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Pseudophakic negative dysphotopsia and intraocular lens orientation: a prospective double-masked randomized controlled trial

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ABSTRACT.

Purpose: **To determine whether horizontal orientation of the intraocular lens optic-haptic junctions has an effect on the incidence of pseudophakic negative dysphotopsia.**

Methods: **Single-centre prospective double-masked randomized controlled trial. 220 eyes of 201 participants undergoing routine cataract surgery were randomized to receive their intraocular lens either orientated with the optic-haptic junctions at 180° ('horizontal') or without manipulation following implantation (control). Patients were excluded according to age (<19 and > 99 years), coexisting eye disease affecting visual function and insufficient cognitive function to complete the study. In the fourth postoperative week, a telephone interview was conducted to determine rates of negative dysphotopsia. The data were analysed to provide the relative risk of negative dysphotopsia with horizontal orientation of the intraocular lens (IOL) optic-haptic junctions compared with standard treatment.**

Results: **Orientating the IOL optic-haptic junctions horizontally halved the incidence of pseudophakic negative dysphotopsia in the fourth postoperative week (9/110 in the intervention group; 18/110 in the control group; RR: 0.50, 95% confidence interval: 0.235–1.064, p = 0.072). The overall incidence of negative dysphotopsia was 12.2% (27/220 participating eyes). No intraoperative adverse effects of intraocular lens rotation were reported.**

Conclusion: **The simple intraoperative manoeuvre of rotating the intraocular lens to orientate the optic-haptic junctions at 180° may be a safe and effective measure to reduce the risk of developing postoperative pseudophakic negative dysphotopsia in the first postoperative month. This is the first report that demonstrates the benefit of horizontal optic-haptic junction positioning to be sustained beyond the first postoperative day.**

Key words: dysphotopsia – haptic – intraocular lens – negative – orientation – pseudophakic

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Introduction

Despite the continuous development of surgical techniques and devices, uncomplicated cataract surgery nonetheless leaves some patients dissatisfied. Negative dysphotopsia, the visual phenomenon that manifests postoperatively as a dark crescent-shaped shadow in the temporal visual field, is the leading cause of this discontent (Olson 2005). Reported incidence is up to 15% in the immediate postoperative week (Osher 2008), though there is considerable variation in the literature (Bournas et al. 2007; Radford et al. 2007; Vámosi et al. 2010). For many, the symptoms spontaneously resolve over time, while others may find them tolerable. However, for around one fifth of those affected, the disturbance is severe and persistent (Osher 2008). The treatment of these patients has often involved challenging secondary and even tertiary surgery (Vámosi et al. 2010; Masket & Fram 2011; Burke & Benjamin 2014; Masket et al. 2018).

Various factors have been proposed to contribute to this photic phenomenon, including incisional corneal oedema (Osher 2008; Cooke 2010) or the overlap of the anterior capsule onto the intraocular lens (IOL) in a 'perfect' capsulorhexis (Masket & Fram 2011; Masket et al. 2018), to shallow orbits, a prominent globe and brown iridies (Osher 2008). Some believe persistent cases of negative dysphotopsia are due to a complex optical interaction between the IOL edge and an anatomically predisposed eye (Holladay et al. 2012; Erie et al. 2019). This theory is supported by the anecdotal observation that rates of negative dysphotopsia can be reduced by orientating the IOL optic-haptic junctions at 180° ('horizontally'), thus interrupting the IOL edge in the

critical nasal region of the capsular bag.[1] To date, the only formal investigation of IOL orientation and negative dysphotopsia examined the effect of inferonasal orientation (Henderson et al. 2016). A significant reduction in negative dysphotopsia was detected on the first postoperative day; however, the significance was lost after 1 week.

This study formally investigates the effect of horizontal orientation of the IOL optic-haptic junctions on the incidence of pseudophakic negative dysphotopsia. If found to be effective, this simple intraoperative manoeuvre could become a valuable and cost-effective preventative measure for reducing patient dissatisfaction and the need for further surgery.

Methods

This prospective, double-masked randomized controlled trial was performed at a surgical Ophthalmology Unit within a National Health Service (NHS) general hospital in Bath, United Kingdom. The trial followed the Tenets of the Declaration of Helsinki and received full ethical approval by the Health Research Authority.

All patients listed for routine cataract surgery were considered for participation. Patients were excluded according to age (<19 and >99 years) and coexisting eye disease affecting visual function, such as retinal pathology, glaucoma or other optic neuropathies with visual field defects. Additionally, patients with insufficient cognitive function to complete the telephone interview were excluded. Each patient meeting the criteria was provided written information prior to surgery, and consent was obtained on the day of surgery. The surgery was performed using a temporal approach by eight operating surgeons over the course of nine months. All patients received the aspheric monofocal Alcon AcrySof® SA60AT acrylic IOL. This lens has an anterior asymmetric biconvex optic design, a sharp truncated edge and a high refractive index of 1.55.[2]

A random number generator was used to assign participants to either the study group or control group. For those in the study group, at the time of implantation, the IOL was rotated until the optic-haptic junctions were orientated at 180 ± 10° (Fig. 1). Those in the control group received standard treatment, that is with no manipulation of the IOL following insertion. For both groups, the surgery was performed in the standard recommended fashion for phacoemulsification cataract surgery.

In the fourth postoperative week, a telephone interview was conducted with each participant consisting of a single question: 'Since your surgery, have you noticed a dark or grey shadow to the side of your vision?' Both the participant and the researcher collating the questionnaires were masked with respect to the lens orientation. The incidence of negative dysphotopsia for each group was calculated, and the relative risk and 95% confidence interval (CI) were calculated according to Altman 1991.

Results

A total of 220 eyes of 201 participants were included in the study, 110 eyes in each study group. About 42% of participants were male, and the average age was 78 years (range: 49–97 years). Each eye received phacoemulsification cataract surgery with continuous curvilinear capsulorhexis and in-the-bag intraocular lens placement. No intraoperative complications or adverse effects of intraocular lens rotation were reported. The overall incidence of pseudophakic negative dysphotopsia in the fourth postoperative week was 12.3% (27/220). In the study group, there were nine cases of negative dysphotopsia (8.2%). There were 18 cases of negative dysphotopsia in the control group (16.4%). The relative risk of negative dysphotopsia with horizontal orientation of the IOL optic-haptic junctions compared with standard treatment was 0.50 (95% CI: 0.235–1.064, p = 0.072). The number needed to treat was 12.2. Chi-squared analysis did not reveal a significant preponderance for gender (p = 0.861) or laterality of eye (p = 0.715).

Discussion

Negative dysphotopsia was first described by Davison (2000). There have since been numerous attempts to characterize the phenomenon both anatomically and optically. Various theories have been suggested and subsequently refuted, though a number of common observations have been established. For example, negative dysphotopsia is characterized by a decrease in severity with pupil dilation, and an increase with pupil constriction (Trattler et al. 2005; Osher 2008), and the shadow is noted to disappear when the temporal visual field is shielded (Osher 2008). Importantly, IOLs with a sharp posterior edge, popular for their reduced risk of posterior capsule opacification, have been repeatedly associated with higher rates of negative dysphotopsia (Davidson 2000; Narváez et al. 2005; Masket et al. 2018). Similarly, IOLs made from material with a high refractive index, such as acrylic, are most commonly implicated (Davidson 2000; Radford et al. 2007; Henderson et al. 2016). The Alcon AcrySof® SA60AT used in the current study is a sharp-edged acrylic IOL and is therefore prone to causing negative dysphotopsia.

In 2012, Holladay et al. reported on a ray-tracing simulation of negative dysphotopsia that accounted for each of these observations (Holladay et al. 2012). In 2017, this was expanded upon by using ray-tracing software to

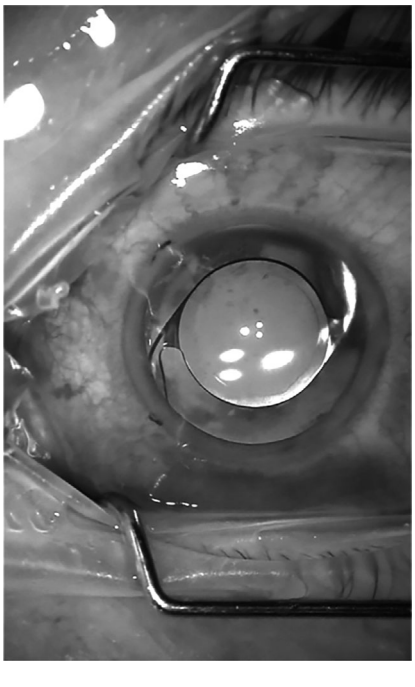

Fig. 1. Horizontal orientation of the optic-haptic junctions in the study group.

[1]Interview with Davidorf JM, Miller KM, Rosenfeld SI: EyeNet Magazine Dec 2014; 23–24.

[2]PRODUCT INFORMATION Alcon Laboratories, Inc., Fort Worth, TX, USA, 40-500-021-005.

evaluate pseudophakic and phakic eye models to show the location of retinal images from various visual field objects (Holladay & Simpson 2017). They concluded that the shadow perceived in negative dysphotopsia results from the gap between rays that are maximally refracted by the IOL and those that miss the IOL and illuminate the retina directly (Fig. 2). This was subsequently verified by further ray-tracing studies in 2019, which clearly demonstrated a 5-degree band of non-illuminated peripheral nasal retina bounded posteriorly by light refracted by the optic and anteriorly by light missing the optic (Erie et al. 2019).

The risk factors identified as increasing the risk of negative dysphotopsia are a smaller photopic pupil, larger angle kappa, the shape of the IOL, the axial location and orientation of the IOL (Holladay & Simpson 2017). In particular, they point out that the anterior capsule, when intact and overlying the IOL nasally, effectively limits the amount and intensity of the maximum refracted rays that serve to overlap the light rays that are missing the IOL optic. The effect of the anterior capsule is contentious. As other researchers have pointed out, opacification of the anterior capsule postoperatively may have different effects – the light scattering either enhancing or masking the shadow (Holladay et al. 2012; Holladay 2013). As a result, moving the IOL optic anterior to the anterior lens capsule, known as reverse optic capture, or removing the anterior nasal lens capsule postoperatively has been proposed as therapeutic manoeuvres in eyes with recalcitrant negative dysphotopsia, or in second 'at risk' eyes as a primary prophylactic measure (Masket et al. 2018). A sulcus fixated supplementary IOL effectively serves the same purpose (Burke & Benjamin 2014; Masket & Fram 2011).

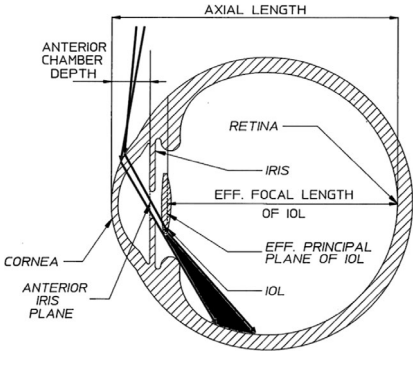

Fig. 2. Ray diagram of horizontal section of the pseudophakic eye. The red ray misses the intraocular lens (IOL) and is not refracted, while the blue ray is refracted by the anterior and posterior IOL surface. The dark area appears as a shadow if it falls on functional retina (Holladay et al. 2012). Reprinted with permission of the Journal of Cataract & Refractive Surgery.

Our study demonstrates that horizontal orientation of the IOL optic-haptic junctions results in a twofold reduction in the incidence of negative dysphotopsia in the first postoperative month when compared with unmodified lens placement. It is the first to demonstrate the benefit of horizontal optic-haptic junction positioning to be sustained beyond the first postoperative day.

This finding supports the proposed positioning by Henderson et al. (2016), and the optical mechanism described by Holladay & Simpson (2017) and Erie et al. (2019). With the optic-haptic junctions positioned horizontally, light from the far temporal visual field that would otherwise have missed the optic and directly illuminated the far peripheral retina, instead falls on the haptic junction. These rays were found to be refracted by a very large angle or totally internally reflected; serving to eliminate the light band that anteriorly delineates the shadow region (Erie et al. 2019). Thus, retinal illumination ends peripherally simply with the light that is refracted by the optic itself. The loss of the highly delineated light-dark-light transition zone reported in Erie's in vitro study is correlated by the reduced perception of the shadow in patients with horizontally orientated IOL optic-haptic junctions demonstrated in this study.

The study was designed to represent a 'real world' population of patients undergoing routine cataract surgery and therefore has certain limitations. Factors previously suggested to predispose to negative dysphotopsia that were not addressed in the current study include the presence of a prominent globe and shallow orbit (Osher 2008), brown iridies (Osher 2008) and incisional corneal oedema (Osher 2008; Cooke 2010). The effect, if any, these may have had on the study outcome is speculative and likely to be insignificant due to natural randomization between groups. Pupil size seems to be important (Trattler et al. 2005; Osher 2008; Holladay & Simpson 2017) but was not included in our metrics. The study also did not address the inter-surgeon differences in surgical technique, the angle kappa, IOL power, preoperative refractive error or capsulorhexis size and placement, particularly with respect to the nasal anterior capsule – IOL relationship.

The authors accept that alerting participants to the existence of negative dysphotopsia preoperatively in the consent process is a potential confounding factor; however, there was no difference in treatment or questionnaire between groups therefore the study outcome is unlikely to have been affected. In the NHS hospital setting, it was not feasible to correlate the postoperative questionnaire with a clinical examination; therefore, it is unknown whether any IOLs rotated during postoperative recovery. The exact orientation of the IOL optic-haptic junctions in the control group is also unknown. It was deemed appropriate by the ethics committee that participants in the control group should not be disadvantaged by having their optic-haptic junctions orientated vertically; therefore, these IOLs underwent no manipulation following implantation. It is likely a proportion of control participants received an IOL with naturally horizontally orientated optic-haptic junctions, which may account for why statistical significance was not reached in this study.

Although longer-term studies are required in order to determine whether the beneficial effects are sustained beyond the first postoperative month, our study shows that horizontal orientation of the IOL optic-haptic junctions during routine cataract surgery results in a twofold reduction in rates of early postoperative negative dysphotopsia. By modifying their surgical technique to adopt this simple manoeuvre, surgeons may reduce the incidence of early negative dysphotopsia and improve patient satisfaction. We plan to revisit our study population to assess whether these effects are maintained or altered over a longer time period.

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