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Incidence of Dysphotopsia in Patients Implanted with the C-flex® Intraocular Lens with 360° Enhanced Edge: A Questionnaire-Based Study

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Abstract

Background: To evaluate the incidence of dysphotopsia associated with the hydrophilic C-flex® monofocal intraocular lens (IOL) with 360° enhanced edge in patients undergoing cataract surgery.

Design: Single-centre (hospital), consecutive case study

Participants: Forty patients (average age, 76.6 years [range, 62-85 years]) without co-morbidity who underwent phacoemulsification surgery.

Methods: All patients were implanted with the hydrophilic C-flex® (570C) monofocal IOL (Rayner Intraocular Lenses Limited, Hove, UK) through a 2.8 mm incision. The C-flex® has 360° enhanced edge designed to reduce the centripetal migration of the lens epithelial cells. Patients underwent a slit lamp examination 1 day, 1 week, 1 month and 3 months postoperative, and were asked to complete a questionnaire describing any visual symptoms at their one-month or three-month visit.

Main outcome measures: Incidence of dysphotopsia and patient satisfaction.

Results: Eighteen (45%) patients reported no ocular symptoms at their 1 or 3 month postoperative visit, and none of the 22 (55%) patients who did report visual disturbances found their symptoms debilitating. The most common post-operative visual phenomenon was glare, reported by 23% of patients; unwanted imagery was noted in 17% (7) patients. Almost all patients (98%) patients stated that they were either very satisfied or satisfied with their visual outcomes following C-flex® lens implantation.

Conclusion: The C-flex® IOL was associated with a low incidence of dysphotopsia and a high degree of satisfaction with postoperative visual outcomes. Unwanted imagery, which could be related to the lens implant, occurred in only one out of forty patients.

Keywords: Dysphotopsia; Questionnaire; 360° enhanced edge; Lens implant- hydrophilic

Introduction

Unwanted optical disturbances, such as arcs, haloes and light sensitivity, collectively known as dysphotopsia, may occur even following an uneventful, successful cataract surgery. Positive dysphotopsias are result of IOL decentration, design and material factors and include rainbows, crescent, streaks, halos, glare and fog. Negative dysphotopsias are relative and absolute scotomas reported as temporal, dark, crescent shaped shadows, which gets better with time. Both are a major cause of patient dissatisfaction and in the worst cases, may require IOL explantation or exchange [1,2].

In the past, numerous factors were identified as potential contributors to dysphotopsia in post-cataract patients, including positioning or dialling holes in posterior chamber IOLs, which, if the lens decentred caused disabling visual disturbances [3-5]. Consequently, the last two decades have seen modifications in lens design, for example, removing positioning holes, employing round rather than oval optics, and using single piece lenses in place of three piece lenses for better centration.

Despite developments in lens technology and design, dysphotopsia may still occur, particularly during scotopic conditions when the pupil is larger, but also when a lens with a high refractive index, and a high radius of curvature to the anterior surface is used [6-8]. An additional factor that may contribute to the occurrence of dysphotopsia is the use of a square-edged optic which may produce an internal reflection off the optic edge. Findings from a prospective randomized study that included 600 patients who underwent phacoemulsification surgery, showed that optic phenomena occurred more frequently in patients implanted with the square-edged AcrySof® (5.5 and 6 mm) IOL (Alcon, Fort Worth, Texas, USA) than with the AMO Clariflex® lens (Abbott Medical Optics, Inc, Abbott Park, Illinois, USA), which has a round anterior and posterior square edge [9].

The C-flex® IOL (Rayner Intraocular Lenses Limited, Hove, UK) made of hydrophilic acrylic biomaterial has several design features which would help to reduces the risk of glare compared with

hydrophobic acrylic biomaterials such as a relatively low refractive index of 1.46 and an absence of vacuoles or glistenings [10,11]. It also incorporates several other features designed to address dysphotopsia including an equiconvex optic and constant thickness of the central optic across different lens powers [10]. Additionally, the C-flex® haptics have an empty slot of 0.6 mm which helps to resist the forces of capsular contraction and ensure accurate centration. Furthermore, the C-flex® also has an Amon-Apple enhanced square edge at the optic-haptic junctions designed to provide a 360° barrier effect to the centripetal migration of the lens epithelial cells (Figure 1) [11,12].

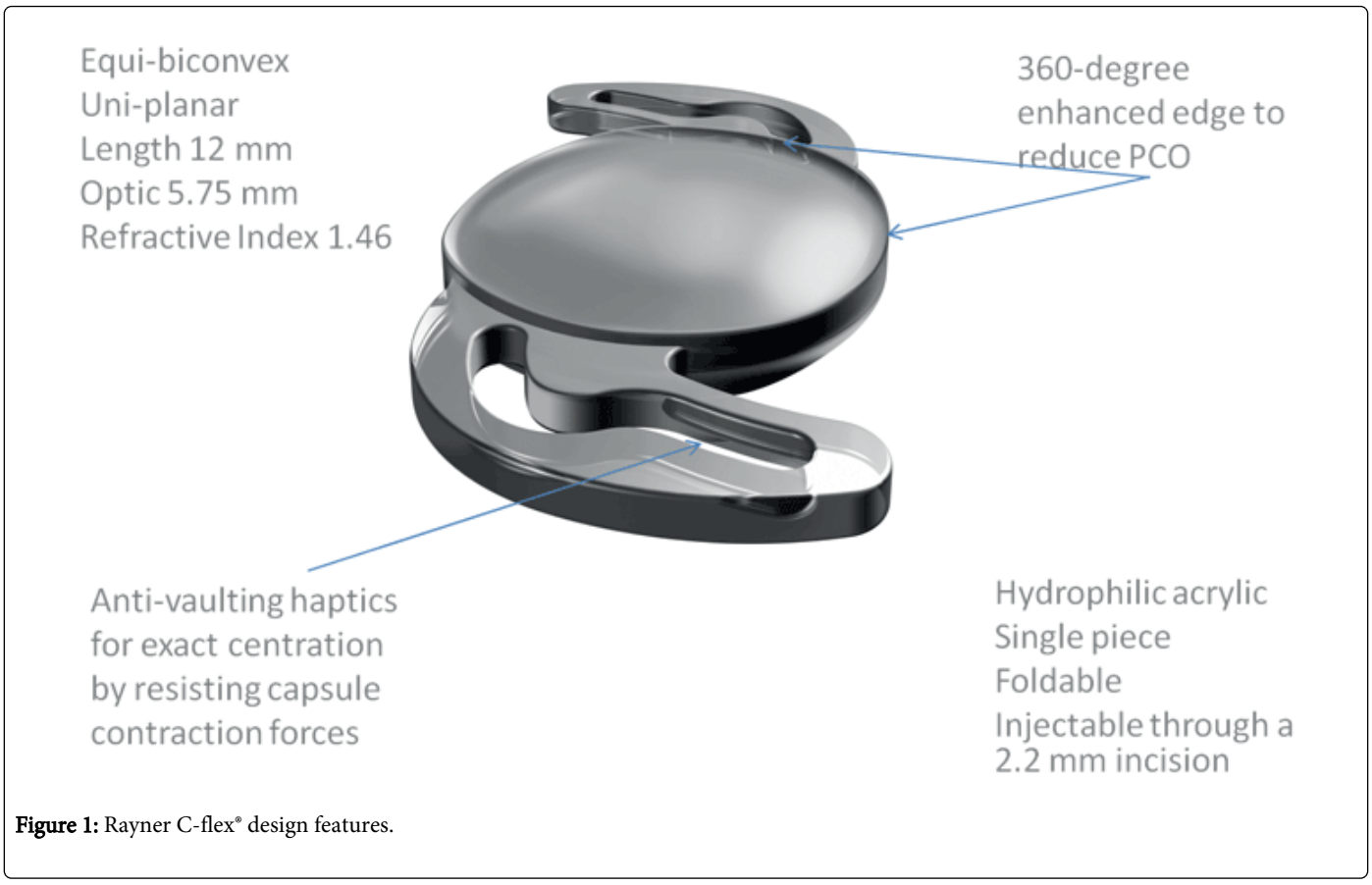

Figure 1: Rayner C-flex® design features.

Although ray-tracing studies show no general increase in glare as a result of the Amon-Apple enhanced square edge, [11] there is a paucity of published literature describing the incidence of optic phenomena associated with this particular lens. The aim of this study, therefore, was to assess the occurrence and nature of any dysphotopsia associated with the C-flex® monofocal IOL.

Methods

Study design and patients

This was a single-centre, single surgeon, consecutive case study that included 40 patients (average age, 76.6 years [range, 62-85 years]) without co-morbidity who underwent phacoemulsification surgery at Scarborough District General Hospital, Scarborough, UK. Only one eye of each patient was operated during the study period. All patients provided written informed consent prior to study procedures. Ethics approval was not required as the data formed part of a departmental clinical audit to capture patient satisfaction, post cataract surgery.

Surgical procedure

All surgical procedures were performed under topical anaesthesia. Following a temporal 2.8 mm incision with a keratome, up to 0.4 ml of 1% lignocaine was injected intracamerally. Every attempt was made to obtain a round centrally placed capsulorrhexis to allow subsequent 360° overlap of the implant optic. Using the 'divide and conquer' technique, each quadrant was removed using phacoemulsification. Viscoelastic was used to ensure proper capsular bag expansion, and the Rayner C-flex® (570C) lens was injected into the bag through an un-enlarged 2.8 mm incision. The viscoelastic was then removed. Good lens centration ensured a 360° overlap of the optic at the end of surgery. None of the eyes required sutures.

Follow-ups

Eyes underwent a slit lamp examination 1 day, 1 week, 1 month and 3 months postoperatively. Pupils were dilated with 1% tropicamide and 2.5% phenylepherine eye drops at the 1 and 3 months visits. All patients were asked to complete a questionnaire based on previously published studies [13,14] (Figure 2) describing any ocular symptoms, at their 1 month or 3 month visit. At each visit, patients were examined on slit lamp. The anterior segment examination was performed to specifically look for posterior capsule opacification, capsule folds, IOL decentration and absence of 360° overlap of IOL optic with the anterior capsule. A macular and retinal periphery examination was also performed to look for posterior vitreous detachment, vitreous floaters and macular pathology.

Since your surgery, have you noticed any persistent:

1. Light caused glare (like driving into the sun)?

Please specify which eye

Yes No Left Eye Right Eye

If yes, is it:

Minimal/annoying/debilitating

2. Increase in light sensitivity (like when looking at lights at nights)?

Yes No Left Eye Right Eye

If yes is it:

Minimal/annoying/debilitating

3. Unwanted images (such as flashes of light, arcs or partial circles to the side of a light)?

Yes No Left Eye Right Eye

If yes, are they:

Minimal/annoying/debilitating

If you have noticed unwanted images, are they primarily:

Halos around lights?	Yes	No
Light to the side causes central flash?	Yes	No
Unwanted generalised light sensitivity?	Yes	No
Arcs of light in the side vision?	Yes	No
Something else? Please describe	Yes	No

In regard to your current vision, would you say you are:

Very satisfied
Satisfied
Neutral
Dissatisfied
Very dissatisfied

If neutral or dissatisfied, how much of your dissatisfaction is related to unwanted images?

None
Little
50%
Most
All

Thank you for your time and participation in this questionnaire

Figure 2: Patient Questionnaire.

Only patients with a postoperative visual acuity of 20/30 or better, with or without correction, were included in the analysis. Results were compared with those reported in Tester-Olson and Wallin-Olson's studies which have used same questionnaire and similar methods. Statistical analysis was done with Fisher's exact test.

Results

All 40 patients included in the study completed the questionnaire and were eligible for study analysis. None of the eyes showed signs of posterior capsule opacification or required YAG capsulotomy at three months. None of the patients found their optical disturbances debilitating and 18 (45%) patients reported no optical symptoms at all. Of the 22 (55%) patients who did report optical disturbances, their symptoms were either 'minimal' or 'annoying', with 17 (43%) patients describing their symptoms as 'minimal' and 5 patients (12%) describing them as 'annoying'.

In total, 9 of 40 patients (23%) reported a degree of glare, while 7 patients (17%) said they had experienced an increase in light sensitivity. Seven patients (17%) stated that they had experienced unwanted images of some kind. These unwanted images comprised a minimal increase in light sensitivity in 2 patients (5%), and an arc of light in the peripheral vision in 2 patients (5%), one of whom had a cloud of floaters in the peripheral and central vitreous. Three patients (8%), who were unable to classify the nature of their unwanted images, described 'little black dots', 'flashing light on the side', or said that they were 'just uncomfortable' (Figure 3).

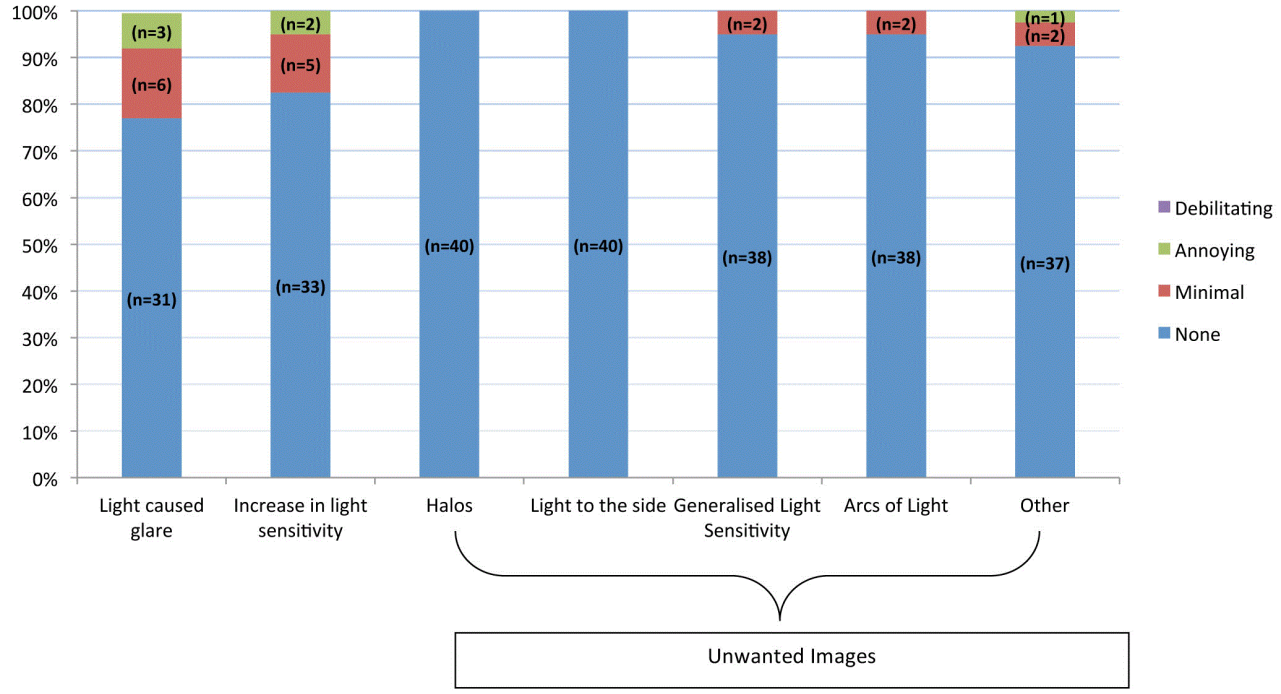

Figure 3: Incidence, Nature and Severity of Optical Disturbances with the C-flex (n=40)

None of the patients included in this study were dissatisfied with their visual outcomes. All but one patient stated that they were very satisfied or satisfied with their vision. The remaining patient assigned a 'neutral' rating to their visual outcomes due to the occurrence of flashes upon wakening (Figure 4).

When incidence of light glare and eye sensitivity with C-flex® was compared with those reported in Tester-Olson's study with AcrySof® (Alcon MA 30 & MA60) and Silicone (Allergan SI-40) lenses, there was no statistically significant difference (Table 1). However, incidence of unwanted imagery was higher with AcrySof® than with C-flex® lens and the difference was statistically significant (p=0.0138). The difference in unwanted imagery between Silicone and C-flex® lenses was not statistically significant (p=0.2933).

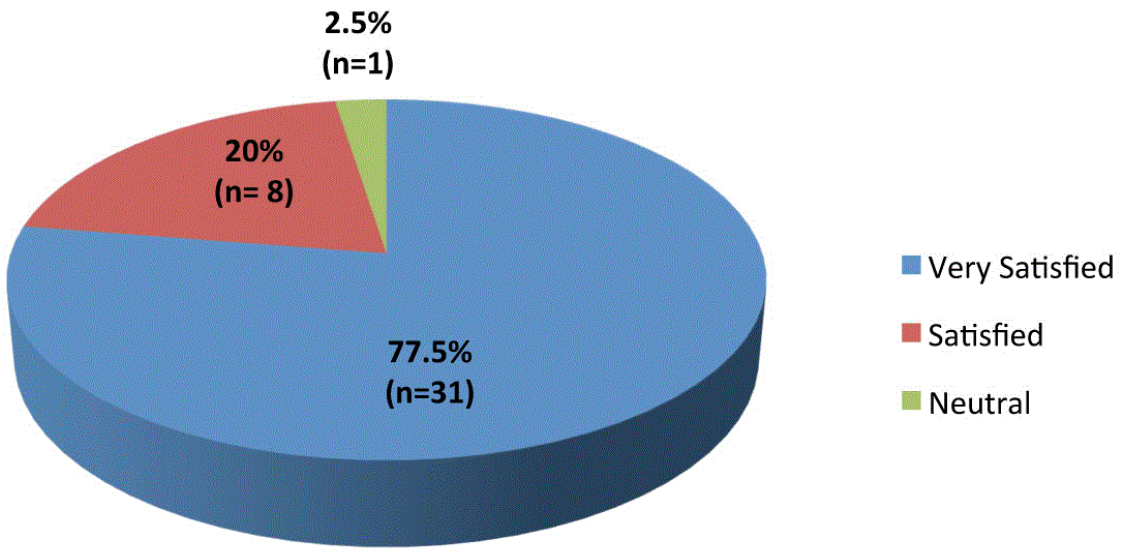

Figure 4: Patient Satisfaction with Visual Outcomes Post-Surgery (n=40).

Lens/Control	n	Light glare %	Eye sensitivity %	Unwanted imagery %
Acrysof® (Alcon MA60 & MA30)	101	19	36	33
Silicone (Allergan SI-40)	50	20	38	24
Phakic Controls	50	22	34	4
C-flex® (Rayner 570C)	40	23	17	17

Table 1: Incidence of C-flex symptoms as compared with lenses evaluated in Tester-Olson's study [13].

Discussion

Despite modifications in lens design, dysphotopsia may still occur in pseudophakic patients.

Pseudophakic dysphotopsia is one of the greatest sources of patient dissatisfaction following cataract surgery, and correlates strongly with visual function [1,2].

Pseudophakic dysphotopsia and its relation to IOL design have been explored in the literature. Bournas and colleagues reported that optic phenomena occurred more frequently in patients implanted with the square-edged AcrySof than with the AMO Clariflex® lens, which has a round anterior and posterior square edge [9]. Data from a prospective randomized study of 61 patients also revealed that at 8 weeks postoperative, the incidence of positive and negative dysphotopsia was 31.3% in the group implanted with the SN60-AT® IOL (Alcon) and 20.7% in the group implanted with the Akreos Adapt® lens (Bausch & Lomb, Rochester, New York, USA). Although both are square-edged, single-piece acrylic lenses with the same optic diameter, the authors noted that the Akreos Adapt IOL has a lower radius of curvature and a lower refractive index design, which, in theory, makes it less prone to dysphotopsia than the SN60-AT® IOL. However, the authors also remark that the Akreos® IOL has a 50% greater edge thickness-a significant factor in a positive dysphotopsia edge effect [15].

Shambhu et al. also compared the incidence of dysphotopsia associated with different lens types, comparing the AcrySof® MA30BA and MA60BM (Alcon) lenses with the Akreos Fit® single-piece lens [16]. Data from this 111-patient study showed that there was significantly less dysphotopsia with the Akreos lens when compared to the Acrysof MA30 and MA60 lenses. The authors noted that aside from lens edge, other aspects of lens design also significantly reduce the incidence of moderate and severe grades of dysphotopic

symptoms. For example, light reflected from the anterior surface of the lens decreases with decreasing refractive index; the AcrySof® refractive index is 1.56 as opposed to the Akreos, which is 1.46.

The present study used a questionnaire based on that used in the study by Tester and colleagues to determine the incidence of optical phenomena at 1 or 3 months post-C-flex® implantation [13]. Although 55% patients reported optical disturbances, their symptoms were either 'minimal' or 'annoying', with 43% patients describing their symptoms as 'minimal'.

In the original telephone questionnaire-based study by Tester et al, [13] which included 302 patients who had received one of six commonly-used IOLs, patients who received an acrylic IOL with flattened edges were at increased risk of experiencing images associated with lens edge reflections [13]. Specifically, 32.5% with AcrySof® lenses (5.5 mm and 6.0 mm), 24% with SI-40® lenses (Allergan, Inc, Irvine, California, USA), 18% with polymethylmethacrylate lenses and 4% with phakic controls reported a degree of unwanted imagery. Light glare or sensitivity was reported by over one-third of all patients including controls [13]. As shown in Table 1, in the present study, the incidence of unwanted optical imagery with C-flex only was 17%-less than that with AcrySof® lens reported in the study by Tester et al [13]. The incidence of dysphotopsia in the present study also compares favourably with that of the SI-40 silicone group in Tester's report [13]. Additionally, when compared with dysphotopsia associated with AcrySof® lenses reported in a similar questionnaire-based study by Wallin et al. [14] no side light causing central flash was reported with the C-flex®, compared with 25% of patients implanted with three-piece and 7% with single piece AcrySof® lenses. Further, an arc of light in the side vision was reported by 2.5% of patients in the present study, compared with 47% with the three piece AcrySof® lens and 14% with the single piece AcrySof® lens in the study by Wallin and colleagues (Table 2) [14].

Lens	n	Side light causing central flash %	Arc of light %
Rayner C-flex®	40	0	2.5
Acrysof® three piece	30	25	47
Acrysof® single piece	36	7	14

Table 2: Incidence of C-flex symptoms as compared with lenses evaluated in Wallin-Olson's study [14].

There are several possible explanations associated with the lower incidence of dysphotopsia with the C-flex®, as compared with lenses evaluated by Tester et al [13]. and Wallin and colleagues [14]. Although previously published studies have given much credence to the relationship between lens edge design and the occurrence of dysphotopsia, other factors must also be considered. Of note, the C-flex® lens is made of hydrophilic acrylic biomaterial which could be a factor in reducing the risk of glare compared with hydrophobic acrylic biomaterials due to the absence of vacuoles or glistenings [10,11]. In contrast, the Acrysof® lenses, used in the Tester and Wallins studies are composed of a hydrophobic acrylic material. As a consequence of its hydrophilic nature, the C-flex® also has a lower refractive index than the AcrySof® (1.46 versus 1.56). As a 2001 study by Erie et al. demonstrated, light reflected from the anterior surface of the lens increases with an increasing refractive index. Moreover, Erie's study also showed that an unequal bi-convex design, as in the AcrySof® lens, produces internal reflections that focus on an area 60 times smaller than that of an equi-convex design such as that of C-flex® lens [8].

Cases of unwanted imagery may also be due to entoptic phenomena, such as from posterior vitreous detachment (PVD). Tester's study did not distinguish between the two but reported these symptoms in 4% of controls [13]. In the present study, unwanted imagery occurred in 7 of 40 (17%) patients. However, clinical examination revealed that unwanted imagery was most likely unrelated to the C-flex® lens in 14.5% of these patients. Specifically, the first patient who reported 'little black floaters' had PVD. The second patient had an arc of light in the peripheral vision, which was mild in nature and not related to a source of light-this patient also had PVD. The third patient also noticed an arc of light in her side vision, but only when she switched on the light first thing in the morning; she was unable to replicate these symptoms later on in the day. On examination, she had a significant cluster of floaters in the periphery and centre of the vitreous. Therefore, her symptoms were most likely due posture-related changes in the vitreous. Moreover, at her 3-month follow-up visit, she reported these floaters to be less noticeable. The fourth patient had reported occasional nonspecific flashing lights, while the fifth and sixth patients had increased but mild light sensitivity. The final patient, however, described an arc of light in her side vision in presence of a light source. She also saw similar arcs in the side when looking at streetlights. Although she reported these persistent symptoms to be annoying, she was very satisfied with her visual outcomes. The slit lamp examination showed a well-centred lens but with 360° overlap missing in a small area and the presence of a single fold on the posterior capsule. Therefore, this patient's positive dysphotopsia was likely related to the lens implant. When examined again at 3 months postoperative, she reported her symptoms to be less annoying.

Overall, the C-flex® monofocal IOL with 360° enhanced edge was associated with a high degree of patient satisfaction with postoperative visual outcomes in this study population. Unwanted imagery, which could be related to the lens implant, occurred in only one patient out of forty patients. The low incidence of dysphotopsia, as compared with previously-published studies that employed the same methodology to determine visual disturbances, is most likely related to the C-flex® lens design and material.

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