Experience with the Tecnis Symfony Extended Range of Vision IOL in Patients with Pre- existing Retinal Pathology

John Odette (jodette@austineye.com)
Austin Eye
David Nguyen
Austin Eye
Amanda Morrisette
Austin Eye

Research Article

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Abstract

Background: There are limited publications about multifocal IOLs and patients with pre-existing retinal pathologies. Published outcomes have been mixed, with some showing good visualization of the retina postoperatively, while others report difficulty with visualization of the retina through MIOL. This study evaluated outcomes with TECNIS Symfony® Extended Range of Vision IOL (Symfony) in patients with and without pre-existing retinal pathology.

Methods: Visual acuity (VA) was retrospectively evaluated for patients who underwent cataract surgery with implantation of the *Symfony* IOL from 09/1/2016 to 05/31/2018 at a single, US clinical site. Month 2 postoperative outcomes were compared for eyes with (70 eyes) and without pre-existing retinal pathology (616 eyes). Outcomes included mean monocular uncorrected visual acuity (±SD) at near (UNVA) at 40 cm, far distance (UDVA) at 20 ft, and with best correction (CDVA).

Results: UNVA was 0.07 ± 0.10 logMAR in the non-pathology eyes vs. 0.17 ± 0.20 logMAR in eyes with pathology ($p<0.0001$). Mean monocular UDVA was 0.11 ± 0.90 logMAR in the non-pathology eyes vs. 0.21± 0.19 logMAR in eyes with pathology ($p<0.0001$). Mean monocular CDVA was 0.02 ± 0.06 logMAR in the non-pathology eyes vs. 0.11± 0.17 logMAR in eyes with pathology ($p<0.0001$). Eyes with mild to moderate pathology had VA comparable with non-pathology eyes.

Conclusion: In this retrospective review, the *Symfony* IOL provided good uncorrected and best-corrected visual acuity at near and far distances in eyes with and without retinal pathology.

Trial Registration: NCT05111106 (clinicaltrials.gov)

Summary

The Symfony IOL, an extended range of vision IOL, provided good uncorrected and corrected visual acuity at near and far distances and is an acceptable option for patients with macular pathology who desire a broader range of vision.

Background

Patients often desire presbyopia-correcting IOL technology to remain spectacle independent after cataract surgery. Extended depth of focus technology improves visual acuity and reduces spectacle dependence after cataract surgery.[1–4] The FDA PMA clinical trial for the TECNIS *Symfony*® Extended Range of Vision IOL [(*Symfony*) Johnson & Johnson Surgical Vision, Inc; Santa Ana, CA, USA) included a specific cohort of patients with no previous ocular surgery and less than 1.0 D of regular corneal astigmatism. (TECNIS Symfony® Extended Range of Vision IOL Package Insert) Unlike patients

participating in the controlled FDA clinical trials who must meet strict inclusion criteria, real-world clinic settings treat patients with ocular co-morbidities who would like presbyopia-correcting IOL options.

It is not uncommon for patients to present with cataracts and retinal disorders. The prevalence of concurrent cataract and retinal disorders can range from 13.2–25%, and in some cases multiple retinal co-morbidities may be present.[5–7] For example, epiretinal membrane (ERM) is commonly observed in older populations and may present alongside cataracts.[8,9]Age-related macular degeneration has also been reported before and after cataract surgery.[10,11] In fact, it can be challenging to manage treatment because either of these co-existing conditions can be exacerbated by treatment.[12,13] For this reason, several approaches can be used to treat patients in need of cataract surgery who have retinal pathologies, such as ERM. Depending on the severity of condition, the retinal surgery can be performed before, during, or after cataract surgery.[7,14–17] In some cases, cataract surgery with subsequent IOL implantation can improve visual outcomes, and possibly delay the need for retinal surgery.[18] However, there are limited publications about multifocal IOLs and patients with pre-existing retinal pathologies. In the few published outcomes, results have been mixed with some showing good visualization of the retina postoperatively, while others report difficulty with visualization of the retina through MIOL.[17,19]

The purpose of this study was to evaluate performance of the *Symfony* IOL in a typical clinical setting with patient presenting with and without retinal pathology and who are in need of cataract/refractive surgery.

Research Design & Study Methods

This research study was conducted retrospectively from data obtained for clinical purposes. In accordance with the Declaration of Helsinki, the protocol was submitted to Salus Investigational Review Board and was deemed exempt from IRB Review and patient consent as this was a retrospective study. A retrospective chart review was performed to evaluate pre-specified endpoints of patients who received treatment at the Austin Eye Clinic and Surgical Center during the dates of September 1, 2016 to May 31, 2018. The trial was registered with clinicaltrials.gov (#NCT05111106 on 08/11/2021). Chart review was conducted by John Odette, MD and research assistants. Eligible charts were identified via a clinic database search of cataract surgeries with IOL implantation of the *Symfony* IOL during the stated date range. Eligible charts included those of patients 18 to 90 years of age who underwent Femto Laser Assisted Cataract Surgery (FLACS) with implantation of a *Symfony* IOL. Charts were excluded for lack of postoperative follow-up or if Symfony IOL was not implanted. All qualifying patient charts were examined and further classified into 2 groups: (1) eyes with no pathology; and 2) eyes with pre-existing retinal pathology. An independent fellowship trained retina specialist reviewed de-identified pre-operative data (scans, images) to objectively quantify eyes with existing pathology into 3 groups defined as mild, moderate, and severe.

Surgical Procedure & Lens Model

All eyes included in the review received the TECNIS *Symfony* Extended Range of Vision Intraocular Lenses (IOLs), lens model ZXR00 or one of the toric lens models ZXT150, ZXT225, ZXT300, and ZXT375. The *Symfony* IOLs are ultraviolet light-absorbing posterior chamber IOLs designed to provide extended depth of focus by virtue of a proprietary achromatic diffractive surface that also corrects chromatic aberration. In addition, the toric IOLs models have various dioptric powers to compensate for ≥ 1.0 D of preoperative corneal astigmatism.

Each patient underwent FLACS at a single center by 1 of 3 surgeons in single site (JO, SW, and MB), and received the same open-label pre-operative, operative and post-operative medications over the course of the study period.

Study Endpoints

The study endpoints were visual acuities at near and far distances. Uncorrected Near Visual Acuity (UNVA) was measured using a handheld near card (Jaeger scale) and are presented as mean logMAR and standard deviation (± SD) and Snellen Equivalent. Uncorrected Distance Visual Acuity (UDVA) and Best-Corrected Distance Visual Acuity (CDVA) were measured using a Snellen Chart at 20 feet and presented as mean logMAR & Snellen Equivalent.

Statistical Program

Statistical analyses were conducted using SAS Software (Version 9.4) and Microsoft Excel. Statistical differences were analyzed by repeated-measures analysis of variance for the continuous endpoints. The Generalized Estimated Equation (GEE model) was used for the binary endpoints (e.g., 20/20 or better). Differences of least squares means (LS means) were used to compare results for non-pathology versus pathology eyes, and toric versus spherical IOL eyes. A difference of 0.05 was considered statistically significant.

Results

Demographics

A total of 463 patient records (686 total eyes) were included in the chart review from 09/1/2016 to 05/31/2018. Of the 463 patients, 407 (87.9%) had no pathology and 56 (12.1%) had pre-existing pathology. Bilateral implantation occurred in 51.3% of non-pathology patients and 25% pathology patients. A total of 686 eyes were included in the analyses: 616 without pathology (non-pathology) and 70 with pathology. The mean age was 65 years for the non-pathology eyes and 69 years in the pathology eyes, with no statistical difference between groups.

Visual Acuity

Mean monocular logMAR visual acuities for UNVA, CDVA, and UDVA are shown in Fig. 1. Mean logMAR visual acuities were approximately 1 line better for the non-pathology group. The percentage of patients achieving UNVA of 20/40 or better was 99.2% for non-pathology (611/616) and 91.4% for pathology eyes

(62/70) (Fig. 2). The percentage of patients achieving CDVA of 20/40 or better was 100% for non-pathology eyes (616/616) and 91.4% for pathology eyes (64/70) (Fig. 3). The percentage of patients achieving UDVA of 20/40 or better was 98.2% for non-pathology eyes (605/616) and 87.1% for pathology eyes (61/70) (Fig. 4).

Visual acuities were compared for eyes with and without pathology and for eyes with toric versus spherical IOLs. For UDVA, toric IOLs had worse outcomes by 0.03 logMAR (about 1.5 letters) ($p < 0.001$), and eyes with pathology were worse by 0.09 logMAR (about 4.5 letters) ($p = 0.0009$) compared with non-pathology eyes. Although, both tests were statistically significant, differences were less than 2 lines for each of the comparisons. For UNVA, differences between toric and spherical IOLs were not statistically significant ($p = 0.1597$). Eyes with pathology showed worse UNVA by 0.09 logMAR (about 4.5 letters) compared with non-pathology eyes ($p < 0.001$). Likewise, although differences were statistically significant, they were not clinically significant.

Visual acuities were also stratified by severity of pathology (Fig. 5). Mean logMAR visual acuity for patients with Grade 1 and Grade 2 pathology were approximately 2 lines better than Grade 3.

Refractive Outcomes

Mean preoperative SE was − 1.51 ± 3.63 D and improved to -0.28 ± 0.43 D postoperatively. Preoperative target versus postoperative refraction for study eyes with retinal pathology is shown in Fig. 6. Predictability of Refraction was within ± 0.5 D for 86.7% of eyes (59/68) and within ± 1.0 D for 98.5% of eyes (67/68). Average post-operative corneal astigmatism in eyes with retinal pathology improved preoperatively 1.07 ± 0.89 vs. postoperatively 0.33 ± 0.33 D (difference of -0.75 D ± 0.90). Postoperative corneal astigmatism was 0.0 to 0.5 D for 85.3% of eyes (58/68), between > 0.5 to1.0 D for 11.8% of eyes (8/68), and > 1.0 D for 2.9% of eyes (2/68).

Safety

There were no patients with > 2-line loss of CDVA, and 1 patient had a 2-line loss of CDVA. Nearly all patients had postoperative CDVA of 20/40 or better. A few patients had postoperative CDVA that was 20/40 or worse; however, when compared with preoperative CDVA these acuities were an improvement from baseline.

Discussion

Results from this retrospective chart review demonstrated good uncorrected near visual acuity at and best-corrected distance visual acuity at 2 months postoperatively for patients with and without pre-existing pathology. Visual acuities favored the non-pathology group by approximately 1 line. Eyes with mild to moderate pathology showed better VA than eyes with severe pathology, although these eyes were also able to achieve average VA of 20/40. Visual acuity with spherical and toric IOL designs were statistically better for the non-pathology group; although differences were less than 1 line. Results

suggest the Symfony IOL provides good corrected and uncorrected VA and can be an IOL option for patients with pre-existing macular pathology who desire an IOL with extended range of vision.

There were two pre-specified metrics we were interested in comparing. One was to compare UNVA results from the present study with those obtained in the pre-market clinical trials of the Symfony IOL, which had a more controlled population.[A] Our monocular UNVA results showed favorable results for non-pathology (0.07 logMAR) and pathology eyes (0.17 logMAR) when compared with those of the Symfony clinical trials (0.24 logMAR).[A] These results suggest patients with pre-existing pathology can be candidates for this IOL.

The second point of interest was to compare mean monocular CDVA in eyes with mild pathology versus those without pathology. Mean monocular CDVA in eyes with mild pre-existing pathology (0.05 logMAR) was comparable to the non-pathology eyes (0.02) in our study. These results demonstrate eyes with mild pre-existing pathology can achieve CDVA comparable to that of non-pathology eyes.

Results from the group of eyes without pathology were similar to those reported for other non-pathology eyes relative to UDVA, but less so for UNVA. In a study of 94 eyes with Symfony IOL implantation and no ocular pathology, mean monocular UDVA was 0.12 logMAR and UNVA was 0.34 logMAR.[20] Comparatively, non-pathology and pathology eyes in our study showed better UDVA and UNVA by nearly two lines. The above-mentioned study also noted patients with lower levels of preoperative corneal astigmatism (< 1.0D) showed better VA outcomes, versus eyes with > 1.0 D of preoperative corneal astigmatism which is consistent with other previous reports of better results for MIOLs when with lower cylinder.[20,21] The effect of preoperative astigmatism in patients with retinal pathology was also a of point of clinical interest in our study. Results with *Symfony* spherical and toric IOL designs were statistically better for the non-pathology group, although differences were less than 1 line. Results from our study support use of the Symfony toric IOLs in patients with co-existing retinal pathology.

At the time of this study, there are no published outcomes regarding retinal pathology and the Symfony IOL; moreover, there are limited publications of retinal pathology with other MIOL technologies. In a study of patients with idiopathic ERM who underwent combined phacovitrectomy and diffractive MIOL implantation, results showed improved VA with successful multifocality, after macular healing and PCO treatment.[14] One study with refractive MIOL implantations in eyes with pathology showed that patients with pre-existing ocular pathologies, such as two branch retinal-vein occlusion and glaucoma, can still achieve good VA comparable with healthy eyes.[7] In another case series of 13 patients with age-related macular degeneration showed promising outcomes with a myopia-targeted multifocal IOL approach, which improved or maintained near vision without severely compromising distance vision.[22] Our study showed comparable VA results for eyes with mild to moderate pathology and normal eyes. Although visual acuities were better for the mild to moderate eyes, those with severe pathology were still able to achieve functional visual acuity. These results suggest that eyes with pre-existing pathology can be candidates for the *Symfony* IOLs.

This study has some noted limitations such as the retrospective, non-randomized nature of the study. However, a strength of this study is that it provides outcomes for patients typically excluded due pre-existing pathology. In particular, published outcomes for *Symfony* IOLs have excluded eyes with pathology, thus results provide outcomes in population under-represented in the literature. Additionally, this study reports on a larger sample size of *Symfony* IOL patients than previously seen in the literature, which provides a robust sampling for understanding visual dynamics in this population. This large sample size allowed us to see differences with the toric IOLs, but not necessarily a clinically relevant difference. These findings may be relevant for providers treating patients with ocular pathology and may be helpful when offering visual correction options. These outcomes suggest that patients with pre-existing ocular pathology can achieve good visual outcomes with this IOL if they desire a lens that provides extended range of vision. Moreover, these results are meaningful for patients that could potentially develop retinal co-morbidities after cataract surgery.

Future studies of the *Symfony* IOL could include other endpoints to evaluate quality of vision, such as contrast sensitivity, visual symptoms, and patient reported outcomes. Other studies have shown minimal visual symptoms with the *Symfony I*OL and acceptable contrast, thus it would be of interest to see if this patient population has similar outcomes.[2,23–25] In addition, because retinal pathology could require additional or future surgical intervention after cataract surgery,(Yoshino) additional research concerning intraoperative visualization through the *Symfony* IOL would be of interest.

Conclusion

In conclusion, results from this retrospective study indicate the *Symfony* IOL provides good visual acuity outcomes for patients with and without pre-existing pathology, and with spherical or toric IOL design.

Declarations

Ethics approval and consent to participate- This research study was conducted retrospectively from data obtained for clinical purposes. In accordance with the Declaration of Helsinki, the protocol was submitted to Salus Investigational Review Board and was deemed exempt from IRB Review and patient consent as this was a retrospective study. The trial was registered with clinicaltrials.gov (#NCT05111106 on 08/11/2021).

Consent for publication- Not applicable

Availability of data and materials- The datasets used and/or analysed during the current study available from the corresponding author on reasonable request from **John Odette** via email at jodette@austineye.com

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Authors' contributions: John Odette participated in the study research, and provided text, references and critical review for the manuscript. David Nguyen, Amanda Morrissette participated in the study research and provided critical review of the manuscript. The authors would like to thank TG (Teagan Gil) and JT (Jo Tan) for their assistance with the chart reviews.

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Figures

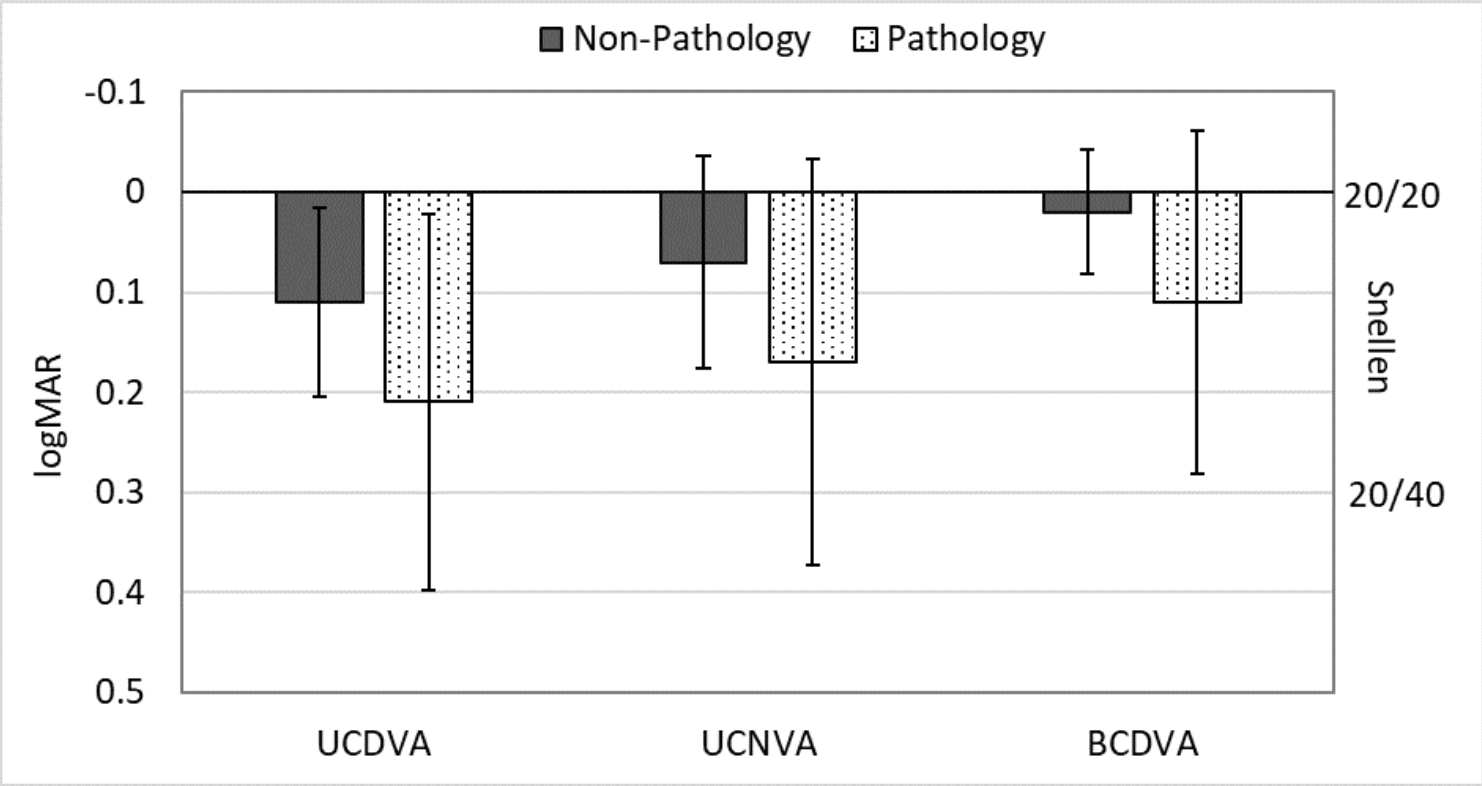

Figure 1

Mean Mononcular logMAR Visual Acuity at 2 months postoperatively for non-pathology eyes (n=616) and pathology eyes (n=70).

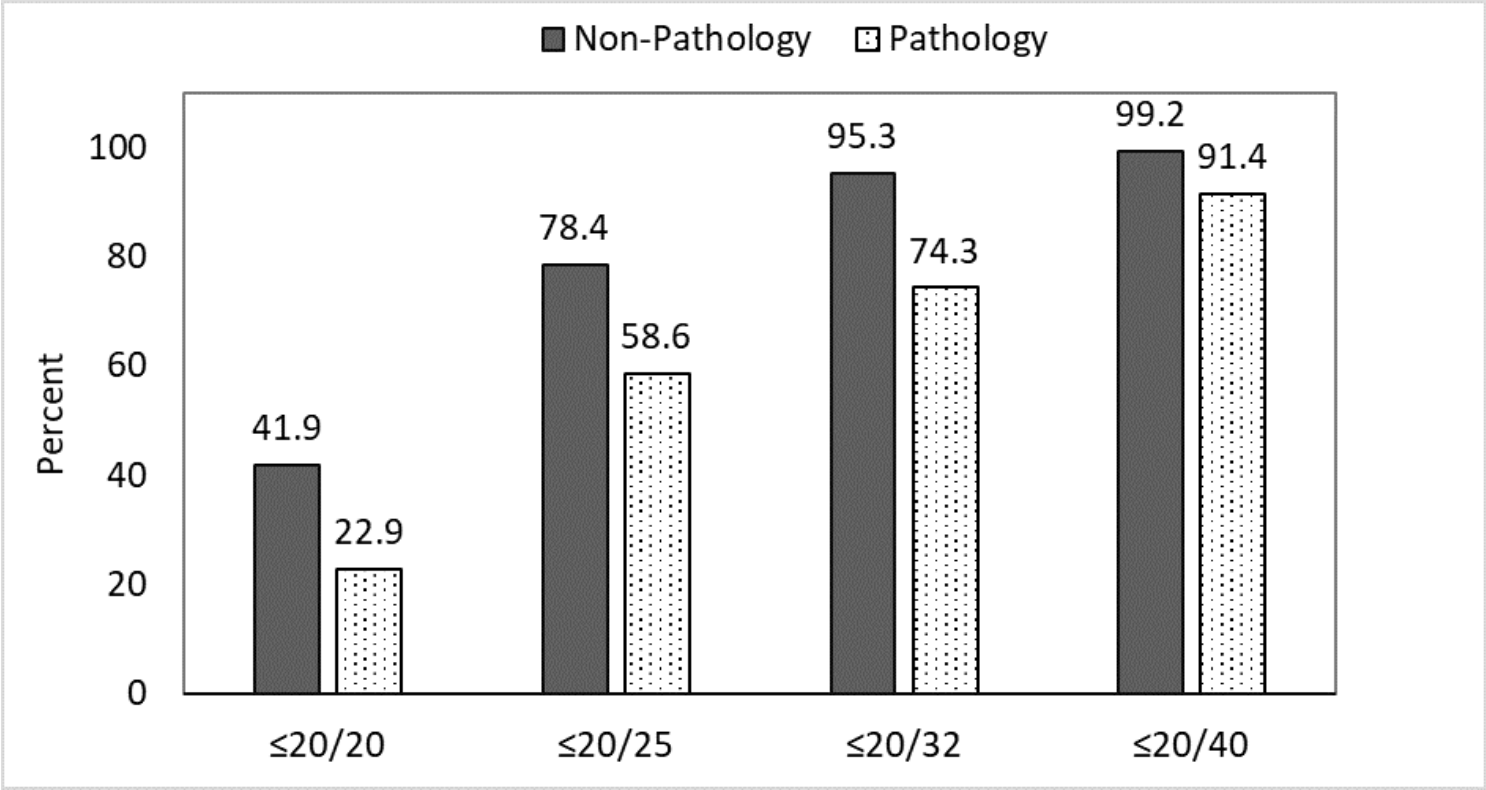

Figure 2

Cumulative Snellen Monocular Uncorrected Near Visual Acuity at 2 months postoperatively.

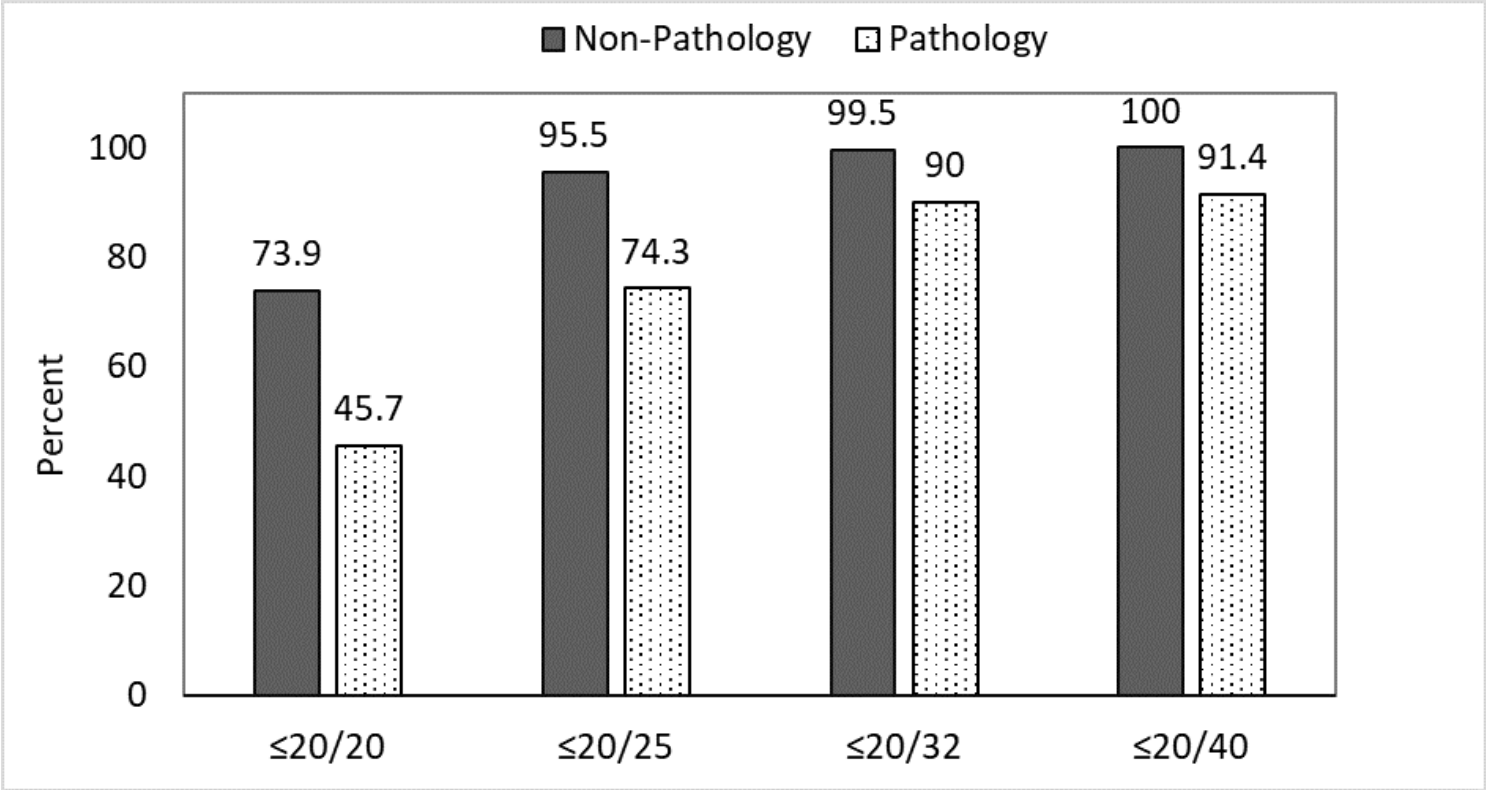

Figure 3

Cumulative Snellen Monocular Best-Corrected Distance Visual Acuity at 6 months postoperatively.

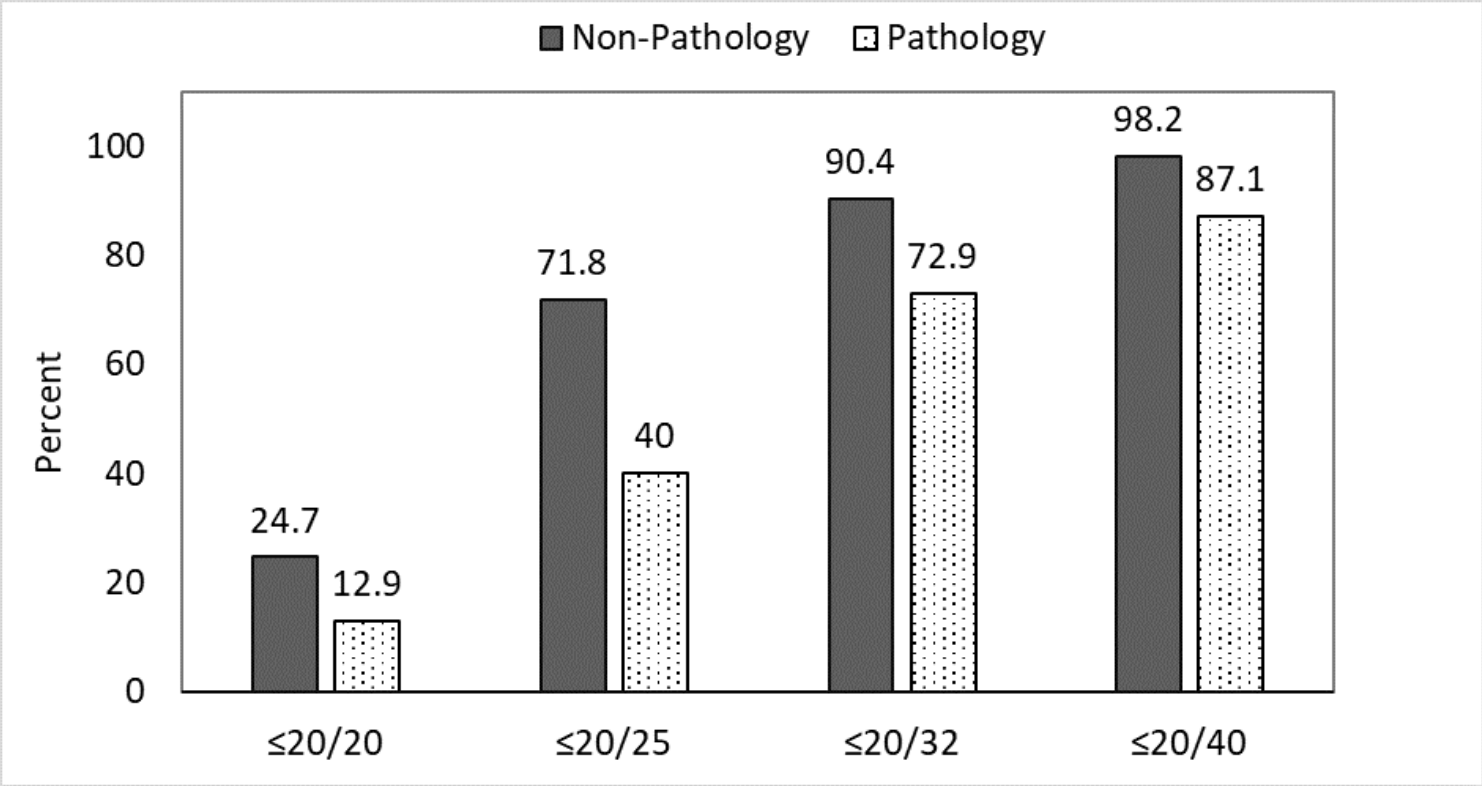

Figure 4

Cumulative Snellen Monocular Uncorrected Distance Visual Acuity at 2 months postoperatively.

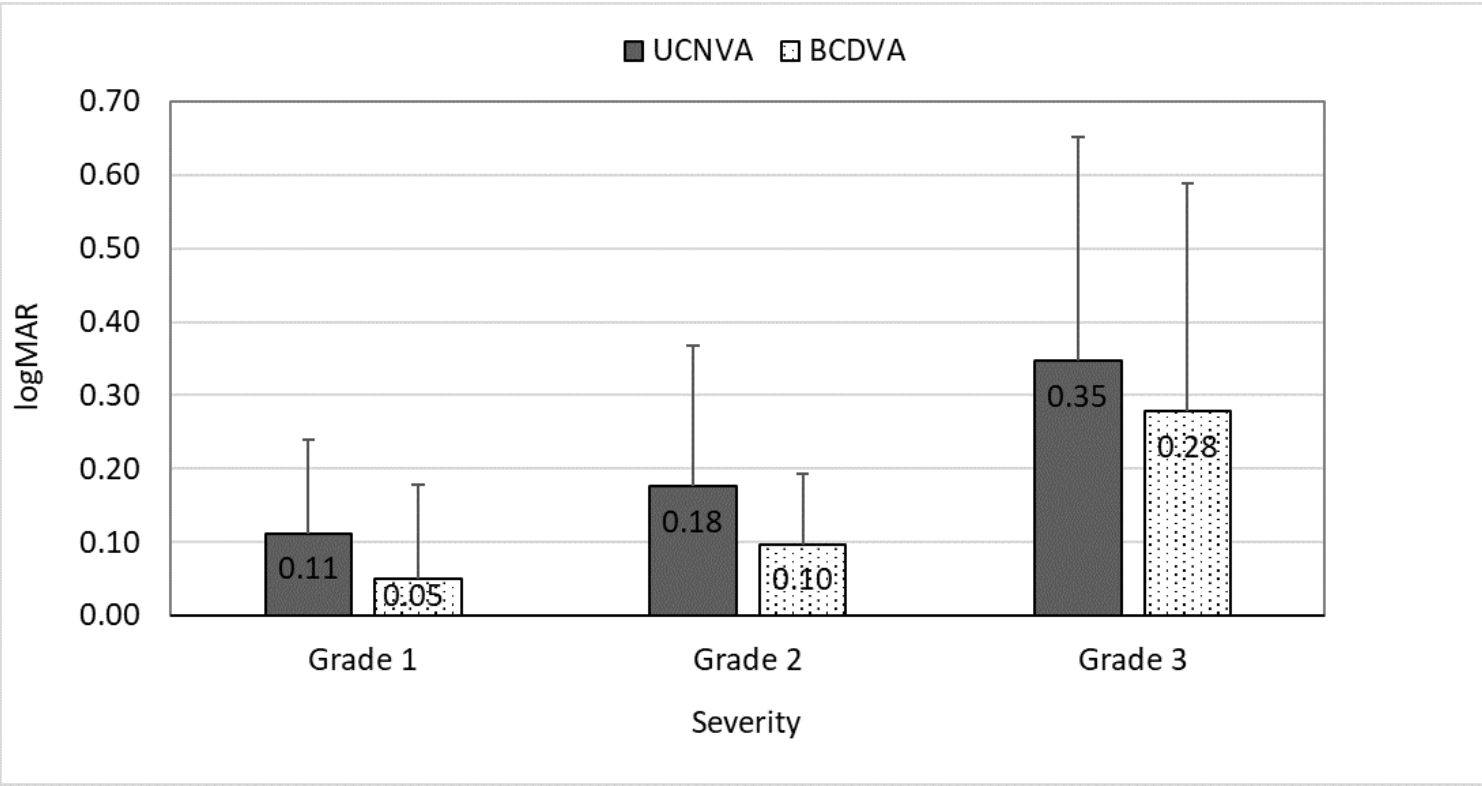

Figure 5

Mean logMAR Visual Acuity at 2 months postoperatively, stratified by severity of retinal pathology.

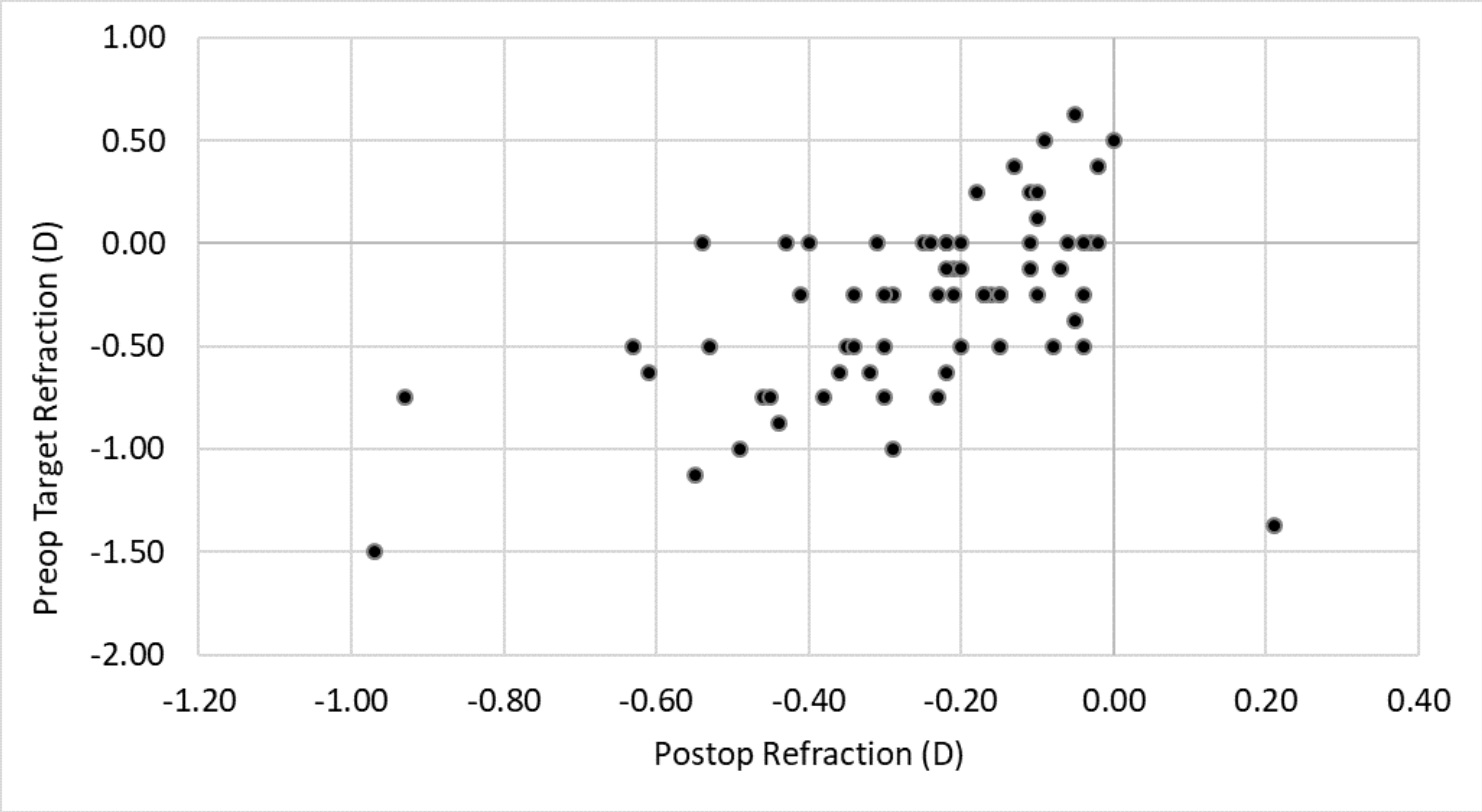

Figure 6

Preoperative target versus postoperative refraction of eyes with retinal pathology.