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BRIEF REPORT

Refractive Outcome and 5-Year Capsulotomy Rate of Hydrophobic and Hydrophilic IOLs with Similar Optical Design: A Contralateral Study

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ABSTRACT

Introduction: To compare the short-term visual and aberrometric outcomes and the long-term capsulotomy incidence in a cohort of patients receiving IOLs with similar structural profile but with a hydrophobic matrix in one eye (PHOB group) and a hydrophilic matrix in the other one (PHIL group).

Methods: In this retrospective, contralateral study, 26 patients sequentially undergoing phacoemulsification were implanted as mentioned above. Refraction and aberrometry were evaluated 6 months after surgery. For the quality of vision, the Hartmann-Shack optical aberration, Double-Pass Modulation Transfer Function (MTF), contrast sensitivity, and dysphotopsia results were compared. Capsulotomy was ascertained and dated by medical chart revision or phone call.

Results: All the considered quantitative and qualitative visual parameters tested statistically comparable between PHIL and PHOB group. After 5 years, four patients (16.7%) in the PHOB group and five patients (20.8%) in the PHIL group underwent a Nd:YAG posterior capsulotomy ($P > 0.5$).

Conclusion: In this contralateral comparative study, the hydrophobic and hydrophilic matrix of the IOL similarly influenced the visual and aberrometric outcomes. Also the long-term laser capsulotomy incidence did not statistically differ between groups. The posterior IOL profile, rather than matrix hydrophilia, could consistently influence the posterior capsule opacification.

Keywords: Aberrometry; Capsulotomy rate; Cataract surgery; Hydrophilic IOL; Hydrophobic IOL

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Key Summary Points

Why carry out this study?

The optical quality of pseudophakic eyes may depend on the hydrophobic or hydrophilic intraocular lens (IOL) material.

Hydrophilic IOL material was associated with higher posterior capsule opacification (PCO) rate and higher need for capsulotomy compared with hydrophobic IOLs.

What was learned from the study?

In this intra-individual study the same optical quality was found with hydrophobic and hydrophilic IOLs of the same design and shape.

The rate of posterior laser capsulotomy was the same with either IOL after 5-year follow-up.

INTRODUCTION

Acrylic hydrophobic and hydrophilic intraocular lenses (IOLs) have long been available for cataract surgery, with subjective or regional preferences for one or the other type still present [1]. Advocates of the hydrophobic material underline the superior mechanical stability and the better resilience to any further surgery [2, 3]. Optic glistening, however, seems to be more common with hydrophobic IOLs, precisely with specific models [4]. Those who prefer the hydrophilic material appreciate higher handling, the ability to inject the lens through smaller ports in micro-incision surgery and the rarer occurrence of dysphotopsia [5]. Late posterior capsule opacification, albeit rare, is more commonly described in relation to hydrophilic material [4, 6].

Considering the posterior capsule opacification (PCO), several studies addressed the possible correlation with the IOL hydrophilia; a quite recent meta-analysis [7] found that the lenses made of hydrophobic biomaterial were overall superior in lowering the Nd:YAG laser capsulotomy rate, with similar long-term visual outcomes. Other studies pointed out the IOL shape and design were factors that influenced the PCO [8]. A prior meta-analysis, which considered this latter outcome among various studies, stated that IOL models with sharp optic edges were superior in lowering the rates of PCO and laser capsulotomy [9]. A strict comparison between hydrophobic and hydrophilic materials however remains difficult because IOLs from different manufacturers change not only for hydrophilia but also in terms of design.

For a comparison to be highly reliable, the evaluation of the functional results, along with the long-term capsulotomy cumulative incidence, should consider patients implanted within a short time interval with a hydrophobic IOL in one eye and a hydrophilic IOL in the other eye, ideally with an IOL model similar in optic design and manufacture. Since this has occurred in our practice, below we have reported the evidence from our database.

MATERIALS AND METHODS

Although the study was originally conceived with a prospective design, the coronavirus pandemic heavily affected the follow-up. The results refer to a retrospective analysis, approved by the area ethics committee (#126/2022) and conducted under the tenets of the Helsinki Declaration of 1964 and its later amendments. Included patients had undergone sequential, bilateral cataract surgery with uneventful in-the-bag IOL implantation. They received a hydrophobic IOL in one eye (then assigned to the PHOB group) and a hydrophilic IOL in the other eye (assigned to the PHIL group). The two types of IOL considered for the study were the Medicontur 877 ABY and the 677 ABY models (Medicontur, Budapest, Hungary), which share the squared posterior edge of the optic, respectively. A comprehensive summary of the technical characteristics of the two devices is reported in Table 1. Supplementary inclusion

Table 1 Characteristics of the study IOLs

Character	Hydrophobic (877 AB)	Hydrophilic (677 AB)
Water content	0%	25%
Refraction index	1.47	1.46
Overall diameter, mm	13	13
Optic diameter, mm	6	6
Aberration design	Aspheric aberration neutral	
Optic design	Biconvex	
PCO prevention	Posterior square edge	
A constant	118.9	118.0
Estimated incision size, mm	2.2–2.4	1.8–2.2

criteria were: postoperative regular astigmatism $\leq$ 1.5D; no history of amblyopia or other recognized ocular pathologies potentially affecting the visual outcome in one eye (chiefly asymmetric age-related macular degeneration, macular edema or optic neuropaties).

The SRK-T formula was used for the power calculation. All surgeries occurred under topical anesthesia (4% lidocaine eyedrops) with a 2.2-mm corneal incision along the steepest meridian. The IOLs were injected using the dedicated injector and the corneal tunnel then being hydrosutured. Postoperative therapy included a topical non-steroidal anti-inflammatory drug (NSAID) agent (bromfenac), a topical steroid (dexamethasone) and a topical antibiotic (tobramycin), adminstered for 3 weeks.

For the refractive and aberrometric analysis, data refer to 6 months after cataract surgery. The following parameters were noted when available in the medical chart: automated refraction (Canon RK-2, Tokyo, Japan); distance best-corrected visual acuity (BCVA, with an early treatment diabetic retinopathy chart at 4 m); optical aberrometric parameters, assessed by means of single-pass optical aberrometer/corneal topographer (KR-1D Topcon, Gamagori, Japan) and a double-pass optical aberrometer (OQAS II, Visiometrics, Barcelona, Spain); the perception of photopsia based on the detection of ghost images. For the PCO management, Nd:YAG laser capsulotomy was indicated whenever BCVA was found $<$ 0.3 LogMAR and the vision loss could be ascribed to PCO. The rate of Nd:YAG laser capsulotomy up to 5 years from cataract surgery was noted referring either to the medical chart or to phone calls.

For the numerical values of refraction and aberration descriptive statistics (i.e., mean and standard deviation, SD) are provided for the variables of interest. The Shapiro-Wilk test was used to check the normality of the distribution of the considered parameters. A paired *t*-test was used to evaluate differences between the study groups for normal parameters and the Wilcoxon sign ranks test to relate samples for non-normal parameters. Post hoc contrast analysis was performed using the Fisher's least significant difference test (95% family-wise confidence level). The statistical analysis was performed with SPSS 28.0.0 (IBM Corp, Armonk, New York, USA), and $p < 0.05$ was defined as the significance threshold. For the 5-year incidence of Nd:YAG laser capsulotomy, the Fisher's test was used to compare the two groups of eyes. To test the power of the study in this regard, we performed a power analysis by using the individually randomized group-treatment (IRGT) calculator to account for the positive intraclass correlation (ICC) expected among members of the same group or cluster (https://researchmethodsresources.nih.gov/irgt-calculator). Considering a type I error at 0.05, an expected distribution of the dichotomic outcome in the general population (i.e., PCO yes/no after 5 years) of 30%, an ICC at 0.50 and a sample size of 30 eyes per group, the power of the study touches the conventional level of 80% (0.79) when the "intervention effect" is set at 0.60.

RESULTS

Twenty-six subjects (11 males and 15 females, age: 74 $\pm$ 8 years, 52 eyes) were included in this

Table 2 Characteristics of the included patients/eyes (mean ± SD)

	Hydrophobic IOL	Hydrophilic IOL	*P*-value
Preoperative			
Axial length, mm	23.22 ± 1.78	23.31 ± 1.84	0.861
K1, D	43.62 ± 1.69	43.67 ± 1.56	0.914
K2, D	43.88 ± 1.75	44.15 ± 1.78	0.585
IOL power, D	21.02 ± 1.82	20.02 ± 1.75	0.049*
Postoperative (6 months after surgery)			
Refraction sphere, D	0.55 ± 0.99	0.48 ± 0.84	0.793
Refraction cylinder, D	− 0.80 ± 0.99	− 0.78 ± 0.91	0.942
Spherical equivalent, D	0.18 ± 0.89	0.04 ± 0.89	0.585
UDVA, D	0.25 ± 0.21	0.20 ± 0.12	0.335
BCVA, D	0.12 ± 0.21	0.09 ± 0.13	0.596

K1 and K2 keratometric values, *IOL* intraocular lens, *UDVA* uncorrected distance visual acuity, *BCVA* best corrected visual acuity

**P*-value statistically significant reflecting the different A-constants of the two IOLs

study. Preoperative axial length, astigmatism and IOL power calculation are detailed in Table 2 for the PHIL and PHOB group. In the same table, the respective postoperative refractive and visual outcomes are reported. Referring to the 5-year capsulotomy rate, the parameter was ascertainable in 24 subjects. Among these, four Nd:YAG laser treatments (16.7%) were performed in the PHOB group and five (20.8%) the PHIL group ($P > 0.5$). In the routine postoperative visits, the posterior capsule was transparent in all the eyes, and no cases of photopsia or IOL optic opacification were reported. Among the 24 patients whose 5-year capsulotomy occurrence was available, none underwent Nd:YAG laser capsulotomy within the first year after surgery (Fig. 1).

Figure 2 reports the distribution of the postoperative clinical spherical equivalent.

The results of the Hartmann-Shack optical aberration at a 4-mm aperture diameter are displayed in Table 3. The wavefront refraction tested comparable between groups, as well as the clinical refraction. The wavefront astigmatism of the two groups was similar at the corneal, ocular and internal level. Even the axis of the internal astigmatism was similar, suggesting no influence from the IOL material. High order aberration showed a similar pattern, again without significant difference between groups at the corneal, ocular and internal level.

The results of the double-pass OQAS aberration study are reported in Figs. 3 and 4. Figure 3 reports a similar width of the Point Spread Function (PSF) curve in arc/min at 10% and at 50% of its height in both groups, and the Modular Transfer Function (MTF) cutoff value, which is the level in cycles/degree at which the modulation transferred to the retina reaches zero. The Objective Scattering Index (OSI) was 2.38 ± 1.13 for the PHOB and 2.65 ± 1.56 for the PHIL group ($P = 0.49$). Figure 4 shows the Strehl ratio computed with the two aberrometers employed. The obtained values are in line with the values commonly obtained with monofocal IOLs and are very similar for the hydrophobic and the hydrophilic IOL model.

DISCUSSION

This study represents a suitable model to selectively investigate the influence of the IOL matrix (hydrophobic and hydrophilic) on some anatomical (PCO) and functional (refraction, aberration) parameters related to cataract surgery. Each of the two materials have proponent surgeons, with the hydrophobic often preferred in the US and the hydrophilic used more in Europe. Despite thorough studies, concerns about possible optical disturbances supported by the hydrophobic material or the mechanical and chemical stability of the hydrophilic material are still debated. In addition, the optical properties of the two materials and the

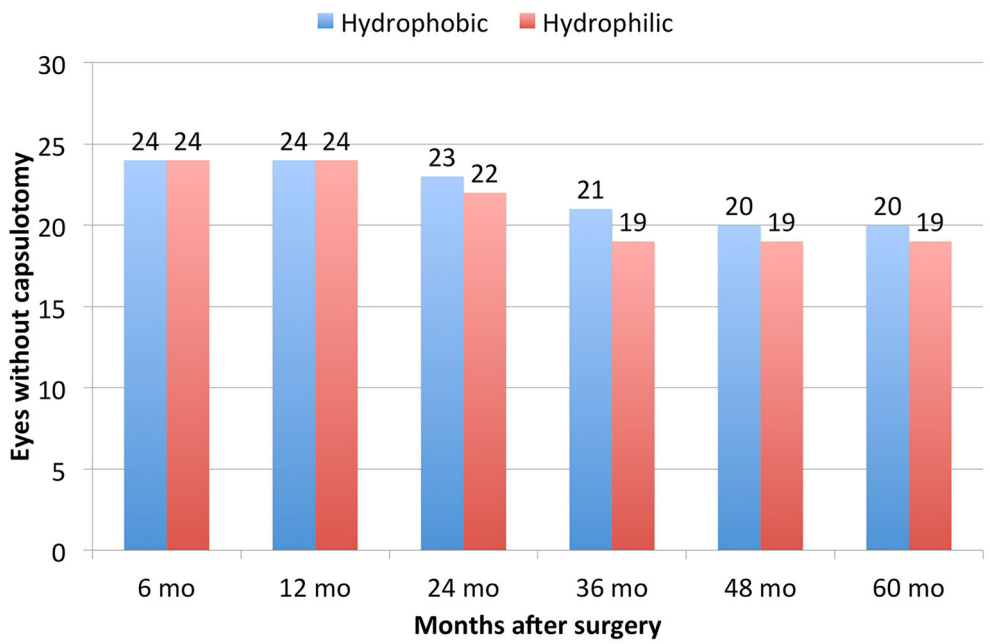

Fig. 1 Survival curve of the posterior capsule with the two lenses: no difference could be detected between the hydrophobic and hydrophilic IOL

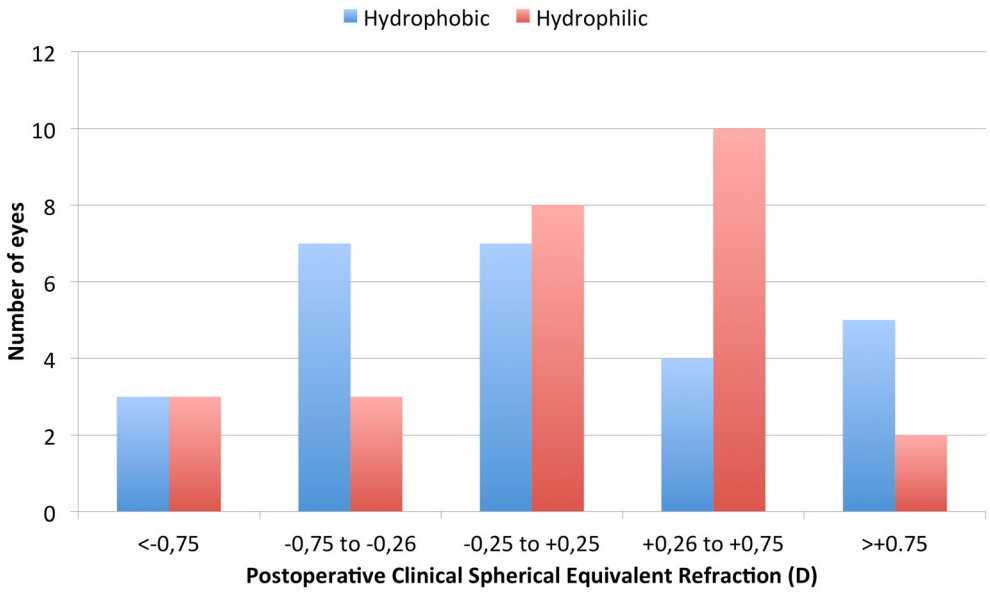

Fig. 2 Distribution of the clinical spherical equivalent 6 months after surgery

efficacy of the posterior squared edge of the optic in the prevention of the PCO need to be fully ascertained.

Our results demonstrated the absence of significant differences between the PHIL and the PHOB groups in terms of either the 5-year capsulotomy cumulative incidence or the visual outcomes. In particular, the rate of Nd:YAG laser capsulotomy after 5 years was 16.7% in the PHIL and 20.8% in the PHOB group, rates which

Table 3 Hartmann-Shack wavefront refraction and aberration with the study IOLs

Parameter (4 mm optical zone)			Hydrophobic	Hydrophilic	*P*-value
Refraction	Ocular	D	− 0.26 ± 0.81	− 0.38 ± 0.91	0.62
Astigmatism	Ocular	D	− 1.34 ± 0.89	− 1.23 ± 0.96	0.67
			@106 ± 37	@117 ± 50	0.37
	Corneal	D	− 1.35 ± 1.21	− 1.52 ± 1.09	0.60
			@96 ± 62	@78 ± 61	0.30
	Internal	D	− 0.97 ± 0.74	− 0.83 ± 0.48	0.42
			@104 ± 27	@97 ± 33	0.41
High order aberrations	Ocular	μ	0.26 ± 0.10	0.27 ± 0.08	0.69
	Corneal	μ	0.16 ± 0.06	0.17 ± 0.06	0.55
	Internal	μ	0.27 ± 0.15	0.25 ± 0.10	0.57
Coma	Ocular	μ	0.20 ± 0.11	0.20 ± 0.10	1.00
			@97 ± 87	@73 ± 62	0.26
	Corneal	μ	0.09 ± 0.05	0.08 ± 0.05	0.47
			@105 ± 90	@126 ± 80	0.38
	Internal	μ	0.22 ± 0.13	0.18 ± 0.11	0.24
			@86 ± 67	@88 ± 93	0.92
Spherical aberration	Ocular	μ	0.07 ± 0.03	0.06 ± 0.03	0.24
	Corneal	μ	0.04 ± 0.02	0.05 ± 0.03	0.16
	Internal	μ	0.03 ± 0.05	0.02 ± 0.04	0.43

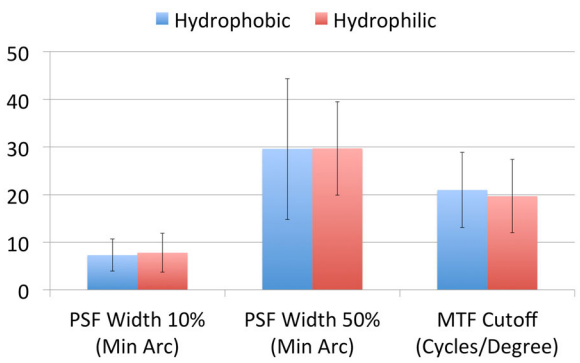

Fig. 3 Double-Pass aberrometer values: width of the PSF curve at 10% and at 50% of its height in Min Arc and MTF cutoff value in cycles/degree for the two IOLs. No difference was statistically significant

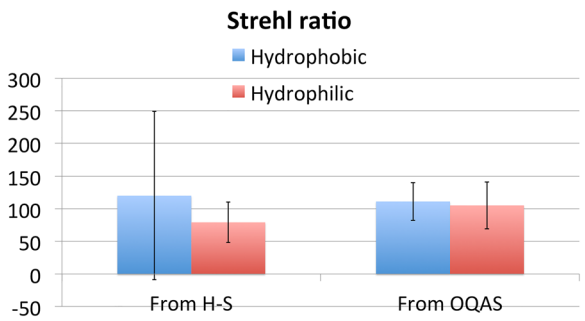

Fig. 4 Strehl ratio as computed by the Hartmann-Shack and by the Double-Pass aberrometer. No difference was statistically significant

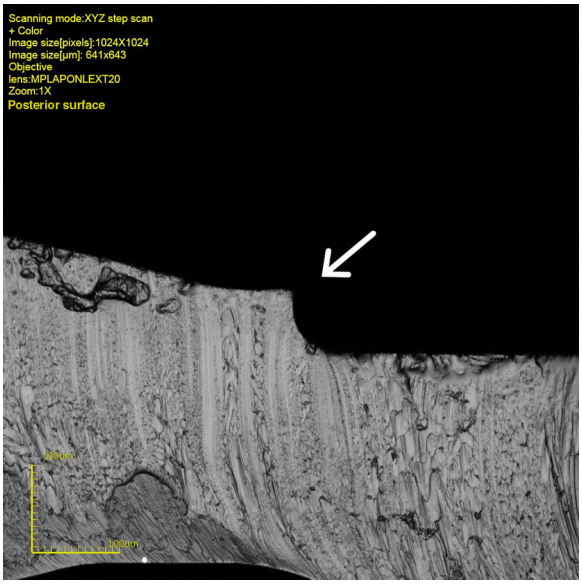

Fig. 5 Microscope view of the posterior square edge (arrow) of the hydrophilic IOL

are quite low and indicate an equal efficacy in limiting postoperative PCO development. The square edge, as microscopically detailed in Fig. 5, present in both the IOL models, could actually explain the lack of difference. Optical quality, MTF, contrast sensitivity and absence of dysphotopsia had similar results in both groups.

Clinical studies on the outcome of cataract surgery after implantation of hydrophobic and hydrophilic IOLs with similar design in the same patient are rare in the literature. One study by Draschl and co-authors targeted the rotational stability of hydrophobic and hydrophilic IOLs with similar design in 80 eyes of 40 patients [10]. The mean rotation of the two IOLs models was the same, although the rotational stability of the hydrophobic IOL was less scattered with a lower standard deviation of the angles of rotation. Nagy et al. studied hydrophobic and hydrophilic trifocal IOLs with the same profile in 25 patients and found no significant difference in visual acuity, defocus curve, contrast sensitivity and reported optical disturbances after 6 months [11]. A thorough study of the chromatic aberration induced by hydrophobic and hydrophilic IOLs of the same design was performed by Vinas et al. [12]. Both the psychophysical and the wavefront measurement of the chromatic aberration indicated better values for the hydrophilic IOL, probably because of the lower refraction index (1.46 vs. 1.52).

The study of Dvali et al. [13] was both intraindividual (34 patients) and interindividual (57 eyes hydrophobic, 73 eyes hydrophilic). No difference in PCO was detected during the first year after surgery, but after 18 months 4 eyes with the hydrophobic IOL (4.4%) and 11 eyes with the hydrophilic IOL (10.3%) required Nd:YAG laser capsulotomy. In another interindividual study, Poyales et al. studied the visual and optical performance in two groups of patients implanted bilaterally with either a hydrophobic trifocal IOL (26 patients) or a hydrophilic trifocal IOL (25 patients) of the same design [14]. They found no difference in the visual, refractive and aberration results after 1 month.

Nd:YAG laser capsulotomy may be performed even when PCO is not the main reason for the visual loss. Chen et al. [15] reported in a large cohort of patients, that dry eye disease, glaucoma, age-related maculopathy, diabetes and other systemic factors were associated with an increased indication for Nd:YAG laser capsulotomy. We did not consider systemic factors in our analysis, but the intra-individual character of our survey minimizes the possible influence of such factors, which are supposed to affect both eyes equally.

The present study has the known limitations related to the retrospective analysis and the limited sample size. However, the contralateral design is still nowadays extremely original, and it inherently balances the different characteristics or the possible dysfunctions of each individual subject. The evaluation by double-pass aberrometer, able to deeply investigate the optical quality of vision, is also novel and reported that results of the PHIL group did not statistically differ from those of the PHOB group.

CONCLUSIONS

In conclusion, compatibly with the limitations mentioned above, we believe that the present

results support the opinion that the shape, rather than the matrix, represents a major parameter to infer the anatomical and functional response to the implanted IOL.

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Disclosures. Carlo Bellucci, Paolo Mora, Salvatore A. Tedesco, Stefano Gandolfi, and Roberto Bellucci have nothing to disclose.

Compliance with Ethics Guidelines. All procedures performed in studies involving human participants were in accordance with the ethical standards of the ethics committee of reference for University Hospital of Parma, Parma (IT) and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study protocol was approved by the Ethics Committee protocol number #126/2022 where informed consent was obtained. Approval was granted by the Ethics Committee of Area Vasta Emilia Nord, Parma (IT).

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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