Aus der Klinik für Augenheilkunde

der Medizinischen Fakultät Charité – Universitätsmedizin Berlin

DISSERTATION

The influence of an intraocular lens design with enlarged 7.0 mm optic on the visual and optic results after a cataract surgery

Einfluss einer vergrößerten Intraokularlinsen-Optik (7,0 mm) auf die funktionellen und optischen Ergebnisse nach einer Katarakt-Operation

zur Erlangung des akademischen Grades
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Preamble

The data, figures and tables in this dissertation were partially used in the paper entitled "Dysphotopsia and functional quality of vision after implantation of an intraocular lens with a 7.0 mm optic and plate haptic design" submitted for publication in the Journal of Cataract and Refractive Surgery on 11th March 2021.

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FIGURES AND TABLES

1. LIST OF ABBREVIATIONS

ACD	anterior chamber depth
ACO	anterior capsule opacification
AL	axial length
BIL	bag-in-the-lens
CCT	central corneal thickness
CDVA	corrected distance visual acuity
CME	cystoid macular edema
CS	contrast sensitivity
ECD	corneal endothelial cell density
IOL	intraocular lens
IOP	intraocular pressure
LT	lens thickness
ND	negative dysphotopsiae
Nd:YAG	neodymium-doped yttrium aluminum garnet [capsulotomy]
PCO	posterior capsule opacification
PD	positive dysphotopsiae
PLF	peripheral light focusing
ROC	reverse optic capture
SER	spherical equivalent
SIA	surgically induced astigmatism
UDVA	uncorrected distance visual acuity
UGH	Uveitis – Glaucoma – Hyphema Syndrome
WTW	white to white distance

2. ABSTRACT

2.1. Abstract (English)

Purpose: To determine the impact of intraocular lens (IOL) design with an enlarged 7.0 mm optic on the incidence of dysphotopsiae, visual acuity and contrast sensitivity after cataract surgery.

Methods: A prospective monocentric randomized patient-blinded comparative clinical study was planned. Following preoperative consent and measurements, patients underwent cataract surgery with the implantation of two IOL designs – with a 7.0 mm optic and plate haptics (group 1) or with a 6.0 mm optic and C-loop haptics (group 2). In months 1, 3 and 12, follow-up patients were examined and answered a questionnaire regarding satisfaction, spectacle dependence, and the frequency and extent of positive and negative dysphotopsiae. Additionally, contrast sensitivity in the second and third examination, and mesopic vision and glare sensitivity in the third examination were tested. The data were analysed as nominal, ordinal and metric values.

Results: Group 1 comprised 57 eyes (43 patients) and group 2 comprised 63 eyes (43 patients). The corrected distance visual acuity was the same between groups and throughout the study. Uncorrected distance visual acuity was higher in group 1 in the first examination, with no differences in further follow-ups. Group 1 showed a lower incidence of positive and negative dysphotopsiae, with significant difference compared to group 2 in the first follow-up ($p = 0.021$ and 0.015, respectively). The frequency and partial extent of dysphotopsiae were lower throughout the whole study in group 1, reaching statistically significant values for the frequency of negative dysphotopsiae ($p = 0.048$) in the first examination. The mean contrast sensitivity and mesopic vision with and without glare were the same in both groups. Persistent positive dysphotopsiae cases revealed lower photopic contrast sensitivity ($p = 0.005$, 0.036 and 0.047), longer AL ($p = 0.04$) and greater preoperative pupil dynamics ($p = 0.06$), whereas cases with persistent negative dysphotopsiae were of significantly younger age ($p = 0.029$).

Conclusions: The IOL design with a 7.0 mm optic diameter reduces positive and negative dysphotopsiae and provides good and stable visual acuity, contrast sensitivity, and mesopic vision with and without glare.

2.2. Abstract (German)

Titel: Einfluss einer vergrößerten Intraokularlinsen-Optik (7,0 mm) auf die funktionellen und optischen Ergebnisse nach einer Katarakt-Operation.

Hintergrund: Das Ziel der Studie war die Beurteilung potenziell klinischer Vorteile eines Intraokularlinse (IOL)-Designs mit 7,0 mm Optik im Vergleich zu einem IOL-Design mit 6,0 mm Optik nach einer Katarakt-Operation.

Methoden: Eine prospektive, monozentrische, randomisierte und einfachblinde klinische Vergleichsstudie wurde geplant. Nach der präoperativen Einwilligung sowie Vorbereitungen, wurden die Katarakt Operationen mit Implantierung von zwei IOL-Designs – mit 7,0 mm Optik und Plattenhaptik (Gruppe 1) oder mit 6,0 mm Optik und C-Schlaufen Haptik (Gruppe 2) – durchgeführt. Die Patienten wurden 1, 3 und 12 Monate postoperativ untersucht, in jeder Kontrolle wurde ein Fragebogen zur Zufriedenheit, Brillenabhängigkeit sowie Wahrnehmung von positiven und negativen Dysphotopsien beantwortet. Die Kontrastsensitivität wurde in den Monaten 3 und 12, das Dämmerungssehen und die Blendempfindlichkeit wurden in der letzten Kontrolle untersucht. Die Daten wurden als nominale, ordinale und metrische Werte statistisch analysiert.

Ergebnisse: Die Gruppe 1 umfasste 57 Augen (43 Patienten) und die Gruppe 2 63 Augen (43 Patienten). Es gab keine statistisch signifikante Abweichung im Hinblick auf den korrigierten Fernvisus in beiden Gruppen in der gesamten Studie. In der ersten Kontrolle konnte in der Gruppe 1 ein höherer unkorrigierter Fernvisus festgestellt werden, der sich im Verlauf jedoch anglich. In der Gruppe 1 zeigte sich eine niedrigere Inzidenz der positiven und negativen Dysphotopsien, mit signifikanten Unterschieden zur Gruppe 2 ein Monat postoperativ ($p = 0,021$ und 0,015 entsprechend). Die Häufigkeit und teilweise die Intensität der Dysphotopsien fielen in der Gruppe 1 während der gesamten Studie geringer aus, mit signifikanten Unterschieden für die Häufigkeit der negativen Dysphotopsien in der ersten Kontrolle ($p = 0,048$). Die Mittelwerte der Kontrastsensitivität sowie das Dämmerungssehen und die Blendempfindlichkeit zeigten keine signifikanten Unterschiede zwischen den Gruppen. Fälle mit persistierenden positiven Dysphotopsien wiesen eine niedrigere photopische Kontrastsensitivität ($p = 0,005$, 0,036 und 0,047), eine längere Axenlänge ($p=0,04$) sowie eine größere Pupillendynamik ($p = 0,06$) auf. Bei persistierenden negativen Dysphotopsien wurde jüngeres Alter festgestellt ($p = 0,029$). ***Schlussfolgerung:*** Das IOL-Design mit 7,0 mm Optik reduziert positive und negative Dysphotopsien, sowie leistet einen guten, stabilen Visus, Kontrastsensitivität, Dämmerungssehen und Blendempfindlichkeit.

3. INTRODUCTION

A successful outcome of a cataract treatment comprises an indefectible surgical technique, spot-on intraocular lens (IOL) selection and calculation, as well as maximal postoperative visual and functional results. The most important aspect, however, is the patient satisfaction, which depends not only on the final visual acuity and possible spectacle independence but also on the freedom from any undesired disturbing optical images.

3.1. Dysphotopsiae

Dysphotopsiae are unwanted light sensations perceived by patients after an uneventful cataract surgery. Due to disturbing the main retinal image, they lower vision quality and, in consequence, the quality of daily life, thus leading to a major source of patient dissatisfaction (1). There are two types of dysphotopsiae – positive and negative.

3.1.1. Positive dysphotopsiae

3.1.1.1. Incidence of positive dysphotopsiae

Positive dysphotopsiae (PD) occur as halos, flashes, glares and light streaks in up to 67% of patients directly postoperatively, with a reduction in its incidence to 0.2-2.2% within a year (2-4). These phenomena can be very disturbing as they may be seen from an angle, but disappear when attempting to focus on them, which may give the patient a feeling of frustration (5).

3.1.1.2. Aetiology of positive dysphotopsiae

In the first report about these visual artefacts in 1993, Masket et al. (6) assumed that they were caused by the lens shape rather than its size.

With time, awareness of this problem grew, focusing on conducting more research including ray-tracing analysis, which enabled the introduction of further possible aetiological factors. Based on such modelling, Holladay (7) stated that PD occur due to a sharp, truncated IOL edge which internally reflects (rather than refracts) light rays onto the opposite side of the main retinal image, creating a thin ring-shaped image there (known as the reflected glare image). Additionally, light rays that completely miss the IOL form an aphakic arc near the main, true image of the glare source.

Other factors contributing to PD, such as surface related secondary internal IOL-fundus reflections (due to IOL design with a flatter anterior curvature in unequal biconvex IOLs), with individual fundus reflectivity and a high refractive index of the IOL (acrylic) have been reported (8) as well.

Coronero et al. (9) extended the optic edge theory by explaining peripheral light focusing (PLF). As a result of corneal convexity and power, peripheral off-axis light rays from a glare source are refracted into intraocular locations and form amplified secondary retinal images in the peripheral field of vision. Light rays that pass through the gap between the iris and the IOL, and completely miss the IOL without striking the optic, are directly projected onto the retina.

Lastly, Das et al. (10) postulated that not only straight (not curved) optic edges but also functionally smaller optic diameter increases the incidence of glare.

3.1.1.3. Anatomical and individual risk factors of positive dysphotopsiae

It is not only the edge and optic design that lead to the formation of positive dysphotopsiae; this also depends on anatomical and individual features such as: large pupils (exposing IOL edges) (11), low corneal power (4), larger size of iris-IOL gap and younger age of patients (3). A positive relation between these photic phenomena and preoperative photopic kappa angle as well as pupil centre shift has also been proven (12).

3.1.2. Negative dysphotopsiae

3.1.2.1. Incidence of negative dysphotopsiae

Negative dysphotopsiae (ND) occur in the form of a crescent-shaped shadow in the peripheral temporal field of vision in 15.2% of pseudophakic patients directly after cataract surgery, reducing its incidence to 3.2% within a year (13), whereas severe symptoms may persist in 0.12-0.3% of patients (14). Compared to the degree of spontaneous resolution of PD, ND seem to be a much more persistent problem.

It is caused by a temporal source of light and diminishes when the light coming from this direction is blocked. The extent of the ND shadow may rapidly change due to quick pupil dynamics and the image behind the shadow is repeated and enlarged. Taken together, this could give the patient a misleading motion perception in the temporal visual field (15).

3.1.2.2. Aetiology of negative dysphotopsiae

Negative dysphotopsiae, as the newcomer of dysphotopsiae duo, were first reported by Davidson in 2000 (4). Their causative mechanism remains unclear, in spite of various attempts at explaining it on ray tracing models and in laboratory analysis.

Holladay (16) made a valuable input by presenting the theory of type 2 and 3 shadows, explaining ND as the result of light discontinuity between light rays refracted through a sharp IOL edge and

rays striking the posterior optic surface, proposing the sharp IOL edge as the main cause, just like in the case of PD.

Simpson (17), however, postulated the double image concept as being a result of forming an illumination gap between the last rays hitting and first rays missing the IOL, and later reached a consensus with Holladay (18).

Masket (19) introduced a further, different theory that the position of the anterior capsulorhexis in front of the IOL is a source of reflection further projected onto the nasal retina.

3.1.2.3. Anatomical and individual risk factors of negative dysphotopsiae

Among many other factors contributing to ND, small photopic pupils (increasing the contrast to perceive the shadow), a high refractive IOL index, the presence of functional nasal retina extending anteriorly enough to perceive the artefacts (16) mostly by a shallow orbit or a prominent globe (13) as well as greater alpha and kappa angles (18) were reported. Makhotkina (20, 21) also pointed out other risk factors, such as shorter axial length (AL), younger age of patients, higher IOL power, a postoperative increase in anterior chamber depth (ACD), and higher corrected distance visual acuity (CDVA).

The contradictory theories about iris-IOL distance (Osher (13) vs. Holladay (16)) have lately been explained well by Erie (15) as either filling or anteriorising the illumination gap. Masket (22), however, still disagreed, claiming that ND appear due to the constellation of the anterior capsule and IOL, not posterior chamber depth, or are even a result of a central neuroadaptive disorder (23).

3.2. Treatment of positive and negative dysphotopsiae

3.2.1. Conservative therapy

3.2.1.1. Reassurance and explanation

No fully effective treatment of dysphotopsiae has been developed as yet (24) (Figure 1). The first step in a conservative therapeutic strategy is cautious consideration of patients' complaints and the explanation of these visual artefacts to show understanding of their problem (25).

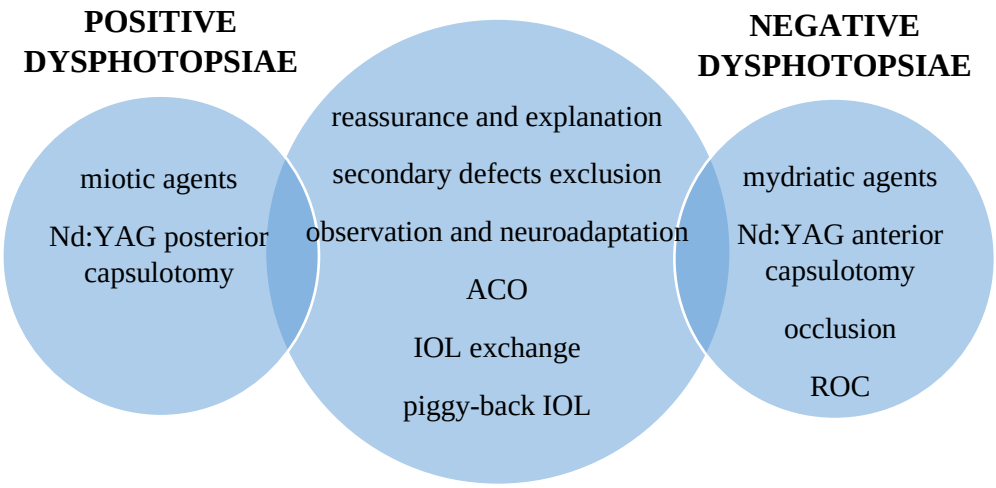

Figure 1. Summary of conservative and surgical strategies against positive (left) and negative (right) dysphotopsiae. Common approaches depicted in the centre of the diagram.

3.2.1.2. Excluding secondary defects

Any potential defects such as dry eye syndrome or minimal residual refraction error should be addressed and corrected. It is unclear whether the correction itself or wearing spectacles with frames blocking temporal light is effective in the case of ND (25).

3.2.1.3. Observation and neuroadaptation

Reassuring patients about the temporary nature of the problem and the probable neuroadaptation is crucial (26). Patients with dysphotopsiae reveal an increased attention and effort brain activity, which objectively confirms the nuisance of these symptoms (27). Due to the new pseudophakic visual experiences, the task-solving cortical area is activated and, possibly, neuroadaptation accelerates; hence, the more the patient is bothered, the better chances for improvement might be.

3.2.1.4. Anterior capsule opacification

In the observational approach an anterior capsule opacification (ACO) may develop, which could contribute to spontaneous resolution of PD and ND. ACO is considered to disperse the off-axis light, thus reducing the incidence and severity of glare (3, 7). In the case of ND, a possible explanation is the filling of the illumination gap with light scattering due to ACO or anterior IOL shift by capsule contraction (16).

3.2.1.5. Pharmacological therapy

Another conservative approach is a pharmacological influence on the pupil size. The use of miotic agents against PD (pilocarpine) has been, however, reported to have doubtful efficacy (4, 28).

On the other hand, mydriatic agents against ND have been recommended (19), as a small pupil would have a pinhole effect and would increase the contrast of the shadow (16).

Regarding this, in the case of simultaneous PD and ND (such patients were present in our study), the therapy with miotic eye drops would even enhance the latter. Moreover, this conservative method does not seem to be a long-term solution due to pharmacological side effects and patient compliance.

3.2.1.6. Occlusion

Occlusion is yet another conservative option for ND treatment; still, it remains as enigmatic as dysphotopsiae itself. Both mono- (25) and contralateral (23, 29) strategies have been reported.

Excluding an eye from the visual tract may take place with the use of a translucent or a fully opaque patch or even with a peripherally dimmed contact lens. Fully opaque occlusion has been reported as the most effective (23).

Contralateral occlusion could be explained as intensifying the cortical task-solving stimulation, as the patient could only see with the affected eye, and no full fellow visual field (i.e., free from ND shadow) would be present as a constant distraction or comparison. On the other hand, Wenzel et al. (25) reported a complete or partial reduction of ND after continuous monolateral occlusion for two weeks.

In conclusion, due to contradictory reports it is difficult to estimate the proper occlusion technique.

3.2.2. Surgical therapy

A number of surgical therapeutic techniques for dysphotopsiae have been discussed in the current literature. However, none of these procedures has proven to be fully effective, and each of them raises risks and additional treatment costs.

3.2.2.1. Neodymium-doped yttrium aluminum garnet capsulotomy

For the treatment of PD, attempts to perform neodymium-doped yttrium aluminum garnet (Nd:YAG) posterior capsulotomy have been reported (4).

In the case of ND, a Nd:YAG anterior capsulotomy has been performed, however, with limited outcome (30). Nevertheless, these partially positive results confirm Masket's theory of the aetiology of ND (19).

Considering the previously mentioned ACO as the reason for the possible spontaneous resolution of both PD and ND, the contradictory nature of these phenomena is again evident. Moreover, performing Nd:YAG capsulotomy might complicate further surgical options, such as IOL exchange, due to capsule instability.

3.2.2.2. IOL Exchange

Exchanging the IOL for a different in-the-bag IOL or a sulcus-fixated IOL has been performed as a treatment of PD (4, 28, 31).

The same techniques are known for ND; nonetheless, it is additionally difficult to decide what kind of IOL to choose for this procedure, as all types of IOLs have been reported to cause ND (32).

Moreover, the exchange itself has a risk profile, such as capsule rupture, cyclodialysis, retinal tears or cystoid macular edema (CME) (31). After replacing the in-the-bag IOL with a sulcus fixated one, pupil capture, iris chafing or IOL decentration may occur.

3.2.2.3. Reverse optic capture

In this technique, used against ND, after a classical in-the-bag implantation, the optic is moved above the margin of anterior capsulorhexis and the haptics remain in the bag (19).

Potential risks following reverse optic capture (ROC) include modest myopic shift deepening the residual refractive error, acceleration of posterior capsule opacification (PCO) development or a capsular block (22).

3.2.2.4. Secondary sulcus-fixated piggy-back IOL

Inserting a secondary piggy-back IOL in the sulcus anterior to the remaining in-the-bag IOL has been performed as treatment for both types of dysphotopsiae (20, 31).

It is considered to be less invasive than IOL exchange and can be implanted as plano or correcting residual refractive defects variants. However, additional risks such as pupillary block, pigmentary glaucoma, Uveitis-Glaucoma-Hyphema Syndrome (UGH) or CME are possible (31).

Erie and Simpson (33) explained the mechanism of the sulcus-fixated piggy-back IOL well in terms of ND: it shifts the iris anteriorly and, to a smaller extent, also the main in-the-bag IOL posteriorly. As a result, the iris-main IOL distance increases, and more light rays at already lower visual angles miss the main optic and fill in the illumination gap. This reduces ND but could also be interpreted as slightly narrowing the main retinal image, which could give a perception of a shadow-free but constricted visual field.

3.3. Preventive strategies against dysphotopsiae

Regarding patient satisfaction, trust, safety and the risk of consecutive surgeries as treatment of dysphotopsiae, a preventive strategy against these visual artefacts is of key importance. As anatomical factors remain constant, the only possibility seems to be changing IOL design or performing a surgical technique.

3.3.1. Modified edge and thickness of IOL

Meacock (3) proved that IOL edge texturing significantly reduces glare symptoms.

Holden (34), however, proposed darkening or complete blackening of the edges to absorb rather than disperse light rays striking the peripheral IOL region, arguing that these rays do not produce a clear image and thus could be completely removed as non-functional. As a solution against both PD and ND, he described anteriorizing these artefacts on the retina by thickening the IOL in order to reduce the iris-IOL distance.

Based on ray-tracing analysis, Francini (35) proposed another IOL modification, namely with round anterior and sharp posterior edges. In this way, the rounded edge partially disperses the reflected light rays, creating a more diffuse and less intense reflected glare image on the retina opposite the main image. At the same time, retaining a sharp posterior IOL edge additionally prevents PCO development.

3.3.2. Masket ND IOL

An interesting option is the Masket ND Type 90S IOL (Morcher, Stuttgart, Germany) designed to prevent ND (36). It resembles the concept of the bag-in-the-lens (BIL) by Tassignon (37) and the mechanism of ROC.

In this approach the complete anterior IOL surface is freed from the capsule margin by a groove designed in the middle of the IOL thickness that captures its anterior edge. The optic is anteriorized but remains in the bag to benefit from its stability. In some cases, the first two versions caused

capsule block and pupil capture. Eventually, enlarging the anterior optic leaf from 6.0 mm to 6.4 mm enabled successful surgeries with no ND reports in all cases.

However, this design may have some limitations. Firstly, the implantation requires a new learning curve. Secondly, the recommended femtosecond laser or other automated capsulotomy devices for the required precise capsulorhexis are not always available in daily clinical conditions. Lastly, in the case of intraoperative capsule defect, this IOL would not be applicable.

3.3.3. Concave margin IOL

Erie and Simpson (15) also introduced a concept of IOL modification to reduce ND.

In their model, the posterior lens surface is provided with a concave margin which redirects light rays more anteriorly and peripherally onto the retina to partially fill the illumination gap. According to the ray-tracing analysis, it eliminates or reduces ND. The concave modification influences the illumination gap, but does not seem to interact with light missing the IOL. The general mechanism is plausible, but because of the latter, it might require improvement. The authors emphasize that IOL modification should be minimal to avoid unforeseen effects.

3.3.4. Haptic orientation

An inferotemporal orientation of the optic-haptic junction during the IOL implantation has been promoted as preventive against ND (38).

The haptic junction functions as a sort of optic extension - it refracts or internally reflects light rays at larger angles, reducing the light missing the IOL (39). The illumination gap remains, but without its anterior boundary, which would make it visible by enhancing the contrast. Regarding this, however, the shadow could be perceived as a constriction of the visual field. Moreover, the mechanism of haptic orientation may lose its function in the case of IOL rotation or dislocation.

3.4. Aims of the study

Given the complexity of PD and ND, including contradictory theories about their aetiology and treatment, it is a great challenge to find a solution to this problem. Therefore, the purpose of this study is to determine the impact of IOL design with a 7.0 mm optic diameter on the incidence of dysphotopsiae and visual functions after cataract surgery.

4. PATIENTS, MATERIALS AND METHODS

4.1. Study model

Following the tenets of the Declaration of Helsinki, a prospective monocentric randomized patient-blinded comparative clinical study was planned and an approval from the local ethics committee was obtained.

4.2. Inclusion criteria

Having been provided detailed information about the purpose of the trial, patients with an indication for cataract surgery were voluntarily recruited and gave a written consent. The inclusion criteria required senile cataract, no history of ocular surgeries or trauma, and age under 78. Patients with corneal astigmatism greater than 1.0 dpt or relevant coexisting ocular comorbidities such as age-related macular degeneration, diabetic retinopathy, uncontrolled glaucoma, pseudoexfoliation syndrome, zonular weakness, uveitis or amblyopia were excluded.

4.3. Preoperative measurements

Patients underwent slit-lamp examination with biomicroscopy in pupillary dilation and preoperative measurements including biometry (IOL Master 500 or 700, Carl Zeiss Meditec, Jena, Germany), keratometry and corneal topography (Keratograph 4/70670, Oculus, Wetzlar, Germany), pupillometry in photopic, mesopic and scotopic conditions (PupillX, Mediol, Unna, Germany), uncorrected distance visual acuity (UDVA), subjective and objective corrected distance visual acuity (CDVA), subjective and objective spherical equivalent (SER), and intraocular pressure (IOP).

4.4. Study groups

One hundred and twenty eyes (86 patients) were preoperatively randomly divided into two groups, receiving one-piece aspheric foldable hydrophilic acrylic IOLs with two different designs (Humanoptics, Erlangen, Germany) (Table 1, Figure 2).

Table 1. Characteristics of IOL designs in group 1 and 2.

IOL Model n eyes	Optic diameter [mm]	Total diameter [mm]	Haptic design	Refractive index	Material
Aspira-aXA (group 1, n=57)	7.0	11.0	Cut-out	1.46	hydrophilic acrylic
Aspira-aA (group 2, n=63)	6.0	12.5	C-loop	1.46	hydrophilic acrylic

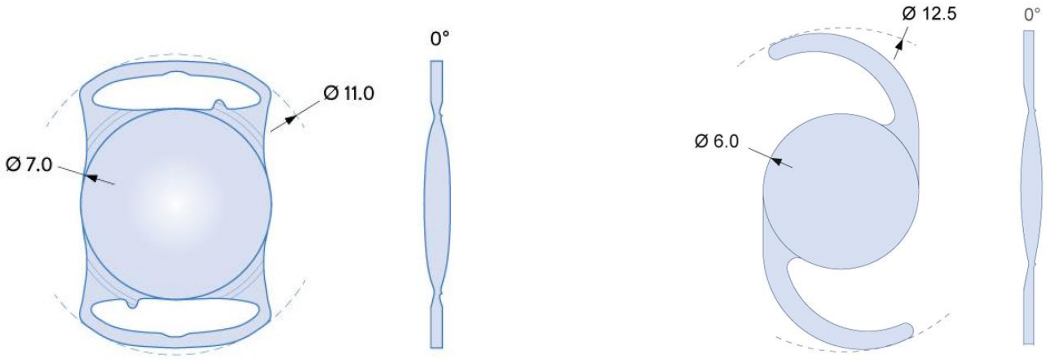

Figure 2. IOL design with the 7.0 mm optic diameter in group 1 (left) and IOL design with the 6.0 mm optic diameter in group 2 (right).

4.5. Cataract surgery

Cataract surgeries were performed under local topical anaesthesia using the standard phacoemulsification technique with computer assistance (Zeiss Callisto eye 3.6.1, Carl Zeiss Meditec, Jena, Germany). A clear corneal incision of 2.5 – 3.0 mm and a capsulorhexis of 6.5 mm and 5.5 mm for group 1 and 2, respectively, were carried out. The IOLs were implanted with the use of Multiject (Medicel AG, Altenrhein, Switzerland) or Accuject 2.2 (Medicel AG, Altenrhein, Switzerland) injectors for 6.0 mm and 7.0 mm optics, respectively. No intraoperative complications were reported. The surgeries were performed by two surgeons.

4.6. Follow-ups

Standard early postoperative examinations took place partly in the referring facilities. The study protocol included 3 follow-ups: 1, 3 and 12 months after the surgery, consisting of objective examinations and a questionnaire. Each examination included UCVA, subjective and objective CDVA, subjective and objective SER, IOP, slit-lamp examination in medical mydriasis to verify IOL centration and possible PCO, and keratometry with corneal topography.

4.6.1. Contrast sensitivity and mesopic vision with and without glare

In the month 3 and month 12 follow-ups, monocular contrast sensitivity (CS) (Functional Vision Analyzer, Stereo Optical, Chicago, USA) in photopic (85cd/m²) and mesopic (3cd/m²) conditions for 1.5, 3, 6, 12 and 18 cycles per degree (cpd) was measured in each case. Additionally, in the month 12 follow-up, mesopic vision and glare sensitivity were tested (Mesotest II, Oculus, Wetzlar, Germany).

4.6.2. Dysphotopsiae questionnaire

During each follow-up, participants were given a questionnaire (Figure 3) to evaluate their satisfaction with the surgery outcome on a scale from 1 to 10 points (1 being excellent and 10 being very poor), and the degree of spectacle dependence for distant, intermediate and near vision on a 4-degree scale, ranging from never (0), sometimes (1), often (2) to always (3).

Further questions referred to perception of PD in the form of glare sensitivity at day- or night-time and halos around light sources at day- or night-time. Regarding ND, a question about noticing a crescent formed shadow limiting the peripheral field of vision was asked. All answers could be located on a 4-degree scale regarding frequency (from never (0), sometimes (1), often (2) to always (3)) and extent (not at all (0), little (1), moderately (2) or strongly (3)) of complaints.

The answers were tabulated into numerical figures for statistical reasons. To exclude binocular perceptions, patients were instructed that each questionnaire concerned each particular examined eye.

QUESTIONNAIRE

Please answer the following questions so that we can assess your satisfaction level after the cataract surgery.

1. How satisfied are you with the general outcome of your vision after the surgery?
   Please grade on a scale from 1 to 10 points (1 = excellent; 10 = very poor):
   ____ Points

2. How often do you need glasses for:

	never	sometimes	often	always
distance vision (e.g. driving, watching TV)	◻	◻	◻	◻
near vision (e.g. reading, sewing)	◻	◻	◻	◻
intermediate vision (e.g. computer work, cooking)	◻	◻	◻	◻

3. Have you noticed any of these phenomena since your cataract surgery or the last examination?

	never	sometimes	often	always
increased glare sensitivity during the day	◻	◻	◻	◻
increased glare sensitivity during the night	◻	◻	◻	◻
light halos (circles) around sources of light during the day	◻	◻	◻	◻
light halos (circles) around sources of light during the night	◻	◻	◻	◻
half-moon-shaped shadows limiting your outer field of vision (sort of blinkers)	◻	◻	◻	◻

4. If you notice one of the phenomena above, how strongly do they disturb you?

	not at all	little	moderately	strongly
increased glare sensitivity during the day	◻	◻	◻	◻
increased glare sensitivity during the night	◻	◻	◻	◻
light halos (circles) around sources of light during the day	◻	◻	◻	◻
light halos (circles) around sources of light during the night	◻	◻	◻	◻
half-moon-shaped shadows limiting your outer field of vision (sort of blinkers)	◻	◻	◻	◻

Figure 3. Questionnaire assessing general patient satisfaction, spectacle dependence, and frequency and extent of positive and negative dysphotopsiae.

4.7. Data and statistical analysis

The sample size calculation was conducted with the G*Power program (3.1.9.4. for Windows, Heinrich Heine University Düsseldorf, Düsseldorf, Germany) with the following input parameters: power = 0.8, alpha = 0.05, effect size d = 0.5, two tailed (Figure 4).

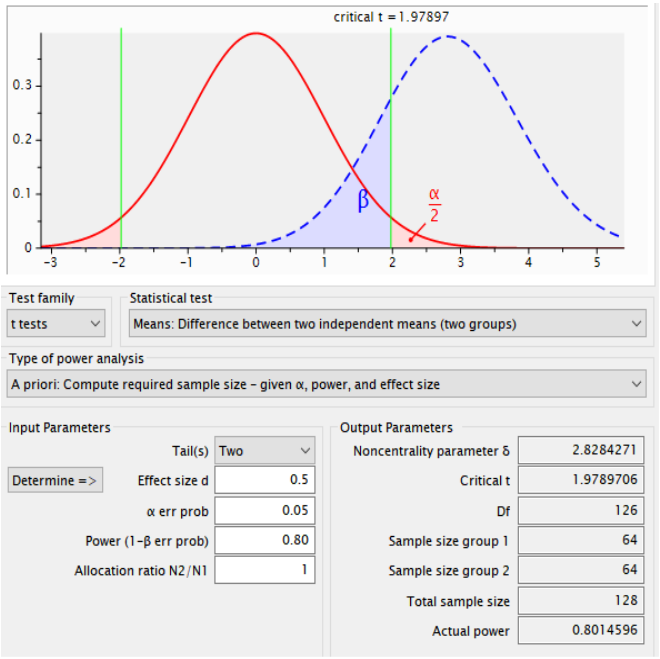

Figure 4. Sample size calculation.

The data were collected in Excel (Microsoft Excel 2013, Microsoft Office 2013) and exported to IBM SPSS Statistics 25.0 (IBM, Ehningen, Germany) for statistical analysis.

Though binocular implantations were allowed in the study protocol, the prerequisite for independent samples of each eye for statistical analysis was set.

The anatomical data and visual acuity were analysed as normally distributed and metric values, the CS values as metric and not normally distributed, and the questionnaire answers on the point scale from 0 to 3 or to 10 as nominal or ordinal and not normally distributed.

The preoperative data were analysed with the Chi-Square test and t-test for independent samples for ordinal or nominal and metric values, respectively.

Postoperatively, questionnaire answers were analysed with Chi-square test as nominal and with the Mann-Whitney U test as ordinal values between the groups as well as with the Wilcoxon test for comparisons within each group between follow-ups. When no difference in medians for ordinal values occurred, means with standard deviation were displayed to support the detected statistical significance.

The postoperative metric data were compared with t-tests for independent or dependent samples and ANOVA for repeated measurements, and the ordinal data were compared with Chi-square tests. In the case of multiple comparisons within or between the groups, the Bonferroni correction was used for adjustment of p-values.

5. RESULTS

5.1. Preoperative demographic and anatomical data

A total of 120 eyes of 86 patients were recruited for the study. Group 1, with the 7.0 mm optic, comprised 57 eyes of 43 participants, and group 2, with the 6.0 mm optic, comprised 63 eyes of 43 participants. Three patients from group 1 and 1 patient from group 2 dropped out of the study.

There was no difference between the groups regarding distribution of sex and eye laterality, AL, pupil size in photo-, scoto- and mesopic conditions, white to white distance (WTW), ACD (measured with IOL Master), lens thickness (LT), central corneal thickness (CCT), IOP or calculated IOL Power. Pupil dynamics were assessed as a difference between pupil diameters in scotopic and photopic conditions preoperatively, revealing no significant difference between the groups (Table 2).

Table 2. Demographic and preoperative anatomical data in group 1 and 2. Number of eyes with percentages (in brackets) and mean values with standard deviation given. No statistical differences found between both groups (p>.05).

Characteristic	Group 1	Group 2	p-value
n eyes (patients)	57 (43)	63 (43)	
n females (%)	30 (52.6)	38 (60.3)	0.396
n left eyes (%)	24 (42.1)	36 (57.1)	0.100
age [y]	68.26 ± 6.8	68.57 ± 6.3	0.798
AL [mm]	23.17 ± 0.74	23.34 ± 0.84	0.244
photopic pupil [mm]	3.92 ± 0.67	4.21 ± 0.92	0.058
mesopic pupil [mm]	4.72 ± 0.80	4.91 ± 0.90	0.213
scotopic pupil [mm]	5.18 ± 0.86	5.37 ± 0.94	0.250
pupil dynamics [mm]	1.26 ± 0.64	1.17 ± 0.56	0.458
WTW [mm]	11.85 ± 0.36	11.91 ± 0.41	0.406
ACD [mm]	3.12 ± 0.41	3.09 ± 0.35	0.677
LT [mm]	4.54 ± 0.39	4.48 ± 0.36	0.404
CCT [µm]	554 ± 32	561 ± 40	0.326
IOP [mmHg]	17.3 ± 2.4	16.9 ± 2.9	0.398
IOL Power [dpt]	22.97 ± 2.22	22.71 ± 2.16	0.505

AL – axial length, WTW – white to white, ACD – anterior chamber depth, LT – lens thickness, CCT – central corneal thickness, IOP – intraocular pressure, IOL – intraocular lens.

The distribution of photopic pupils ≤ 3.0 mm was the same in both groups: 6 cases (10.5%) in group 1 and 7 cases (11.5%) in group 2 (p = 0.869). Scotopic pupils ≥ 5.5 mm were found in 21 cases (36.8%) in group 1 and in 31 cases (50.0%) in group 2 (p = 0.148). A WTW of at least 11.8 mm was in 35 eyes (61.4%) in group 1 and in 40 eyes (63.5%) in group 2 (p = 0.813). Three cases (5.3%) in group 1 and 3 cases (4.8%) in group 2 had an ACD flatter than 2.5 mm (p = 0.900).

From preoperative measurements, the corneal radii measured with IOL Master and keratometry were significantly larger in group 2. The flat, steep, mean and the steepest keratometric values were significantly larger in group 1 (Table 3).

Table 3. Preoperative values of corneal radii measured with IOL Master and keratometry in group 1 and 2. Mean values given in millimetres [mm] with standard deviation.

	IOL Master			**Keratometry**						
Group	**R**	**R1**	**R2**	**Rh**	**Rv**	**Rm**	**K1**	**K2**	**Km**	**Kmax**
1	7.69 ±0.21	7.75 ±0.21	7.65 ±0.22	7.71 ±0.21	7.71 ±0.24	7.71 ±0.22	43.85 ±1.19	43.87 ±1.34	43.83 ±1.28	43.8 ±1.32
2	7.80 ±0.27	7.85 ±0.28	7.76 ±0.27	7.84 ±0.27	7.81 ±0.27	7.82 ±0.27	43.10 ±1.50	43.32 ±1.51	43.19 ±1.49	44.14 ±1.49
p-value	0.019	0.027	0.012	0.005	0.032	0.015	0.004	0.037	0.014	0.010

IOL – intraocular lens, IOL Master: R – mean corneal radius, R1 – horizontal corneal radius, R2 – vertical corneal radius, Keratometry: Rh – horizontal corneal radius, Rv – vertical corneal radius, Rm – mean corneal radius, K1 – flat keratometric value, K2 – steep keratometric value, Km – mean keratometric value, Kmax – steepest keratometric value.

5.2. Visual acuity, refraction and spectacles

Preoperative UDVA and subjective CDVA were the same in both groups, whereas the preoperative subjective spherical equivalent (SER) was significantly larger in group 2 compared to group 1 (p = 0.001).

Postoperatively, the UDVA in the month 1 follow up was greater in group 1 compared to group 2 (p = 0.021 after the Bonferroni correction). The subjective cylinder power measured in the first follow-up was, however, of no difference between the groups (group 1 mean -0.40 ± 0.35 dpt, group 2 mean -0.44 ± 0.37 dpt, p = 0.506).

No other differences between the groups in further follow-ups were measured. For the calculation of postoperative UDVA and SER, one eye from group 1 with myopic target refraction was excluded (Table 4).

Table 4. Pre- and postoperative monocular uncorrected and subjective corrected distance visual acuity (logMAR) and subjective spherical equivalent in group 1 and 2 in all three follow-ups. Mean values with standard deviation given. Statistically significant differences marked with asterisks.

	Group 1			Group 2		
	UDVA	**CDVA**	**SER [dpt]**	**UDVA**	**CDVA**	**SER [dpt]**
Preop.	0.54±0.33	0.28±0.22	-0.14±2.12*	0.57±0.25	0.24±0.20	+1.01±1.71*****
Month 1	0.08±0.08**	-0.05±0.12	-0.14±0.47	0.13±0.14**	-0.02±0.14	-0.07±0.41
Month 3	0.10±0.13	-0.06±0.08	-0.06±0.39	0.10±0.13	-0.04±0.08	+0.01±0.43
Month 12	0.10±0.15	-0.07±0.08	-0.01±0.42	0.09±0.14	-0.06±0.09	+0.06±0.40

UDVA – uncorrected distance visual acuity, CDVA – corrected distance visual acuity, SER – subjective spherical equivalent refraction, Preop. – preoperative, *p=0.001, **p=0.021.

Comparing the values between particular follow-ups within a given group, significant differences were observed in group 2: the UDVA and SER increased from month 1 to month 12 (p = 0.027 and 0.042, respectively, ANOVA with repeated measures after the Bonferroni correction). Within group 1, no significant changes regarding UDVA, CDVA or SER were measured (p = 0.238, 0.543 and 0.056, respectively, ANOVA with repeated measures after the Bonferroni correction).

Analysing the subjective monocular spectacle dependence, the need for reading glasses in group 1 was lower compared to group 2, reaching significant levels in the month 12 follow-up (Table 5). Regarding far and intermediate distances, there was no difference in spectacle dependence between the groups.

Table 5. Near vision monocular spectacle dependence in group 1 and 2 in all 3 follow-ups. Mean values with standard deviation and medians (in brackets) based on the answer scale from 0 to 3 points from the questionnaire given. Significant p-values (after the Bonferroni correction) marked with an asterisk.

Follow-up	**Group 1**	**Group 2**	**p-value**
Month 1	2.2 ± 1.07 (3.00)	2.63 ± 0.65 (3.00)	0.078
Month 3	2.14 ± 1.10 (3.00)	2.52 ± 0.89 (3.00)	0.090
Month 12	2.11 ± 1.06 (3.00)	2.56 ± 0.78 (3.00)	0.048*

5.3. Negative dysphotopsiae

One month after the surgery, there were 3 cases (5.4%) of ND in group 1 and 13 cases (20.6%) in group 2 (p = 0.015). Three months postoperatively, 2 eyes (3.6%) from group 1 and 8 eyes (12.7%) from group 2 still had ND, showing a 3.5-fold reduction in ND in group 1 compared to group 2, however, without statistical significance (p = 0.073). In the last month 12 follow-up, there were no cases of ND in group 1 and 2 cases (3.2%) in group 2 (p = 0.183), both of which were described as totally undisturbing (Figure 5).

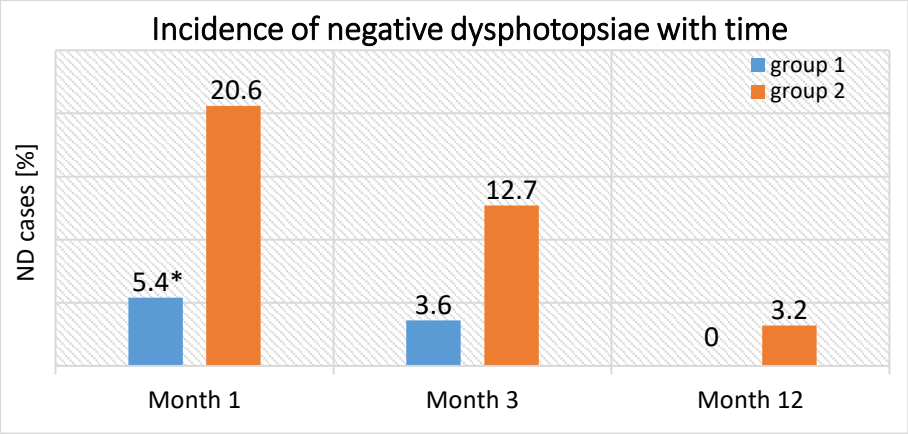

Figure 5. General incidence of negative dysphotopsiae in group 1 and 2 in all 3 follow-ups. Significant reduction in negative dysphotopsiae in group 1 compared to group 2 measured during the first examination (p<.05) marked with an asterisk. Values in percent.

Out of all the cases with ND in the month 1 follow-up, in group 1 two cases (66.7%) were reported as “sometimes” and 1 case (33.3%) as “always.” In group 2, nine cases (69.2%) were reported as “sometimes,” 2 cases (15.45) as “often” and 2 cases (15.4%) as “always” (Figure 6).

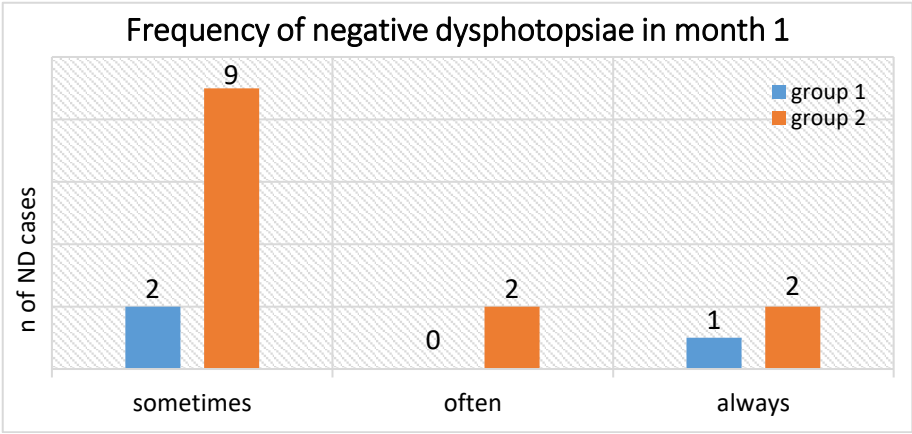

Figure 6. Frequency of negative dysphotopsiae in group 1 and 2 in month 1 follow-up. No significant p-value reached. Number of cases given.

Regarding the extent of ND in all the cases in month 1 follow-up, in group 1 one case (33.3%) was reported as “not at all,” 1 case (33.3%) as “little,” and 1 case (33.3%) as “moderately” disturbing. In group 2, four cases (30.8%) were reported as “not at all,” 6 cases (46.2%) as “little,” and 3 cases (23.1%) as “moderately” disturbing. Neither group had “strongly” disturbing ND cases (Figure 7).

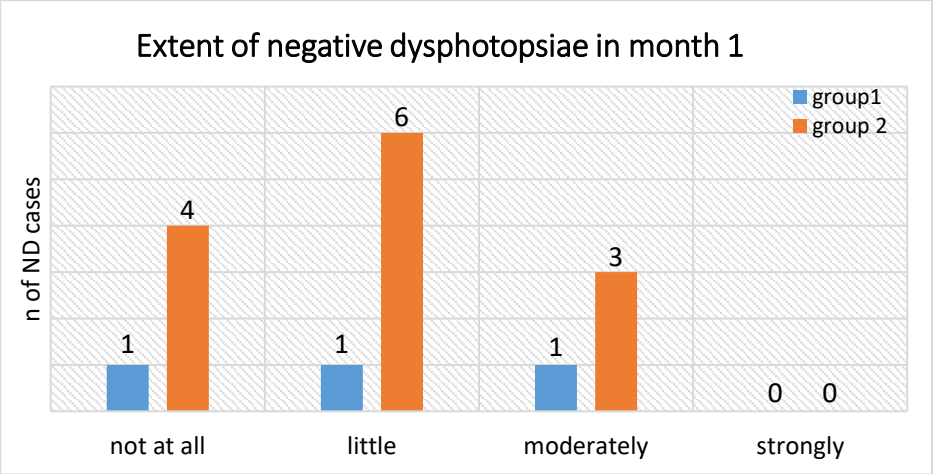

Figure 7. Extent of negative dysphotopsiae in group 1 and 2 in month 1 follow-up. No significant p-value reached. Number of cases given.

5.4. Positive dysphotopsiae

Analysing daytime and night-time glare and halos together as general PD, a significantly lower incidence was measured during month 1 follow-up in group 1 (18 cases (31.6%)) compared to group 2 (33 cases (52.4%)) ($p = 0.021$). In month 3 follow-up, PD were found in 14 eyes (24.6%) in group 1 and in 24 eyes (38.1%) in group 2 ($p = 0.111$). In month 12, PD were present in 5 cases (9.3%) in group 1 and in 14 cases (22.6%) in group 2, showing a 2.4-fold reduction in PD in group 1 compared to group 2 ($p = 0.053$) (Figure 8).

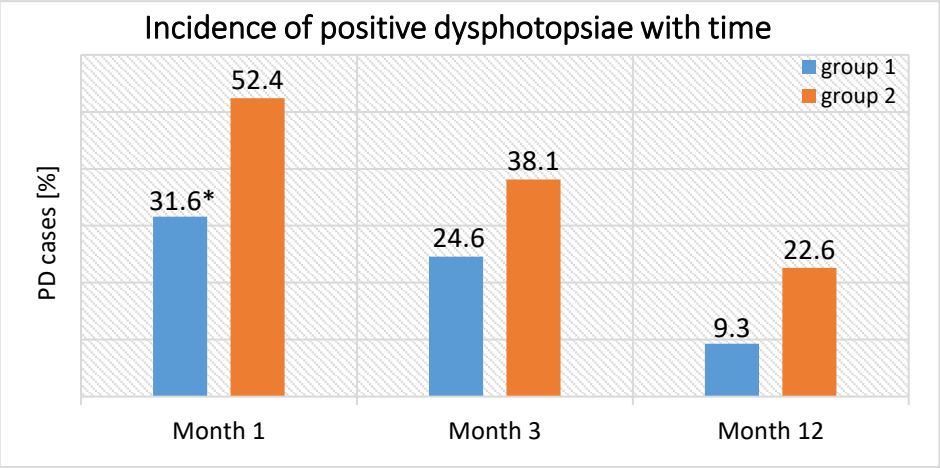

Figure 8. General incidence of positive dysphotopsiae in group 1 and 2 in all 3 follow-ups. Significant reduction in positive dysphotopsiae in group 1 compared to group 2 measured during the first examination ($p<.05$) marked with an asterisk. Values in percent.

Regarding the distribution of frequency of general PD in month 1 follow-up, out of a total 18 cases in group 1, sixteen cases (88.9%) were reported as "sometimes," 2 cases (11.1%) as "often," and none as "always" disturbing. In group 2, fifteen cases (45.5%) out of 33 were reported as "sometimes," 8 cases (24.4%) as "often," and 10 cases (30.3%) as "always" (Figure 9).

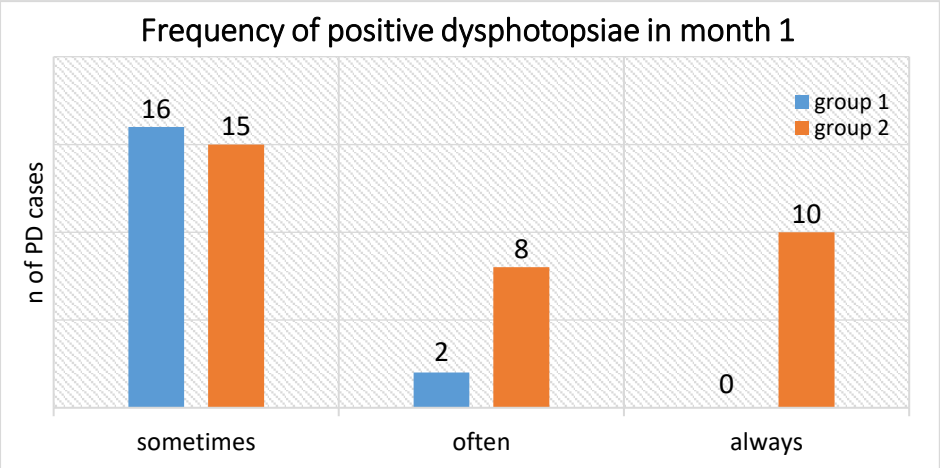

Figure 9. Frequency of general positive dyspotopsiae in group 1 and 2 in month 1 follow-up. No significant p-value reached. Number of cases given.

Out of all the cases reporting PD in month 1 follow-up, 3 (16.7%) from group 1 and 6 (18.2%) from group 2 were reported as “not at all” disturbing. Thirteen cases (72.2%) from group 1 and 10 cases (30.3%) from group 2 described PD as “little,” 1 case (5.6%) from group 1 and 12 cases (36.4%) from group 2 as “moderately,” and 1 case (5.6%) from group 1 and 5 cases (15.2%) from group 2 as “strongly” disturbing (Figure 10).

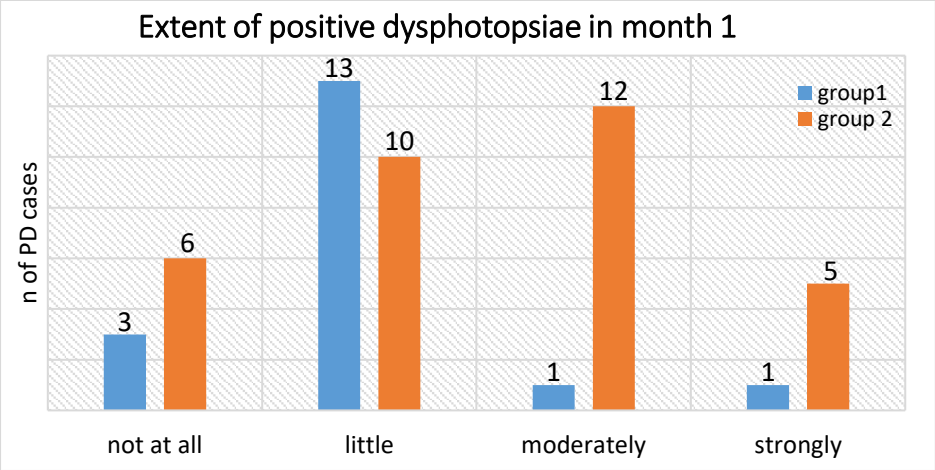

Figure 10. Extent of general positive dyspotopsiae in group 1 and 2 in month 1 follow-up. No significant p-value reached. Number of cases given.

The incidence of each PD type from the questionnaire was lower in group 1 compared with group 2, with exception of daytime halo in month 12 follow-up (presenting 1 case in each group), however, reaching no significant levels of differences. Daytime glare was the most common type of dysphotopsiae reported throughout the study in both groups (Table 6).

Table 6. Incidence of particular positive dysphotopsiae from the questionnaire in group 1 and 2 in all 3 follow-ups. Values given in number of cases and percent (in brackets). No significant p-value reached.

Dysphotopsiae		Follow-up					
		Month 1		Month 3		Month 12	
		Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
glare	day	14 (25.0)	22 (34.9)	13 (23.2)	20 (31.7)	5 (9.3)	10 (16.1)
	night	6 (10.7)	14 (22.2)	6 (10.7)	10 (15.9)	0 (0)	2 (3.2)
halo	day	3 (5.4)	9 (14.3)	2 (3.6)	6 (9.5)	1 (1.9)	1 (1.6)
	night	4 (7.1)	10 (15.9)	5 (9.1)	9 (14.3)	3 (5.6)	5 (8.1)

Comparing the results of each question about PD and ND separately between the groups, the frequency and extent values for each type of dysphotopsiae were lower or the same in group 1

compared to group 2 (with the exception of the extent of night-time halo in month 12 follow-up), with significant p-values reached for the frequency of ND in month 1 follow-up (p = 0.048 after the Bonferroni correction) (Tables 7 and 8).

Table 7. Frequency of positive and negative dysphotopsiae in group 1 and 2 in all 3 follow-ups. Mean values with standard deviation based on the answer scale from 0 to 3 points (never (0), sometimes (1), often (2), always (3)) from the questionnaire given. All median values = 0.00. Significant p-value (after the Bonferroni correction) for comparison between the groups within particular follow-up marked with an asterisk.

Dysphotopsiae		Follow-up					
		Month 1		Month 3		Month 12	
		Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
glare	day	0.29 ± 0.53	0.60 ± 0.94	0.25 ± 0.48	0.54 ± 0.93	0.15 ± 0.53	0.19 ± 0.51
	night	0.13 ±0.38	0.25 ± 0.51	0.13 ± 0.38	0.25 ± 0.67	0.00 ± 0.00	0.05 ± 0.28
halo	day	0.05 ± 0.23	0.32 ± 0.86	0.04 ± 0.19	0.11 ± 0.36	0.02 ± 0.14	0.02 ± 0.13
	night	0.07 ± 0.26	0.30 ± 0.80	0.09 ± 0.29	0.22 ± 0.63	0.06 ± 0.23	0.08 ± 0.27
ND		0.09 ± 0.44*	0.30 ± 0.69*	0.07 ± 0.42	0.21 ± 0.63	0.00 ± 0.00	0.03 ± 0.18

ND – negative dysphotopsiae, *p=0.048.

Table 8. Extent of positive and negative dysphotopsiae in group 1 and 2 in all 3 follow-ups. Mean values with standard deviation based on the answer scale from 0 to 3 points (not at all (0), little (1), moderately (2) or strongly (3)) from the questionnaire given. All median values = 0.00. No significant p-value for comparison between the groups within particular follow-up reached.

Dysphotopsiae		Follow-up					
		Month 1		Month 3		Month 12	
		Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
glare	day	0.27 ± 0.59	0.65 ± 0.99	0.23 ± 0.47	0.47 ± 0.82	0.09 ± 0.45	0.16 ± 0.41
	night	0.14 ± 0.48	0.19 ± 0.50	0.13 ± 0.38	0.24 ± 0.64	0.00 ± 0.00	0.03 ± 0.18
halo	day	0.02 ± 0.13	0.14 ± 0.50	0.02 ± 0.13	0.06 ± 0.31	0.00 ± 0.00	0.02 ± 0.13
	night	0.05 ± 0.23	0.16 ± 0.52	0.05 ± 0.23	0.16 ± 0.52	0.04 ± 0.27	0.00 ± 0.00
ND		0.05 ± 0.30	0.19 ± 0.50	0.04 ± 0.27	0.08 ± 0.28	0.00 ± 0.00	0.00 ± 0.10

ND – negative dysphotopsiae.

Within group 1, no significant changes in the frequency or extent of dysphotopsiae were measured between month 1 and month 12 follow-ups. Within group 2, the frequencies of daytime and night-time glare as well as daytime halo significantly lowered during the study (p-values after the

Bonferroni correction = 0.006, 0.027 and 0.039, respectively) (Table 7). The same observation was made within group 2 for the extent of day- and night-time glare, night-time halo and ND (p-values after Bonferroni correction = 0.003, 0.039, 0.042 and 0.018, respectively) (Table 8).

5.5. Contrast sensitivity

The mean CS calculated for all five spatial frequencies (1.5 to 18 cpd) was the same in both groups 3 and 12 months after the surgery, in all four light conditions (Table 9).

Table 9. Mean monocular CS in group 1 and 2 in month 3 and 12 follow-ups. Logarithmic values with p-values given.

Contrast sensitivity		Follow-up					
		Month 3			Month 12		
		Group 1	Group 2	p-value	Group 1	Group 2	p-value
photopic	without glare	1.57	1.48	0.202	1.49	1.57	0.271
	with glare	1.61	1.55	0.351	1.58	1.61	0.760
mesopic	without glare	1.50	1.51	0.911	1.48	1.53	0.433
	with glare	1.48	1.51	0.632	1.46	1.55	0.084

Three months postoperatively, the photopic CS with and without glare was the same for all measured spatial frequencies in both groups. At the same time point in mesopic conditions, CS without glare for 3 cpd and with glare for 6 cpd was higher in group 2 (p = 0.035 and 0.012, respectively).

Statistically significant differences in CS in month 12 follow-up between the groups for all light conditions and spatial frequencies are depicted in Figure 11.

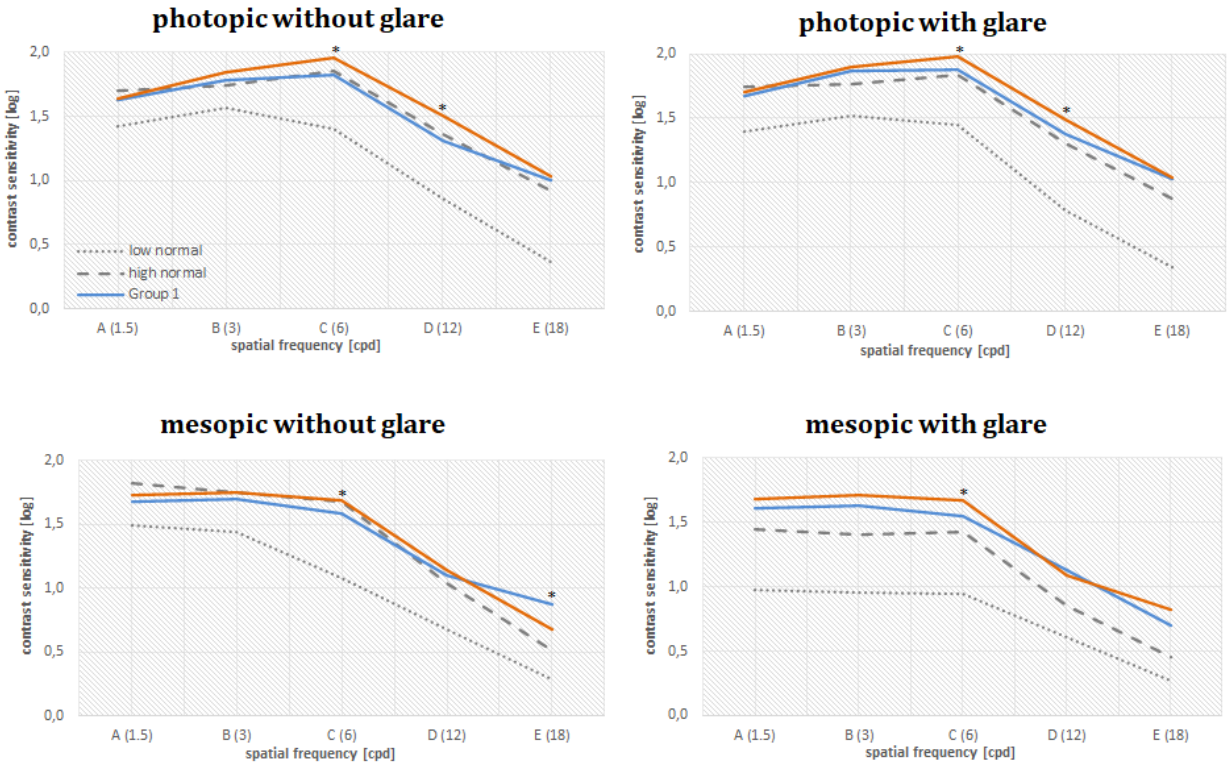

Figure 11. Monocular contrast sensitivity (CS) in group 1 and 2 in photopic and mesopic conditions, with and without glare, measured at month 12 follow-up. Scores given in logarithmic values. Norm values for age >60 years from: Hohberger et al. (40). Legend for all graphs on the left top side. Significant differences in CS for particular spatial frequencies in particular light conditions marked with asterisks.

5.6. Mesotest

The mesopic vision and glare sensitivity were tested in 35 eyes from group 1 and in 50 eyes from group 2 at month 12 follow-up. No statistically significant differences between both groups were observed: 16 cases (45.7%) in group 1 and 26 cases (54.2%) in group 2 showed maximal values ($p = 0.770$). The maximal glare sensitivity was reached in 4 eyes (11.4%) in group 1 and in 8 eyes (16%) in group 2 ($p = 0.649$).

5.7. Positive dysphotopsiae and contrast sensitivity

No influence of PD on CS values in all light conditions and spatial frequencies in month 3 follow-up was observed, irrespective of the IOL design.

In month 12 follow-up, patients with PD revealed lower photopic CS without glare for 1.5 and 3 cpd ($p = 0.005$ and 0.036, respectively), and lower photopic CS with glare for 3 cpd ($p = 0.047$). In mesopic conditions with glare, patients with PD showed higher values for 18 cpd ($p = 0.013$).

5.8. Preoperative anatomical factors and incidence of dysphotopsiae

5.8.1. Persistent negative dysphotopsiae

Irrespective of the IOL design, cases with persistent ND in the last follow-up revealed a significantly younger age compared to those without ND. No significant differences were detected in preoperatively measured AL, photo-, meso- and scotopic pupil size, pupil dynamics, distribution of scotopic pupils ≥ 5.5 mm and photopic pupils ≤ 3.0 mm, WTW, ACD, IOL power, corneal radii, Km, Kmax and pre- and postoperative CDVA (in month 12) (Table 10).

Table 10. Comparison of preoperative data and postoperative subjective CDVA between cases with and without persistent ND in month 12 follow-up. Mean values with standard deviation or number of cases with percent (in brackets) given. Visual acuity in logarithmic values [logMAR]. Significant p-value marked with an asterisk.

	ND cases		**p-value**
	Yes	**No**	
Age [y]	59.00 ± 5.66	68.82 ± 6.25	0.029*
AL [mm]	22.79 ± 0.14	23.27 ± 0,81	0.402
scotopic pupil [mm]	5.80 ± 0.25	5.26 ± 0.91	0.409
mesopic pupil [mm]	5.00 ± 0.14	4.81 ± 0.87	0.759
photopic pupil [mm]	4.00 ± 0.14	4.07 ± 0.83	0.908
pupil dynamics [mm]	1.80 ± 0.42	1.20 ± 0.59	0.155
scotopic pupil ≥ 5.5 mm	2 cases (100%)	48 cases (42.5%)	0.187
photopic pupil ≤ 3.0 mm	0 cases (0%)	13 cases (11.6%)	0.784
WTW [mm]	11.89 ± 0.11	11.89 ± 0.39	0.997
ACD [mm]	3.01 ± 0.03	3.10 ± 0.38	0.736
IOL Power [dpt]	23.25 ± 1.77	22.80 ± 2.20	0.776
R [mm]	7.65 ± 0.31	7.76 ± 0.25	0.554
R1 [mm]	7.70 ± 0.28	7.81 ± 0.26	0.547
R2 [mm]	7.60 ± 0.34	7.71 ± 0.25	0.549
Km [mm]	44.15 ± 1.77	43.48 ± 1.43	0.513
Kmax [mm]	45.00 ± 2.12	44.43 ± 1.46	0.585
CDVA preop.	0.25 ± 0.19	0.10 ± 0.14	0.257
CDVA postop.	-0.09 ± 0.13	-0.06 ± 0.08	0.673

ND – negative dysphotopsiae, AL – axial length, WTW – white to white, ACD – anterior chamber depth, IOL – intraocular lens, R – mean corneal radius, R1 – horizontal corneal radius, R2 – vertical corneal radius, Km – mean keratometric value, Kmax – steepest keratometric value, CDVA – corrected distance visual acuity.

5.8.2. Persistent positive dysphotopsiae

Between cases with and without persistent PD in month 12 follow-up, irrespective of the IOL design, significant differences in AL and pupil dynamics were found (Table 11).

Table 11. Comparison of preoperative data and postoperative CDVA between cases with and without persistent PD in month 12 follow-up. Mean values with standard deviation or number of cases with percent (in brackets) given. Visual acuity in logarithmic values [logMAR]. Significant p-values marked with asterisks.

	PD cases		p-value
	Yes	No	
Age [y]	67.79 ± 5.77	68.82 ± 6.48	0.518
AL [mm]	23.61 ± 0.90	23.20 ± 0.77	0.040*
scotopic pupil [mm]	5.62 ± 0.99	5.20 ± 0.88	0.070
mesopic pupil [mm]	5.04 ± 0.91	4.77 ± 0.86	0.206
photopic pupil [mm]	4.07 ± 0.66	4.07 ± 0.86	0.996
pupil dynamics [mm]	1.55 ± 0.69	1.14 ± 0.55	0.006*
scotopic pupil ≥ 5.5 mm	8 cases (44.4%)	42 cases (43.3%)	0.928
photopic pupil ≤ 3.0 mm	2 cases (11.1%)	11 cases (11.5%)	0.644
WTW [mm]	12.00 ± 0.31	11.87 ± 0.40	0.518
ACD [mm]	3.14 ± 0.32	3.09 ± 0.39	0.609
IOL Power [dpt]	22.08 ± 2.18	22.94 ± 2.17	0.126
R [mm]	7.84 ± 0.28	7.74 ± 0.25	0.112
R1 [mm]	7.89 ± 0.28	7.79 ± 0.25	0.114
R2 [mm]	7.79 ± 0.28	7.69 ± 0.25	0.108
Km [mm]	43.57 ± 1.39	43.07 ± 1.61	0.161
Kmax [mm]	43.87 ± 1.60	44.57 ± 1.41	0.058
CDVA preop.	0.26 ± 0.16	0.25 ± 0.19	0.906
CDVA postop.	-0.08 ± 0.07	-0.06 ± 0.08	0.367

PD – positive dysphotopsiae, AL – axial length, WTW – white to white, ACD – anterior chamber depth, IOL – intraocular lens, R – mean corneal radius, R1 – horizontal corneal radius, R2 – vertical corneal radius, Km – mean keratometric value, Kmax – steepest keratometric value, CDVA – corrected distance visual acuity.

5.9. Intraocular pressure

In both groups, the IOP significantly decreased from preoperative to month 1 follow-up ($p < 0.001$ in both groups) and further from month 1 to month 3 ($p = 0.026$ in group 1, and $p = 0.024$ in group 2). There was no statistically significant difference in the IOP between month 3 and 12 follow-up (Figure 12). No significant difference in IOP values between the groups pre- and postoperative in all 3 follow-ups was measured (Table 12). The IOP course throughout the study had no difference between the groups ($p = 0.700$, ANOVA for repeated measures with Greenhouse-Geisser adjustment for sphericity and after the Bonferroni correction).

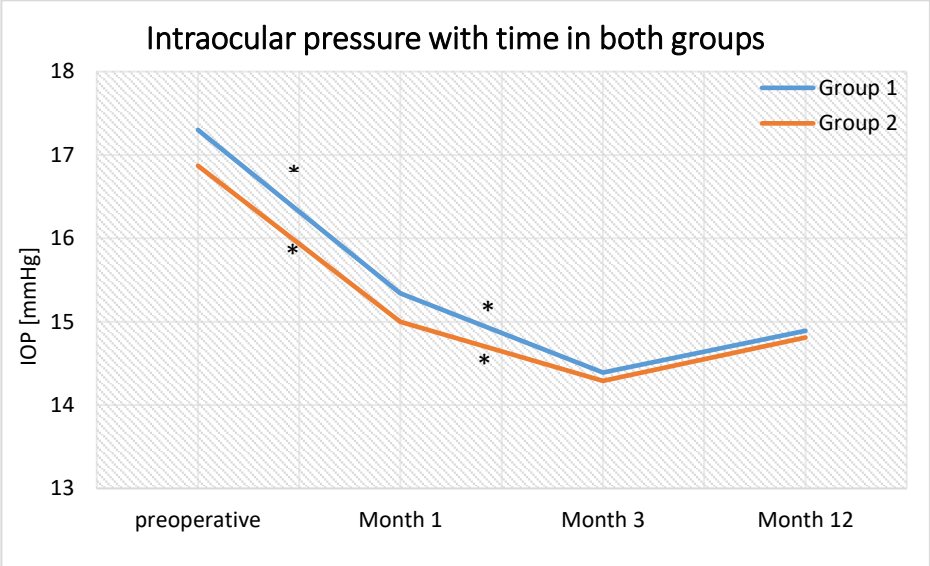

Figure 12. Changes in intraocular pressure in group 1 and 2 in all 3 follow-ups. Significant p-values marked with asterisks.

Table 12. Pre- and postoperative intraocular pressure in group 1 and 2 in all 3 follow-ups. No significant differences between groups measured. Values in [mmHg].

Follow-up	Group 1	Group 2	p-value
Preoperative	17.30 ± 2.45	16.87 ± 2.98	0.398
Month 1	15.34 ± 2.68	15.00 ± 2.85	0.507
Month 3	14.39 ± 2.76	14.29 ± 2.52	0.825
Month 12	14.89 ± 2.79	14.81 ± 3.79	0.900

5.10. Patient satisfaction

The degree of general patient satisfaction showed lower numbers (meaning higher satisfaction) in group 1 compared to group 2, reaching a statistically significant difference in month 3 follow-up (Table 13). Within each group, the satisfaction levels remained unchanged throughout the study.

Table 13. General satisfaction level of patients in group 1 and 2 in all 3 follow-ups. Median with mean values and standard deviation (in brackets) based on the answer scale from 0 to 10 points (1 being excellent and 10 being very poor) from the questionnaire given. Significant p-values (after the Bonferroni correction) for comparison between the groups within particular follow-up marked with an asterisk.

Follow-up	Group 1	Group 2	p-value
Month 1	1.00 (1.70 ± 1.29)	2.00 (2.21 ± 1.66)	0.156
Month 3	1.00 (1.57 ± 1.11)	2.00 (2.44 ± 2.06)	0.006*
Month 12	1.00 (1.54 ± 0.93)	2.00 (2.08 ± 1.39)	0.06

6. DISCUSSION

6.1. Reduction of dysphotopsiae and neuroadaptation

The findings of this study suggest that the IOL design with an enlarged 7.0 mm optic diameter reduces PD and ND. These findings are similar to those available in the literature referring to approaches reducing ND up to 4 weeks postoperatively (38, 41).

To conclude clinically, the incidence, frequency and partial extent of dysphotopsiae were lower throughout the whole study in group 1; however, they reached statistically significant values between the groups only in month 1 follow-up. Moreover, the process of neuroadaptation had a larger impact on the group with the 6.0 mm optic IOL design. The obtained data suggest that the IOL design with a larger optic reduces dysphotopsiae from the early postoperative course prior to slower, and in this context minor, neuroadaptation. Possibly because of the preventive IOL effect, the disturbance with dysphotopsiae in this group was lower; thus, there was also less need for slower neuroadaptation.

6.2. Incidence of dysphotopsiae

The data from this study confirm the general incidence of ND (13) and early PD (3) reported in the literature. Regarding the incidence of persisting PD, however, higher numbers were found.

In both groups in month 12 follow-up there were cases of PD, but of no degree of disturbance (2 out of 5 cases in group 1, and 3 out of 14 cases in group 2), which, if excluded, would decrease the general PD incidence. Additionally, it could be concluded that when asked the same questions about dysphotopsiae throughout the study, patients became more sensitized to the symptoms and gave more positive answers. Also, the known discrepancy between self-declared and enquired dysphotopsiae (21) might have affected our results.

Out of all the photic phenomena analysed, the most common, intense and persistent in both groups was glare in the daytime, with a 2.7-fold reduction in group 1 and a 2.2-fold reduction in group 2 within a year. This could be due to reaccustomizing to normal light conditions after years of cataract development and general higher activity of patients during the day rather than at night, together with stronger light sources present in the daytime comparing to night-time, which could trigger dysphotopsiae.

6.3. Dysphotopsiae risk factors

The comparison of preoperative anatomical data revealed some significant differences which could serve as predictive factors for dysphotopsiae.

In the first place, patients with persistent ND symptoms were of a younger age. These data confirm the findings of Makhotkina (21) and could be explained by younger patients' higher degree of awareness of dysphotopic symptoms, and their criticisms and expectations.

Makhotkina also reported higher postoperative CDVA, higher IOL power, shorter AL and smaller WTW as significant risk factors for ND (21, 42). The numbers in this study are in agreement with these findings, without reaching statistical significance, however. Finally, the same observations regarding larger scotopic and smaller photopic pupils, as well as flatter ACD in persistent ND cases were made both by Makhotkina (42) and in our study; however, they were of no statistical significance.

Our data also demonstrated significantly longer AL and greater pupil dynamics among cases with persistent PD. To our knowledge, this is the first report showing a statistically significant difference in pupil dynamics and AL in cases with and without PD as possible predictive factors for PD.

The tendency for larger pupils and a younger age among PD cases already described in the literature (3, 11) was confirmed here, but without reaching significant levels. Moreover, cases with persistent PD in our study revealed a predisposition for greater WTW, deeper ACD and lower IOL power, which was of no statistical significance, however.

6.4. Visual performance

6.4.1. Visual acuity and spherical equivalent

The IOL design with a 7.0 mm optic seems to enable quicker stabilization of the final visual acuity and refraction. However, it is not to be excluded that the higher UDVA in the first follow-up had an impact on the lower incidence of dysphotopsiae, which might be a limitation of this study.

In the group with the 7.0 mm IOL design, SER remained slightly more myopic compared to the group with the 6.0 mm IOL design, which might be confirmed by a significantly lower subjective need for reading glasses among these cases in the last examination. This could also contribute to the higher degree of satisfaction in this group.

6.4.2. Contrast sensitivity

The IOL design does not seem to have an effect on the mean CS, mesopic vision or glare sensitivity. The peak CS occurring between 3 and 6 cpd as a possible predictive factor for everyday functioning (43) was higher in the cases with the IOL design with the 6.0 mm optic. Nevertheless, the IOL design with a 7.0 mm optic reached very good CS values, comparable with high norms for the age group from this study, and the general level of satisfaction was higher than that in the 6.0 mm optic group (reaching significant levels in month 3 follow-up), which might indicate that freedom from dysphotopsiae is subjectively more important for the patient than the highest CS results.

6.4.3. Dysphotopsiae and contrast sensitivity

Our data suggest that PD have a negative impact on photopic CS. Moreover, glare symptoms showed a stronger tendency in daytime conditions, whereas halos seemed to be more bothersome at night-time. Altogether, it may be concluded that glare has a larger impact on CS than halos.

6.5. Intraocular pressure

The IOL design and optic size does not seem to have an influence on the intraocular pressure. IOP values in each examination and its general course in time were of no difference between both groups throughout the whole study. Moreover, the IOL design with a 7.0 mm optic has a smaller total diameter than the design with a 6.0 mm optic.

The postoperative decrease in IOP after cataract surgery is generally known and was confirmed in this study. A further decrease in IOP from month 1 to month 3 follow-up might be due to the discontinuation of postoperative treatment with local topical agents that include steroids.

6.6. Concept of an enlarged IOL optic

The idea of an enlarged optic as a solution against dysphotopsiae has been discussed since its first reports in the literature.

Tester (44) hypothesized that it would reduce PD, but reached no statistical significance in the results regarding the comparison of IOLs of different sizes and rates of PD. A higher incidence of both PD and ND in an IOL with a smaller optic was also clinically proven by Bournas (45). The discrepancy in the size of the natural lens and implanted IOL has lately been reported as the primary cause of ND (46). Also, Masket (47) recently pointed out the need for further investigation into the influence of optic size on dysphotopsiae.

Holladay (7) previously described the effect of an enlarged optic working against PD in ray-tracing analysis. Later, this theory was also extended onto ND, stating that a larger optic diameter would affect both the missing and refracted rays similarly and move the shadow gap (18). Anteriorizing (which is the moving of the shadow gap) onto already nonfunctional retina has been claimed to be a solution against ND (39), together with the second option in the form of illuminating the shadow gap. We hypothesise that the most problematic factor for ND is the light missing the optic – it sets the anterior boundary of the illumination gap and thus enhances the contrast of the shadow. Furthermore, if both the shadow and light missing the IOL create non-physiological images, they should be both excluded from the functional retina, possibly by anteriorizing.

Basing on ray-tracing calculations in a 70-year-old eye model, Simpson (5) reported a visual angle of 105° as the total limit for the main phakic image and 95° for the main pseudophakic image on the retina. Shifting the shadow and light missing the IOL by about 10° might hypothetically resolve or reduce ND and extend the main pseudophakic image, so that it could be comparable to the phakic one. In this matter, using the IOL with an enlarged optic seems to be a plausible solution in order to perceive a continuous, close to physiological, non-constricted retinal image. Additionally, an optic larger enough than scotopic and mesopic pupil size should also reduce PD by preventing direct lens edge exposure and internal ray reflection.

Further analysis including optical modelling using the IOL design with a 7.0 mm optic from this study is therefore required to investigate our hypothesis based on the promising clinical data obtained. It should be verified whether using the IOL design with a 7.0 mm optic would cause light to miss the optic, at which peripheral visual angle it would be projected on the retina, if it would have an impact on peripheral vision, and if particular orientation of the plate haptics would be of antidysphotopic advantage.

6.7. Advantages of an enlarged IOL optic

The IOL design with an enlarged optic has also several other advantages.

Clinically, a large optic reduces the risk of PCO development (48), and enables a wider capsulorhexis (which, according to the ND theory by Masket, would also anteriorize the capsule shadow on the retina), which even in the case of capsule contraction should keep a large enough clear central optic zone. Moreover, the size of a 7.0 mm optic may mimic the natural crystalline lens better than the commonly used 6.0 mm diameter and thus contribute to pseudophakic retinal view without IOL edge disturbance. Additionally, it requires significantly less IOP elevation during scleral indentation and, consequently, less intraocular stress compared to the 6.0 mm optic

(49). These advantages are particularly relevant for the diagnosis and treatment of peripheral retinal pathologies and diabetic patients.

Technically, the implantation with a safe-loader injector does not seem to be problematic and enables a classical well-mastered surgical technique, with no need for starting a new learning curve for the ophthalmic surgeons. Moreover, contrary to sulcus-fixated IOLs, the in-the-bag implantation allows multifocal and toric variants. The larger optic does not raise the risk of postoperative inflammation, surgically induced astigmatism (SIA) or the loss of corneal endothelial cell density (ECD) (50). Finally, in our study, no intraoperative complications occurred.

6.8. Limitations of the study

Besides the above-mentioned limitations of this study, a few other points should be made.

We are aware of the fact that the IOL designs differ not only in the optic size, but also in the haptic type. On the other hand, both IOLs come from the same manufacturer, are made of the same materials, and the design with the 6.0 mm optic was chosen as a trusted and well verified one, providing very good results for the control group.

Moreover, the number of participants was relatively small and a prerequisite of independent samples of each eye had to be made, as the study protocol allowed binocular implantations.

Regarding the study protocol, the numbers of follow-ups and the intervals between them were adjusted to the daily clinical practice. More frequent follow-ups, especially between months 3 and 12, could give a better insight into the process of neuroadaptation.

Lastly, using a questionnaire as the only assessment tool for dysphotopsiae might put the objectivity of the results into question. However, in our opinion, and to the best of our knowledge, no fully objective dysphotopsiae measurement method has been developed yet, and the attempts made so far have also aroused controversy.

6.9. Conclusions

To our knowledge, this is the first report on the influence of the IOL design with a 7.0 mm optic diameter on the functional quality of vision after cataract surgery. The IOL design used reduces dysphotopsiae, and provides good CS, good and stable visual acuity and refraction, together with high general patient satisfaction. Considering its clinical and technical advantages, it is an attractive choice among the wide variety of available IOLs, most of all when it comes to preventing dysphotopsiae.

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8. STATUTORY DECLARATION

“I, Małgorzata Kalina Bonsemeyer, by personally signing this document in lieu of an oath, hereby affirm that I prepared the submitted dissertation on the topic “The influence of an intraocular lens design with enlarged 7.0 mm optic on the visual and optic results after a cataract surgery” / ,,Einfluss einer vergrößerten Intraokularlinsen-Optik (7,0 mm) auf die funktionellen und optischen Ergebnisse nach einer Katarakt-Operation,” independently and without the support of third parties, and that I used no other sources or aids than those stated.

All parts which are based on the publications or presentations of other authors, either in letter or in spirit, are specified as such in accordance with the citing guidelines. The sections on methodology (in particular regarding practical work, laboratory regulations, statistical processing) and results (in particular regarding figures, charts and tables) are exclusively my responsibility.

My contributions to any publications to this dissertation correspond to those stated in the below joint declaration made together with the supervisor. All publications created within the scope of the dissertation comply with the guidelines of the ICMJE (International Committee of Medical Journal Editors; www.icmje.org) on authorship. In addition, I declare that I shall comply with the regulations of Charité – Universitätsmedizin Berlin on ensuring good scientific practice.

I declare that I have not yet submitted this dissertation in identical or similar form to another Faculty.

The significance of this statutory declaration and the consequences of a false statutory declaration under criminal law (Sections 156, 161 of the German Criminal Code) are known to me.”

Date Signature

9. CURRICULUM VITAE

My curriculum vitae is not be included in the electronic version because of my personal data security.

10. ACKNOWLEDGEMENTS

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11. CONFIRMATION BY A STATISTICIAN

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Bescheinigung

Hiermit bescheinige ich, dass Frau Malgorzata Bonsemeyer innerhalb der Service Unit Biometrie des Instituts für Biometrie und Klinische Epidemiologie (iBikE) bei mir eine statistische Beratung zu einem Promotionsvorhaben wahrgenommen hat. Folgende Beratungstermine wurden wahrgenommen:

- Termin 1: *10.7.2020*
- Termin 2: *1.9.2020*

Folgende wesentliche Ratschläge hinsichtlich einer sinnvollen Auswertung und Interpretation der Daten wurden während der Beratung erteilt:

- *Deskription der Daten, separat für beide Gruppen und die Follow-up Messungen*
- *Annahme der Unabhängigkeit von linkem und rechtem Auge bzw. der jeweiligen Messung ist vermutlich kritisch zu sehen*
- *Für den Vergleich von zwei unabhängigen Gruppen Verwendung des t-Tests bzw. des Mann-Whitney-U-Tests, für den Vergleich von zwei abhängigen Gruppen den gepaarten t-Test bzw. den Wilcoxon-Test – je nachdem ob die Parameter hinlänglich normalverteilt sind.*
- *Falls mehrfache Vergleich gemacht werten, ggf. p-Werte für multiples Testen adjustieren (zB mit der Bonferroni-Methode)*

Diese Bescheinigung garantiert weder die richtige Umsetzung der in der Beratung gemachten Vorschläge, die korrekte Durchführung der empfohlenen statistischen Verfahren noch die richtige Darstellung und Interpretation der Ergebnisse. Die Verantwortung hierfür obliegt allein dem Promovierenden. Das Institut für Biometrie und Klinische Epidemiologie übernimmt hierfür keine Haftung.

Datum: 2.9.2020

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