EXTENDED DEPTH OF FOCUS INTRAOCULAR LENSES (EDOF IOLs) SEEM TO BE A COMPROMISE BETWEEN CONVENTIONAL MULTIFOCAL AND MONOFOCAL IOLs BY OFFERING A GOOD RANGE OF FUNCTIONAL VISION FOR EVERYDAY ACTIVITIES, WHILE HAVING MINIMAL IMPACT ON DISTANCE VISION OR OVERALL QUALITY OF VISION.

IN A PREVIOUS STUDY, WE PRESENTED OUR INITIAL EXPERIENCE WITH THE AT LARA 829MP IOL (CARL ZEISS MEDITEC, JENA, GERMANY). THIS EDOF IOL IS BASED ON A DIFFRACTIVE PRINCIPLE AND HAS, IN ADDITION TO A DISTANCE FOCAL POINT, TWO ELONGATED FOCI FOR FAR-INTERMEDIATE AND NEAR-INTERMEDIATE VISION, THEREBY creating a continuous range of sharp vision from far through near-intermediate distances. THE STUDY EVALUATED CLINICAL AND PATIENT-REPORTED OUTCOMES IN PATIENTS IMPLANTED WITH THIS IOL, AND RELATIVELY HIGH SPECTACLE INDEPENDENCE AND SATISFACTION RATES HAVE BEEN ACHIEVED.

ABSTRACT

PURPOSE: To identify independent factors associated with postoperative satisfaction after refractive lens exchange with an extended depth of focus intraocular lens (EDOF IOL).

METHODS: Patients who underwent a refractive lens exchange with bilateral implantation of the AT LARA 829MP IOL (Carl Zeiss Meditec, Jena, Germany) and attended the 3-month follow-up visit were included in the analysis (N = 351 patients). Demographics, preoperative and postoperative clinical parameters, and patient-reported outcomes were used in a regression model to determine predictors of 3-month postoperative satisfaction.

RESULTS: The mean age of the study group was 58.2 ± 7.0 years (range: 45 to 79 years) and the mean preoperative sphere ranged between -12.50 and +6.75 diopters (D). At 3 months postoperatively, 86.6% of patients were very satisfied or satisfied with outcomes and 93.2% would recommend the procedure to their family or friends. Of all patients, 90.6% achieved binocular uncorrected distance visual acuity of 20/20 or better, 92.0% achieved binocular near vision of 20/50 or better, and 85.5% of eyes were within ±0.50 D of emmetropia. Logistic regression identified postoperative dry eye symptoms, binocular near and distance visual acuity, and glare symptoms as significant independent factors affecting patient satisfaction.

CONCLUSIONS: Several factors were independently predictive of postoperative satisfaction after EDOF IOL implantation and addressing these may further improve patient satisfaction with the procedure, specifically, proper management of early symptoms of dry eye, ensuring good refractive predictability to maximize unaided vision, and counseling patients about the possibility of visual phenomena in the early postoperative period.
Assuming no vision-threatening complications, patient satisfaction is arguably the most important outcome after an elective procedure. However, factors that predict satisfaction after EDOF lens implantation have not been well described. In the current study, we evaluate predictors associated with postoperative satisfaction in patients bilaterally implanted with this IOL. Using these, we suggest strategies for surgeons to improve patient satisfaction and aid in counseling and patient selection.

PATIENTS AND METHODS

This study involved retrospective data analysis of patients who underwent cataract or refractive lens exchange surgery in Optical Express, United Kingdom, with bilateral implantation of the AT LARA 829MP IOL. All patients provided a written informed consent at the time of surgery and agreed to use of their records for statistical analysis. The study was exempt from full review by the Committee of Human Research at the University of California, San Francisco, because it used only retrospective, de-identified patient records.

Data were extracted from the Optical Express electronic medical record with the following criteria: bilateral implantation of the AT LARA 829MP IOL between September 2017 and May 2019, attended the 3-month postoperative visit, completed the preoperative and 3-month postoperative patient experience questionnaire, and had corneal astigmatism (determined by IOLMaster, Carl Zeiss Meditec) of 1.50 diopters (D) or less in each eye. Patients with retinal/macular pathology, neuro-ophthalmic diseases, glaucoma, any active or history of ocular inflammation, and previous refractive surgery were excluded from analysis. All patients either underwent a refractive lens exchange (in the absence of cataract) or had mild cataract changes with corrected visual acuity not worse than 20/40.

Preoperative examination included evaluation of refractive status, slit-lamp biomicroscopy, dilated fundus examination, corrected (CDVA) and uncorrected (UDVA) distance visual acuity, and 40 cm uncorrected near visual acuity (UNVA). The methodology of obtaining visual acuity measurements has been previously described.\(^3\)

Preoperative diagnostic scans included autorefraction and tonometry (Tonoref II; Nidek Co. Ltd., Gamagori, Japan), corneal tomography (Pentacam software version 1.21r43; Oculus Optikgeräte GmbH, Wetzlar, Germany), wavefront aberration measurement (Design Advanced WaveScan System; Johnson & Johnson Vision Care, Inc., Santa Ana, CA), endothelial cell count (SP 2000P specular microscope; Topcon Corporation, Tokyo, Japan), biometry (IOLMaster 700 software version 1.18; Carl Zeiss Meditec), and retinal optical coherence tomography (Cirrus 4000/500 OCT; Carl Zeiss Meditec).

All patients underwent phacoemulsification with the implantation of the fully preloaded AT LARA 829MP lens into the capsular bag. The surgery was performed with the assistance of a femtosecond laser (Catalys Precision Laser System; Johnson & Johnson Vision Care, Inc.) using the previously described surgical technique.\(^3\) Femtosecond laser-assisted astigmatic keratotomy was performed in eyes with corneal astigmatism between 0.75 and 1.50 D. A nomogram developed in our clinics was used for eyes with post-the-rule astigmatism (Table A, available in the online version of this article), whereas a previously described nomogram\(^4\) was used for all other cases. All intrastromal arcuate incisions were performed with a depth between 20% and 80% of corneal pachymetry and a diameter of 8 mm. Surgeries were performed in 11 surgical centers by 10 surgeons.

Patients were advised to return for postoperative evaluation at 1 day, 1 week, 1 month, and 3 months. At each visit, refraction and near and distance visual acuities were recorded. All patients included in this study completed preoperative and 3-month postoperative patient experience questionnaires. The questionnaire was self-administered by the patient using a password-protected and secure computer terminal in a private area of the clinic and stored in the secured central database, which is compliant with ISO 27001 for information security management systems. All response fields used a Likert scale to obtain the patient’s preferences or degree of agreement. The questionnaire evaluated general satisfaction with vision, visual phenomena and dry eye symptoms, spectacle independence, and difficulties with common tasks that require the use of distance and near vision. Patients were informed that the postoperative responses were not available to clinic personnel or the treating surgeon. The questionnaire items are described in detail in Table 1.

STATISTICAL ANALYSIS

Logistic multivariable regression analysis was used to identify significant predictors of 3-month postoperative satisfaction with vision (Question 1 from Table 1). Variables included in the regression model were patient demographics (age, gender), surgeon and surgical center, preoperative and postoperative clinical variables (visual acuity and refraction), questionnaire responses, and postoperative adverse events occurring within the first 3 months, such as cystoid macular edema, anterior uveitis, or clinical signs of dry eye (punc-
tate epithelial erosions, reduced tear break-up time, meibomitis, or blepharitis). Some medical conditions from preoperative screening were also included in the model, such as current or history of depression/psychiatric disorders, dry eye, or any ongoing health issues (eg, diabetes mellitus, thyroid imbalance, or rheumatoid arthritis). Binocular visual acuities were used in the regression model because they demonstrated a stronger association with postoperative satisfaction compared to monocular vision.

The paired Student’s *t* test was used to compare the change between preoperative and postoperative...
continuous variables, and an unpaired t test was used to compare independent groups of patients. The chi-square test was used to compare percentages. Where percentages and number of cases are presented, “N” refers to the number of patients and “n” to the number of eyes. Data tabulation and statistical operations were performed with SAS (version 9.3; SAS Institute, Inc., Cary, NC) and Microsoft Office Excel (version 11.0; Microsoft Corporation, Redmond, WA) software.

RESULTS

The total number of patients who met preoperative study inclusion criteria was 569 (1,138 eyes), of whom 702 eyes of 351 patients (61.7% of the cohort) attended the 3-month postoperative visit and completed the patient experience questionnaire. The demographics of the study group and the basic preoperative and postoperative clinical variables are described in Table 2. Preoperative refractive sphere ranged from -12.50 to +6.75 D, but most of the patients (88.9%, N = 312) were hyperopic preoperatively. All patients had a statistically significant reduction in refraction with the mean postoperative manifest spherical equivalent at 3 months close to plano (-0.06 ± 0.39 D). Of all eyes, 85.5% (n = 600) were within ±0.50 D of emmetropia and 97.9% (n = 687) were within ±1.00 D of emmetropia. The percentage of eyes with a postoperative refractive cylinder of 0.50 D or less was 71.4% (n = 501).

The mean binocular UDVA at 3 months was -0.06 ± 0.08 logMAR (Snellen equivalent 20/17.5) with 90.6% (N = 318) of patients having binocular UDVA of 20/20 or better and all patients achieving UDVA of 20/40 or better. Binocular near visual acuity of 20/32, 20/40, and 20/50 or better was achieved in 52.1% (N = 183), 78.3% (N = 275), and 92.0% (N = 323) of patients, respectively. The mean binocular UNVA at 3 months was 0.27 ± 0.13 logMAR (Snellen equivalent 20/37). The mean CDVA remained unchanged between the preoperative and 3-month postoperative visits (Table 2). The standard graphs for reporting outcomes of lens-based surgery are presented in Figure 1.

PATIENT SATISFACTION

Table 1 presents outcomes of the 3-month postoperative questionnaire. Of all patients, 86.6% (N = 304) were very satisfied/satisfied, 5.7% (N = 20) of patients were neither satisfied nor dissatisfied, and 7.7% (N = 27) were dissatisfied/very dissatisfied with their visual outcomes. Additionally, 93.2% (N = 327) of patients would recommend the procedure to their family/friends.

Table 3 shows some of the most relevant preoperative parameters in relation to postoperative satisfaction. Patients who were “satisfied” (very satisfied or satisfied) with vision postoperatively tended to have a higher refractive error preoperatively (both myopic and hyperopic) and a higher proportion of preoperative...
tive hyperopia compared to patients who were “not satisfied” (neither satisfied nor dissatisfied, dissatisfied, or very dissatisfied). However, most of these differences were not statistically significant. There was no significant difference in preoperative refractive or corneal astigmatism between “satisfied” and “not satisfied” patients. Patients who were “not satisfied” tended to have more reported depression symptoms and ongoing health issues preoperatively, but the differences did not reach statistical significance.

The association between postoperative parameters and satisfaction with vision is presented in Table 4. Postoperatively, “not satisfied” patients had worse binocular UDVA and UNVA. The mean postoperative spherical equivalent was similar between “satisfied” and “not satisfied” patients, although the standard deviation was higher for “not satisfied” patients and the percentage of eyes within ±0.50 D of emmetropia was also lower among “not satisfied” patients. Postoperative refractive cylinder was slightly worse in “not satisfied” patients, but the difference was not statistically significant. There was no difference in the percentages of patients who required astigmatic keratotomy between “satisfied” and “not satisfied” patients.

Exploring the refractive target and predictability further, a group of patients who achieved bilateral emmetropia (defined as manifest spherical equivalent within ±0.25 D with no more than 0.75 D of refractive cylinder, N = 151) was compared to a group of patients who were targeted and achieved slight (mini)
monovision (manifest spherical equivalent in the non-dominant eye of -0.50 D or more of myopia, N = 25). Higher satisfaction rates were achieved in patients who achieved bilateral emmetropia (94% “satisfied”) compared to those with mini-monovision (80% “satisfied,” \( P = .02 \)).

Postoperatively, patient-reported outcomes such as difficulty with dry eye or glare, difficulty with night driving, close-up vision, and distance activities and dependence on near or distance vision correction were worse among patients who were “not satisfied” with vision (Table 4). Interestingly, clinical signs of dry eye had less impact on patient satisfaction than patient-reported dry eye symptoms. Of all satisfied patients, 10.9% had some clinical signs of dry eye postoperatively compared to 17% in the group of “not satisfied”
patients, \( P = .22 \). In contrast, patient-reported significant difficulty with dry eye was indicated in 1.6% of all “satisfied” patients, and 19.1% of all “not satisfied” patients (\( P < .01 \)).

**Regression Analysis**

A multivariable logistic regression model was developed using a stepwise approach to identify significant independent predictors of being “not satisfied” (combination of patients who were neither satisfied nor dissatisfied, dissatisfied, or very dissatisfied, Question 1 from Table 1) with vision 3 months postoperatively. Of all variables included in Tables 3-4, patient-reported glare symptoms, patient-reported postoperative difficulty with dry eye, and postoperative binocular UNVA and UDVA were the only independent factors affecting patient satisfaction. Overall, the predictive power of the model was strong with a C-statistics value (a measure of predictive accuracy in logistic regression, ranging from 0.50 for a poor model to 1 for a perfect model)\(^6\) of 0.889.

Specifically, for every unit increase in patient-reported glare (on a discrete scale from 1 = no difficulty to 7 = severe difficulty), the odds of being “not satisfied” increased by a factor of 5.39 (95% confidence interval [CI]: 2.78 to 10.43). Using the same scale (1 to 7) for patient-reported dry eye symptoms, for every unit increase in dry eye difficulty, the odds of being “not satisfied” increased by a factor of 3.08 (95% CI: 1.45 to 6.55). The relationship between glare and satisfaction and dry eye and satisfaction is further explored in Figures 2A-2B. More than 96% of patients were “satisfied” with vision if they reported no glare or dry eye symptoms, whereas the percentage of satisfied patients gradually decreased with increasing glare/dry eye difficulty. There also is some association between dry eye and glare: 50% of all patients who reported significant dry eye (score 5 to 7, Table 1) also reported significant glare.

For binocular UDVA, for every Snellen line decrease of binocular UDVA, the odds of being “not satisfied” increased by a factor of 1.71 (95% CI: 1.10 to 2.64). Postoperative binocular UDVA is plotted against satisfaction in Figure 2C. The percentage of “satisfied” patients gradually decreased from 98.2% for patients who achieved binocular visual acuity of 20/12.5 to 40.0% for patients who had postoperative UDVA of 20/32 or worse.

Likewise, for every Snellen line decrease of binocular UNVA, the odds of being “not satisfied” increased

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**Figure 2.** Postoperative satisfaction with vision stratified by postoperative (A) glare difficulty, (B) dry eye difficulty, (C) binocular uncorrected distance visual acuity, and (D) uncorrected near visual acuity.
by a factor of 1.84 (95% CI: 1.36 to 2.49) and this relationship is graphically presented in Figure 2D. Of all patients who had 20/25 binocular near vision, 95.2% were “satisfied,” whereas this percentage gradually decreased to 46.4% in patients with postoperative binocular UNVA of 20/60 or worse.

**DISCUSSION**

Patient satisfaction should be considered as one of the most important outcome metrics for elective procedures. Patients who have a suboptimal visual outcome (eg, residual refractive error of less than 20/20 visual acuity) may report that they are happy with the procedure. It is also not unusual for a patient to express dissatisfaction despite adequate objective outcomes.

EDOF IOLs are increasingly being used in presbyopic patients, and clinical outcomes of different types of these IOLs have been previously reported. The AT LARA 829MP IOL is a relatively new addition to the current portfolio of EDOF IOLs and was designed to minimize visual aberrations that have affected previous generations of multifocal lenses. To our knowledge, this is the first study investigating factors affecting patient-perceived performance of an EDOF IOL.

Although many clinical factors were included in our regression model, it is not surprising that the actual achieved Snellen visual acuity was a strong predictor of postoperative satisfaction with vision. Blurry distance vision is likely to be the main driver of dissatisfaction after any refractive surgery and has been reported as a common reason for dissatisfaction with other types of presbyopia-correcting lenses.

However, although EDOF lenses offer more natural vision for intermediate/near distances and a smoother defocus curve, they may be less effective compared to conventional high-add multifocal IOLs at near distance. Hence, it is important to set realistic expectations with EDOF IOL candidates and discuss the possibility of needing reading glasses. Although 92.0% of patients achieved binocular 20/50 or better near vision (equivalent to J6), those with worse near acuity expressed dissatisfaction with outcomes.

Interestingly, although dissatisfied patients had poorer refractive predictability, the postoperative refractive error was not an independent predictor of dissatisfaction in multivariate analysis. This is possibly because the sample of patients with a significant residual refractive error was small, or the lens might be more tolerant to small amounts of residual refraction. This mostly applies to the amount of residual refractive astigmatism, which was not significantly different between “satisfied” and “not satisfied” patients. Other types of EDOF lenses have also previously shown higher limits of tolerance for uncorrected refractive error.

Despite the fact that postoperative residual refractive error was not an independent predictor in our regression model, it is a variable correlated to postoperative visual acuity. Hence, improving refractive predictability should maximize the visual acuity achieved with the AT LARA IOL and result in higher satisfaction rates. Targeting slight monovision with EDOF IOLs has been previously proposed for improvement of the near vision performance.

However, the trade-off of improved near vision with monovision at the expense of distance vision and/or quality of vision needs to be carefully considered. We found significantly higher satisfaction rates in those patients who achieved bilateral emmetropia than those with mini-monovision, but our sample size of patients with monovision was relatively small (N = 25). Additional studies would be useful to further elucidate the value of targeting a small amount of myopia in one eye.

Photic phenomena after multifocal IOLs are associated with patient dissatisfaction. The EDOF lenses should theoretically induce less glare and halo symptoms compared to conventional multifocal IOLs, but photic phenomena can still be present with these lenses in the early postoperative time period. Patients may opt for EDOF IOLs to reduce the chance of visual phenomena, and can be disappointed if they become symptomatic. As we have previously demonstrated with the AT LARA IOL, the symptoms are often transient and a gradual improvement is expected with time. In our dataset, patients generally expressed dissatisfaction with their visual outcomes when their postoperative glare score was 6 or 7 (on the scale 1 to 7, Figure 2), and such significant glare was reported by 5.6% of patients at 3 months postoperatively. Photic phenomena can be associated with factors other than multifocal IOL design. In our study, glare was strongly associated with symptoms of dry eye, because 50% of patients who reported significant dry eye also reported significant glare.

The increase in dry eye symptoms after cataract surgery has been commonly reported and its effect on the performance of advanced technology IOLs should not be underestimated. The increase in dry eye following intraocular surgery is multifactorial and commonly recognized factors include surgical manipulation/
transection of corneal nerves,\textsuperscript{25,26} medication toxicity,\textsuperscript{24,26} goblet cell loss,\textsuperscript{25,26} inflammation,\textsuperscript{27} or aggravated meibomian gland dysfunction.\textsuperscript{27,28} There is also often discordance between signs and symptoms of dry eye after cataract surgery.\textsuperscript{29}

In our model, we considered both clinical signs found on examination and patient-reported dry eye symptoms. We found that subjective symptoms were a much stronger predictor of patient satisfaction than clinical signs. This is a curious finding, because objective signs of dry eye would be expected to lead to decreased visual quality and thus decreased patient satisfaction. It may be that patients reporting dry eye symptoms without signs had a fluctuating tear film quality that interfered with vision but was adequate to maintain a healthy ocular surface, or that patients who were dissatisfied were experiencing ocular surface pain from a different source that they interpreted as dryness. Nevertheless, prophylactic ocular surface treatment in the early postoperative period and intensive therapy in patients with either objective or subjective signs of dry eye should considerably improve satisfaction with EDOF IOLs. Appropriate clinical management of dry eye has also been shown to have an impact on the performance of other types of multifocal IOLs.\textsuperscript{30}

The outcomes of this study were based on a dataset of 351 patients bilaterally implanted with the AT LARA IOL. As more patients undergo surgery, it is possible that other factors will be recognized as being significant, such as preoperative refractive error or preoperative visual acuity. Preliminary outcomes showed that patients with lower preoperative refraction and better preoperative UDVA were less satisfied with the AT LARA lens (Table 3), although this was not significant in the multivariate model. Patients with lower preoperative refractive error may have higher expectations for presbyopia.

To improve satisfaction in patients undergoing refractive lens exchange with implantation of advanced technology IOLs, this study highlights the need for the management of postoperative dry eye symptoms, avoiding mini-monovision, targeting emmetropia with multifocal IOLs.

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AUTHOR CONTRIBUTIONS


TABLE A  
**Nomogram for Astigmatic Keratotomy in Eyes With With-the-Rule Astigmatism**

<table>
<thead>
<tr>
<th>Age (y)</th>
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<td>70+</td>
<td>30°</td>
<td>40°</td>
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</table>

*Corneal Astigmatism (Diopters)*

*a A clear corneal incision is placed on the steep meridian, and a single arcuate incision is created opposite to the corneal incision. The numbers in the table represent degrees of arc.*