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Clinical and Aberrometric Evaluation of a New Refractive Intraocular Lens with Central Extended Depth-of-Focus (Lucidis ©)

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Abstract

Purpose: To assess the visual performance of a new refractive/extended depth of focus (EDOF) hybrid intraocular lens (IOL).

Methods: This is a monocentric, retrospective study of 94 patients (158 eyes), carried out in a tertiary-care glaucoma research center. All patients underwent implantation of the Lucidis (Swiss Advanced Vision, SAV-IOL SA, Neuchâtel, Switzerland) IOL during cataract surgery. Near, intermediate and far best corrected visual acuity and uncorrected visual acuity were collected at baseline and 3-month postoperatively. Adverse events, contrast sensitivity, optical aberrations, subjective satisfaction and spectacle independence were also analyzed at 3-month.

Results: At 3-month post-operatively, mean photopic uncorrected monocular distance, intermediate and near Snellen visual acuity were 0.2 logMAR (~20/32), 0.07 logMAR (~20/23) and 0.15 logMAR (~20/28) respectively. Mean best corrected Snellen visual acuity was 0.1 logMAR (~20/25) for distance and 0.03 logMAR (~20/21) for near vision.

Conclusion: The Lucidis IOL demonstrates good safety profile, with an acceptably low complication rate. The uncorrected visual performances of this new optical design are inferior to those of other EDOF IOLs for distance-vision, but achieve better results in intermediate and near vision, with consistently near-normal contrast sensitivities. Interestingly, self-reported spectacle independence and subjective patient satisfaction are high for all distances.

Keywords: Intraocular lens; IOL; Extended depth of focus; EDOF; Refractive; Cataract surgery

Introduction

Cataract is the loss of transparency of the normally clear crystalline lens, which impairs the quality and clarity visual perception. Since 1949 when Harold Ridley performed the first cataract extraction with implantation of intraocular lens (IOLs) in London [1], considerable development has occurred in the field of intraocular lenses (IOLs) to correct a wider range of refractive errors and achieve better visual performances. Amongst the most researched properties are the capacities to achieve spectacle independence and optimal visual acuity at regardless of focal length and light conditions, as well as the reduction of visual aberrations [2] A wide range of designs and optical properties were developed in an attempt to achieve this, including refractive, diffractive, refractive-diffractive and apodized-diffractive multifocal IOLs [3,4].

The main benefit of multifocal IOLs is the ability to restore visual function at long as well as reading distance [5]. They are, however, known to produce subnormal intermediate visual performance, which, with the rise of computers use, can significantly impair patients' quality of life [6, 7] Other common adverse outcomes of multifocal IOLs are visual aberrations and photic phenomena, including glare and halos, as well as a reduced contrast perception [2, 8].

To reduce such side effects and improve spectacle independence in intermediate situations, manufacturers have developed the extended depth of focus (EDOF) technology. Intraocular lenses relying on this technology are theoretically characterized by an extended range of vision and depth-independent resolution, in order to achieve satisfactory vision in more diverse distances and more variable light conditions [9].

The Lucidis IOL (Swiss Advanced Vision, SAV-IOL SA, Neuchâtel, Switzerland) is a new type of refractive/EDOF hybrid IOL involving a central aspheric element surrounded by an outer refractive ring. The patented design is an attempt to achieve patient satisfaction in distance situations as well as constant near-intermediate vision regardless of pupil size, while minimizing dysphotopsia [10].

This retrospective study assessed visual performance, clinical and quality of life outcomes, and subjective satisfaction achieved with this new IOL design.

Methods

Study design

This is a monocentric, retrospective study of 94 patients (158 eyes) who underwent implantation of the Lucidis IOL during cataract surgery by a single experienced surgeon (Mermoud A.) between September 2017 and April 2019 at Montchoisi Clinic, Genolier Swiss Visio Network, Switzerland. The study was lead in compliance with the Human Research Act and the Declaration of Helsinki.

Patient recruitment

All patients who underwent cataract surgery with a Lucidis IOL implantation at Montchoisi Clinic, a tertiary glaucoma center, between September 2017 and April 2019 who complied with the study criteria were included retrospectively. The main exclusion criteria were ≤18 years of age, the presence of a concomitant ophthalmic condition that could potentially affect the visual outcome, including age-related degeneration, diabetic retinopathy, advanced glaucoma, or an astigmatism of >1.00D. Population demographics and clinical characteristics are listed in Table 1. The decision to perform cataract surgery and the choice of the IOL were based on clinical indications.

Demographic & clinical data	Eyes / Patients n = 158 / 94
Male / Female	64 (40.5%) / 94 (59.5%)
Age (years)	72.9±12
Stand-alone / Combined	123 (77.85%) / 35 (22.15%)
Average IOL power	20.5 D (8 – 27)
Cataract grade (I, II, III)	2.21±1.01

Table 1: Cohort demographics.

Surgery

All surgeries were performed under regional anesthesia. Phacoemulsification was carried out following a standard procedure briefly outlined below: following anesthesia and appropriate cleaning and draping of the eye, a 2.75 mm incision was made in the clear cornea. The position of the incision was decided on an individual basis to minimize astigmatism. Additional paracentesis was performed for instrumentation. Viscoelastic were used to maintain anterior chamber integrity, and continuous curvilinear capsulorrhexis and hydrodissection were performed. The lens was emulsified, and the device settings were adjusted according to each case. Cortical remnants were removed by irrigation and aspiration and a foldable Lucidis IOL was implanted in the capsular bag. No Lucidis IOLs were implanted in the sulci. Viscoelastic was washed out and the incisions were hydro-sealed. Postoperative care comprised of topical nepafenac (Novartis Pharma, ZG, Switzerland) and a combined tobramycin-dexamethasone suspension eye drop (Novartis Pharma, ZG, Switzerland) four times a day initially, and titrated according to the inflammatory response for a month.

Follow-up visits

Postoperatively, patients attended follow-up visits as per the center's protocol, at 1 day, 7 days, 1 month and 3 months. Additional appointments were planned at the surgeon's discretion. At each of the follow-up visits, tests were performed based on clinical indications. All the results were recorded in the patients' medical notes. At 3 months post-operatively, all patients

underwent aberrometry measures (MSE, Root Mean Square [RMS], Point Spread Function [PSF], Alpha angle, Kappa angle) using an iTrace Wavefront Aberrometer (Tracey Technologies, TX, USA). Contrast sensitivity (CS) testing using a Pelli-Robson CS chart, and full refraction were also performed. Monocular UCVA and BCVA were tested for near, intermediate and far distances in photopic conditions. The investigating ophthalmologist recorded observations through slit-lamp examination, and any subjective impressions or adverse events volunteered by the patient subject to open questioning.

Data collection

Data collected retrospectively for the study included the last pre-operative visual acuities, corrected and uncorrected, for near, intermediate and distance vision. The same visual acuities as recorded during the 3-month follow-up. The 3-month contrast sensitivities, aberrometries (MSE, RMS, and PSF), spherical equivalent, and any recorded adverse event were also collected.

Intraocular lens

The Lucidis is a single piece foldable multizone refractive/aspheric IOL, with a 360° square edge design and closed loop haptics. The lens has a 6.0 mm optical diameter and a total diameter of 10.8 mm or 12.4 mm. It is made from hydrophilic acrylic with a 26% water-content. The IOL is designed for capsular bag implantation and is available in a power range from +5.0 D to +30.0 D in 0.5 D steps with +3.0 D addition/EDOF power. Optically, the Lucidis IOL uses both refraction and an aspheric element. The 1 mm aspheric zone occupies the center of the IOL and is surrounded by a 6 mm refractive ring (Figure 1). According to the manufacturer's documentations, the benefit of this particular design is to provide some degree of near and intermediate vision compared to classic monofocal optics calculated for emmetropia, while achieving the same optical qualities and visual acuity for far vision, and being aberrations-neutral to keep the rate of dysphotopsia to a minimum.

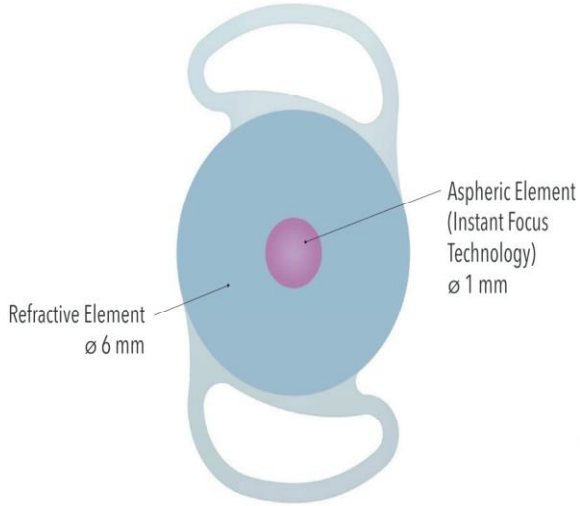

Figure 1: Lucidis IOL optical design.

Statistical Analysis

Statistical analysis was performed on the 3-month data available for all included patients. The quantitative variables are described in terms of sample size, mean, standard deviation, median, range and missing data. The qualitative variables are described in terms of sample size, percentage and missing data.

All the quantitative variables are assessed for the normal distribution. Qualitative data are represented in percentage. Excel (Microsoft, WA, USA) with the software XLSTAT (XLSTAT, Paris, France) was used for analysis of the data. The following analysis was performed for all parameters: independent t-test to compare two means, Wilcoxon test to compare non-parametric continuous data. Results were considered statistically significant if $p < 0.05$.

Results

One hundred fifty-eight eyes (158 eyes) of 94 implanted patients were included, all of which had exploitable 3-month data. In the cohort, 94 eyes belonged to females (59.5%) and 64 to males (40.5%). The average age of the study population was 72.9±12 years. The average power of implanted IOLs was 20.5 D (8-27). The average cataract grade noted by the surgeon was 2.2±1.01. The research center being a tertiary glaucoma clinic, 35 eyes presented concurrent history of primary open-angle glaucoma and underwent combined filtering surgery (deep sclerectomy (n=9), XEN gel stent (Allergan, Dublin, Ireland) (n=3), iStent inject (Glaukos, San Clemente CA, USA) (n=12)) and trabecular meshwork lavage (n=11).

Visual acuity

Postoperative visual acuities in photopic conditions are summarized in Table 2.

Parameters			Mean±SD (logMAR)		
	Near UCVA	Near BCVA	Intermediate UCVA	Far UCVA	Far BCVA
Preoperative	0.5 (~20/63)	0.2 (~20/32)	0.2 (~20/32)	0.55 (~20/66)	0.2 (~20/32)
3 months	0.15 (~20/28)	0.03 (~20/21)	0.07 (~20/23)	0.2(~20/32)	0.1 (~20/22)

Table 2: Pre- and post-operative visual acuities in photopic conditions.

Uncorrected visual acuity

Statistically significant improvement (P<0.0001) in distance UCVA was noted for all patients between the preoperative and the 3-month visit. In average, between the baseline and 3-month measures, near, intermediate, and far distance UCVA had improved by 0.35 logMAR (P<0.0001), 0.13 logMAR (P<0.0001) and 0.35 logMAR (P<0.0001) respectively. (Figure 2).

Best corrected visual acuity

Between the baseline and 3-month measures, near and distance BCVA had improved in average by 0.17 logMAR (P<0.0001) and 0.1 (P<0.0001) respectively (Figure 2).

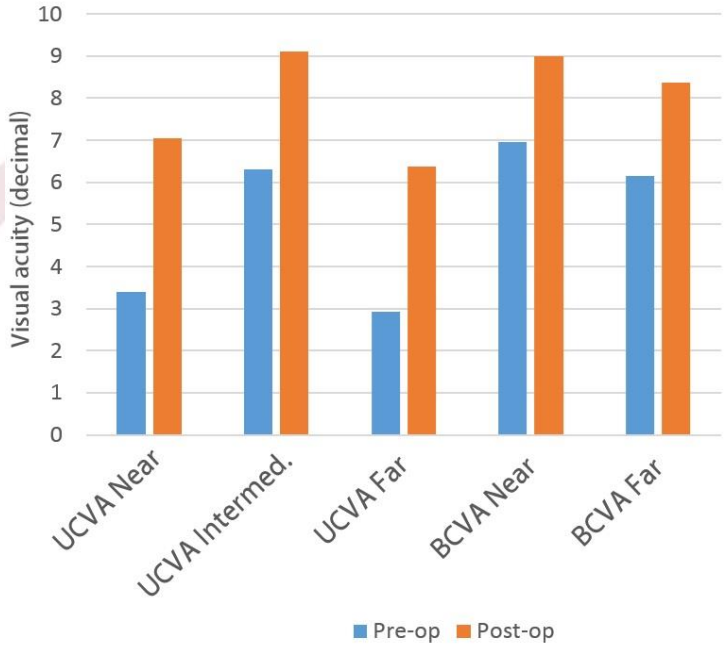

Figure 2: Evolution of mean vision pre and post operatively.

Contrast sensitivity

Contrast sensitivity as measured with a Pelli-Robson chart at 3 months was 1.5 log.

Aberrometry

The mean spherical equivalent (SE) at 3 months post-operatively was -0.3 D (± 2.58), with 58.1% of patients achieving a SE between -0.50 and +0.50 D. The distribution of SE in patients at 3 months is shown on Figure 3.

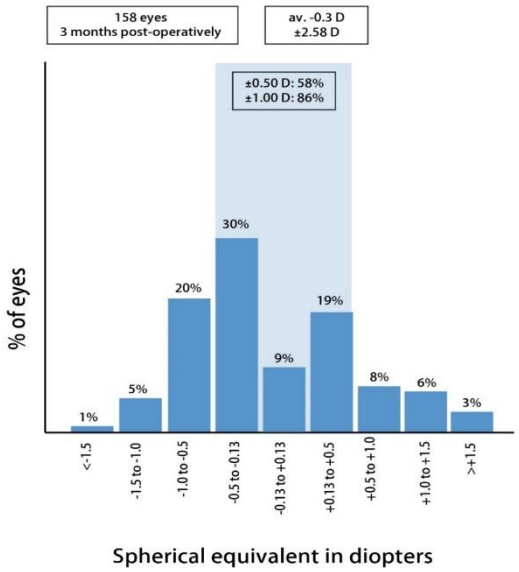

Figure 3: Distribution of spherical equivalence in patients at 6 months postoperatively.

At 3 months, the mean high order RMS was 0.147±0.054 µm and the mean PSF was 0.16±0.15.

Through the follow-up period, 1 patient (0.6%) complained of dysphotopsia consisting of glares and mild photophobia which presented at 1-month post-operatively and had spontaneously subdued by 3 months.

Discussion

In the last decades, the importance of intermediate distance activities, such as computer work, has grown to play an essential part in most patients' lives [7]. As such, maintaining good intermediate vision has become a crucial stake to maintain patients' quality of life [11,12]. Intermediate distance vision has often been regarded as a weakness of multifocal IOLs' optical design [13], but the EDOF optical design has recently shown its ability to improve acuity and comfort in this range of vision [14]. According to its manufacturer's information, the Lucidis IOL was designed as an alternative to multifocal IOLs. It was designed to remove some visual limitations of multifocals such as a limited intermediate vision, reduced contrast sensitivity and disabling dysphotopsia, while achieving some degree of spectacle independence in near and intermediate vision, and specifically addressing the sub-standard distance performance achieved with their previous EDOF hybrid design (diffractive /refractive /aspheric) used in the InFo - Instant Focus IOL (Swiss Advanced Vision, SAV-IOL SA, Neuchâtel, Switzerland) [10].

The mean monocular distance UCVA achieved with the Lucidis IOL at 3-month was 0.2 logMAR (~20/32). In comparison, the mean postoperative distance UCVA achieved after multifocal IOL implantation in 24 studies of 5570 eyes as cited by Rosen et al. in a recent meta-analysis was 0.11 logMAR (~20/26) [15], and the mean UCVA achieved by a similar EDOF IOL, the Tecnis Symfony ERV IOL (Abbott Medical Optics Inc, Santa Ana CA, USA), was 0.04 logMAR (~20/22) [16]. For near and intermediate vision, the Tecnis EDOF IOL achieved a mean uncorrected acuity of 0.28 (~20/38) and 0.18 logMAR (~20/30) respectively.

The Lucidis IOL achieves lower uncorrected distance visual performances than the average of EDOF or multifocal IOLs studied in literature, and similar results to its hybrid counterpart, the InFo – Instant Focus IOL [17]. This could be accounted for by its optical design, or by external factors, including a myopic post-operative spherical equivalent, concomitant ocular pathologies or the rate of posterior capsule opacification. However, considering that, when calculated for the subgroup of patients with a SE between -0.25 D and +0.25 D, mean distance UCVA only marginally improved to 0.16 logMAR, it can be hypothesised that the optical design of the implant would be the main culprit. On the other hand, it compares favourably to the Tecnis Symfony IOL and the average of multifocal IOLs studied by Rosen et al. in near and intermediate vision.

This confirms that the central EDOF element of the lens allows for a wider range of focus length than classic multifocal designs, improving intermediate acuity without impairing near-vision. This promising property of EDOF technology had already been elicited by several studies [3,12] including Gatinel et al in 2016 [18] but the significant difference in performance between two EDOF designs suggests that variations in the addition power of this type of IOL can lead to a dramatic shift in visual performance. The Tecnis Symfony achieving better distance acuities with its

addition power of +1.75D, and the Lucidis achieving better near and intermediate acuities with an addition power of +3.00D.

In our study cohort, only one patient (0.6%) complained of glares and photophobia, which resolved spontaneously within 3 months. This suggests an extrinsic cause, such as ocular dryness or inflammation, rather than a relation with the IOL design. This compares extremely favorably with multifocal designs. In Alcon's "Directions for Use" [19], the reported prevalence of dysphotopsia was 24.2% for glare and 32.7% for halos, for the AcrySof IQ ReSTOR multifocal IOL, and 16.9% and 11.3% respectively, for the AcrySof IQ Monofocal IOL. These symptoms were shown to be less frequent in patients whose IOLs use fewer and wider concentric diffractive rings like the one in this study [20] This observation can explain the low rate of dysphotopsia in the Lucidis IOL, which appears to be similar to those of monofocal IOLs despite its central ring design.

In a study assessing the Acri.Lisa 366D multifocal IOL (Acri.Tec, Berlin, Germany), Pomares et al. found a mean post-operative MSE of +0.39±0.51 D and a mean RMS of 1.45±0.73 µm [21]. The aberration results of the Lucidis IOL from our present study compared favorably with those, confirming its aberration-neutral nature.

The rate of posterior capsule opacification 3 months following the implantation of the IOL was of 3.3%, considerably lower than the 10.8% initially reported for this new lens [22]. The hydrophilic nature of the Lucidis IOL can certainly account in part for this complication, as well as the fact that combined surgery was performed in a number of cases who subsequently went on to develop early posterior capsule opacification [23].

The current study has several limitations. Firstly, its retrospective nature, carried out in a tertiary glaucoma center and including patients suffering with concomitant ocular diseases is a good reflection of clinical reality but inherently introduces a statistical bias and compares poorly with prospective refractive studies that rely on much stricter inclusion criteria. Secondly, this study lacks long-term follow-up with only 3 month data available that does not allow any analysis of potential long-term complications. Lastly, the retrospective nature of the study restricted the range of measures available, which did not include distance-corrected near/intermediate visual acuity that would have allowed confirming whether the modest performances of this IOL for distance vision were due to its design or to a myopic post-operative spherical equivalent.

In conclusion, the Lucidis IOL is effective for the management of age-related cataract and demonstrates good safety profile, with an acceptably low complication rate. Its design achieves the similar rates of dysphotopsia as those of a monofocal IOL. The uncorrected visual performances of the Lucidis IOL are inferior to those of other EDOF IOLs for distance-vision, but achieve better and more homogenous results for intermediate and near vision, with consistently near-normal contrast sensitivities. Further investigations with larger cohorts of patients should be performed to confirm the outcomes observed in this study, and explore the long-term performance of this new IOL.

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