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Visual Outcomes After Bilateral Implantation of AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens

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Abstract

Background

To assess the visual and refractive outcomes of the non-diffractive extended depth of focus (EDOF) AcrySof ® IQ Vivity™ (Alcon, Fort Worth, TX, USA) intraocular lens (IOL) after bilateral implantation in patients undergoing phacoemulsification surgery.

Methods

In this prospective non-comparative study, 20 patients willing to undergo bilateral implantation of AcrySof ® IQ Vivity™ IOL were recruited at a single center (Eye Day Clinic, Athens, Greece). Pre- and post-operative clinical assessment of the patients included slit lamp examination, assessment of corrected distance visual acuity (CDVA) at 6 m, uncorrected distance visual acuity (UDVA) at 6 m, uncorrected intermediate visual acuity (UIVA) at 66 cm, uncorrected near visual acuity (UNVA) at 33 cm and optical biometry. Moreover, the presence of visual disturbances and the contrast sensitivity (CS) thresholds of all patients were assessed.

Results

The mean ± standard deviation (SD) of monocular UDVA, UIVA and UNVA were 0.05 ± 0.08, 0.07 ± 0.09 and 0.23 ± 0.09 LogMAR, respectively. More specifically, 97.5%, 70% and 15% of eyes achieved UDVA, UIVA and UNVA of 20/25 or higher, while 6 patients in total reported mild glare, blurred vision, fluctuation in vision and/or depth perception difficulty. The mean ± SD of LogCS threshold was 1.68 ± 0.26.

Conclusions

Bilateral implantation of AcrySof ® IQ Vivity™ IOL could be a solution to patients seeking independence from optical aids. Further comparative studies are warranted to confirm our results.

Introduction

Cataract surgery is one of the most common and cost-effective medical procedure performed worldwide, aiming to restore patients' visual impairment [1]. In most cases and especially in developing countries cataract surgery is performed to treat cataract blindness and severe visual impairment, whose prevalence is going to increase in the next years according to the World Health Organization [2]. However, in economically developed countries, implantation of intraocular lenses (IOLs) is increasingly used to additionally address the problem of presbyopia at the time of cataract removal or refractive lens exchange in adults of working or productive age and older patients, who want to be independent of optical aids.

The advent of multifocal IOLs more than 30 years ago [3] has led to an increased interest in presbyopia management with IOLs. The mechanism of action for multifocal IOLs is based on the principles of light

refraction or diffraction, where two or more separate focal points are created, thus providing near and distance vision without dependency on ciliary body function [4]. However, since this multifocal effect creates superimposition of focused and defocused images on the retina, multifocal IOLs are associated with reduced contrast sensitivity (CS) in mesopic and scotopic conditions and patient may experience adverse visual events, like glare and halos [5, 6].

Extended depth of focus (EDOF) is a relatively new technology that has been implemented in IOLs for presbyopia management [7]. In contrast to monofocal (where a single focal point is created) and multifocal (where multiple focal points are present) IOLs, EDOF IOLs increase depth of focus by creating a single elongated focal point [8]. By focusing light waves in a longitudinal plane, EDOF IOLs aim to eliminate the photic phenomena associated with multifocal IOLs, while ideally increasing intermediate and functional near vision without affecting distance vision performance. The optical quality produced by these types of IOLs has been found by several studies to be superior compared to monofocal and multifocal IOLs [9, 10].

Since the introduction of the first EDOF IOL (Tecnis ® Symfony ZXR00, Johnson and Johnson Vision, Jacksonville, Florida) in the market of Europe and USA in 2014 and 2016, respectively, several EDOF IOLs have been commercially available [8, 11]. AcrySof ® IQ Vivity IOL (Alcon, Fort Worth, TX, USA) represents the newest addition to the variety of EDOF IOLs and the second Food and Drug Administration (FDA) - approved EDOF IOL [12]. In a clinical study conducted for FDA-approval, patients with AcrySof ® IQ Vivity IOL were found have lower incidence of visual disturbances, like haloes, similar CS and an extended focal range from distance to near, compared to the monofocal control IOL [12]. Thus, we designed the present study to evaluate the early promising visual and refractive outcomes of AcrySof ® IQ Vivity™ IOL after bilateral implantation in patients undergoing cataract surgery or refractive lens exchange.

Patients And Methods

Study Design, Inclusion and Exclusion criteria

In this prospective non-comparison study, patients willing to undergo bilateral implantation of AcrySof ® IQ Vivity™ IOL from an experienced ophthalmic surgeon at a single center (Eye Day Clinic, Athens, Greece) were recruited and clinically assessed pre- and post-operatively. Eligible for inclusion in our study were patients aged ≥ 45 years old at the time of preoperative assessment, who had bilateral cataracts or clear intraocular media and were motivated to have spectacle independency, were in good general health and had the ability to perform the necessary pre- and post-operative examinations of the study. Additional inclusion criteria included potential postoperative visual acuity of Snellen ≥ 20/25 and keratometric astigmatism ≤ 0.75 D in both eyes. Exclusion criteria of our study included any ocular or systemic disease that could affect the visual outcomes, ocular trauma history, any condition increasing zonular instability, history of refractive surgery and the use of any medication with the potential of affecting vision.

The study was conducted in accordance with the tenets of Declaration of Helsinki for the use of human participants in biomedical research, as well as other applicable regulations of Greek law. Moreover, study methods were approved by an independent ethical committee and written informed consent was obtained from all patients, after the operating surgeon discussed with each patient the surgical complications of cataract surgery, the possibility of spectacles dependency and visual disturbances postoperatively.

Intraocular lens characteristics

AcrySof ® IQ Vivity™ IOL was bilaterally implanted in all eligible patients of our study. It is a single-piece EDOF IOL, consisted of a high-refractive index (n=1.55) hydrophobic acrylic material. The EDOF effect of this IOL is exerted by utilizing a novel patented technology, called Wavefront-Shaping technology (X-Wave technology) incorporated in the anterior aspheric IOL surface, while the posterior IOL surface is spherical. This technology is different from the ones used in other EDOF IOLs, which are based on diffraction or refraction of light. The AcrySof ® IQ Vivity™ has a central 2.2 mm zone consisting of two transitional elements: the first element stretches the incoming light that hits the retina in the myopic and hyperopic direction, while the second element moves the wavefront anteriorly, to the myopic direction, producing the EDOF effect and utilizing the maximum on incoming light energy [13]. The positive spherical aberrations of the cornea are compensated from the negative spherical aberrations of the anterior surface. Moreover, AcrySof® IQ Vivity™ contains chromophores, which reduce the transmittance of ultraviolet and blue light, and as a result approximating the normal human crystalline lens [14]. The optic zone diameter and overall length of the IOL is 6 mm and 13 mm, respectively.

Preoperative and Postoperative Assessment

All eligible participants underwent a complete ophthalmologic examination before phacoemulsification surgery, including slit lamp examination, assessment of monocular and binocular corrected distance visual acuity (CDVA), Goldmann applanation tonometry, fundoscopy, optical biometry (IOLMaster 500; Carl Zeiss Meditec AG, Jena, Germany) for measuring axial length, anterior chamber depth and keratometry indices and autorefraction (RT-5100; Nidek Co., Ltd., Gamagori, Japan).

Uncorrected distance (UDVA), intermediate (UIVA) and near visual acuities (UNVA) were measured at 6 meters, 66 cm and 33 cm, respectively, 1, 3 and 8 weeks postoperatively. UIVA and UNVA from the last follow up visit were measured using the University of Crete (UoC) chart, a modified Early Treatment Diabetic Retinopathy Study (ETDRS) chart for Europe-wide use for near and intermediate distance recordings [15]. In order to reduce time of postoperative ophthalmological examinations at 1 and 3 weeks, UIVA and UNVA were assessed using Jaeger cards [16]. Preoperative CDVA and postoperative UDVA were assessed using the Snellen acuity chart at 6 meters and all visual acuity assessments were performed under photopic conditions (85 cd/m^2). Visual acuities assessed with Snellen charts were converted to logarithm of the minimum angle of resolution (LogMAR) values for analysis. Automated refraction (RT-5100; Nidek Co., Ltd., Gamagori, Japan), slit lamp examination, Goldmann applanation tonometry and fundoscopy were performed in all postoperative follow up visits of our study participants.

We employed the Freiburg Visual Acuity and Contrast Test (FrACT, version 3.10.5) [17] to assess uncorrected CS at the last follow up visit (8 weeks postoperatively), using a computer screen (1920 x 1080 pixels) at 2 meters. FrACT is a free software, available online at http://michaelbach.de, created by Michael Bach, which has been utilized and validated in several studies [18]. The illumination of the LCD screen was calibrated at 100 cd/m^2 and the gamma value of the system and FrACT was set to 1.0, according to the software developer instructions. CS thresholds were measured by presenting to the study participants single constant Landolt-C optotypes (50 arc-min in diameter corresponding to a dominant spatial frequency of 3 cycles per degree) over a range of CS and with the gap at eight possible positions. Every participant performed a practice test of about 5 trials before testing in order to clearly understand the task. The position of the gap was indicated verbally by the study participants and the examiner pressed the corresponding button on an 8-arrow keyboard. CS of the optotypes were adjusted real time to the participants according to their performance during the task, because FrACT employs a best parameter estimation by sequential testing (best PEST) algorithm, based on maximum likelihood estimation, in order to maximize information gain [19]. The CS thresholds in FrACT are initially derived from the Weber CS formula (CS_{Weber} = difference between surround and optotype luminance divided by the surround luminance) and converted to absolute Log_{10} values of CS ($Log_{10}[1/CS_{Weber}]$).

Finally, specific visual disturbances at night usually associated with multifocal and EDOF IOLs, including glare, haloes, starbursts, hazy vision, blurred vision, double vision, distortion, fluctuation of vision, focusing difficulties and depth perception difficulties were assessed using the Quality of Vision (QoV) questionnaire [20]. QoV is an instrument to subjectively measure quality of vision by providing 30 questions on the frequency, severity and bothersome of specific visual disturbances.

Surgical Technique

All study participants underwent conventional phacoemulsification under topical anesthesia by a single experienced ophthalmic surgeon using the Centurion phacoemulsification device (Alcon Laboratories, Inc., Fort Worth, TX, USA). Phacoemulsification was performed through a sutureless clear corneal 2.2 mm incision created manually, after which AcrySof™ IQ Vivity™ IOL could be implanted in the capsular bag. The first Purkinje reflex was used to center the IOL. The required IOL power for each eye was determined preoperatively by combining the SRK/T formula with the “A” constant provided by the company. The lowest possible residual myopia was the refraction target for all participants. The postoperative medical regimen included topical chloramphenicol 0.1% with dexamethasone 0.5% eye drops (Nezefib, RAFARM, Greece) four times a day for 1 month and topical dorzolamide 2% (Optodrop, RAFARM, Greece) eye drops two times a day for 1 month.

Statistical Analysis

Descriptive statistics of the study population preoperatively and postoperatively were reported using percentage values for categorical variables and mean ± standard deviation (SD) for continuous variables. We used Microsoft Excel to collect the data and all statistical analyses were performed with the statistical software R (version 3.5.1, Foundation for Statistical Computing, Vienna, Austria; package) [21].

Additionally, the paired t-test was used to compare the differences preoperatively and postoperatively in continuous variables, while normality of our study variables was assessed with the Kolmogorov–Smirnov test. A P value less than 0.05 was considered as statistically significant and all statistical tests were two-sided.

Results

A total of 46 eyes from 23 patients underwent implantation of AcrySof™ IQ Vivity™ IOL in our center. Among the 23 eligible patients, 3 patients were excluded from our study because they did not attend the final follow-up visit 8 weeks postoperatively. All the excluded patients reported that the reason for not attending the last follow up visit was that they were satisfied with their postoperative visual outcomes in conjunction with living in remote areas. Thus, the final sample comprised 40 eyes from 20 participants. The demographic characteristics of our sample can be seen on Table 1, while the preoperative parameters are listed on Table 2.

Table 1. Demographics of the study population (20 participants/40 eyes).

Parameters	Values
Age (years, mean ± SD)	
Mean ± SD	58.45 ± 8.82
Median (min – max)	56.5 (47 – 81)
Age group (years), n (%)	
<50	2 (10)
50-59	11 (55)
60-69	4 (20)
>70	3 (15)
Sex, n (%)	
Women	10 (50)
Men	10 (50)
SD: standard deviation	

Table 2
Preoperative monocular characteristics of the study population (20 participants/40 eyes).

	Mean (SD)	Min	Max
CDVA (LogMAR)	0.20 (0.36)	0.00	1.20
Axial length (mm)	23.80 (1.10)	22.11	26.24
Anterior chamber depth (mm)	3.16 (0.34)	2.21	3.83
Sphere (D)	0.82 (2.98)	-7.50	7.00
Cylinder (D)	-0.70 (0.51)	-2.25	0.00
Spherical equivalent (D)	0.47 (3.03)	-8.00	6.50
Flat keratometry (D)	42.61 (1.48)	39.75	45.50
Steep keratometry (D)	42.83 (1.41)	40.15	46.00
Corneal astigmatism (D)	0.41 (0.22)	0.00	0.75

CDVA: corrected distance visual acuity, LogMAR: logarithm of the minimum angle of resolution, SD: standard deviation

The mean ± SD of postoperative monocular UDVA, UIVA and UNVA were 0.05 ± 0.08, 0.07 ± 0.09 and 0.23 ± 0.09 LogMAR, respectively (Table 3). More specifically, 65% of eyes had UDVA of 20/20 and 97.5% of eyes had UDVA of 20/25 or higher. The cumulative distributions of postoperative UDVA and preoperative CDVA, as well as their differences can been seen on Figure 2A and Figure 2C. Regarding intermediate vision, the visual outcomes were also quite satisfactory with 50% of eyes achieving 20/20 and 100% of eyes having visual acuity of 20/32 or higher. Additionally, 20/25 was the best UNVA reported in our study, which was achieved by 15% of eyes, while 87.5% of eyes had UNVA of 20/40 or higher. The cumulative distribution of postoperative visual acuities can be seen on Figure 1. The postoperative spherical equivalent did not differ significantly from the targeted spherical equivalent (p-value>0.05) (Figure 2C and Figure 2D). The mean ± SD of CS threshold was 1.68 ± 0.26 (CS_{Weber} = 2.01%) and within normal limits.

Table 3
Postoperative characteristics of the study population (20 participants/40 eyes).

	Mean (SD)	Min	Max
Monocular UDVA (LogMAR)	0.05 (0.08)	0.00	0.36
Monocular UIVA (LogMAR)	0.07 (0.09)	-0.10	0.20
Monocular UNVA (LogMAR)	0.23 (0.09)	0.10	0.40
Spherical equivalent (D)	-0.68 (0.38)	-1.63	0.38
CS threshold ($Log_{10}[1/CS_{Weber}]$)	1.68 (0.26)	1.36	2.53

UDVA: uncorrected distance visual acuity, UIVA: uncorrected intermediate visual acuity, UNVA: uncorrected near visual acuity, LogMAR: logarithm of the minimum angle of resolution, CS: contrast sensitivity

Regarding postoperative visual disturbances, no patients reported starbursts, distortion, fluctuation, hazy vision or double vision during the last follow up visit, while mild glare, blurred vision, haloes, focusing difficulties and/or depth perception difficulties were reported by 6 patients (Table 4, Supplementary Table 1). These patients refused a further IOL exchange procedure, since they reported that their visual disturbances were acceptable. No postoperative or intraoperative complications were noted.

Table 4
Percentage of patients with visual disturbances assessed with the Quality of Vision questionnaire.

Visual disturbances	No. of patients (%)
Glare	3/20 (15)
Haloes	3/20 (15)
Starbursts	0/20 (0)
Hazy vision	0/20 (0)
Blurred vision	3/20 (15)
Distortion	0/20 (0)
Double or multiple images	0/20 (0)
Fluctuation	0/20 (0)
Focusing difficulties	1/20 (5)
Depth perception difficulty	2/20 (10)

Discussion

In this prospective non-comparison study of 20 patients who were bilaterally implanted with AcrySof ® IQ Vivity™ IOL, the visual and refractive results were quite promising, since all patients achieved unaided vision at far and intermediate distances without significant visual disturbances.

The high worldwide prevalence of presbyopia in conjunction with no recognized treatment or prevention strategy, has led the research towards the development of new IOLs. Although, the majority of IOL in the market are monofocal, the rising request for independence from optical aids is pushing the surgeons to the use of premium IOLs in the management of presbyopia [3]. EDOF lenses have implemented a new technology to provide unaided vision in most of the daily activities with less visual disturbances, compared to the multifocal IOLs. A recent systematic review and meta-analysis has shown that implantation of EDOF lenses is safe and at the expense of near vision, patients receiving EDOF IOLs can achieve better CS than those receiving trifocal IOLs [22]. The preliminary descriptive results of our study suggest that the AcrySof ® IQ Vivity™ IOL can further reduce the visual disturbances associated with multifocal IOLs.

As with other EDOF IOLs, patients who underwent AcrySof ® IQ Vivity™ IOL implantation experienced significantly satisfying improvements in uncorrected distance and intermediate visual acutiy, showing good performances also in functional near activities, thus limiting the use of glasses to near activities requiring higher quality of vision. However, all patients in order to achieve the best possible near vision required further near addition, which was not documented reported in our data. In our study the most frequently reported visual disturbances were mild glare and halos. In these patients neuroadaptation could play a crucial role in reducing the impact of these photic phenomena.

The results of a recent case series study with larger sample size (54 patients/108 eyes) conducted in Italy were in accordance with our visual and refractive outcomes [23]. In this study, bilateral implantation of AcrySof ® IQ Vivity™ IOL was performed in patients undergoing cataract surgery. Arrigo et al. reported a statistically significant improvement in BCDVA (from 0.4 ± 0.3 LogMAR to 0.0 ± 0.03) with good refractive outcomes also at intermediate distances (mean UIVA ± sd of 0.05 ± 0.03 at 80 cm and 0.06 ± 0.16 at 60 cm). Additionally, they also found that all patients in their study required a mean near addition of 1D in order to achieve the optimal near visual acuity, which was not assessed in our study. Regarding the visual disturbances experienced by the patients, their results are also similar to ours, since haloes and glares were the most commonly reported disturbances, which were well tolerated, while, in contrast to our study, CS threshold were not assessed.

The strengths of this study include its prospective design and the fact that to the best of our knowledge studies assessing this new type of EDOF IOL are scarce. However, we need to take into consideration several important limitations. First, we excluded 3 patients that did not attend the final follow up visit at 2 months. Although, the main reasons for not attending the last follow up visit were the satisfactory visual outcomes and living in remote areas far from our ophthalmology clinic, exclusion of these patients could have affected the results of our study. Second, since it’s a non-comparative study we cannot make

comparisons of visual and refractive outcomes with different types of monofocal, multifocal or other EDOF IOLs. Specifically, comparing the quality of vision and patient's satisfaction after implantation of AcrySof ® IQ Vivity™ IOL with other types of EDOF IOLs currently available on the market, could give us an insight on how to meet expectations of patients by choosing the right EDOF IOL. Third, a potential limitation could be the short period of follow up, since visual assessment of patients beyond 2 months could possibly mitigate the reported visual disturbances through neuroadaptation.

In conclusion, bilateral implantation of AcrySof ® IQ Vivity™ IOL could be a solution to patients undergoing cataract surgery or clear lens extraction, seeking independence from optical aids. Further comparative studies with larger sample sizes are warranted to confirm our preliminary results.

Declarations

Author contributions: AK conceived and designed the presented study and performed the analysis. MA collected the data. All authors wrote and critically reviewed the manuscript.

Conflict of Interest: All authors have no financial disclosures

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Figures

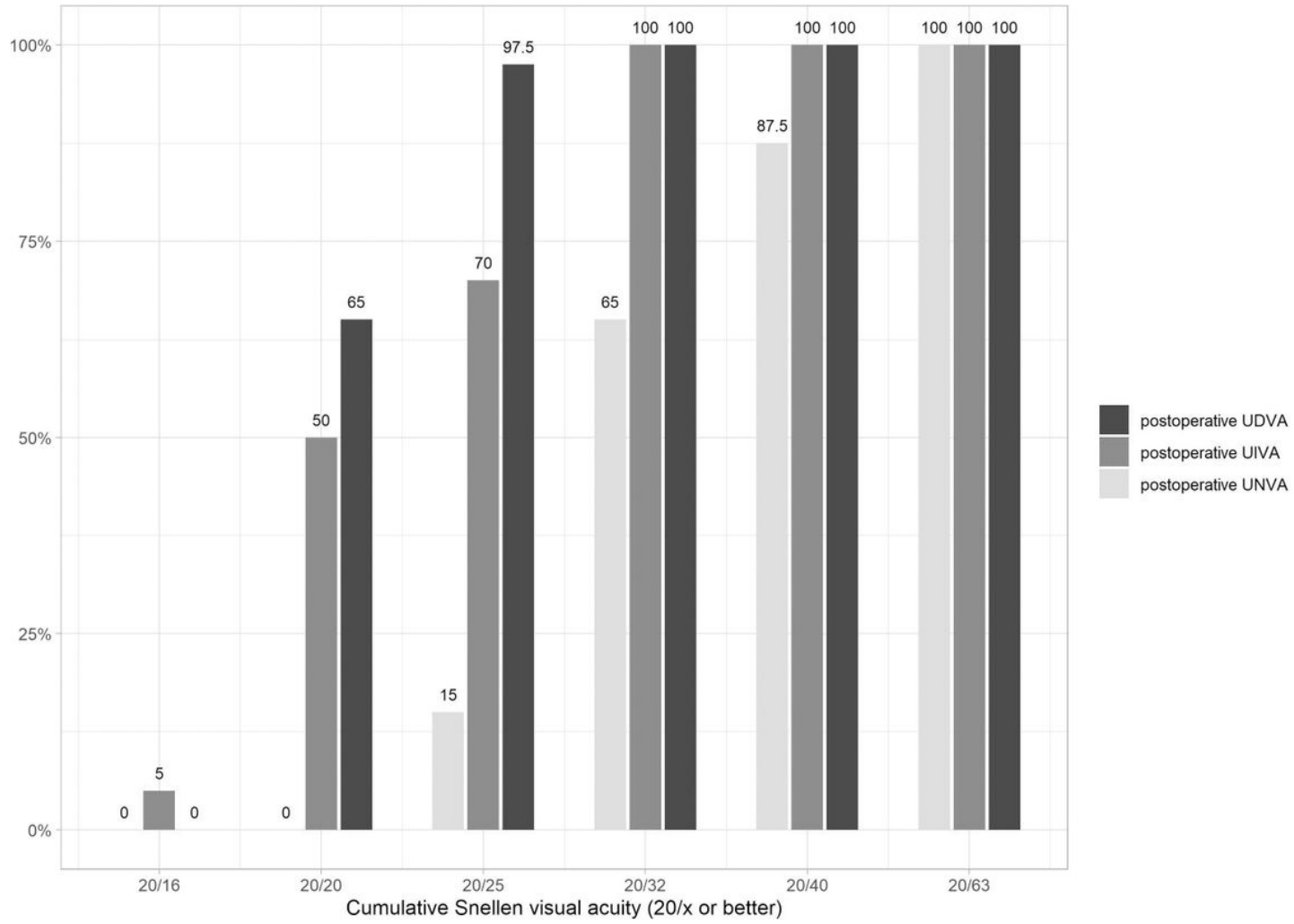

Figure 1

Cumulative distribution of monocular postoperative uncorrected near (UNVA), intermediate (UIVA) and distance (UDVA) visual acuity of the study participants.

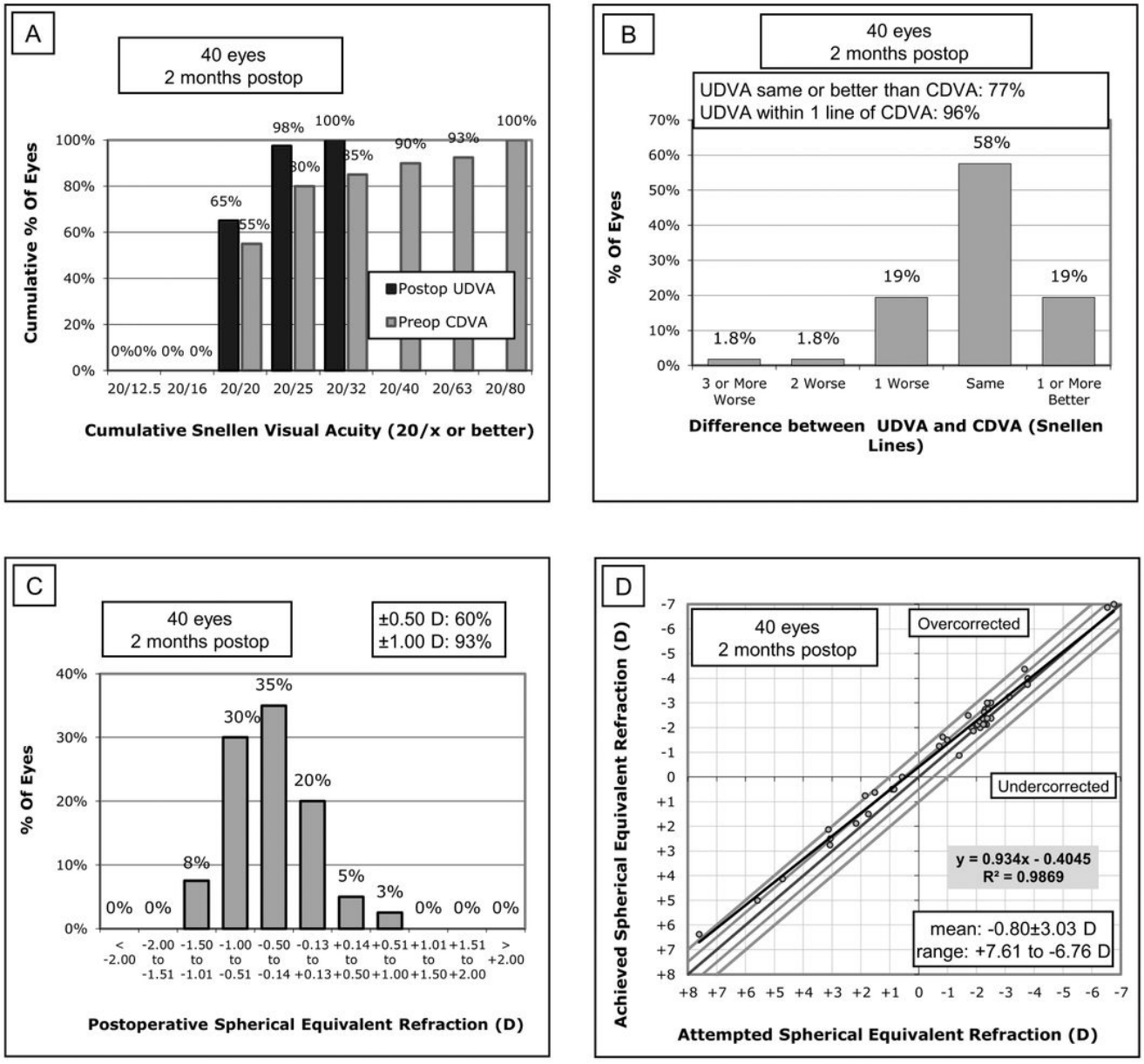

Figure 2

(A) Cumulative distribution of monocular postoperative uncorrected distance (UDVA) and monocular preoperative corrected distance (CDVA) visual acuity of the study participants; (B) histogram of lines of difference between monocular postoperative UDVA and monocular preoperative CDVA of the study participants; (C) histogram of postoperative spherical equivalent relative to the intended target; (D) achieved versus attempted spherical equivalent scatter plot.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryTable1.docx