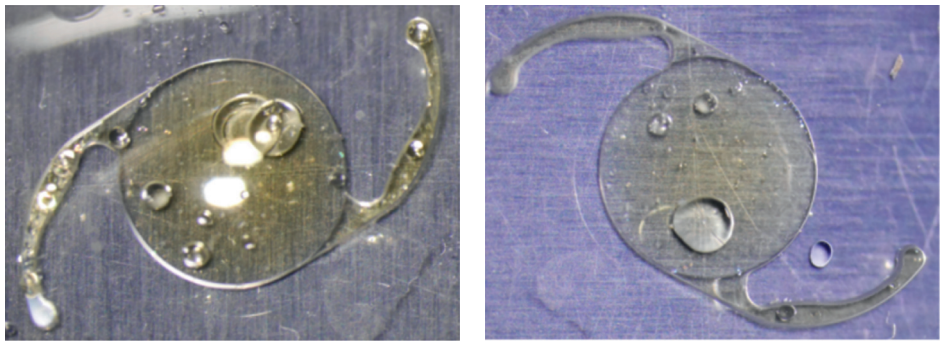
SN60WF Posterior Surface Coverage = 1%

(a)

CNA0T0 Anterior Surface Coverage = 22%

SN60WF Anterior Surface Coverage = 17%

(b)



CNA0T0 Anterior Surface Coverage = 8%

SN60WF Anterior Surface Coverage = 9%

(c)

Figure 4: Digital images of silicone oil coverage on the IOL: (a) lowest coverage, (b) highest coverage, and (c) mean coverage (representative examples). IOL: intraocular lens.

adhesion to human lenses would therefore not be expected to have clinically significant effects on visual acuity [4].

Silicone IOLs stored in oil for long periods of time (≥1 year) exhibited a chemical interaction between the lens polymer and oil, resulting in a continuous layer of oil on the surface of the lens [14]. In a study evaluating silicone oil adhesion to 7 different IOL materials, adhesion ranged from a mean ± SD of 9% ± 7% for heparin-surface-modified IOLs to 100% ± 0% for silicone IOLs [4]. All other lens biomaterials had significantly less adhesion than silicone lenses ($P < 0.001$) [4]. Hydrophilic acrylic IOLs, such as those with heparin surface modification, generally showed less silicone oil adhesion than hydrophobic acrylic IOLs due to the larger contact angle between silicone polymers and hydrophobic materials [3]. However, heparin coatings on IOLs are no longer common. Hydrophobic acrylic lenses (AcrySof) had mean adhesion of 34% ± 14% [4]. In a later study comparing multiple types of acrylic lenses, mean silicone oil adhesion to AcrySof was reported as 17% ± 3% [8].

In the current study, 8% to 9% silicone oil adhesion was observed for both hydrophobic acrylic IOL materials, indicating that the new Clareon CNA0T0 IOL has oil interaction equivalent to that of the AcrySof SN60WF lens. It is interesting to note that the Clareon CNA0T0 and AcrySof SN60WF IOLs had silicone oil adhesion comparable to that reported previously for the human crystalline lens (11%), and therefore may not cause significant visual disruption in patients who require silicone oil tamponades during vitreoretinal surgery [4].

5000 mPas silicone oil (Siluron® 5000 (Ultrapurified Silicone Oil, Geuder AG, Heidelberg, Germany) was used in this study. It is the common silicone oil in our clinic. Other departments may use different oils, and other studies [8] used 1000 mPas silicone oil. Demonstrated by Senn et al. [15], no obvious differences between the viscosities of 1000 mPas and 5000 mPas silicone oils in terms of oil-lens interaction could be observed.

Also of interest is the decrease in reported silicone oil adhesion to AcrySof SN60WF lenses compared with earlier

studies. Since its introduction in the 1990s, there have been improvements to the AcrySof material and lens manufacturing process that have led to a decrease in glistening density [16, 17]. The improvements in manufacturing may have altered the affinity of the AcrySof biomaterial for silicone oil, causing the decreased adhesion observed in this study. This in vitro study demonstrated equivalent silicone oil adhesion to the Clareon CNA0T0 lens compared with the AcrySof SN60WF lens. Clinical studies of the new generation of hydrophobic acrylic lenses may be needed to confirm that silicone oil adhesion and silicone oil opacification may now be regarded as an unlikely complication for cataract patients receiving the new hydrophobic lens.

5. Conclusion

Silicone oil adhesion to the surface of the new Clareon CNA0T0 lens ranged from 4% to 22%, with a mean ± SD coverage of 8% ± 4% (Table 1). Silicone oil adhesion to the surface of the established AcrySof SN60WF lens ranged from 1% to 17%, with a mean coverage of 9% ± 4% (Table 1). The silicone oil adhesion of CNA0T0 was equivalent to that of SN60WF ($P > 0.05$). Additionally, silicone oil adhesion on the anterior surfaces and posterior surfaces of CNA0T0 and SN60WF was equivalent ($P > 0.05$).

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Disclosure

The funding organization had no role in the design or conduct of this research.

Conflicts of Interest

G. Auffarth reports grants, personal fees, nonfinancial support, and consulting fees from Johnson & Johnson and Alcon, grants, personal fees, and nonfinancial support from Carl Zeiss Meditec, Hoya, Kowa, Oculentis/Teleon, Rayner, Santen, Sifi, and URSAPHARM, grants and personal fees from Biotech, Oculus, and EyeYon, and grants from AcuFocus, Anew, Contamac, Glaukos, PhysIOL, and RHEACELL. R. Khoramnia reports grants, personal fees, and nonfinancial support from Alimera, Alcon, Bayer, Johnson & Johnson, Hoya, Novartis, PhysIOL, Rayner, and Roche, grants from Chengdu Kanghong, and personal fees and nonfinancial support from Allergan, Kowa, Oculentis/Teleon, Oculus, Santen, and AcuFocus. S. Schickhardt, H. Fang, Q. Wang, H. Son, and F. Hengerer declare no conflicts of interest.

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Research Article

Long-Term Clinically Significant Posterior Capsular Opacification Development Pattern in Eyes Implanted with an Aspheric Monofocal Intraocular Lens with a Square Optic Edge

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Purpose. To analyse the posterior capsular opacification (PCO) development pattern in the long term in eyes implanted with a monofocal intraocular lens (IOL) with a square edge all around the optic. *Methods*. Longitudinal retrospective study is data analyzed from a total of 7059 eyes from 4764 patients (mean age: 75.8 years) undergoing cataract surgery with implantation of an aspheric monofocal IOL (Bi-Flex HL 677AB/677P, Medicontur, Budapest, Hungary). These data were retrospectively collected using the electronic medical record of the hospitals involved. Nd : YAG capsulotomy rates were calculated per year during a follow-up of more than 10 years. The Kaplan–Meier analysis was used to establish the transparent capsule survival rate. *Results*. The Nd : YAG capsulotomy rate increased from 1.1% at 1 year postoperatively to 17.2% at 5 years after surgery. No significant differences were found between eyes with and without capsulotomy in terms of age ($p = 0.202$), gender ($p = 0.061$), type of anaesthesia used ($p = 0.128$), and presence of conditions such as hard cataract ($p = 0.111$) or pseudoexfoliation ($p = 0.137$). IOL power was significantly lower in those eyes of patients requiring Nd : YAG capsulotomy during the follow-up ($p < 0.001$). Significantly more eyes implanted with the preloaded model of the IOL required capsulotomy ($p < 0.001$). Mean survival time and rate were 9.38 years and 85.9%, respectively. *Conclusions*. Most eyes undergoing cataract with implantation of the Bi-Flex IOL do not develop a clinically significant PCO requiring Nd : YAG capsulotomy in the long term. IOL material and design may be the main factors accounting for this finding.

1. Introduction

Posterior capsular opacification (PCO) is a relatively frequent complication after cataract surgery, which is the result of the proliferation and migration of residual crystalline epithelial cells from the posterior periphery of the capsular bag towards the space between the capsule and the optics of the intraocular lens (IOL) [1]. Its prevention is crucial since it induces a significant decrease in visual acuity and quality deterioration [2]. The material of the IOL is one relevant factor for the development of both anterior and posterior capsular opacification, with a trend to higher rates of PCO when using IOLs made of hydrophilic material instead of hydrophobic material [3–6]. Some experimental data previously reported suggested that that interleukin-6 (IL-6) contributes to the development of PCO by promoting the transformation of the growth factor β_2 (TGF-β_2) activation and extracellular matrix (ECM) synthesis through a JAK/STAT3 signalling-dependent mechanism [7].

Besides material, other factors, such as the design of the IOL, the configuration of the IOL optics, IOL power, and the positioning of the IOL into the capsular bag, have also great relevance [8–14]. A meta-analysis of the studies evaluating the impact of IOL design on PCO concluded that IOLs made

of acrylic material and silicone, as well as those with sharp optic edges, were superior in terms of a minor incidence of PCO. In addition, some studies have confirmed the benefit of a square edge all around the optic to control cell migration [15, 16].

The prevention of PCO is crucial, and its solution is the creation of a hole in the posterior capsule (capsulotomy) using YAG laser. This hole in the posterior capsule promotes the migration of epithelial cells to the periphery and the transparency of the central area of the optic [17]. Despite YAG capsulotomy is a procedure easy to perform, it should be considered that it has some risks [18–20] and economic costs associated [21], being preferrable to delay it as much as possible. It should be considered that relevant complications, such as an accidental macular hole [19], retinal detachment, or cystoid macular oedema [20], have been described after YAG laser capsulotomy. Likewise, Nd : YAG laser can induce evident changes in PMMA IOL morphology and organic alterations in their chemistry that should be considered and controlled [18]. The objective of this study was to evaluate the long-term incidence of PCO requiring YAG capsulotomy in a large hospital population of eyes implanted with a monofocal IOL with a square edge all around the optic.

2. Methods

2.1. Patient Selection and Data Collection. Longitudinal retrospective study enrolled a total of 7059 eyes undergoing cataract surgery with implantation of a specific model of aspheric monofocal IOL (Bi-Flex HL 677AB/677P, Medicontur, Geneva, Switzerland) at the Department of Ophthalmology of the University Hospitals of Torrevieja and Elche-Vinalopó (Alicante, Spain). The primary objective of this retrospective analysis was to evaluate the incidence of PCO requiring YAG capsulotomy with this model of IOL. Clinical data were collected retrospectively using the electronic medical record (Florence) and with the help of the IT Department of the Hospitals of Torrevieja and Vinalopó. Specifically, this Department provided an anonymized database in Excel format of patients who met the study criteria during the period from January 2007 to October 2020. The study was conducted following the tenets of the Declaration of Helsinki and was approved by the ethics committee of the University Hospitals Torrevieja and Elche-Vinalopó (Alicante, Spain) (MEDICONTUR-1, data approval 25/09/2020).

Inclusion criteria were patients undergoing cataract surgery without intraoperative complications, including posterior capsular rupture, vitreous loss, retrobulbar hemorrhage, suprachoroidal effusion/hemorrhage, IOL drop or nucleus drop, and implanted with the monofocal IOL Bi-Flex HL. Exclusion criteria for the study were patients implanted with other different types of monofocal IOL, chronic or recurrent uveitis, diabetes with retinal changes, keratoconus, and endothelial corneal dystrophy.

2.2. Surgical Procedure. The same protocol for phacoemulsification cataract surgery was used in both hospitals involved in the study. The surgical procedure began with disinfection of the operative area using povidone iodine or chlorhexidine. After this, the surgical field was prepared, and the anaesthesia was applied through the topical use of drops or by peribulbar injection of anaesthetic depending on the potential level of collaboration of the patient. Once the surgical field was prepared, a 2.2 mm peripheral corneal incision was made manually with a calibrated knife. A viscoelastic substance was then introduced into the anterior chamber to maintain its volume, allowing the surgeon to manoeuvre with sufficient safety. At this moment, the capsulorhexis was performed using a manual technique followed by cataract partition and aspiration using different extraction techniques by microinfiltrated ultrasound through the phacoemulsifier. Afterwards, the capsule was cleaned of possible remains of cataract adhered by means of a specific irrigation-aspiration device. More viscoelastic product was injected again into the anterior chamber to avoid damaging the capsular bag with the introduction of the IOL. Finally, the aspheric monofocal IOL was introduced into the capsular bag using the MEDJET PIL-MA injector (Medicontur, Budapest, Hungary). The surgery was finished after cleaning the anterior chamber by means of an irrigation-aspiration cannula connected to the phacoemulsifier, eliminating all possible remains, with additional prophylactic intraocular instillation of antibiotics (cefuroxime), except in case of allergy (use of vancomycin instead), and topical ocular instillation of antibiotic and anti-inflammatory drops.

2.3. Intraocular Lens. The Bi-Flex HL IOL (Medicontur, Budapest, Hungary) is a single-piece aspherical lens (25% water content), with a square optic edge at 360°. It is made of a copolymer of hydrophobic and hydrophilic monomers, with 25% water content, and ultraviolet (UV) absorber. The refractive index of the IOL material is 1.46 and the Abbe number is 58. Concerning its design and geometry, this IOL is biconvex, with a total diameter of 13 mm and a diameter of 6 mm in the optic zone. The haptic angle is 0°, with an asymmetric design with posterior vaulting. The IOL is available in optic powers from −10.0 to −1.0 D in 1.0 D steps, from 0.00 to 30.00 D in 0.5 D steps, and from 31 to 35 D in 1.0 D increments. Two different models of this IOL were used in the current study: 677AB model, which is the conventional model, and 677P model, which is its preloaded model.

2.4. Statistical Analysis. Most data analysis was performed with the commercially available software package SPSS Version 22.0 (IBM Corporation, Armonk, NY, USA). The normality of data distributions was confirmed using the Kolmogorov–Smirnov test. Mean, standard deviation, and range were used to characterize the distribution of each variable evaluated in the sample. The Student *t*-test for unpaired data was used to compare quantitative variables among the groups of eyes requiring Nd : YAG capsulotomy during the follow-up and those not requiring it. The comparison of percentages for binary data (male/female, 677AB/

677P, or peribulbar/topic) between groups was performed using the chi-square test. The Kaplan–Meier analysis was used to establish the transparent capsule survival time after cataract surgery and YAG capsulotomy-free interval. Statistical significance was determined using the log-rank test. This analysis was performed with the MedCalc software version 19.8 (MedCalc Software Ltd, Ostend, Belgium). All statistical tests were 2 tailed, and p values below 0.05 were considered statistically significant.

3. Results

This retrospective analysis included data from 7059 eyes from 4764 patients ranging in age from 33 to 100 years old (mean: 75.8; standard deviation, SD: 8.7 years). The distribution of the sample in terms of gender was as follows: 2413 males (50.7%) and 2351 females (49.3%). A total of 3409 (48.3%) and 3650 (51.7%) right and left eyes were included, respectively. Concerning the IOL model, a total of 2139 eyes (30.3%) and 4920 eyes (69.7%) were implanted with the 677AB and 677P models, respectively. The IOL power implanted ranged from −6.0 to 36.0 D (mean: 20.8 D; SD: 3.6 D), with a mean target postoperative refraction of −0.14 D (SD: 0.20; range: −2.00 to 0.50 D). Peribulbar anaesthesia was used in 3776 eyes (53.5%), whereas topic anaesthesia was used in the rest of the sample (3283 eyes, 46.5%). Mean follow-up for the patients included in the study was 4.5 years (SD: 1.3), ranging from 0.1 to 10.5 years.

3.1. YAG Capsulotomy Rate. Nd : YAG capsulotomy was performed in a total of 956 eyes (13.5%) of the sample retrospectively analysed. Figure 1 shows changes in Nd : YAG capsulotomy rate during the follow-up. The YAG capsulotomy rate increased from a value of 1.1% at 1 year after the implantation of the IOL to 17.2% at 5 years postoperatively. No significant differences were found between eyes requiring Nd : YAG capsulotomy or not in terms of age ($p = 0.202$), gender distribution ($p = 0.061$), type of anaesthesia used ($p = 0.128$), presence of hard cataract ($p = 0.111$), pseudoexfoliation ($p = 0.137$) or intraoperative floppy iris syndrome (IFIS) ($p = 0.382$), and combined surgery of implantation of an iStent ($p = 0.352$) or pars plana vitrectomy (PPV) ($p = 0.398$) (Table 1). In contrast, patients requiring Nd : YAG capsulotomy were implanted with an IOL of significantly lower power ($p < 0.001$). Furthermore, significantly more eyes implanted with the 677P IOL model required Nd : YAG capsulotomy ($p < 0.001$) (Table 1).

3.2. Survival Analysis. The Kaplan–Meier plot illustrating the transparent posterior capsule survival profile is shown in Figure 2. Most of Nd : YAG capsulotomies were performed from the first to the fourth year of follow-up after IOL implantation (843 eyes). The mean survival time was 9.38 years (standard error, 0.036; 95% confidence interval, 9.31–9.45) and the mean survival rate was 85.9% (standard error, 0.0043). As most of the patients enrolled in the study had a follow-up of 7 years or below (Figure 3), the Kaplan–Meier analysis was only repeated considering a follow-up of 7 years as maximum (Figure 4), obtaining a mean survival time of 6.22 years (standard error, 0.020; 95% confidence interval, 6.19–6.26) and a mean survival rate of 85.9% (standard error, 0.0043).

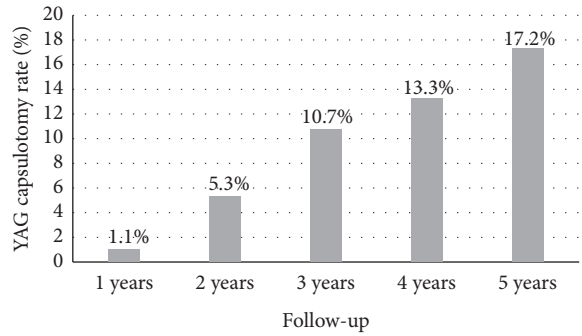

Figure 1: Changes in YAG capsulotomy rate during the follow-up in the sample of eyes evaluated.

4. Discussion

In the current retrospective analysis, an analysis of the percentage of eyes needing Nd : YAG capsulotomy was performed in a large sample of eyes (7059 eyes) undergoing cataract surgery in a public hospital with implantation of a monofocal IOL with square optic edge at 360°. This IOL is made of a material combining hydrophobic and hydrophilic monomers. As in other retrospective studies analysing large populations [8], Nd : YAG capsulotomies were used as an estimate of clinically significant PCO. Indeed, different studies have shown similar percentage of eyes with clinically significant PCO and laser capsulotomy, with only a slight trend to obtain lower values for the Nd : YAG capsulotomy rate. Maxwell and Suryakumar [22] reported, for a hydrophobic IOL, rates of clinically significant PCO and laser capsulotomy at 3 years after surgery of 2.2% and 1.4%, respectively [4, 21, 23]. In our sample, the YAG capsulotomy rate increased from a value of 1.1% during the first year after the implantation of the IOL to 17.2% at 5 years after surgery. It should be considered that the percentage of clinically significant PCO might be slightly superior according to what was previously mentioned.

The Nd : YAG rate found in the current study was lower than that reported for different hydrophilic IOLs [3–6, 24]. Vasavada et al. [6] found Nd : YAG capsulotomy rates at 3 years after surgery of 12.9% and 16% for two different types of hydrophilic IOLs. Auffarth et al. [24] reported in a multicenter study a 3-year laser capsulotomy rate of 31.1% for a specific model of hydrophilic acrylic IOL. Furthermore, the laser capsulotomy rates of the sample evaluated were similar to those reported for some models of hydrophobic IOLs [5, 8, 25] but higher than those reported for some other models of hydrophobic acrylic IOLs [6, 10, 21, 24, 26, 27]. Hecht et al. [8] found in a large population study (14,264 cases) a Nd : YAG capsulotomy rate for a square edge hydrophobic IOL increasing from 1.1% at 1 year after surgery to 10.2% at 4 years postoperatively. Ling et al. [25] reported

Table 1: Differences between eyes requiring YAG capsulotomy and those not needing it in different preoperative and intraoperative variables.

Mean (SD) Range	No YAG capsulotomy (6102 eyes/3914 patients)	YAG capsulotomy (956 eyes/849 patients)	p value
Age (years)	75.9 (8.7) 33.0 to 100.0	75.5 (9.0) 38.0 to 98.0	0.202
IOL power (D)	20.86 (3.48) −6.00 to 36.00	20.40 (4.51) −5.00 to 36.00	<0.001
Gender (male/female) % male	1962/1952 50.1%	451/398 53.1%	0.061
Anaesthesia (peribulbar/topic) % peribulbar	3246/2854 53.2%	530/429 55.3%	0.128
Simultaneous implantation iStent (yes/no) % yes	132/5971 2.1%	23/933 2.4%	0.352
Presence of hard cataract (yes/no) % yes	357/5746 5.8%	46/910 4.8%	0.111
Presence of pseudoexfoliation (yes/no) % yes	57/6046 0.9%	5/951 0.5%	0.137
Simultaneous PPV (yes/no) % yes	61/6040 1.0%	8/950 0.8%	0.398
Presence of IFIS (yes/no) % yes	67/6036 1.1%	12/944 1.3%	0.382
IOL model (677AB/677P) % 677AB	1976/3985 33.1%	163/935 14.8%	<0.001

SD, standard deviation; IOL, intraocular lens; PPV, pars plana vitrectomy; IFIS, intraoperative floppy iris syndrome.

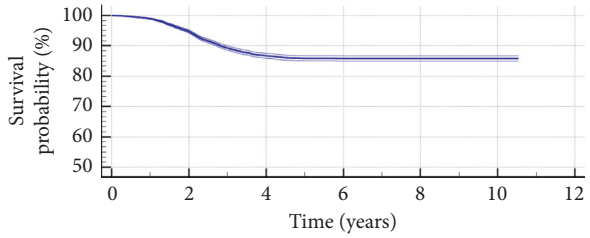

Figure 2: Kaplan–Meier survival curve with its confidence interval concerning transparent posterior capsule survival after cataract surgery (log-rank test: $p < 0.01$) for the sample of eyes evaluated. Mean survival time was 9.38 years for the complete follow-up, and mean survival rate was 85.9%.

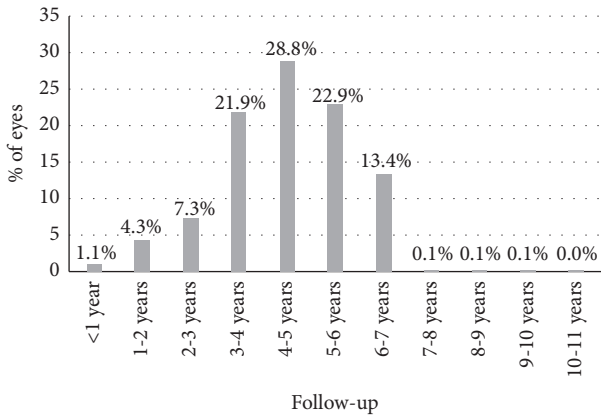

Figure 3: Distribution of the follow-up of cases enrolled in the current retrospective analysis.

for another type of hydrophobic IOL a Nd : YAG capsulotomy rate increasing from 4.5% at 1 year after surgery to 12% at 3 years. However, the IOL material is not the only factor contributing to the development of PCO with a specific type of IOL. The optic edge design has been demonstrated to be a crucial factor defining the PCO development pattern [9, 10, 12, 27]. The IOL evaluated in the current series has a square optic edge at 360° that has been shown to be a continuous posterior enhanced barrier reducing the PCO rate [9].

The most significant increase in the Nd : YAG rate in our sample was found to occur during the first four years of follow-up, with a limited increase afterwards. It should be considered that the number of cases completing a follow-up of more than 7 years was reduced. This trend was consistent with the findings of other studies showing similar PCO progression rates [8, 25, 28]. Hecht and coauthors [8] showed for a specific model of hydrophobic IOL that the PCO rate increased from 1.1% at 1 year after surgery to 7.1% and 10.2% at 3 and 4 years, respectively. Praveen et al. [28] reported a significant increase of PCO rate for a hydrophobic acrylic IOL during the first 3 years after surgery, with a more limited increase afterwards.

A significant difference in IOL power was found between eyes with and without laser capsulotomy during the follow-up. Specifically, eyes requiring YAG capsulotomy were implanted with an IOL of significant lens power. In another large population study [8], significantly less PCO rates were found in eyes implanted with a hydrophobic IOL with a power of 20 D or below. Indeed, these authors identified by means of logistic regression that there was an increased risk for PCO formation with lower diopter IOLs [8]. This can be related to the anatomical dimensions of the eyes that

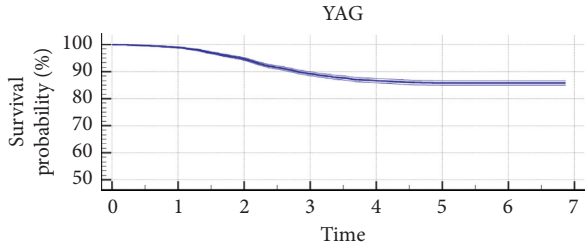

Figure 4: Kaplan–Meier survival curve with its confidence interval concerning transparent posterior capsule survival after cataract surgery (log-rank test: $p < 0.01$) for the sample of eyes evaluated with a follow-up of 7 years or below. Mean survival time was 6.22 years for a 7-year follow-up, and mean survival rate was 85.9%.

normally need a low-power IOL which are those with long axial lengths. It should be considered that axial length has been shown to be a valuable clue to expected size of capsular bag [29], being positively correlated with capsule shrinkage [30] and capsular bag diameter [31]. Possibly, the optic edge has a more limited barrier effect in long eyes due to less stability and level of adhesion to a larger capsule with more level of shrinkage. Wang et al. [32] demonstrated that 360° anterior capsule polishing in high myopes can effectively reduce the extent of the anterior capsule contraction and increase the stability of the IOL implanted.

In the sample evaluated, no significant differences were found in age and gender between eyes requiring or not Nd:YAG capsulotomy. In addition, the type of anaesthesia used and the presence of IFIS or hard cataract were not differential factors among eyes with and without capsulotomy. Likewise, pseudoexfoliation was not related to the requirement of Nd:YAG capsulotomy in medium and long term in eyes implanted with the IOL evaluated. Østern et al. [33] also found that the development of long-term posterior capsular opacification was not increased in patients with pseudoexfoliation syndrome after uncomplicated cataract surgery. No association was found between the performance of capsulotomy in the medium and long terms and the simultaneous implantation of an iStent for the management of glaucoma or the combination with pars plana vitrectomy (PPV). Previous studies have shown that no increased PCO rate was present in eyes undergoing a combined procedure of PPV and cataract surgery, with rates even lower than those associated to eyes undergoing sequential surgeries [34]. Finally, more eyes implanted with the preloaded model of the IOL evaluated in the current sample required Nd:YAG capsulotomy to treat a clinically significant PCO. It should be considered that events such as trapped trailing haptic, problems of haptic-optic adhesion, overriding of the plunger over the optic, and trauma to optic edge have been described when using preloaded IOL implantation systems [35]. Possibly, these potential events as well as the mode of releasing the lens into the capsular bag are related to a less adjusted position of the IOL into the capsular bag. More studies are needed to corroborate if less optic edge-capsule adhesion is present in eyes implanted with the preloaded version of the IOL evaluated.

Finally, a Kaplan–Meier analysis was performed to estimate the transparent posterior capsule survival rate for the eyes implanted with the monofocal IOL evaluated. Mean survival time and rate for the whole follow-up were 9.38 years and 85.9%, respectively. Chang and Kugelberg [36] found in a comparative study that the median survival time exceeded 9 years for a hydrophobic IOL and was 2.6 years for a specific type of hydrophilic IOL. As most of the patients from the current sample had a follow-up of 7 years or less, this survival analysis was repeated considering a period of 7-year follow-up. A mean survival time of 6.22 years was obtained with this new analysis. Likewise, the survival rate was 85.9%, which was the same rate obtained considering the whole follow-up.

This study has limitations that should be acknowledged. The most important limitation is the retrospective nature of the study, limiting the type of variables that could be analysed (only those reported in the clinical histories were evaluated). Likewise, a comparative study with other types of IOLs would have been adequate to know exactly the superiority or not of the IOL evaluated in terms of PCO formation in comparison with other IOLs.

In conclusion, most of eyes undergoing cataract with implantation of the monofocal IOL evaluated in the current sample do not develop a clinically significant PCO requiring Nd:YAG capsulotomy, with a mean transparent capsule survival rate of 85.9%. The capsulotomy rate of this IOL increases over time during the four first years after surgery, with a minimal increase in the long term and a PCO rate maintained below 20%. Eyes implanted with low IOL powers using the preloaded design seem to be more predisposed to develop PCO for the specific IOL type evaluated in the current series. Future prospective comparative studies should be conducted corroborating these findings as well as comparing them with those obtained with other types of IOLs.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Disclosure

The authors have no proprietary or commercial interest in the medical devices that are involved in this study.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Research Article

Clinical Outcomes of Combined Implantation of an Extended Depth of Focus IOL and a Trifocal IOL in a Korean Population

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Purpose. To evaluate monocular and binocular visual performance and patient-reported outcomes following combined implantation of a diffractive extended depth of focus (EDoF) IOL (Carl Zeiss AT LARA 829MP) and a diffractive trifocal IOL (Carl Zeiss AT LISA tri 839MP). *Methods*. This prospective study enrolled consecutive patients undergoing lens phacoemulsification of cataract and combined implantation of an EDoF IOL in the dominant eye and a trifocal IOL in the nondominant eye. Assessment included uncorrected visual acuity at near distances (UNVA), intermediate distances (UIVA), and far distances (UDVA), uncorrected defocus curve, contrast sensitivity (CS), reading speed, and patient satisfaction, evaluated six months after the surgery with the Visual Function Questionnaire (VFQ-25). *Results*. A total of 25 patients were enrolled. At six months postoperatively, outcomes of binocular UNVA, UIVA, and UDVA were superior to those of monocular outcomes. The binocular defocus curve showed significantly better results in comparison with the AT LISA tri IOL eyes at defocus levels of −1.0 D and −1.5 D ($P = 0.008$ and $P = 0.002$, respectively) and compared to the AT LARA IOL eyes at defocus levels of −3.0, −3.5 D, and −4.0 D ($P = 0.019$, $P = 0.019$, and $P = 0.035$, respectively). All of the patients were spectacle-free at far and intermediate distances, while 4% of patients needed spectacles at the near distance. Reading speed showed a rather high and gentle slope curve between 0.1 logMAR and 0.4 logMAR, and optical phenomena were improved after combined implantation of IOLs except halos. There were no significant differences in CS between the binocular and monocular results of each IOL. *Conclusions*. The combined implantation of an EDoF IOL and a trifocal IOL seems to be a good option for patients with demands for spectacle independence in their daily life, with minimal photic phenomena.

1. Introduction

With the advancements in intraocular lenses (IOL) and cataract surgery techniques, it has become increasingly important to minimize visual side effects while improving visual acuity. Traditional cataract surgery with monofocal IOLs can provide excellent uncorrected distance visual acuity outcomes, while spectacle correction is needed for tasks at near and intermediate distances. However, the increasing use of laptops, tablets, and smart phones has made intermediate and near-distance vision important for most patients' daily lives. In recent years, several types of presbyopia-correcting IOLs have been designed, among which trifocal IOLs and extended depth of focus (EDoF) are two mainstream options [1–4]. There are many studies which compare the clinical performance of these presbyopia-correcting IOLs. Trifocal IOLs have almost completely substituted bifocal IOLs because the addition of a third focus can provide better uncorrected visual acuity results at intermediate distances [1, 3, 5, 6]. However, it has been reported that such IOLs may reduce contrast sensitivity and increase visual side effects such as glare and halos because

the incoming light energy is split and directed to multiple focal points. For these reasons, in patients with corneal pathologies or other ocular abnormalities, trifocal IOL implantation would lead to dissatisfied patients after surgery, so monofocal IOL implantation may be better in these cases [7, 8]. EDoF IOLs, on the other hand, have been designed to elongate the focal point in order to provide continuous vision from far to near distances without compromising qualitative and quantitative vision [9]. However, worse results for near visual acuity may be achieved in comparison with bifocal or trifocal IOLs [10–12]. A combination of presbyopia-correcting IOLs with different designs is one of the ways to compensate for these limitations and to further enhance results at intermediate and near distances [13–15]. Such a combination in a blended approach has become a topic of interest. This mix-and-match approach has previously been shown to increase visual acuity results while decreasing unwanted photic phenomena [16].

The purpose of this study was to evaluate the monocular and binocular visual performance, contrast sensitivity, reading speed, and patient satisfaction in patients with combined implantation of an EDOF IOL in the dominant eye and a trifocal IOL in the nondominant eye.

2. Patients and Methods

This prospective study included patients with age-related cataract who underwent bilateral cataract extraction with phacoemulsification and blended IOL implantation of a diffractive EDoF IOL (AT LARA 829MP, Carl Zeiss, Germany) and a diffractive trifocal IOL (AT LISA tri 839MP, Carl Zeiss, Germany). The study comprised 50 eyes of 25 patients with blended implantation of an AT LARA 829MP in the dominant eye and an AT LISA tri 839MP in the nondominant eye. Table 1 provides the preoperative patient characteristics. All patients were 21 years or older at the time of enrollment and underwent surgery of the second eye within seven days after surgery of the first eye. The exclusion criteria were the same as previous studies [17]. This study was approved by the Institutional Review Board of Kangbuk Samsung Hospital (IRB File No. 2019-12-039–002), and the tenets of the Declaration of Helsinki were followed. All participants gave their informed consent before enrollment.

2.1. Preoperative Assessment. Before surgery, all patients received a complete ophthalmological examination, including uncorrected and corrected visual acuities at far distance (UDVA, CDVA), uncorrected visual acuity at intermediate (UIVA at 66 cm) and near (UNVA at 40 cm) distances, refractive status, mesopic (3 cd/m^2) pupillometry, topography (Galilei G6; Ziemer Ophthalmic Systems AG, Port, Switzerland), corneal aberration (KR-1W wavefront analyzer, Topcon Europe Medical B. V., Netherlands), optical biometry and keratometry (IOL-Master 700, Carl Zeiss Meditec, Oberkochen, Germany), slit lamp examination, and fundoscopy.

Table 1: Preoperative characteristics of patients.

	LARA	LISA tri	*P* value
Age (years)		66.6 ± 6.38	
Gender			
Male		5	
Female		20	
Pupil size (mm)	3.77 ± 1.13	3.65 ± 1.07	0.617
Refraction			
Sph (D)	1.09 ± 1.79	1.19 ± 1.70	0.803
Cyl (D)	−0.83 ± 0.67	−0.83 ± 0.53	0.939
SE (D)	0.68 ± 1.71	0.78 ± 1.72	0.811

Data are expressed as mean ± standard deviation or number. Sph, sphere; Cyl, cylinder; D, diopter; SE, spherical equivalent.

2.2. Surgical Technique. One surgeon (CYC) performed the surgeries using topical anesthesia. Phacoemulsification with a 2.2 mm temporal corneal incision and manual capsulorhexis was performed in all cases. All IOLs were implanted in the bag. Postoperative refraction was targeted at the minus value closest to zero using the Barrett True-K formula and Haigis formula for IOL power calculation.

2.3. Postoperative Assessment. Follow-up examinations were performed 1 week, 1 month, 3 months, and 6 months after implantation of the second IOL. Main outcome measures included visual performance, monocular and binocular defocus curves, contrast sensitivity (CS), reading speed, and a patient questionnaire. UDVA, UIVA at 66 cm, and UNVA at 40 cm were measured using the Early Treatment Diabetic Retinopathy Study charts (ETDRS; Vector Vision, Ltd., Greenville, OH, USA). Uncorrected monocular and binocular defocus curves were obtained for distance vision with the ETDRS charts at intervals of 0.50 spherical diopters from −4.00 to +1.00 D. CS was measured at 3.0, 6.0, 12.0, and 18.0 cycles per degree (cpd) under photopic (85 cd/m^2) and mesopic (3cd/m^2) conditions with and without glare with the CSV-1000 (Vector vision, Inc., Greenville, OH, USA). Patients' subjective satisfaction (quality of vision (QoV) and vision-related quality of life (QoL)) and spectacle independence were assessed with the 25-item National Eye Institute Functional Questionnaire (NEI VFQ-25). Binocular reading speed at 40 cm was measured 6 months postoperatively as described by the Korean Reading Speed Application tester introduced by Kim et al. [18] and using the application of Song et al. [19]. Letter sizes from 0.0 logMAR to 1.0 logMAR were displayed in steps of 0.1 logMAR. Patients were asked to read sentences of different sizes one after the other. Reading speed (words per minute) was automatically calculated by the system. All preoperative and postoperative evaluations were conducted similarly to previous studies [17].

2.4. Statistical Analysis. Data analysis was conducted using SPSS (Version 24.0, SPSS Inc., Chicago, IL, USA). Intragroup and intergroup comparisons of monocular and binocular visual outcomes were performed using the Wilcoxon signed-rank test and chi-square test. The

Mann–Whitney test was used to compare quantitative variables (such as refraction) and reading speed. Spearman's rank correlation and Pearson's correlation were used to investigate correlations of photopsia. The Student's *t*-test for independent samples was used to compare overall satisfaction and spectacle independence. For the adjustment of *P* values, the Bonferroni correction was used. Data were expressed as means and standard deviations. For all analyses, the level of significance was a *P* value of less than 0.05.

3. Results

The mean postoperative UDVA, UIVA, UNVA, CDVA, and refraction are given in Table 2. There were no statistically significant differences between lenses in postoperative uncorrected visual acuity at all distances or in CDVA ($P > 0.05$). The eyes with the AT LARA 829MP achieved a better monocular UIVA compared to the eyes with the AT LISA tri 839MP ($P = 0.09$), while the eyes with the AT LISA tri showed a better monocular UNVA compared to the eyes with the AT LARA ($P = 0.59$). Although not statistically significant, binocular visual acuities at all distances were better in patients with combined IOL implantation in comparison with monocular visual acuity results achieved with each IOL. A binocular UDVA and UIVA of 0.1 logMAR or better was achieved by 100% of patients with a combined implantation of AT LARA and AT LISA tri. In addition, 100% of patients showed a binocular UIVA 0.2 logMAR or better. Although the spherical equivalent was significantly skewed toward myopic values in the eyes with AT LARA 829MP IOLs compared to the eyes with AT LISA tri 839MP IOLs ($P < 0.05$), the eyes with the AT LISA tri 839MP IOLs showed better visual acuity results in the defocus curve from −3 D to −4 D. Figure 1 shows the mean monocular and binocular defocus curves. Regarding distance vision (at a vergence of 0.0 D), monocular visual acuity results with both IOLs were similar to the binocular visual acuity outcomes ($P = 0.485$, the eyes with the AT LARA; $P = 0.154$, the eyes with the AT LISA tri). At an intermediate distance, the binocular defocus curve showed significantly better visual acuity outcomes than the monocular defocus curve in AT LISA tri 839MP IOL-implanted eyes ($P < 0.05$ at −1.5 D and −2.0 D, respectively), and binocular visual acuity results in the near distance were significantly better than monocular outcomes in the eyes implanted with the AT LARA 829MP IOL ($P < 0.05$ at −3 D, −3.5 D, and −4 D, respectively). Overall, the combined implantation of the AT LARA IOL and the AT LISA tri IOL demonstrated better visual acuity results at all distances compared to the monocular results of both IOLs implanted.

Figure 2 demonstrates the results of postoperative monocular and binocular CS measurements obtained under mesopic conditions with and without glare and photopic conditions. There were no statistically significant differences for any spatial frequency and light conditions between the two IOLs or between the monocular and binocular outcomes. Figure 3 shows the binocular reading speed at 40 cm. It shows a rather high and gentle slope curve with a smooth decrease from 0.1 logMAR to 0.4 logMAR, but for smaller letters, the decreasing slope of the reading speed is more pronounced.

The postoperative results of the VFQ-25 are shown in Figure 4. Compared to preoperative values, all participants responded with improved outcomes in almost all categories except for ocular pain. Patient-reported postoperative visual phenomena are presented in Figure 5. A noticeable increase in postoperative perception of halos was noted. The proportion of patients bothered by halos rose from 8% before surgery to 29.2% after surgery. A postoperative improvement regarding all the other questions on visual phenomena was noticed. The results of the questionnaire evaluating spectacle independence in daily life are presented in Figure 6. All patients could experience clear vision at the far and intermediate distances, while only 4% of patients needed spectacles at the near distance.

4. Discussion

In this study, we implanted the AT LARA 829M in the patients' dominant eye and the AT LISA tri 839MP in the nondominant eye. Visual outcomes of patients with combined IOL implantation demonstrated improved visual acuities at far, intermediate, and even near distances with minimal photic phenomena except for halos.

With the proven benefit of EDoF IOLs with regard to refractive tolerance, improved visual acuity from distance to near is provided, while undesirable visual phenomena are reduced [4, 20]. Although visual acuity at all distances has been improved compared to monofocal IOLs, it has already been shown that bilateral implantation of EDoF IOLs provides inferior visual acuity results at the near distance compared to the results achieved with other types of presbyopia-correcting IOLs [11, 21, 22]. Recently, the blended implantation strategy has been attempted to take advantage of the merits of both IOL types, and good results have been reported [13, 23, 24]. In a previous study, we compared the visual performance of patients with mix-and-match implantation of an EDoF IOL in the dominant eye and a bifocal IOL in the nondominant eye with trifocal IOL implantation in both the eyes [17]. According to this study, patients with the mix-and-match implantation showed better visual acuity results from the far to intermediate distance, while patients with the trifocal IOL achieved better visual acuity results at the near distance. Other studies confirmed the advantages of trifocal IOLs [25]. De Carneros-Llorente et al. reported that trifocal IOLs provide better results at the intermediate distance in comparison with bifocal IOLs without compromising near or distance visual acuity [26]. Since trifocal IOLs can provide a wide range of vision including intermediate distance vision due to the additional focal point, we attempted to perform a combination approach. It was speculated that trifocal IOLs might compensate for the worse visual acuity results of EDoF IOLs at near distances. According to the visual outcomes reported in this study, this assumption turned out to be correct.

In this study, the uncorrected defocus curve was measured to assess the results in real-life conditions. However, a corrected defocus curve rather shows the inherent

Table 2: Monocular and binocular visual outcomes 6 months postoperatively.

	LARA	LISA tri	L&L	*P* value		
				LARA vs. LISA tri	LARA vs. L&L	LISA tri vs. L&L
VA						
UDVA	0.04 ± 0.06	0.04 ± 0.09	0.02 ± 0.05	0.85	0.18	0.23
UIVA	0.04 ± 0.07	0.07 ± 0.10	0.03 ± 0.05	0.09	0.48	0.05
UNVA	0.11 ± 0.12	0.09 ± 0.09	0.07 ± 0.08	0.59	0.17	0.33
CDVA	−0.01 ± 0.06	0.00 ± 0.10	−0.02 ± 0.07	0.74	0.51	0.41
Refraction						
Sph (D)	−0.47 ± 0.44	0.00 ± 0.42		<0.001		
Cyl (D)	−0.63 ± 0.52	−0.81 ± 0.52		0.21		
SE (D)	−0.79 ± 0.36	−0.41 ± 0.29		<0.001		

Data are expressed as mean ± standard deviation (range). VA, visual acuity; UDVA, uncorrected distance visual acuity (logMAR); UIVA, uncorrected intermediate visual acuity (logMAR); UNVA, uncorrected near visual acuity (logMAR); CDVA, corrected distance visual acuity; Sph, sphere; Cyl, cylinder; D, diopter; SE, spherical equivalent.

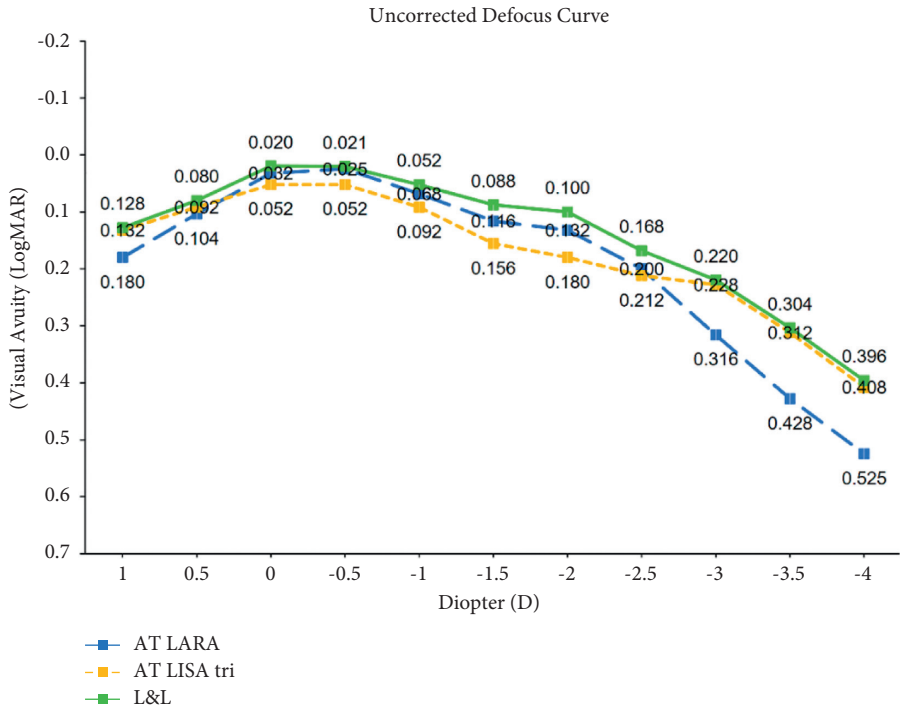

Figure 1: Mean monocular and binocular defocus curves of the eyes implanted with the AT LARA 829MP IOL in the dominant eye and the AT LISA tri 839MP IOL in the nondominant eye.

characteristics of each IOL. Defocus curves allow ophthalmologists to measure the expected range of vision and understand the visual performance of IOLs in order to counsel their patients correctly. The binocular defocus curve of patients with combined IOL implantation represented a slightly wider curve with a higher plateau from the far to near distance than the monocular defocus curve of each IOL. The binocular defocus curve showed significantly better visual acuity results compared to the AT LISA tri IOL eyes at defocus levels of −1.0 D and −1.5 D ($P = 0.008$ and $P = 0.002$, respectively) and the AT LARA IOL eyes at defocus levels of −3.0, −3.5 D, and −4.0 D ($P = 0.019$, $P = 0.019$, and $P = 0.035$, respectively). Richard et al. showed a similar defocus curve in patients with combined IOL implantation and also presented better visual acuity results at defocus levels of −1.0 D in patients with bilateral EDoF IOL implantation [27]. However, there were only 5 patients with bilateral EDoF IOLs, and no other information is available. For accurate assessment and a direct comparison, a similar number of patients with bilateral implantation of EDoF IOLs and trifocal IOLs would be required.

Patients in this study successfully achieved a visual improvement after cataract surgery at all distances. Spectacle independence at far and intermediate distances was achieved in all patients, while the rate of spectacle independence was just slightly lower at the near distance (96%). Although there was a small number of patients who still needed spectacles for working in the near distance, a very high degree of

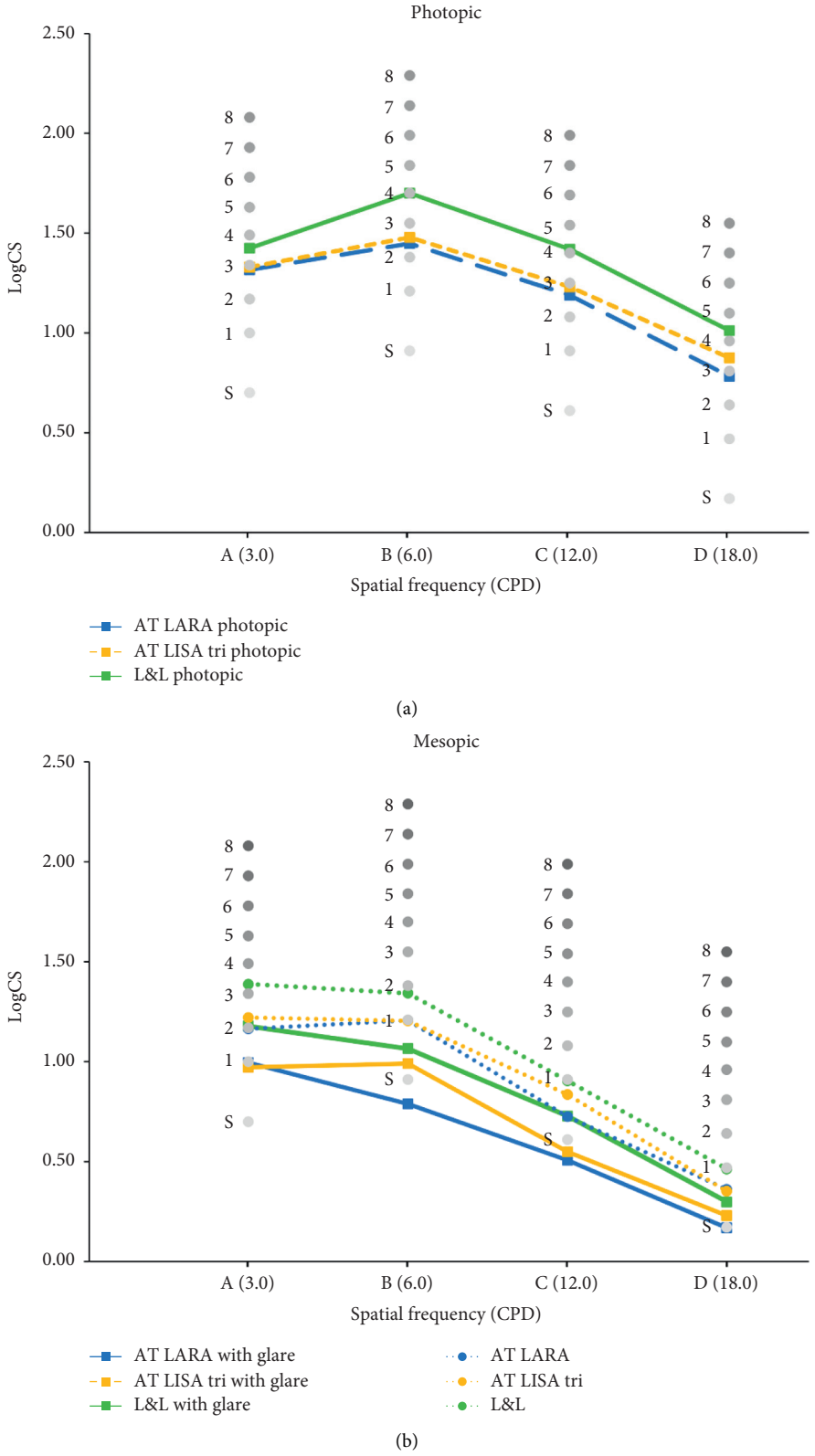

Figure 2: Mean monocular and binocular contrast sensitivity functions under photopic conditions (a) and under mesopic conditions with and without glare (b).

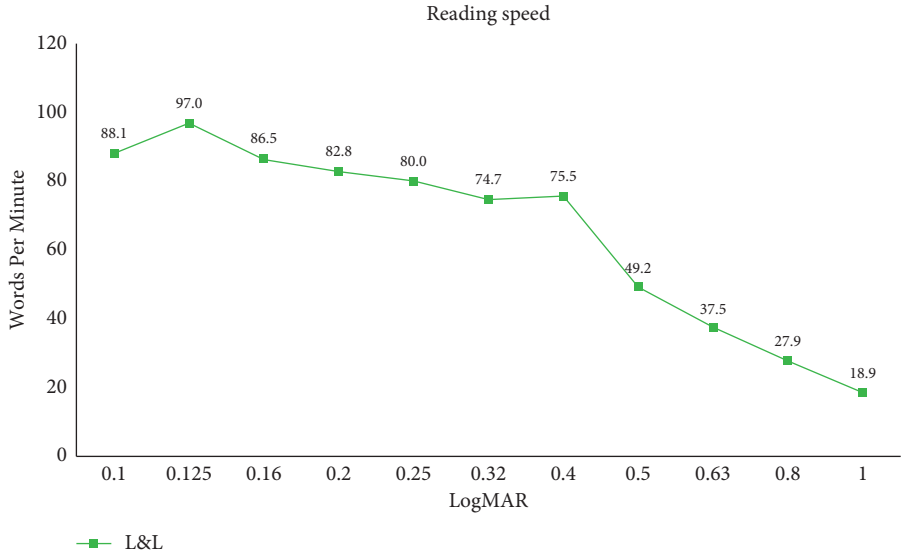

Figure 3: Results of postoperative reading speed at the 6-month follow-up (words per minute).

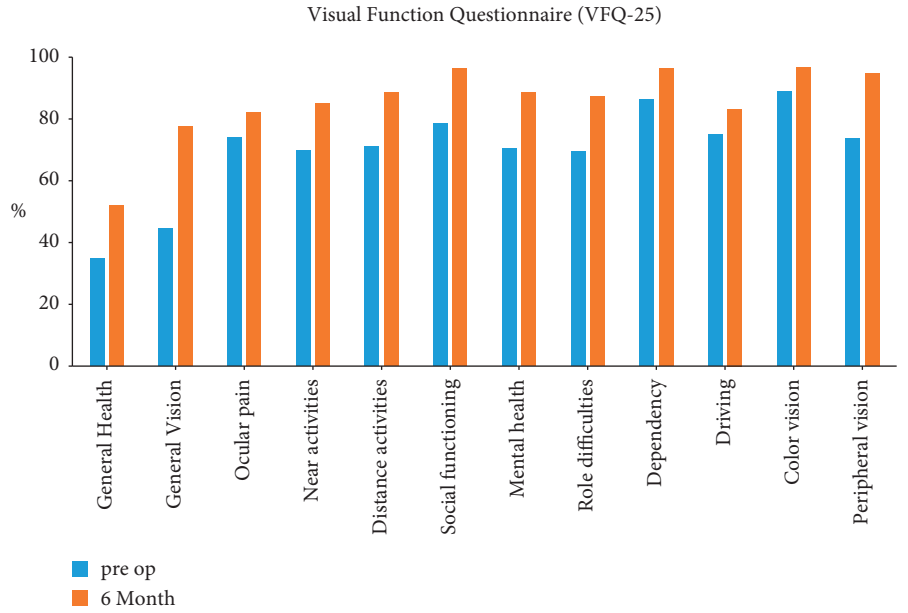

Figure 4: Preoperative and 6-month postoperative results of the VFQ-25.

spectacle independence was achieved with similar outcomes compared to rates in previous studies with the same IOLs [27].

As the use of laptops and smartphones increases, reading speed measurement becomes a valuable predictor that reflects visual performance in everyday life in terms of near vision function [28]. The most widely known devices for reading speed measurements are the MNREAD Chart and Radner Reading Chart, but unfortunately, there is no Korean version available [29–31]. In this study, we used a Korean reading speed application test which is developed appropriately for the Korean writing system called "Hangul." Hangul is fundamentally based on an alphabetic principle, and letters are printed in square-like blocks composed of three consonants including first, medial, and final consonants. For this reason, reading Korean might be more sensitive to blurring.

In the present study, we also evaluated patients' experience with optical phenomena such as glare, halos, starbursts, hazy vision, blurred vision, distortion, and double vision to understand patients' satisfaction in their daily life. Based on the results of the QoV questionnaire, the most frequently perceived phenomenon was halos (29.2% of patients were suffering from halos), while other optical phenomena were improved compared to before surgery. Previous studies have reported that the neuroadaptation process may reduce these optical phenomena over time after surgery [32, 33]. The neuroadaptation process after

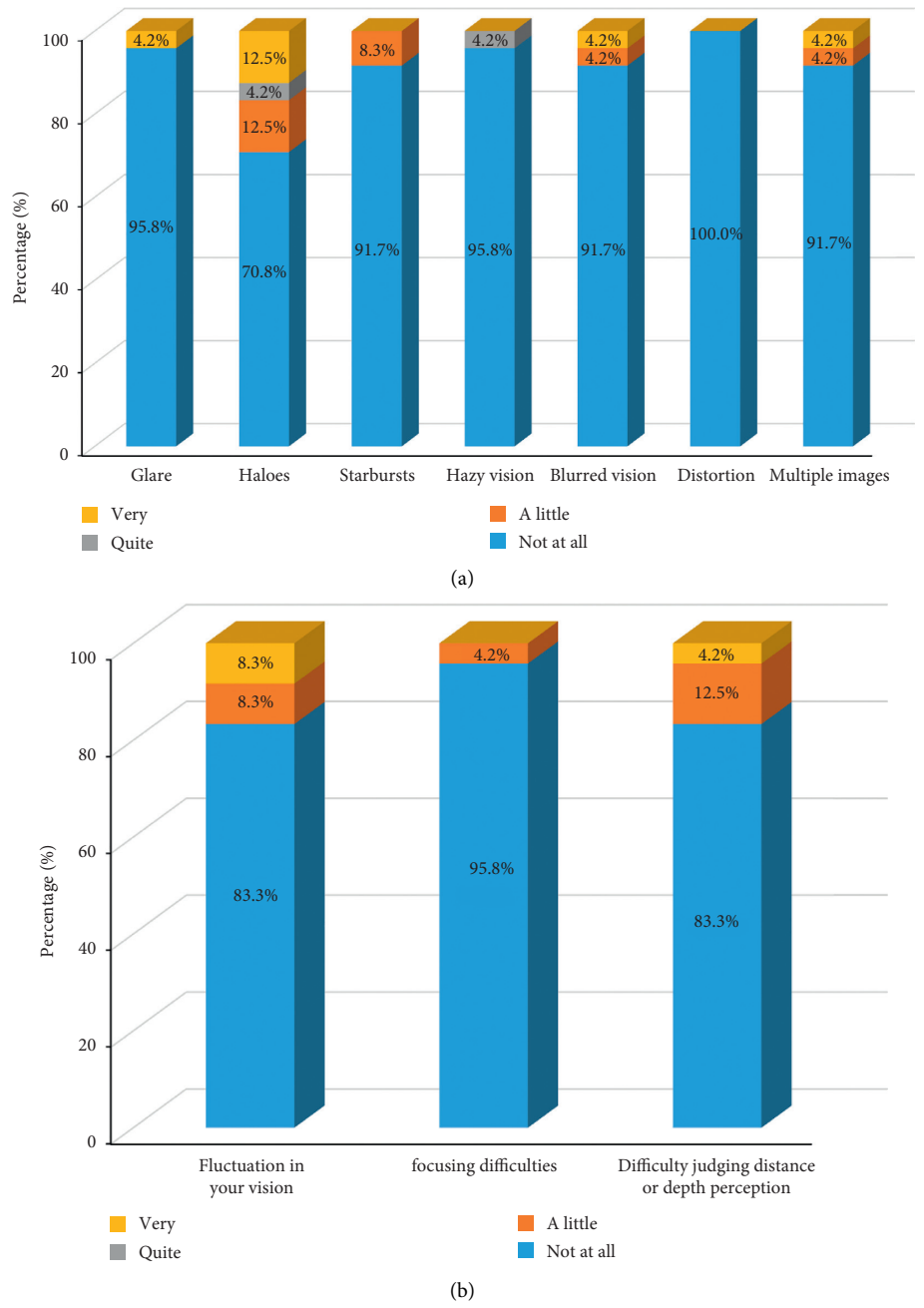

Figure 5: Patient-reported outcomes regarding the perception of optical phenomena.

presbyopia-correcting IOL implantation usually involves a minimum of 3 months and can last up to 1 year. In this study, however, the last follow-up was at 6 months, when the neuroadaptation process is still in process. It could be assumed that difficulties related to optical phenomena might decrease over time; thus, further research with a longer follow-up would be needed.

To summarize, the combined implantation of EDoF and trifocal IOLs can improve corrected and uncorrected visual acuities from far to near distances. Spectacle independence was high at all distances. As shown by the defocus curve, patients with combined IOL implantation achieved better visual acuity results at intermediate and near distances without compromising far distance vision compared to the monocular outcomes of each IOL. The combined implantation of an EDoF and a trifocal IOL can be a viable option for patients with high demands for spectacle independence in their daily life with minimal optical phenomena. In addition, it can be used as a background study of relatively safe recommendations other than monovision for patients who complain of each deficiency after the insertion of an EDoF or trifocal IOL in their first eye.

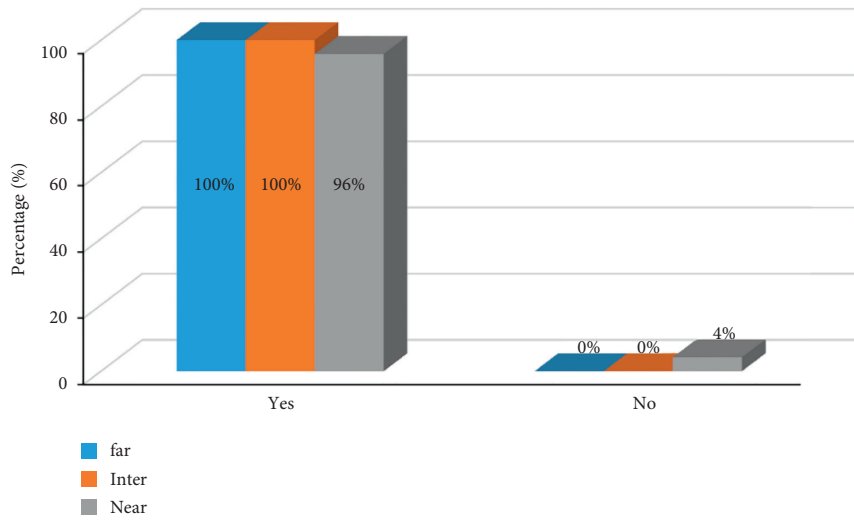

Figure 6: Results of the questionnaire for spectacle independence in daily life for near, intermediate, and far distances.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Disclosure

The funders had no role in study design, data collection, analysis, decision to publish, or manuscript preparation.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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