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SPECIAL ASPECTS OF INTRAOCULAR LENS IMPLANTATION

Ph.D. Thesis

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LIST OF ABBREVIATIONS

ACD: anterior chamber depth

ACO: anterior capsular opacification

CDVA: corrected distance visual acuity

D: diopter

ECD: endothelial cell density

ELP: effective lens position

ETDRS: Early Treatment Diabetic Retinopathy Study

FLACS: femtosecond laser assisted cataract surgery

IOL: intraocular lens

IOP: intraocular pressure

LASIK: Laser-Assisted In Situ Keratomileusis

logMAR: logarithm of the Minimum Angle of Resolution

LRI: limbal relaxing incision

MGD: meibomian gland dysfunction

MTF: modulation transfer function

Nd-YAG: Neodymium-doped Yttrium Aluminum Garnet

OSI: objective scatter index

PCO: posterior capsular opacification

PRK: photorefractive keratectomy

SE: spherical equivalent

TBUT: tear break-up time

TF-OSI: tear film objective scatter index

UBM: ultrasound biomicroscope

UDVA: uncorrected distance visual acuity

1 INTRODUCTION

1.1 Cataract surgery

Cataract is a pathological condition characterised by a significant reduction in the transparency in the lens that leads to optical opacification. Globally, it is recognised as the most prevalent cause of treatable blindness, and surgical intervention is the primary treatment modality. Simultaneously, cataract surgery is one of the most widely performed and highly successful procedures, primarily aimed at restoring the patient's vision and consequently improving their quality of life [1, 2, 3, 4]. The individual and societal burden of cataract has also been highlighted in Hungary, where the Rapid Assessment of Avoidable Blindness (RAAB) study conducted at the Department of Ophthalmology, Semmelweis University, demonstrated cataract as a leading cause of visual impairment and avoidable blindness in the population [5]. Postoperative vision improvement is not only a functional advantage but also contributes to slowing cognitive decline and reducing the gradual deterioration of quality of life in older patients [6]. Postoperative satisfaction is not solely determined by clinical outcomes but also strongly depends on the patient’s expectations and lifestyle requirements. Patients generally anticipate achieving the best possible visual outcome, which often translates to a desire for a spectacle-free lifestyle [7]. As a result, cataract surgery has evolved into a refractive procedure in developed countries, enabling the correction of various refractive errors, including myopia, hyperopia, astigmatism, and presbyopia [8]. However, even with the greatest attention of the surgeon, patients after cataract surgery may still experience significant spherical or astigmatic refractive errors requiring spectacle correction. Additionally, some patients may later decide that they would have preferred a multifocal intraocular lens (IOL) [9]. According to a survey conducted in 2021, even with the use of modern IOL calculation formulas, postoperative refractive outcomes fall within ±0.50 D and ±1.0 D of the intended target only in 81% and 98% of cases, respectively [10]. Several factors may contribute to patient dissatisfaction despite the anticipated visual improvement following surgery. In addition to residual refractive errors, postoperative visual quality deterioration may be attributed to the optical properties of the IOL, subtle variations in surgical techniques, as well as individual anatomical and physiological characteristics [11].

Factors such as the condition of the cornea, the quality of the tear film or the subsequent glistenings in the IOL can also have a significant impact on the final visual acuity, contrast sensitivity and general visual comfort [12, 13, 14].

1.2 Postoperative visual quality

Despite the anticipated improvement in vision following surgery, some patients may experience dissatisfaction. Even after an uncomplicated cataract surgery, postoperative visual quality may not always reach the optimal level expected by both patients and surgeons. Suboptimal visual outcomes may result from residual refractive errors, tear film insufficiency, improper IOL positioning, or pathological changes in the IOL material, among others.

1.2.1 Postoperative refractive error and visual quality

Despite the use of modern IOL calculation formulas and advanced surgical techniques, it is not uncommon for postoperative refractive results in patients to not coincide with the target values formulated in the preliminary plans. According to certain surveys, only a subset of patients achieves the refractive range considered optimal by surgeons. Consequently, a significant proportion of patients exhibit residual refractive errors that necessitate additional corrective interventions or compensation through spectacles or contact lenses [10]. Several options exist for the correction of residual refractive errors, including spectacle or contact lens correction and various surgical interventions. Among the surgical options, IOL exchange is most commonly considered within the first three months following surgery. However, this procedure is associated with a relatively high risk, which may potentially have an impact on visual outcomes [15]. During IOL exchanging, damage to the capsular bag may occur, which endangers the stable attachment of the new IOL, and a worsening of posterior capsular opacification (PCO) may also occur. It is not uncommon to experience vitreous complications such as prolapse of the vitreous and an increased risk of retinal detachment [16, 17]. In addition, the risk of infection and inflammation increases, which may require additional treatments and a longer rehabilitation period. As an alternative solution, corneal laser procedures such as photorefractive keratectomy (PRK) and Laser-Assisted in Situ Keratomileusis (LASIK)

may provide satisfactory outcomes. However, these procedures are not suitable in cases of significant postoperative refractive error, severe dry eye, or thin corneal thickness [18, 19, 20]. In general, PRK or LASIK procedures can be performed safely if the extent of the corrective ablation does not exceed the safe ablation threshold of the cornea. For myopic errors, this threshold is typically around 6–8 diopters (D), while for hyperopic errors, it is approximately 4–5D [21, 22]. Refractive errors exceeding these limits may restrict the depth of ablation, making correction with these techniques challenging or unfeasible. However, it is important to note that these values vary depending on individual corneal thickness, topography, and other anatomical characteristics [21]. PRK and LASIK have been demonstrated to be safe, effective, and predictable in patients with residual refractive errors following cataract surgery. Nevertheless, in this specific clinical application, neither technique has shown a definitive advantage over the other [23]. According to international reports, topography-guided PRK or LASIK may be effective in addressing certain corneal irregularities that contribute to ametropia or impair visual quality in pseudophakic patients. Some authors have compared conventional excimer laser refractive procedures with wavefront-guided approaches; however, due to a lack of statistical power, no definitive conclusion has been reached regarding the superiority of either method [24]. If postoperative refractive defects cannot be corrected with simpler methods in the case of dry eyes or thin cornea, secondary IOL implantation may represent the most suitable solution. In this approach, a second IOL is implanted over the existing capsular bag-fixated IOL, typically in the ciliary sulcus [25]. As an intraocular option for correcting pseudophakic ametropia, a secondarily implanted supplementary IOL offers greater safety, efficacy, and predictability compared to IOL exchange procedure [26]. Some studies suggest that, especially for astigmatic defects, LASIK is a more efficient and predictable option, although both groups acknowledge that IOL-based methods play a crucial role in the correction of higher spherical errors [18, 19]. It is worth mentioning that the secondarily implanted supplementary IOL not only serves to correct refractive errors but can also be effectively used to treat negative dysphotopsia, which is a rare complication following cataract surgery that can significantly impair the patient's visual experience [27].

1.2.2 Negative dysphotopsia and visual quality

Negative dysphotopsia following uncomplicated cataract surgery is a phenomenon in which patients perceive dark, shadowy areas in their visual field, most commonly in the temporal region. This phenomenon can occur due to the interaction between the optical properties of the IOL—particularly its edge and position—and anatomical factors such as the capsular bag and the iris [28, 29]. Although the pathophysiology of negative dysphotopsia is not yet fully understood, it is believed that the design elements of the IOL and the modification of the light path are responsible for the appearance of peripheral dark shadows [30]. In many cases, negative dysphotopsia improves spontaneously over time or even disappears completely, but in some patients it is a persistent symptom, which significantly impairs postoperative visual quality and patient satisfaction. In such cases, additional interventions may be required, including IOL exchange or modifications to the capsular bag structures. These may involve disrupting the continuity of the anterior capsulorhexis using a Neodymium-doped Yttrium Aluminum Garnet (Nd:YAG) laser, employing 'reverse optic capture', or implanting a secondary supplementary IOL in the ciliary sulcus, ensuring coverage of the anterior capsulorhexis with the sulcus IOL [22, 31]. In addition, the large distance between the anterior surface of the primary implanted IOL and the posterior part of the iris may also play a role in the manifestation of negative dysphotopsia symptoms. The implantation of a secondary supplementary IOL into the ciliary sulcus can significantly reduce the aforementioned distance and is associated with a good likelihood of resolving negative dysphotopsia symptoms [32]. In addition to these therapeutic strategies, a new intraocular lens design has been developed to prevent the occurrence of negative dysphotopsia. The Morcher 90S IOL (Morcher GmbH, Stuttgart, Germany) designed by Masket and colleagues, incorporates a circumferential groove at the optic equator that captures the anterior capsulorhexis, eliminating a sharp lens edge, partially positioning the optic in the sulcus, and reducing the iris–IOL distance. Early clinical experience indicates that implantation of this IOL in the fellow eye may prevent the development of negative dysphotopsia, a finding that has also been supported by preliminary experience in our institution [33].

1.2.3 Postoperative tear film and visual quality

An unstable tear film can lead to poorer functional visual acuity and decreased contrast sensitivity [34, 35]. After cataract surgery, the thickness of the lipid layer of the tear film decreases significantly, while other parameters of dry eye disease and meibomian gland dysfunction (MGD) also deteriorate [36]. The thickness of the lipid layer is closely related to the symptoms of dry eye and the MGD parameters. This means that a thinning of the lipid layer and further deterioration of meibomian gland functions are expected after cataract surgery. MGD affects the stability of the tear film and is closely related to the development of dry eye disease. In MGD tear evaporation is accelerated, which leads to excessive evaporation of tears and thus promotes the development of dry eyes. One study found that preoperative MGD treatment can help effectively reduce obstructive MGD induced by cataract surgery and the associated dry eye symptoms [37]. One of the most determining factors of light transmission after cataract surgery is the instability of the tear film: if the quality of the tear film deteriorates or becomes unstable, it can be accompanied by a significant deterioration in the postoperative visual experience and the visual comfort perceived by the patients [38]. The importance of the postoperative state of the tear film has been confirmed by several studies. Especially in the case of multifocal IOLs, dry eyes have been shown to be the second or third most common cause of dissatisfaction, which illustrates the clinical significance of tear film problems [39]. In some cases, artificial tears applied after surgery can help restore the tear film, thus improving the quality of vision after surgery [40]. Traditionally, artificial tears containing 0.1% sodium hyaluronate have been used to treat dry eye after cataract surgery; however, more complex formulations are increasingly being introduced. [41]. For example, diquafosol tetrasodium solution has been shown to be more effective in treating dry eye than conventional eye drops [42]. Furthermore, the addition of trehalose to sodium hyaluronate has been shown to improve tear film break-up time (T-BUT) and Ocular Surface Disease Index (OSDI) scores, owing to its ability to promote deep hydration, stabilize lipids and proteins, and protect against oxidative stress [43]. Pre- and postoperative use of antioxidant solutions as well as oral lactoferrin and omega-3 fatty acid supplements also contribute to maintaining the balance of the eye surface [44, 45].

1.2.4 Postoperative glistenings and visual quality

The phenomenon of glistenings can be defined as the scattering of light in the material of the IOLs, which is caused by the formation of microvacuoles filled with microscopic fluids. Although numerous studies have investigated the phenomenon of glistenings and their effects, the extent to which glistenings impact visual function remains unclear [46, 47, 48, 49]. Increased glistenings density clearly increases light absorption and light scattering, which can result in a deterioration in the optical quality of the IOL [19, 50, 51]. The microvacuoles typical of glistenings range in diameter from 1 to 30 micrometres, and these microvacuoles are found in different IOL materials with different densities and degrees [52, 53]. According to the prevailing theory of glistenings formation, water-filled microvacuoles develop within the IOL after implantation as a result of water absorption by the IOL material [54]. Different IOL materials exhibit varying responses to water absorption, resulting in differences in the intensity of glistenings among various IOL types [55]. The glistenings phenomenon is a well-known problem with hydrophobic acrylic IOLs. Several studies have shown that several factors can play a role in the development of glistenings, including the manufacturing process, the characteristics of the lens material (hydrophobic acrylic), and the time that has passed since the operation [56, 57]. The advantage of hydrophobic acrylic IOLs is that they have a less protein adhesion and a lower rate of post-cataract PCO. At the same time, the hydrophobic property also carries the possibility that a certain amount of water is absorbed into the material in the moist environment of the eye, which can lead to the formation of microvacuoles. As the postoperative time progresses, glistenings are more likely to be observed, as there is a longer time for the lens material to react to the inner environment of the eye by water absorption and phase separation [58]. The development of glistenings can also be influenced by the tightness of the capsular bag and the degree of anterior capsular opacification (ACO). Some studies have shown that the ZCB00 IOL (AMO, Santa Ana, Ca, USA) made of hydrophobic acrylic exhibits less glistenings than the similar Alcon AcrySof IOL (Alcon, Fort Worth, TX, USA), which is partly due to the raised anterior rim design of the ZCB00 IOL, which reduces anterior capsular fibrosis as opposed to the biconvex design of the AcrySof IOL. From all this, it can be concluded that the formation of ACO and the tightness of the capsular bag may play a role in the formation of glistenings [59]. Additionally, thicker IOLs with higher dioptric power are

more prone to material degradation, making the development of glistenings more likely [60]. The increase in the number and size of microvacuoles can result in a gradual deterioration in the quality of vision, reduce visual acuity and contrast sensitivity, and can also affect visual comfort. These considerations highlight the importance of determining the extent to which glistenings affect postoperative visual quality, particularly above a certain threshold where their density or size may begin to cause functional visual disturbances.

1.2.5 Postoperative IOL's position and visual quality

The position and stability of the IOL implanted during cataract surgery are crucial to postoperative visual acuity. A properly selected IOL design (diopter value) and a precise surgical technique alone do not guarantee the desired refractive result. It is at least as important that the IOL is well centred in the capsular bag and in the optimal position. If the IOL is decentered, tilted, or positioned outside the intended effective lens position (ELP), optical aberrations may occur, potentially reducing postoperative visual acuity and contrast sensitivity [61, 62]. In addition, weak zonular apparatus, pseudo-exfoliation, tension in the capsular bag, possible shrinkage of capsular bag or other postoperative complications can also affect the final position of the IOL [63, 64]. Modern surgical techniques and IOL design, such as advanced haptic configurations and specialized optical zones aim to minimize postoperative displacement and ensure stable fixation within the capsular bag. One of the primary objectives of modern cataract surgery is to minimize postoperative IOL displacement and to ensure stable fixation of the IOL within the capsular bag. Among contemporary surgical approaches, femtosecond laser-assisted capsulorhexis has emerged as a particularly precise and effective technique. Femtosecond laser-assisted capsulorhexis provides a high degree of accuracy, creating an almost perfectly circular and well-centred capsular opening. In contrast, manual, hand-crafted capsulorhexis may exhibit a certain degree of variability in circularity and centration, even in the hands of an experienced surgeon.

Laser-assisted capsulorhexis ensures uniform IOL positioning within the capsular bag, as the edge of the opening is circular and precisely shaped. As a result, the haptics are tensioned symmetrically, which helps the IOL to be stable in the long term and reduces the chances of decentralization or tilt [65, 66, 67]. The haptics of modern IOLs

are designed in such a way (e.g. C-haptics, plate-haptics) that the IOL is firmly fixed in the capsular bag. The flexibility and design of the haptics allow the IOL to adapt to the internal tension of the capsular bag, minimizing any rotation or tilt [68].

However, individual anatomical characteristics of patients (e.g., intraocular spatial dimensions, capsular bag elasticity) and surgical factors (e.g., surgeon experience, occurrence of intraoperative complications) also influence the accuracy of achieving the intended IOL position [69]. Accurate IOL positioning and close postoperative monitoring are both essential to achieving the intended refractive outcome and preserving long-term visual quality. Corrective interventions such as laser capsulotomy, secondary IOL implantation or IOL exchange may be required to achieve and maintain optimal visual acuity. If the IOL position becomes stable but optical aberrations persist, corneal laser procedures such as LASIK or PRK may be considered to address residual refractive errors.

1.2.6 Postoperative higher-order aberrations and visual quality

Postoperative higher-order aberrations play a critical role in determining visual quality after cataract surgery. These aberrations represent subtle distortions in the optical system of the eye that extend beyond conventional lower-order defects such as spherical and astigmatic errors. Higher-order defects include, for example, coma and other complex wavefront abnormalities that cause subtle but substantial distortion of the light transmission. The optical properties of the implanted IOL – such as the aspherical design, the proper design of the haptics, and the precise centring of the IOL – fundamentally determine the extent to which postoperative aberrations occur [70]. If the IOL is not well centred or if there are small deviations in the surgical technique, it can increase the degree of higher-order aberrations [71]. These distortions can become particularly noticeable in low light conditions, which can reduce contrast sensitivity, impair visual acuity, and cause halo and light scattering phenomenon [72]. Modern ophthalmic technologies such as wavefront aberrometry allow for precise quantification of higher-order aberrations, enabling surgeons to select the most appropriate IOL type and to refine their surgical approach accordingly [73]. The studies found no significant difference between femtosecond laser-assisted cataract surgery (FLACS) and conventional manual standard phacoemulsification in terms of visual rehabilitation and refractive outcomes [74].

Notably, the size of the corneal incision also influences the outcomes [75]. Overall, conventional phacoemulsification and FLACS induce a comparable degree of higher-order aberrations. Through precision measurements, the postoperative optical system can be optimized, contributing to an enhanced visual experience by improving visual acuity and contrast sensitivity. Even a decentration of less than 0.5 mm can induce significant aberrations, potentially leading to noticeable visual disturbances. Statistical data indicate that in approximately 10% of patients undergoing cataract surgery, the IOL tilt exceeds 5°, and the degree of decentration surpasses 0.5 mm [53]. This indicates that such deviations are relatively common and pose a challenge to the success of refractive cataract surgery.

Cataract surgery is also a refractive intervention in developed countries, which is suitable for correcting various refractive errors. The 2020 ESCRS Working Group on Functional Vision concluded that the main goal of cataract surgery should be to preserve full visual function at all distances [76]. In light of these considerations, if postoperative visual quality after cataract surgery is suboptimal, appropriate corrective measures should be undertaken to ensure the best possible visual outcome for the patient.

1.3 Objective and subjective assessment of postoperative outcomes after cataract surgery

1.3.1 Postoperative visual examination

During the examinations, the remaining abnormalities can be identified by precisely determining the patient's refractive errors. Autorefractometer and manifest refraction measurements can be used to record the extent to which the patient's manifest refractive state deviates from the ideal goal. Uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) can be measured with the ETDRS (Early Treatment Diabetic Retinopathy Study) chart and serve as key indicators of postoperative refractive outcomes. Contrast sensitivity can be evaluated using the CSV-1000 system (Vector Vision, Greenville, Ohio, USA) which provides information on the patient’s ability to perceive fine spatial detail under varying contrast conditions [77].

1.3.2 Examination of the tear film

Methods for assessing the tear film encompass a variety of objective and subjective procedures aimed at evaluating its condition and stability. These include traditional clinical tests, such as the Schirmer test for quantifying tear production and the measurement of TBUT, which reflects tear film stability [78]. Aberrometry enables the non-invasive examination of the ocular surface and optical performance [79]. During tear film degradation, any localized changes in tear film thickness or uniformity result in the formation of aberrations, ultimately compromising retinal image quality [80]. Instability and irregularity of the tear film consistently contribute to an increase in higher-order aberrations affecting both the cornea and the entire optical system, in both normal and dry eyes [81].

1.3.3 Examination of Glistenings

The severity of glistenings can be assessed using a numerical rating scale during the slit lamp examination [52]. Although this semi-quantitative method relies on the subjective judgement of the examiner. For a more objective and reproducible evaluation, Scheimpflug imaging (Oculus Optikgeräte GmbH; Wetzlar, Germany) has been shown to provide investigator-independent quantification of glistenings. The Scheimpflug imaging method can be used to quantitatively evaluate the extent and distribution of glistenings in the IOL [82]. In this procedure, the Scheimpflug camera captures high-resolution images of the IOL structure, enabling the quantitative assessment of glistenings density. By analyzing these images using digital image processing programs, the intensity of scattered light can be quantified on a numerical scale that reflects the degree of glistenings.

1.3.4 Examination of the position of the IOL

The initial step in evaluating the position of the IOL is slit-lamp biomicroscopy, which allows for the assessment of IOL centration relative to the pupillary axis, the degree of tilt, and the condition of the capsular bag. Anterior segment optical coherence tomography (AS-OCT) provides highly accurate measurements of IOL displacement and its relationship to the capsular bag, while Scheimpflug imaging and analysis generate a

three-dimensional representation of the IOL position and associated optical aberrations [83]. Ultrasound biomicroscopy (UBM) or B-scan ultrasound can be utilized to evaluate deeper ocular structures and detect posterior IOL dislocation [84].

2 OBJECTIVES

INVESTIGATION OF SPECIFIC ASPECTS OF INTRAOCULAR LENS IMPLANTATION

2.1 Glistenings and tear film instability: assessment and clinical relevance

2.1.1 Comparison of glistenings severity

To compare the severity of glistenings using slit lamp examination with a semiquantitative scale and computer-based analysis of Scheimpflug imaging.

2.1.2 Impact of glistenings and tear film instability on visual quality

To investigate the presence of glistenings in different IOL models and assess the optical consequences of tear film instability, focusing on their combined effect on postoperative visual quality. By employing both subjective and objective assessment techniques, the study sought to clarify the role of these factors in the optimization of visual performance.

2.2 Long -term results of 1stQ AddOn IOL implantation

In the context of intraocular correction for pseudophakic ametropia, to evaluate the long-term visual outcome following secondary implantation of the 1stQ AddOn IOL in the sulcus, with particular attention to its stability and biocompatibility.

3 METHODS

3.1 Evaluation of the impact of glistenings on visual performance in relation to tear film quality in two different hydrophobic acrylic lenses

3.1.1 Patients

In this retrospective observational study, we evaluated the postoperative visual outcomes of 51 pseudophakic eyes from 42 patients who had undergone cataract surgery. The hydrophobic monofocal IOLs implanted were the Z-Flex 860FAB (Medicontur Medical Engeneering Ltd., Zsámbék, Hungary) and the AcrySof® IQ SN60FW (Alcon Inc., Fort Worth, TX, USA) (see Table 1). To analysis, all collected data were processed anonymously. The study was conducted in accordance with the principles of the Helsinki Declaration [85]. Written informed consent was obtained from all patients at the time of surgery. Prior to surgery, all patients underwent a comprehensive clinical evaluation and provided informed consent. The analysis included patients who underwent cataract surgery between January 1, 2011, and December 31, 2012, with postoperative follow-up examinations conducted between January 2016 and December 2019. Exclusion criteria included any severe ocular surface disease, glaucoma, uveitis, clinically significant PCO, and corneal or vitreous opacities. Eyes with any signs of age-related macular degeneration (AMD) were also excluded, based on detailed slit-lamp biomicroscopy and optical coherence tomography (OCT) evaluation. Additionally, patients with complicated cataract surgery or those with a history of intraocular procedures other than cataract surgery were excluded from the study.

Table 1. Manufacturer-reported technical specifications of the Z-Flex 860FAB and AcrySof IQ SN60WF IOLs.

Characteristic	Z-Flex 860FAB	AcrySof IQ SN60WF
Optic material	Hydrophobic acrylic copolymer	Hydrophobic acrylate/methacrylate copolymer
Refractive index	1.47	1.55
Abbe number	58	37
Optic design	Biconvex, square edge, anterior and posterior aspheric surface	Biconvex, square edge, anterior and posterior aspheric surface
Optic diameter (mm)	6.0	6.0
Length (mm)	13.0	13.0
Haptic configuration	Double C-loop	Modified L
Haptic angulation (°)	0°with posterior vaulting	0°
Ultraviolet filter	Yes	Yes + blue light filter
A-constant (SRK/T)	119.1	119.0

3.1.2 Surgical technique

All patients underwent the same surgical procedure and were examined using standardized preoperative and postoperative protocols. All surgeries were performed by a single experienced surgeon using a conventional phacoemulsification technique, followed by the implantation of either a Z-Flex 860FAB or an AcrySof IQ SN60FW intraocular lens into the capsular bag. In all cases, the 2.7 mm corneal tunnel incision was closed without sutures, and no intraoperative or postoperative complications were observed.

3.1.3 Assessment methods

3.1.3.1 Evaluation of visual performance parameters

During preoperative measurements, UDVA and CDVA were assessed using a standard ETDRS chart. Patients returned for follow-up approximately six years (±0.5 years) postoperatively, during which objective and manifest refraction (UDVA, CDVA) as well as contrast sensitivity under mesopic conditions were reassessed. These measurements were conducted using the CSV-1000 system as part of the postoperative visual assessment protocol. To evaluate visual performance, the ETDRS chart was used at 2.44 meters, while the CSV-1000 chart was employed at the same distance to assess contrast sensitivity at different spatial frequencies (3, 6, 12, and 18 cycles/degree) under both "glare" and

"non-glare" conditions. Glare conditions refer to lighting environments in which excessive intraocular light scattering leads to visual glare and a reduction in contrast sensitivity. This phenomenon can cause discomfort and impair visual performance due to uneven light distribution, leading to distracting reflections and shadows. In contrast, non-glare conditions refer to lighting environments with minimal light scattering, allowing for optimal visual acuity and contrast sensitivity. Under such conditions, visual measurements more accurately reflect the actual optical capabilities of the eye. These factors are particularly important to consider in clinical trials, as lighting quality directly influences the measured values and the visual experience perceived by the patient.

3.1.3.2 Evaluation of Glistenings

First, prior to pupil dilation, pupil size was measured under mesopic light conditions with the Pentacam HR Scheimpflug camera (Oculus Optikgeräte GmbH; Wetzlar, Germany), using high-resolution anterior iris mode. In the captured images, the pupil size was measured along the X and Y axes. This method allows for the exact size and shape of the pupil to be recorded in detail, without pupil size or dilation affecting the measurement. Following full pupil dilation using 0.5% tropicamide and 10% phenylephrine eye drops, glistenings were first assessed subjectively and semi-quantitatively via slit-lamp biomicroscopy. A four-point grading scale (0–3) was applied, where 0 indicated no glistenings, 1 mild, 2 moderate, and 3 severe glistenings. For objective quantification, Scheimpflug image analysis was subsequently performed using the '25 images' programme mode of the Pentacam HR, which captures 25 images under mesopic lighting conditions. From the captured images, the mean intensity of scattered light was determined by focusing on the IOL, reflecting the degree of glistenings within and just beneath its optical surface, on a grayscale scale ranging from 0 to 255. The numerical data were analysed using the ImageJ digital image processing software (National Institutes of Health, Bethesda, MD, USA), with measurements confined to a 1.5 mm zone around the visual axis to ensure that the values represent the most optically relevant central region. In addition, surface light scattering was analysed separately on the anterior and posterior surfaces of the IOL. This phenomenon, known as surface light scattering, is primarily attributed to the phase separation of water molecules at the IOL surface. This mechanism is distinct from the formation of glistenings, the actual degree of glistenings

was determined by excluding surface scattering and focusing on the light scatter originating from within the IOL material.

3.1.3.3 Light scattering and tear film examination

For the quantitative assessment of intraocular light scattering, this study employed the HD Analyzer OQAS (Visiometrics S.L., Cerdanyola del Vallès, Spain), a double-pass wavefront-based optical system [86]. The operating principle of this device is based on the double-pass imaging technique, in which both the forward-propagating light and the reflected light passing through the patient's optical system are recorded. This dual-path method allows for the quantification of intraocular light scattering, expressed as the Objective Scatter Index (OSI). Prior to measurement, the patient's manifest cylindrical refractive error was corrected using trial lenses, while spherical error was automatically compensated by the device. Consequently, the resulting OSI value reflects only light scattering originating from intraocular opacities. Accordingly, higher OSI values indicate increased intraocular light scattering, which is associated with a decline in visual quality. The HD Analyzer OQAS was also used for the quantitative analysis of the tear film, although the measurement procedure differed slightly in this case. During the examination, the patient was instructed to fixate on a predetermined target while the system captured double-pass images at 0.5-second intervals throughout the 20-second recording period. As a result, a total of 40 images were obtained, allowing for the dynamic tracking of changes in light scattering caused by tear film variations. Based on these data, the device automatically generated the TF-OSI (Tear Film Objective Scatter Index) value, which quantifies the degree of light scattering induced by the tear film. This approach enables an objective comparison of tear film quality at different time points or between different patients, as well as an assessment of the extent to which tear film condition influences visual quality.

3.1.4 Statistical analysis

All data were processed using GraphPad Prism 7.04 statistical software (GraphPad Software, San Diego, CA, USA). Descriptive statistical analyses were conducted, including the calculation of the mean, standard deviation, median, minimum, maximum, and 95% confidence interval. The normality of data distribution was assessed using the

D'Agostino & Pearson test. Based on the results, comparisons between paired preoperative and postoperative data, as well as between the two study groups, were performed using a paired-sample t-test for normally distributed variables or the nonparametric Wilcoxon signed-rank test for non-normally distributed variables. The frequency distribution of specific data between the two groups was analyzed using the Kolmogorov-Smirnov test. To assess potential correlations between the severity of glistenings and parameters related to visual quality, a nonparametric Spearman correlation analysis was performed. The results obtained from different glistening evaluation techniques were compared using multiple t-tests with the Holm-Sidak method. All measured visual acuity values were recorded in logMAR format and assessed under photopic conditions. A p-value of <0.050 was considered statistically significant in all cases.

3.2 Evaluation of the visual performance and stability of the 1stQ AddOn IOL secondarily implanted in the ciliary sulcus for the correction of pseudophakic ametropia

3.2.1 Patients

A retrospective analysis was conducted based on cataract surgeries performed at the Department of Ophthalmology, Péterfy Sándor Street Hospital. To ensure comparability, only patients who received a 1stQ AddOn monofocal IOL in the ciliary sulcus as a secondary correction for residual refractive error after primary cataract surgery were included. The study was conducted in accordance with the principles of the Declaration of Helsinki [85]. Written informed consent was obtained from all patients at the time of surgery.

3.2.2 Surgical technique

The same surgical procedure was applied to all patients, and all surgeries were performed by a single experienced surgeon. The 1stQ AddOn IOL (Medicontur Medical Engineering Ltd., Zsámbék, Hungary) was used as a secondary implant. This IOL has a total diameter of 13 mm and features four flexible haptics supporting a 6.0 mm convex-concave optic

(Figure 1). The surgery was performed under retrobulbar anesthesia. A 2.7 mm clear corneal tunnel incision and 3 less than 1.0 mm side ports were created. A cohesive viscoelastic material was injected into the anterior chamber and the ciliary sulcus, and the 1stQ AddOn IOL was implanted into the anterior chamber using an injector. After that, the four haptics were inserted one by one through the main incision and the side ports in the posterior chamber using Sinskey or Lester hooks. After removal of the viscoelastic material the pupil was constricted with acetylcholine, the wounds were closed by hydration, and 0.1 ml of 1% cefuroxime solution was injected into the anterior chamber. In all cases, the 2.7 mm tunnel incision was closed without sutures, and no intraoperative or postoperative complications were observed.

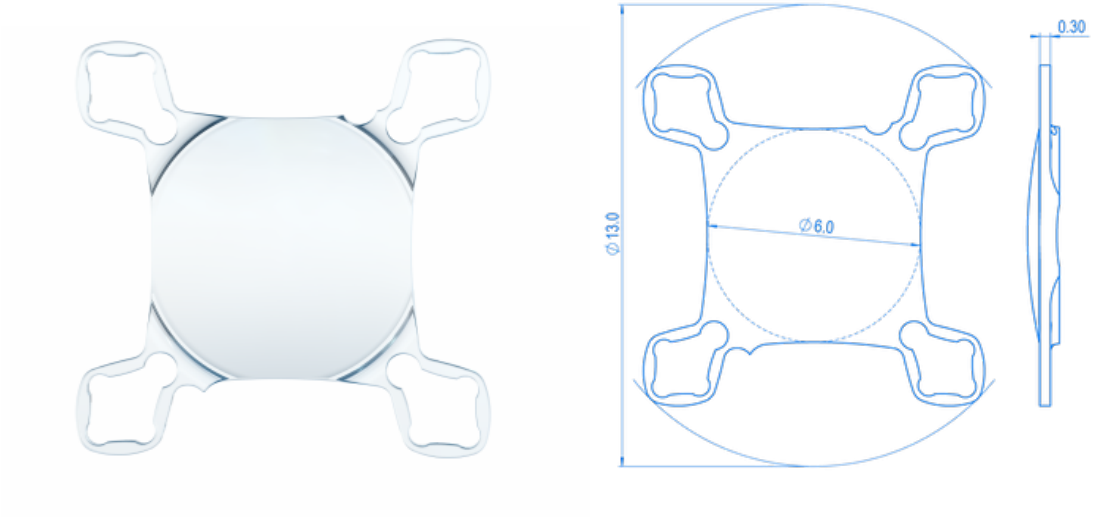

Figure 1. Left: Photograph of the monofocal 1stQ AddOn Refractive A46R IOL. Right: Schematic illustration of the IOL's key parameters, including a total diameter of 13 mm and a 6.0 mm convex-concave optic supported by four flexible haptics. The image has been reproduced with permission from Medicontur Medical Engineering Ltd.

3.2.3 Evaluation methods

Prior to the additional implantation of the IOL, all patients underwent a comprehensive ophthalmological examination. Objective and manifest refractive values were determined, along with UDVA and CDVA. For optical biometric measurements, the IOLMaster 500 device (Carl Zeiss Meditec AG, Jena, Germany) was used to record axial length, keratometric values, and anterior chamber depth (ACD). Corneal endothelial cell density (ECD) was assessed using the NIDEK CEM-530 specular microscope. Detailed

evaluations of the anterior and posterior segments of the eye were conducted using a slit lamp, and intraocular pressure (IOP) was measured via Goldmann applanation tonometry. Patient records included data on the primary implanted IOLs, specifically the model type and diopter value. Manifest refractive results, biometric measurements, and parameters of the primary IOL were systematically documented on a data collection sheet designed by the manufacturing company. The manufacturer uses dedicated calculation software that primarily relies on subjective refraction to suggest the appropriate dioptric power of the AddOn IOL. The input form requires specification of the primary IOL type and power, current biometric parameters (including keratometry values, axial length, and pseudophakic ACD), as well as the incision location and the anticipated surgically induced astigmatism. Based on these inputs, the calculator provides a recommendation for the spherical—and, if needed, toric—power of the AddOn IOL. In the case of toric lenses, it also suggests the ideal axis alignment and recommended incision site. During postoperative evaluation following the implantation of the secondary 1stQ AddOn IOL, the measurement protocols used in the preoperative assessment were repeated, with the exception of biometric measurements. Slit lamp examinations also included an assessment of potential inflammatory symptoms and signs of pigment dispersion. Additionally, particular attention was given to evaluating the position of the 1stQ AddOn IOL after pupil dilation in comparison to the primary IOL implanted in the capsular bag. The centration of the 1stQ AddOn IOL was also examined, ensuring that the distance between the optical centre of the AddOn IOL and the centre of the pupil did not exceed 0.5 mm, thus verifying optimal lens positioning. The relative position and potential tilt of the 1stQ AddOn IOL and the primary IOL were analyzed using the VuMAX Sonomed Escalon UBM device (Sonomed Escalon, New York, USA). This technique enabled the acquisition of detailed images depicting the spatial relationship between the two IOLs. The distances between the optical zone centres of both lenses were precisely measured using these images.

3.2.4 Statistical analysis

Data were processed using GraphPad Prism 10.2.2 statistical software (GraphPad Software, San Diego, CA, USA). Descriptive statistical indicators, including the mean, standard deviation, median, minimum, maximum, and 95% confidence interval, were calculated for each dataset. The normality of data distribution was assessed using the D'Agostino & Pearson test. Depending on the results, comparisons between preoperative and postoperative variables were performed using either a paired-sample t-test (for normally distributed data) or the nonparametric Wilcoxon signed-rank test (for non-normally distributed data). Visual acuity was expressed in logMAR format, and statistical significance was set at $p < 0.050$.

4 RESULTS

4.1 Results: The impact of glistenings on visual performance in relation to tear film quality in two different hydrophobic acrylic intraocular lenses

4.1.1 Patients and visual outcomes

The evaluation included 51 eyes from 42 patients. The preoperative demographic characteristics of the two studied groups, in which IOL implantation was performed using either the Z-Flex 860FAB (n=26) or the AcrySof IQ SN60WF (n=25), are presented in Table 2. The patients in the Z-Flex group were approximately five years older, resulting in a significant difference in the mean age between the two groups (p=0.019). No complications or pathological events were observed during the postoperative follow-up period, except for PCO, which was treated with Nd:YAG laser capsulotomy prior to our postoperative examinations. The mean axial length was similar in both groups (p=0.338). No significant differences were found between the two groups in manifest spherical and cylindrical refractions, the spherical equivalent of manifest refraction, or UDVA and CDVA values (see Table 3). Mesopic contrast sensitivities, measured at different spatial frequencies, were comparable under both glare and non-glare conditions in the two groups (see Figure 2. A and B). The mean diopter value of the implanted IOLs was slightly higher in the AcrySof IQ group (p=0.034). Pupil sizes in both groups were similar along the X-axis (AcrySof IQ: 3.17 mm; Z-Flex: 3.12 mm) and the Y-axis (AcrySof IQ: 3.22 mm; Z-Flex: 3.13 mm), with p=0.799 for the X-axis and p=0.645 for the Y-axis.

Table 2. Demographic characteristics of the two studied groups, in which IOL implantation was performed using either the Z-Flex 860FAB (n=26) or the AcrySof IQ SN60WF (n=25). [87]

Data	Z-Flex 860FAB		AcrySof IQ SN60WF		Significance (p)
	Mean ± SD	Range	Mean ± SD	Range	
Age (years)	71.9 ± 5.3	64 - 81	66.6 ± 8.4	50 - 79	**0.019**
Female	17 (77.3%)		12 (60.0%)		
Male	5 (22.7%)		8 (40.0%)		
Axial Lenght (mm)	23.65 ± 1.07	22.39 - 26.95	23.24 ± 0.78	21.42 - 24.62	0.338
UDVA (logMAR)	0.68 ± 0.37	1.7 – 0.1	0.78 ± 0.45	1.7 – 0.3	0.546
CDVA (logMAR)	0.35 ± 0.36	1.7 – 0.0	0.48 ± 0.45	1.7 – 0.0	0.218
IOL Power (D)	+20.4 ± 2.69	+12.0 - +25.0	+21.7 ± 1.98	+17.0 - +25.0	**0.034**

Table 3. Six-year postoperative refractive outcomes and distance visual acuity in eyes implanted with Z-Flex 860FAB or AcrySof IQ SN60WF IOLs. [87]

Data	Z-Flex 860FAB		AcrySof IQ SN60WF		Significance (p)
	Mean ± SD	Range	Mean ± SD	Range	
spherical refraction (D)	+0.51 ± 0.50	-0.25 - +1.5	+0.49 ± 0.70	-0.75 - +2.5	0.999
cylindrical refraction (D)	-0.36 ± 1.12	-2.0 - +1.5	-0.63 ± 0.96	-3.5 - +0.75	0.406
SE of manifest refraction (D)	+0.36 ± 0.65	-1.0 - +1.75	+0.18 ± 0.70	-1.5 – +1.5	0.356
UDVA (logMAR) 6 years postop.	0.19 ± 0.16	0.5 – 0.0	0.14 ± 0.17	0.6 – 0.0	0.361
CDVA (logMAR) 6 years postop.	0.01 ± 0.03	0.1 – 0.0	0.02 ± 0.06	0.2 – 0.0	>0.999

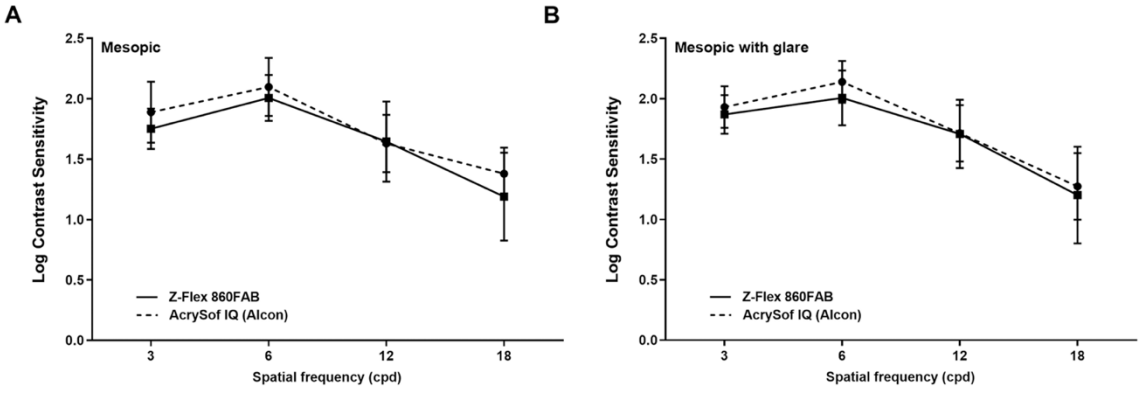

Figure 2. The mesopic non-glare **(A)** and mesopic with glare **(B)** contrast sensitivity values of two IOLs in different spatial frequencies. There were no statistically significant differences in any spatial frequencies. Own representation. [87]

4.1.2 Evaluation of glistenings

Based on our glistenings measurements, we found that the Z-Flex IOL group exhibited significantly fewer microvacuoles than the AcrySof IQ IOL group. According to the results of the semiquantitative evaluation using slit lamps, the difference was significant ($p < 0.001$), with the severity of glistenings averaging 0.57 ± 0.60 in the Z-Flex IOL group, compared to 1.82 ± 0.90 in the AcrySof IQ IOL group (Figure 3A). Our quantitative glistenings measurements using Scheimpflug image analysis clearly confirmed the results obtained from the semiquantitative slit-lamp evaluation. With a significant difference ($p < 0.001$), the Z-Flex IOL group demonstrated fewer glistenings (35.1 ± 1.63) compared to the AcrySof IQ IOL group (39.6 ± 3.69) (Figure 3B). When comparing the two glistenings assessment methods based on aggregated data from both groups (Z-Flex IOL and AcrySof IQ IOL, n = 51), a strong correlation was observed between the results (Spearman $r = 0.448$; $p = 0.001$; see Figure 3C).

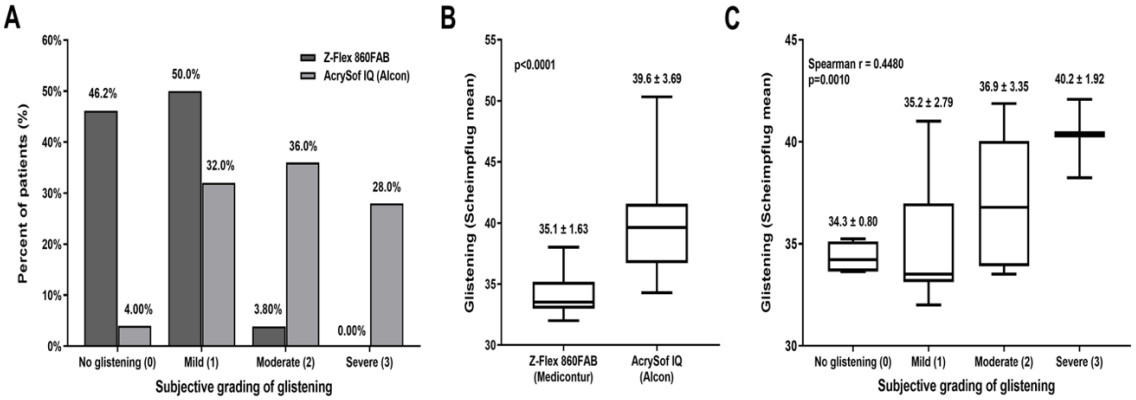

Figure 3A. Distribution of glistenings severity based on a semiquantitative scale, assessed by subjective slit-lamp examination in eyes implanted with Z-Flex 860FAB and AcrySof IQ SN60WF IOLs.

Figure 3B. Objective assessment of glistenings in AcrySof IQ SN60WF and Z-Flex 860FAB IOLs using Scheimpflug imaging followed by computer-based image. analysis.

Figure 3C. Correlation analysis of subjective slit-lamp grading and objective Scheimpflug image evaluation of glistenings in both IOL groups (Z-Flex 860FAB and AcrySof IQ SN60WF, n = 51), demonstrating a significant association between the two methods (Spearman $r = 0.448$; $p = 0.001$) [87]

The impact of glistenings on postoperative visual outcomes

Based on the semiquantitative slit-lamp assessment of glistenings, the number of cases per category (n=3–11) remained relatively low, even after combining data from all eyes. Therefore, the potential impact of glistenings on visual performance was evaluated solely using the results of Scheimpflug image analysis. These results indicated that glistenings did not have a significant effect on CDVA (p=0.951), regardless of their severity.

4.1.3 Evaluation of light scattering

No significant difference was found in the OSI values between the two IOL groups (p=0.888): the mean OSI was 2.52 ± 1.73 in the Z-Flex IOL group and 2.42 ± 1.69 in the AcrySof IQ IOL group. A slight inverse correlation was observed between OSI and CDVA (r^2=0.394; p=0.063), indicating that higher OSI values were associated with lower CDVA.

The light scattering caused by the tear film, represented by the average TF-OSI value, was 1.58 ± 1.03 in the AcrySof IQ IOL group, while it was significantly higher in the Z-Flex IOL group (2.79 ± 1.76). This difference was statistically significant between the two IOL groups (p=0.045) (see Figure 4A). Furthermore, a significant inverse correlation was found between TF-OSI and CDVA (r^2=0.440; p=0.035), suggesting that poorer tear film quality, which leads to higher TF-OSI values, results in lower CDVA (see Figure 4B)

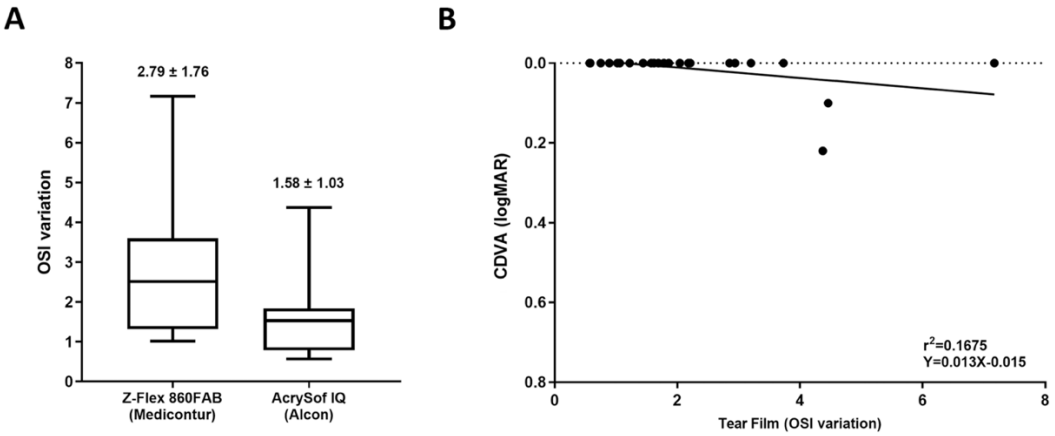

Figure 4A. The quality of the tear film was examined by the HD Analyzer and expressed as TF-OSI values for the different IOLs.

Figure 4B. Correlation between the TF-OSI and CDVA. Own representation. A significant inverse correlation was found between TF-OSI and CDVA (r^2=0.440; p=0.035) [87]

4.2 Visual performance and stability of 1stQ AddOn IOL secondarily implanted in the ciliary sulcus to correct pseudophakic ametropia

4.2.1 Patients and visual outcomes

The analysis included 14 eyes of 12 patients who underwent secondary surgery involving the implantation of a monofocal 1stQ AddOn IOL between 2013 and 2018. The mean follow-up duration was 34.34 ± 16.13 months. The indication for AddOn implantation was refractive correction in 13 eyes and the reduction of negative dysphotopsia in 1 eye. Ocular history included prior PRK in 3 eyes and non-exsudative age-related macular degeneration in 1 eye, which remained stable during the study period. The implanted AddOn IOLs ranged in power from −5.5 D to +8.5 D.

The preoperative UDVA for 1stQ AddOn IOL implantation was 0.53 ± 0.35 logMAR, while CDVA was 0.01 ± 0.04 logMAR (see Figure 5). In the first month following implantation, the mean UDVA improved to 0.05 ± 0.08 logMAR and CDVA to 0.03 ± 0.06 logMAR (Figure 6). At the final follow-up, UDVA was recorded as 0.05 ± 0.07 logMAR, while CDVA improved to 0.00 ± 0.07 logMAR (Figure 7). A significant improvement in UDVA was observed both at the first postoperative month ($p < 0.001$) and at the final follow-up ($p < 0.001$), based on the Wilcoxon paired rank test. However, for CDVA, no significant change was observed in the first month ($p = 0.500$) or at the final follow-up ($p = 0.625$), and no significant differences were found between different postoperative evaluations ($p = 0.250$).

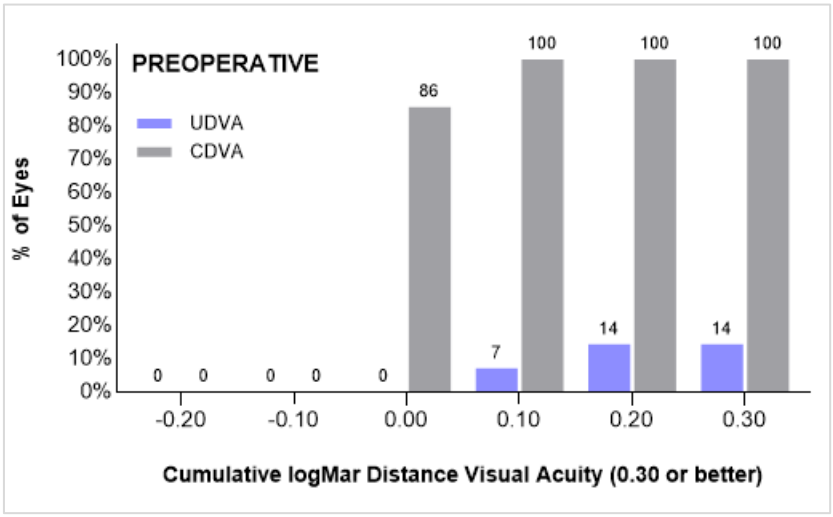

Figure 5. Preoperative UDVA and CDVA in patients undergoing 1stQ AddOn IOL implantation. Own representation. [88]

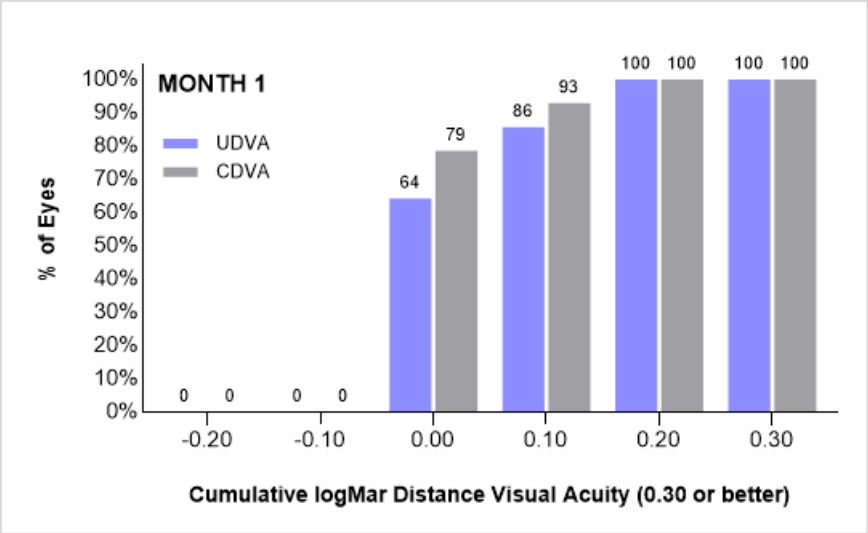

Figure 6. UDVA and CDVA at 1 month postoperatively in patients undergoing 1stQ AddOn IOL implantation. Own representation. [88]

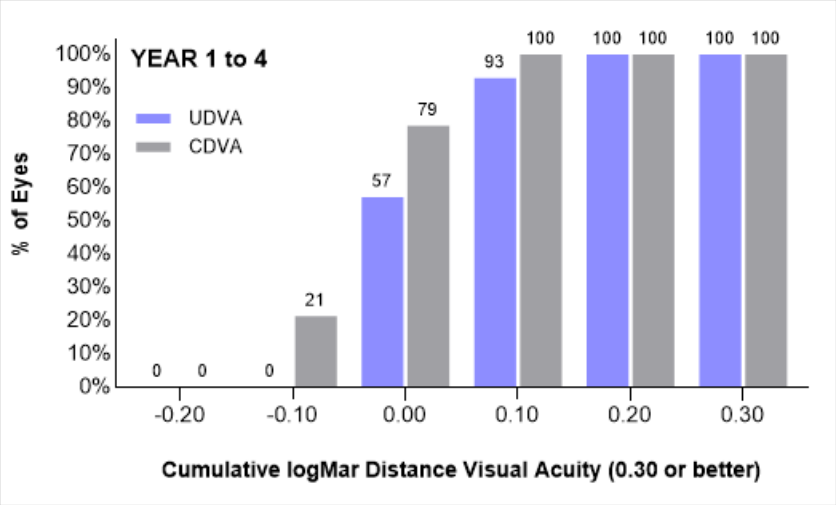

Figure 7. UDVA and CDVA at final follow-up (1–4 years postoperatively) in patients undergoing 1stQ AddOn IOL implantation. Own representation. [88]

Preoperatively, the spherical equivalent (SE) value of the required distance correction could not be achieved within 0.5D for any eye (0%), and only 50% of cases were within the 1D threshold. In contrast, at postoperative follow-ups, 85.7% and 71.4% of the eyes were within 0.5D at the first and final follow-ups, respectively, while 92.9% and 100% were within 1D (see Figure 8). Regarding preoperative cylindrical correction, the proportion of eyes within 0.5D increased to 57.1%, and within 1D, to 85.7%. At the 1-month postoperative control, these values were 92.9% for both 0.5D and 1D, and at the final follow-up, they remained around 92% (0.5D) and 100% (1D).

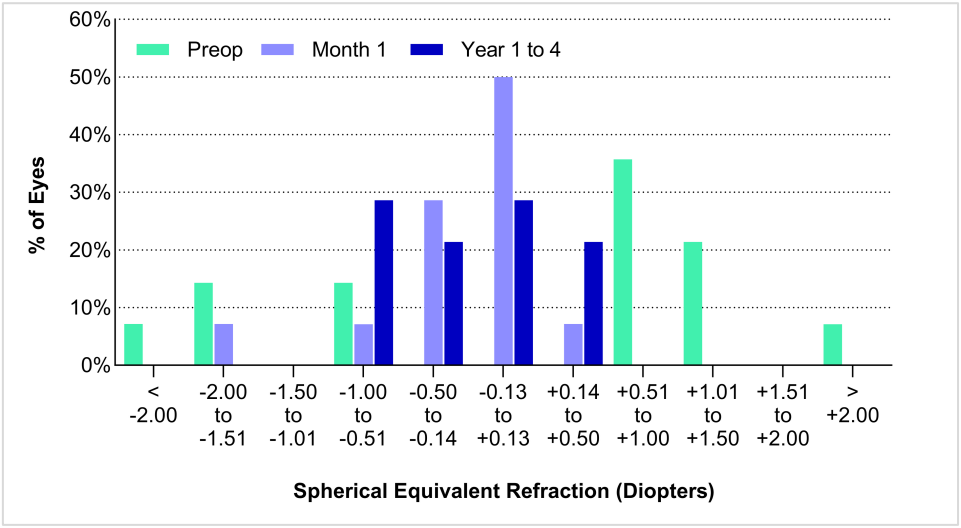

Figure 8. Distribution of spherical equivalent values pre- and postoperatively in eyes undergoing 1stQ AddOn IOL implantation. Own representation. [88]

No significant differences were found between preoperative and postoperative ECD (2302.8 ± 158.7 cells/mm² vs. 2234.1 ± 302.3 cells/mm², p = 0.125, based on the Wilcoxon paired rank test). During slit-lamp examinations, no postoperative inflammatory symptoms or signs of pigment dispersion were observed in any of the eyes. IOP values also showed no significant changes: the preoperative value was 15.2 ± 3.5 mmHg, while the postoperative values were 15.4 ± 3.9 mmHg at the 1-month follow-up (p = 0.891) and 15.3 ± 2.6 mmHg at the final follow-up (p = 0.668).

Additionally, no disturbing visual symptoms were reported by the patient who underwent 1stQ AddOn IOL implantation for the treatment of negative dysphotopsia.

4.2.2 Stability of the 1stQ AddOn IOL

The results of the studies indicated that the 1stQ AddOn IOLs were properly positioned and well-centered during both the initial and final postoperative evaluations. At the last follow-up, UBM measurements revealed that the mean distance between the two IOLs was 0.38 ± 0.16 mm (see Figure 9).

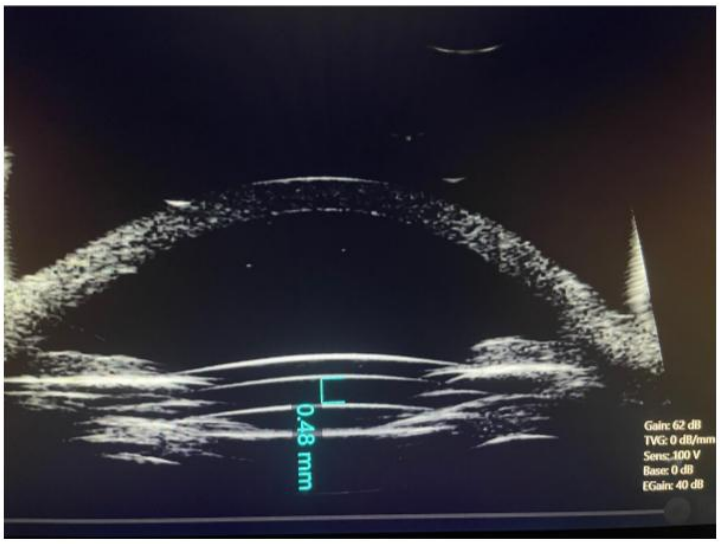

Figure 9. UBM image showing a secondarily implanted 1stQ AddOn IOL in the ciliary sulcus and a primary monofocal IOL positioned in the capsular bag. The interlenticular distance between the two lenses is 0.48 mm. Own image. [88]

5 DISCUSSION

Several studies have investigated the phenomenon of glistenings; however, their impact on visual function remains not fully understood. According to multiple studies, glistenings do not have a significant effect on either visual acuity or contrast sensitivity [89, 90, 91]. In contrast, other studies have reported reduced visual acuity in association with the presence of glistenings, along with a decline in contrast sensitivity, particularly at higher spatial frequencies [14]. Data suggest that glistenings may contribute to deviations in the visual field, as indicated by increased loss of variance and mean deviation values observed in visual field studies [78, 80]. Most studies suggest that glistenings have a moderate impact on visual function. However, in certain hydrophobic IOLs with a high degree of glistenings, a significant decrease in contrast sensitivity has been observed due to increased light scattering [39]. Glistenings in IOLs lead to a reduction in the modulation transfer function (MTF) at the IOL [92]. However, it remains unclear how critical this reduction is and at what threshold it leads to a noticeable decrease in contrast sensitivity for the patient. The study by DeHoog and Doraiswamy demonstrated that glistenings composed of 2-µm microvacuoles have the most significant impact on light scattering [89]. Examining the percentage area ratio of glistenings and the area/size ratio, it was found that glistenings composed of microvacuoles with diameters ranging from 6 to 25 µm correlate with light scattering measured at a critical size. This suggests that at this specific size, glistenings influence light scattering [93]. Based on these findings, glistenings composed of smaller vacuoles induce greater light scattering even at the same area ratio compared to glistenings composed of larger vacuoles. While most studies do not indicate a significant optical impact of glistenings, in certain cases, the optical effect can be so pronounced that explantation of the IOL and implantation of a new, glistenings-free IOL becomes the only solution due to the visual disturbances caused by glistenings. Cases have been reported where AcrySof IOLs were removed due to glistenings, as they caused intolerable visual symptoms for the patient in bright light and during nighttime driving [94, 95]. There are also known cases where the removal of the AcrySof IOL was necessary because it significantly impaired even the examination of the fundus [96]. Based on our own previous unpublished experience, the IOL had to be removed from two eyes due to glistenings, as the 3+ level of glistenings assessed on

the slit lamp scale caused severe contrast sensitivity reduction and difficulties in night driving for the patient. Following the replacement of the IOL and the implantation of a new, glistenings-free IOL, the patient's complaints completely resolved. Overall, the data suggest that although the effect of glistenings on vision is generally moderate, in certain cases, they may induce clinically significant changes. The integrated application of glistenings assessment methods enables the identification of cases where glistenings substantially affect visual function. The severity of glistenings can be evaluated during a slit lamp examination using a predefined numerical scale by the examiner; however, this method largely depends on the subjective judgment of the evaluator. For a more objective and examiner-independent assessment, the computer-based analysis of Scheimpflug images appears to be more suitable. In recent years, further advances have been made in this field. Fernández-Vigo et al. introduced a swept-source OCT (SS-OCT)-based classification system, later complemented by a deep learning algorithm, to automatically quantify hyperreflective foci in pseudophakic eyes [97]. Although these studies demonstrated the feasibility of OCT-based analysis, they lacked direct validation against established methods. This limitation was addressed in a subsequent study, in which SS-OCT was compared with light microscopy and straylight measurements in vitro. Their results showed a strong correlation with microscopy and a proportional relationship with straylight, confirming that OCT-detected hyperreflective foci can indeed be interpreted as glistenings [98]. In this study SS-OCT measurements were validated against light microscopy and straylight assessment, but not against Scheimpflug imaging, which represents another objective method applied in our investigation. It should also be emphasized that these OCT-based techniques and the corresponding results were published only after our study had been completed, at a time when Scheimpflug imaging was the objective approach available. In our investigation, we applied both slit lamp grading and Scheimpflug-based image analysis, and found that the results were statistically equivalent, showing a strong correlation. This confirms that the subjective method can also provide reliable data for the clinical characterization of glistenings. Based on measurements performed with both techniques, the Z-Flex IOL exhibited significantly fewer glistenings than the AcrySof IQ IOL. A statistically significant difference was found between the IOL diopter values of the two examined groups, with the average diopter value being higher in the AcrySof IQ group compared to the Z-Flex

IOL group. This partially explains why the extent of glistenings was greater in the AcrySof IQ IOL group, as material degradation, including the formation of glistenings, is more likely to occur in higher D, thicker IOLs [47]. It is known that the instability and inadequate quality of the tear film have a negative impact on the quality of vision [99]. The tear film plays a crucial role in determining postoperative visual quality following cataract surgery; therefore, this factor must be carefully considered [100, 101]. Considering that the tear film has a significant influence on optical performance, we excluded patients with severe ocular surface diseases, including pronounced dry eye disease. However, we found a significant difference in TF-OSI values between the two examined IOL groups, with a notably higher TF-OSI value in the Z-Flex group.

One limitation of our study is that we focused only on the overt symptoms of dry eye, which may not be sufficient for an accurate assessment of dry eye disease. Consequently, TBUT, Schirmer tests, and tear meniscus measurements were not performed.

Based on the results, since the Z-Flex IOL exhibited a lower degree of glistenings, it could have been expected to yield better visual acuity and higher contrast sensitivity compared to the AcrySof IQ group. However, all visual parameters measured during the study, including UDVA, CDVA, and contrast sensitivity, were comparable between the two groups, with no statistically significant differences. The advantage of reduced glistenings in the Z-Flex IOL was partially counterbalanced by increased light scattering from the tear film (TF-OSI). Compared to the AcrySof IQ IOL group, the TF-OSI value was significantly higher in the Z-Flex group, whereas the total intraocular light scattering (OSI) value did not differ significantly between the two groups.

These findings suggest that in the Z-Flex IOL group, tear film quality has a substantial impact on visual quality, potentially offsetting the benefits of reduced glistenings over the AcrySof IQ IOL group. Considering these results, it is evident that tear film instability or insufficiency may influence postoperative visual quality as significantly as the degree of glistenings, indicating that the interaction of these two factors plays a critical role in the final optical outcome.

The main limitation of this study lies in the inability to isolate the visual effects of glistenings-related light scattering. Consequently, it was not possible to determine the exact extent to which glistenings alone contribute to intraocular light scatter or affect

visual function directly. Moreover, OSI values may be confounded by other variables, such as tear film instability, potentially leading to misinterpretation of the results. Finally, the relatively small sample size in both groups limits the generalizability of our findings, highlighting the need for larger-scale studies to confirm these observations.

In modern clinical practice, patients increasingly expect not only refractive lens exchange but also conventional cataract surgery to yield optimal refractive outcomes. Nevertheless, postoperative results are not always ideal, and residual refractive errors may persist. Such suboptimal outcomes can be addressed through secondary procedures, including the implantation of additional monofocal, toric, or, when appropriate, multifocal intraocular lenses in the ciliary sulcus. The results achieved after secondary lens implantation in the ciliary sulcus have demonstrated both high efficacy and safety [102]. Residual refractive astigmatism may be managed with spectacles or contact lenses; however, a substantial proportion of patients prefer to achieve optimal visual acuity without dependence on external optical aids [103]. Surgical alternatives for correcting residual refractive astigmatism include corneal refractive surgery, the use of arcuate partial-depth incisions, IOL exchange, and secondary IOL implantation [104, 105, 106, 107]. However, corneal refractive procedures such as PRK and LASIK may, in certain cases, exacerbate dry eye symptoms and negatively impact visual outcomes. Additionally, their feasibility depends on corneal thickness [108]. Limbal relaxing incisions (LRI) and femtosecond arcuate keratotomies have been found to be effective in treating mild to moderate (<2.5–3.0 D) astigmatism. However, for moderate to high astigmatism, these techniques are less suitable, as such cases require toric IOL correction [106]. On the other hand, LRI and femtosecond arcuate keratotomy are typically only suitable for reducing mild corneal astigmatism. Laser corneal refractive procedures are insufficient for correcting larger residual refractive errors, in which case IOL exchange or secondary supplementary IOL implantation is required [109]. Although IOL exchange can yield favourable refractive outcomes, this procedure carries significant risks, including potential zonular injury and rupture of the capsular bag. Compared to IOL exchange, secondary intraocular lens implantation in the ciliary sulcus represents a less invasive and safer alternative. These so-called piggyback or add-on IOLs not only provide effective correction of residual refractive errors following primary monofocal IOL implantation but may also offer additional clinical advantages [20]. Secondary IOL

implantation serves as an effective strategy for managing residual refractive errors in more complex post-keratoplasty cases, particularly in pseudophakic patients requiring astigmatism correction. Postoperative astigmatism following penetrating keratoplasty often emerges as a limiting factor in visual quality, with up to 20% of patients experiencing refractive errors that cannot be adequately corrected with spectacles or contact lenses. Clinical evidence indicates that the implantation of a supplementary intraocular lens may serve as a reliable and effective option for refractive correction in pseudophakic patients, including those with a history of penetrating keratoplasty [110]. Attaining optimal uncorrected visual acuity at near, intermediate (e.g., for computer use), and distance ranges remains a primary goal of cataract surgery. However, multifocal intraocular lenses (IOLs) may not consistently deliver satisfactory visual outcomes, particularly in the presence of factors such as insufficient neuroadaptation, ocular surface disease, IOL misalignment, or postoperative retinal pathology—including diabetic macular oedema, age-related macular degeneration, or sequelae of retinal detachment. In such cases, multifocal IOLs may fail to deliver satisfactory visual performance, necessitating their removal. While the explantation of a multifocal IOL primarily implanted in the capsular bag is associated with a higher risk of complications—including damage to the capsular bag or zonules, as well as vitreous loss—the removal of a supplementary IOL implanted in the ciliary sulcus is significantly simpler and carries a lower risk [111]. Considering these factors, the implantation of a supplementary multifocal IOL, either as a primary or secondary procedure, may sometimes be the optimal solution for achieving pseudophakic multifocality. The primary implantation of a supplementary intraocular lens (IOL) into the ciliary sulcus—commonly referred to as the 'Duet procedure'—is a two-step surgical approach performed during cataract surgery. In this technique, a monofocal IOL is first placed into the capsular bag, followed by the implantation of a supplementary multifocal IOL in the ciliary sulcus within the same operative session. This strategy offers a safe and flexible alternative for patients with uncertain preoperative candidacy for multifocal IOLs or with concerns regarding neuroadaptation. In cases where patients exhibit intolerance to the multifocal IOL due to insufficient neuroadaptation or postoperative complications—such as ocular surface disease, macular pathology (including oedema, degeneration, epiretinal membrane, or sequelae of retinal detachment), or IOL decentration—the sulcus-implanted multifocal

lens can typically be explanted in a safe and straightforward manner. The Duet procedure is also applicable in cases of extreme refractive error, allowing the refractive power to be distributed between the two IOLs. Furthermore, if residual refractive errors remain within the correction range of the supplementary IOL, they can be addressed by simply exchanging the supplementary IOL [112]. Following vitrectomy procedures with silicone oil tamponade, changes in ocular refraction can occur, potentially leading to significant anisometropia. In selected cases, the temporary implantation of a supplementary IOL into the ciliary sulcus may serve as an interim refractive solution, which can be safely removed at the time of silicone oil extraction if necessary [113]. The implantation of two IOLs in one eye, known as the piggyback technique, was first described in 1993 [114]. Initially, both lenses were implanted within the capsular bag; however, this frequently resulted in interlenticular opacification due to the proliferation of capsular epithelial cells [115]. Subsequently, the supplementary IOL began to be implanted in the ciliary sulcus. However, early reports indicated that inappropriate IOL models were used, originally designed for capsular bag implantation, such as the AcrySof MA60MA, SA60AT, and MA60BM [116]. The literature includes multiple reports of complications associated with the implantation of IOL originally designed for capsular bag fixation into the ciliary sulcus [117, 118, 119]. These complications included pigment dispersion, iris transillumination defects, dysphotopsia, pigmentary glaucoma, intraocular haemorrhage, cystoid macular oedema, hyperopic defocus, and pupillary margin entrapment within the IOL [120, 121, 122, 123]. These IOLs are originally designed for implantation into the capsular bag, and when implanted in the ciliary sulcus, their sharp edges may cause irritation to the iris [124]. In 2009, the Cataract Clinical Committee of the American Society of Cataract and Refractive Surgery concluded that IOLs specifically designed for implantation within the capsular bag should not be placed in the ciliary sulcus. This recommendation is grounded in the anatomical consideration that the haptics of these lenses are typically oversized for sulcus placement, which may lead to mechanical contact with the posterior iris surface. Moreover, their overall dimensions are often insufficient for stable positioning within the ciliary sulcus, increasing the risk of decentration, particularly in eyes with larger anatomical dimensions [106]. This issue was successfully addressed in 2007 with the introduction of the Sulcoflex piggyback IOL family (Rayner, United Kingdom). Subsequently, this was followed by the Medicontur 1stQ AddOn®

IOL family and the Reservo multifocal piggyback IOL (Cristalens, France) [113]. At the Department of Ophthalmology, Péterfy Sándor Street Hospital, one of the most widely used supplementary intraocular lenses (IOLs) is the 1stQ AddOn® IOL. This lens is typically selected when visual outcomes following uncomplicated cataract surgery are suboptimal and additional refractive correction is required.

As part of the preoperative assessment, a comprehensive ophthalmic evaluation is essential in all cases. This includes visual acuity testing, determination of objective and manifest refraction, slit-lamp biomicroscopy, ECD measurement, and a detailed biometric examination. According to the biometric evaluation, the ACD must be at least 2.8 mm, as this is the minimum implantation criterion defined by the manufacturer.

Our study comprehensively analyzed the visual performance and stability of the monofocal 1stQ AddOn® IOL secondarily implanted in our department. Our observations indicate that the supplementary IOL resulted in a significant long-term improvement in uncorrected vision during the postoperative period, with postoperative UDVA remaining stable even years after surgery. No postoperative complications, such as increased IOP, chronic inflammation, or pigment dispersion, were observed, and there was no significant decrease in ECD. The findings of our study demonstrated that the 1stQ AddOn® IOLs were properly positioned and well-centered at both the initial and final postoperative follow-ups. Both slit-lamp biomicroscopy and UBM confirmed that the secondarily implanted 1stQ AddOn® IOL in the ciliary sulcus maintained an appropriate separation from the primary IOL positioned in the capsular bag. The mean distance between the two IOLs, measured using UBM (0.38 ± 0.16 mm), was sufficient to prevent the formation of interlenticular opacity. Our results align with previously published data, indicating that supplementary IOLs implanted in the ciliary sulcus provide satisfactory refractive outcomes and ensure safe applicability.

6 CONCLUSIONS

A strong correlation was found between the numerical grading of glistenings using slit-lamp examination and its quantitative assessment via Scheimpflug image analysis. This confirms that the quantitative evaluation of Scheimpflug images can reliably describe the presence of glistenings in a clinical setting. The methodology we employed, integrating Scheimpflug image analysis and computational image processing, provided an objective and reliable tool for the quantitative assessment of IOL glistenings, which may serve as a valuable basis for future clinical studies.

Overall, the findings of our study suggest that although a higher degree of glistenings was observed in the AcrySof IQ IOL group, this difference did not lead to statistically significantly worse visual outcomes in terms of either visual acuity or contrast sensitivity compared to the Z-Flex IOL group. Our results indicate that while the Z-Flex IOL group exhibited a lower degree of glistenings, this advantage was partially offset by the increased light scattering (TF-OSI) measured in the Z-Flex IOL group, which was induced by the tear film. While no significant differences were found in total intraocular light scattering (OSI) between the two groups, the scattering caused by the tear film was significantly higher in the Z-Flex IOL group. This suggests that in the Z-Flex IOL group, the quality of the tear film is a dominant factor influencing postoperative visual quality, potentially offsetting the advantage of lower glistenings compared to the AcrySof IQ IOL group, where a higher degree of glistenings was observed. The formation of postoperative visual outcomes is influenced not only by the extent of glistenings but also by the stability and quality of the tear film. The complex, multifaceted evaluation methodology applied in our study allowed for a comprehensive assessment of postoperative refractive outcomes, the degree and distribution of glistenings, and the optical quality of the tear film, thereby contributing to an objective evaluation of patients' visual performance and comfort. It is well established that the impact of glistenings can sometimes be severe enough that, in extreme cases, IOL exchange becomes the only viable solution to restore visual quality. In conclusion, there appears to be a glistenings threshold above which the optical imperfections of the IOL may have clinically significant adverse effects on the patient's visual performance. Long-term follow-up is necessary to precisely quantify this threshold and determine its impact.

Our study, in line with the literature, confirms that the implantation of the 1stQ AddOn® IOL in the ciliary sulcus provides an effective and safe solution for residual refractive errors following cataract surgery, offering several advantages over IOL exchange procedures. This intervention ensures the long-term stable positioning of the supplementary IOL in the ciliary sulcus while maintaining sufficient distance between the primary IOL implanted in the capsular bag and the 1stQ AddOn IOL in the sulcus to prevent the development of interlenticular opacity. Our findings demonstrate a significant, long-term improvement in uncorrected visual acuity without postoperative complications such as increased IOP, chronic inflammation, or pigment dispersion, and without a significant decrease in ECD. The implantation of a supplementary IOL in the ciliary sulcus is particularly beneficial for patients with residual refractive astigmatism that cannot be adequately corrected with glasses or contact lenses, as well as for those who do not achieve satisfactory visual outcomes with conventional multifocal IOLs implanted in the capsular bag. The application of supplementary IOLs in the ciliary sulcus across various indications facilitates optimal correction of pseudophakic ametropia and enhances multifocality. Overall, the use of the supplementary 1stQ AddOn® IOL implanted in the ciliary sulcus provides a reliable, long-term stable, and safe approach for optimizing suboptimal refractive outcomes. It represents a significant advantage over IOL exchange procedures, particularly within the framework of the Duet procedure, which serves as a reliable and safe alternative for achieving optimal pseudophakic multifocality.

Expanding the sample size of our study and incorporating advanced ophthalmic imaging techniques would significantly enhance the accuracy of data collection regarding the clinical application of the 1stQ AddOn IOL. This would allow for a more detailed assessment of the stability and refractive outcomes of the 1stQ AddOn IOL, contributing to the refinement of treatment strategies and the optimization of future clinical decision-making.

In summary, both studies underscore the importance of selecting appropriate IOL materials and accounting for tear film quality to optimize postoperative visual outcomes. The implantation of AddOn IOLs in the sulcus ciliaris presents a promising strategy for correcting residual refractive errors and enhancing patient satisfaction with cataract surgery outcomes.

7 SUMMARY

Cataract surgery is among the most commonly performed and most successful procedures worldwide, yet visual outcomes do not always meet expectations. Even after uneventful surgery, postoperative visual quality may be compromised due to residual refractive errors, tear film instability, or microstructural changes in the IOL material such as glistenings. This thesis aimed to investigate two specific aspects related to visual performance in pseudophakic eyes.

In the first study, we analyzed 42 eyes of 51 patients implanted with either AcrySof IQ or Z-Flex hydrophobic acrylic IOLs. Glistenings were assessed using both semiquantitative slit-lamp grading and computer-assisted Scheimpflug image analysis. A strong correlation was found between subjective grading and objective measurements ($r = 0.81$, $p < 0.001$). Although glistenings were more pronounced in the AcrySof IQ group (mean score: 3.2 vs. 1.7, $p < 0.01$), visual acuity and contrast sensitivity did not differ significantly between the groups. However, the tear film–related scatter index (TF-OSI) was significantly higher in the Z-Flex group (2.65 ± 0.81 vs. 1.92 ± 0.65; $p = 0.004$), indicating that tear film quality may offset the potential optical benefits of reduced glistenings.

The second study focused on the clinical outcomes of secondary implantation of the 1stQ AddOn IOL in the ciliary sulcus for the correction of pseudophakic ametropia. Fourteen eyes of 12 patients were followed for a mean of 34.3 ± 16.1 months. Uncorrected visual acuity improved significantly (from 0.42 to 0.81 on the decimal scale), and the lenses remained stable without complications such as elevated intraocular pressure, pigment dispersion, or endothelial cell loss.

In conclusion, our findings underscore the importance of both IOL material properties and ocular surface quality in determining postoperative visual performance. Supplementary IOL implantation in the sulcus offers a safe and effective solution for residual refractive errors, providing a minimally invasive alternative to IOL exchange and contributing to improved patient satisfaction.

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