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Patient-reported vision-related quality of life after laser in situ keratomileusis, surface ablation, and phakic intraocular lens

The 5.5-year follow-up study

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Abstract

To evaluate the long-term efficacy of refractive surgery of all cases in a single center via the use of a patient-reported outcome (PRO) refractive status questionnaire using descriptive statistics. This study was prospective, single-center, cohort study that involved 1422 patients who underwent refractive surgery (laser in situ keratomileusis, surface ablation, and phakic intraocular lens) at Baptist Eye Institute, Kyoto, Japan. The patients were asked to answer the Refractive Status and Vision Profile (RSVP) questionnaire before the surgery after 6 months (n = 1133 patients) and after 5.5 years (n = 232 patients). During the same period, examination by slit-lamp biomicroscopy and visual acuity tests were performed. Moreover, the patients were asked to rate their satisfaction with the surgery 6 months and 5.5 years after it. We examined overall RSVP scale (S), 8 RSVP subscales, rate of satisfaction with surgical outcome, slit-lamp biomicroscopy findings, and refractive error. The mean preoperative S was 36, yet that score significantly improved to 19 at 6 postoperative months postoperatively ($P < .01$), and basically remained the same (i.e., 20) throughout the 5.5-year postoperative period. During the 5-year follow-up period, mean refractive error became slightly myopic (0.3 D). No change in the rate of satisfaction was observed at both 6 months and 5.5 years postoperative period. The findings of this study help to clarify long-term PRO quality of vision (QOV) postrefractive surgery in a single center, and show that minor change in refractive error during 5 years postoperative period had no influence on the mean RSVP scores among outpatients. Nearly all patients reported short-term improvement of QOV, which continued throughout the long-term follow-up period.

Abbreviations: Epi-LASIK = epipolis-laser in situ keratomileusis, ICL = Implantable Collamer Lens, IOL = intraocular lens, LASIK = laser in situ keratomileusis, PRK = photorefractive keratectomy, PRO = patient-reported outcome, QOV = quality of vision, RSVP = Refractive Status and Vision Profile.

Keywords: laser in situ keratomileusis, patient-reported outcome, phakic intraocular lens, refractive surgery, surface ablation

1. Introduction

Refractive surgery is a well-known and commonly used surgical method to treat patients with myopia, hyperopia, and astigmatism. However, the number of published reports regarding the long-term surgical outcome is very small.[1,2] Laser in situ keratomileusis (LASIK) is a standard method used for refractive surgery, and approximately 95% of patients are reportedly satisfied with their vision post LASIK.[3] It has been reported that for patients with a thin or irregular cornea, surface ablation procedures such as photorefractive keratectomy (PRK) and epipolis-laser in situ keratomileusis (Epi-LASIK) may be more suitable than LASIK.[4] For cases of extremely high myopia[5] or suspected keratoconus,[6] implantation of a phakic intraocular lens (IOL) is a better option than corneal refractive surgery.

For evaluation of medical treatments, a "patient-reported outcome" (PRO) is important, even though the patient's evaluation is subjective. PRO scale includes a generic scale to evaluate the condition of general health, as well as a disease-specific scale. The Refractive Status and Vision Profile (RSVP)[7,8] and the National Eye Institute Refractive Error Quality of Life Instrument (NEI-RQL-42)[9] were produced as disease-specific scales of refractive error. It should be noted that according to the reports[10,11] for the short-term outcome of refractive surgery, those PRO scales improved. Little is, however, unknown for the long-term PRO.[12,13] Baptist Eye Institute, Kyoto, Japan is one of the few clinics in Japan that recommends regular checkups for postrefractive surgery patients after the initial 6 months recommended by the Japanese guidelines "Guidelines for refractive surgery (7th edition)."[14] Here we report our findings for the first 5.5 years after refractive surgery.

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The purpose of the current study was to investigate and clarify the long-term PRO for patients who attended regular medical checkups after all types of refractive surgeries in our institute by descriptive statistics.

2. Methods

This prospective, single-center cohort study involved 1422 patients who were deemed eligible to participate and who agreed to respond to the RSVP questionnaire before undergoing refractive surgery at the Baptist Eye Institute from January 25, 2001 to December 23, 2010. For all cases of refractive surgery performed during this period, RSVP was handed and as many patients as possible were targeted. Our institute recommends as long as possible follow-up observation to all cases after the initial postoperative 6 months. The patients were asked to respond to the RSVP before surgery, at 6 postoperative months, and annually at each 1-year-interval follow-up visits until 5.5 years postoperative. Prior written informed consent was obtained from all patients in accordance with the tenets set forth in the Declaration of Helsinki, and approval for this study was obtained from the Institutional Review Board of Kyoto Prefectural University of Medicine, Kyoto, Japan.

In this study, each patient underwent either LASIK or surface ablation for corneal refractive surgery. For the LASIK procedure, a femtosecond laser or a mechanical microkeratome was used for creation of the flap. For surface ablation, either PRK (using either a laser or brush to remove the epithelium) or Epi-LASIK was performed. For the patients who underwent intraocular refractive surgery, an Implantable Collamer Lens (ICL; STAAR Surgical, Nidau, Switzerland) was inserted. Our indication for refractive surgery adhered to the treatment guidelines of the Japanese Ophthalmological Society.[14] When the preoperative corneal topography was deemed normal, and when the residual corneal bed was more than 250 μm with a 150 μm flap, we performed LASIK. On the contrary, when surface ablation was performed to patients with normal preoperative corneal topography, a residual stromal bed of more than 300 μm with a 50 μm epithelial flap was produced. Because LASIK and surface ablation procedures are not suitable for patients whose preoperative corneal topography was deemed forme fruste keratoconus, or whose refractive error was extreme myopia, implantation of an ICL was performed.

The RSVP was developed by Schein[7,8] in 2000 to measure the functional status and quality of life of individuals with refractive errors. The RSVP has 42 questions and is evaluated in overall score S with 8 subscales (concern, expectation, physical /social function, driving, symptoms, optical problems, glare, and problems with the corrective lens). The score "0" means no difficulty, and the score "100" means numerous difficulties. We also evaluated "Post S," which is calculated by subtracting the "expectation" from S. Post S was used as an index of changes before and after srugery.[10] In this study, we used the Japanese edition of RSVP, which is the Japanese language version of the original RSVP. We obtained a license to use the Japanese-language version of RSVP in 2001, and examined the reliability and validity of the Japanese edition in our previously published study.[15]

In the current study, we observed the dynamics of changes the RSVP score between before and after the refractive surgery. Furthermore, we evaluated spherical-equivalent refractive error. In addition, at 6 months and 5.5 years postoperative period, the patients were asked to personally grade their satisfaction of the surgical outcome by selecting 1 of the following 4 scores: very satisfied, satisfied, moderately dissatisfied, and dissatisfied.

Excel table was used to create graphs with the mean values obtained from the RSVP data collected from every patient. Because the number of people to be targeted changes at each measurement time point, statistical test was not performed, and conclusions were made based on the changes in PRO and satisfaction.

3. Results

The 1541 total patients who underwent refractive surgery during the study period, 1422 patients (92.3%) completed the preoperative RSVP. At 6 months postoperative period, 1264 patients underwent postoperative follow-up. Of those, 1133 patients were able to complete the 6 months postoperative RSVP. At 5.5 years postoperative period, only 232 completed the questionnaire. Throughout the study period, none of the patients experienced serious vision-threatening complications such as keratectasia or infection. The baseline clinical characteristics of the study population are shown in Table 1. A total of 2730 eyes of 1422 patients underwent surgery. Of those, 40 eyes (1.5%) were hyperopic and 1283 eyes (47.0%) were greater than 6-diopters (D) myopic. Of the cases that completed the preoperative RSVP, LASIK was performed on 1851 eyes (67.8%), followed by surface ablation on 819 eyes (30.0%), phakic IOL implantation on 62 eyes (2.3%), and enhanced LASIK and surface ablation on 39 eyes (1.4%). Seventy-one unilateral case eyes (2.6%) underwent LASIK and surface ablation. The mean preoperative refractive error was -5.91 ± 3.86 D (range, +6.50 to −26.63 D).

The mean pre- and postoperative RSVP scores are shown in Figure 1. The total score S, concern, physical/social function, driving, symptoms, optical problems, problems with corrective lens, and post S improved postoperatively. These scores at 6 months postoperative period and during subsequent visits at the 1-year intervals until the end of follow-up period were approximately the same in Figure 1. The standard deviations and

Table 1

Baseline characteristics (2730 eyes).

Characteristic	Percentage
Age, y	
18–39	72.2
40–49	20.5
50+	7.4
Sex	
Female	51.0
Corrective lenses	
Contact lens only	2.7
Glasses and contact lens	33.3
Glasses only	64.0
Refractive error (D)	
Hyperopic	1.5
0 to −2.9	12.2
−3 to −5.9	39.0
−6.0 to −9.9	39.1
−10.0 or higher	8.2
BCVA	
Decimal 1.0 or better	95.8

BCVA = best corrected visual acuity, D = diopter.

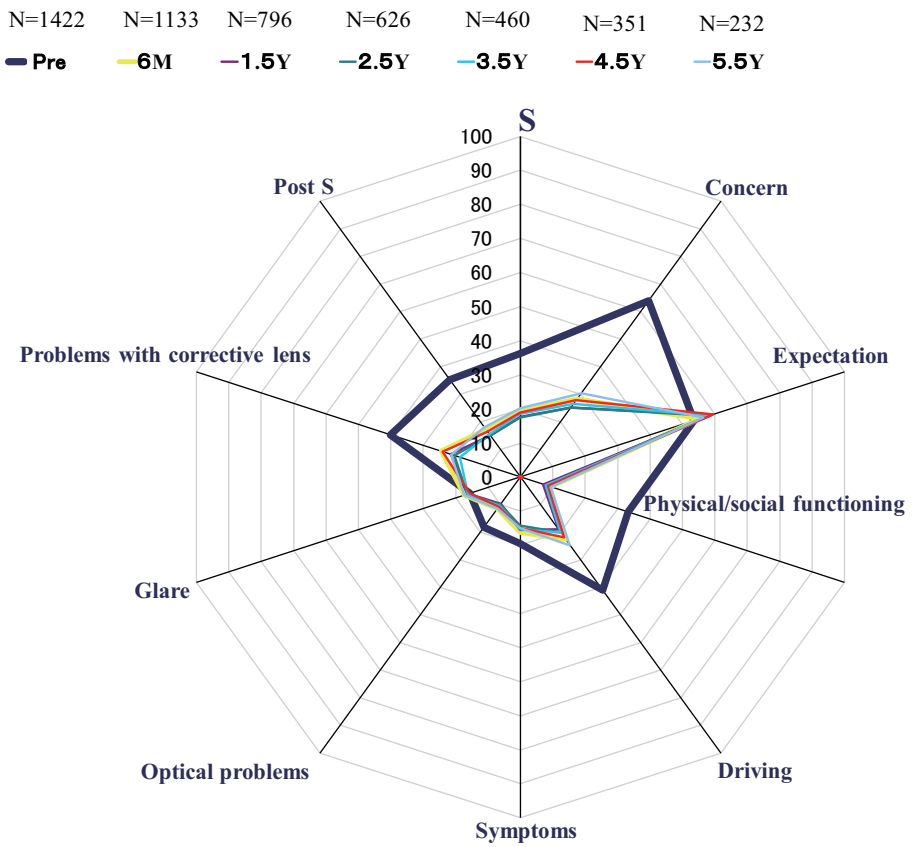

Figure 1. Change of the mean Refractive Status and Vision Profile (RSVP) score (S) between preoperative period and 0.5 to 5.5 years postoperative period. All RSVP items except glare and expectation significantly improved after surgery, and there was little change over the 5-year postoperative time course. Post S (i.e., score, subtracting expectation from S). Dark blue represents the preoperative RSVP score. The postoperative RSVP scores were assigned different colors for each follow-up time-point.

the ranges of the scores at each follow-up time period are shown in Table 2.

At 6 postoperative months, 81.2% of the operated eyes were within ±0.5 D of emmetropia and 93.0% were within ±1.0 D, and the mean refractive error was −0.21 ± 0.73 D (range, +3.88 to −11.75 D). At 5.5 postoperative years, 70.1% of the operated eyes were within ±0.5 D of emmetropia and 86.2% were within ±1.0 D, and the mean refractive error was −0.50 ± 0.65 D (range, +2.38 to −8.50 D). In average the myopia grew by 0.3 D in postoperative period from 6 months to 5.5 years.

At 6 months postoperative period, the number of patients who completed RSVP was 1133. Of whom 70.7% underwent LASIK,

Table 2

The mean score change of pre- and postoperative Refractive Status And Vision Profile.

	S	Concern	Expectation	Physical/social functioning	Driving	Symptoms	Optical problems	Glare	Problems with corrective lens	Post S
Pre	36.3 ± 14.6 (5.6–93.9)	64.0 ± 19.1 (0–100)	53.5 ± 21.3 (0–100)	33.3 ± 21.3 (0–100)	41.0 ± 29.4 (0–100)	19.4 ± 19.9 (0–100)	18.2 ± 18.9 (0–100)	15.5 ± 19.7 (0–100)	40.1 ± 21.2 (0–100)	35.3 ± 15.5 (3.1–97.5)
6 mo	19.4 ± 14.7 (0–86.11)	28.3 ± 21.2 (0–100)	55.5 ± 24.8 (0–100)	9.2 ± 15.2 (0–97.73)	22.5 ± 24.8 (0–100)	16.3 ± 15.7 (0–100)	11.5 ± 15.8 (0–100)	17.4 ± 19.3 (0–100)	24.5 ± 24.7 (0–100)	17.2 ± 15.5 (0–100)
1.5 y	17.7 ± 13.5 (0–96.9)	25.4 ± 18.8 (0–100)	58.9 ± 23.3 (0–100)	7.0 ± 12.5 (0–85.71)	19.1 ± 22.0 (0–100)	15.6 ± 16.2 (0–75)	9.7 ± 13.8 (0–75)	16.0 ± 19.8 (0–100)	21.6 ± 24.5 (0–100)	15.2 ± 13.9 (0–100)
2.5 y	17.6 ± 13.4 (0–84.6)	26.3 ± 18.7 (0–100)	58.1 ± 24.2 (0–100)	7.9 ± 14.7 (0–100)	20.0 ± 23.9 (0–100)	14.2 ± 15.3 (0–100)	10.0 ± 14.3 (0–100)	16.5 ± 18.9 (0–100)	20.4 ± 20.2 (0–67.9)	15.1 ± 14.1 (0–84.6)
3.5 y	18.6 ± 13.9 (0–84.4)	26.6 ± 18.9 (0–91.7)	58.6 ± 23.2 (0–100)	7.7 ± 14.7 (0–100)	20.0 ± 22.5 (0–100)	15.2 ± 16.4 (0–93.8)	10.4 ± 14.0 (0–100)	16.3 ± 18.9 (0–100)	18.7 ± 21.8 (0–75)	15.6 ± 14.2 (0–83.3)
4.5 y	18.9 ± 13.9 (0–70)	27.8 ± 19.4 (0–100)	59.4 ± 24.4 (0–100)	8.5 ± 15.2 (0–96.9)	21.9 ± 24.6 (0–100)	14.9 ± 16.0 (0–75)	10.8 ± 13.9 (0–75)	15.5 ± 18.6 (0–75)	24.1 ± 25.5 (0–100)	16.4 ± 14.6 (0–71.7)
5.5 y	20.2 ± 13.9 (0–67.5)	30.4 ± 19.0 (0–87.5)	56.3 ± 25.7 (0–100)	9.3 ± 13.6 (0–71.9)	24.8 ± 25.5 (0–100)	15.0 ± 15.2 (0–70)	11.4 ± 15.6 (0–75)	17.3 ± 19.8 (0–91.67)	21.3 ± 25.7 (0–100)	18.0 ± 14.8 (0–70.83)

Overall score S, 6 subscales (concern, physical/social function, driving, symptoms, optical problems, and problems with corrective lens) and Post S: subtracting expectation from S improved at 6 postoperative months and were stable over the following 5 years. The score shows mean ± standard deviation and (range).

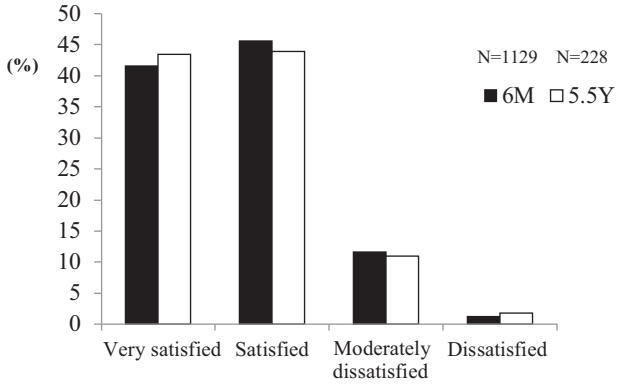

Figure 2. Reported patient satisfaction of the surgical outcome. Patient satisfaction of the surgical outcome 5 years postoperatively was approximately the same as 6 months postoperatively.

20.0% surface ablation, 2.9% phakic IOL implantation, and 6.4% enhanced LASIK. At 6 months postoperative period, 41.6%, 45.6%, 11.6%, and 1.2% of the patients indicated that they were very satisfied, satisfied, moderately dissatisfied, and dissatisfied, respectively, with the postoperative outcome.

At 5.5 years postoperative period, the number of patients who completed RSVP was 232. Of whom 73.3% underwent LASIK, 20.7% surface ablation, 3.0% phakic IOL implantation, and 3.0% enhanced LASIK. At 5.5 years postoperative period, the patients indicated nearly similar levels of satisfaction, 43.6% very satisfied, 43.9% satisfied, 11.0% moderately satisfied, and 1.8% dissatisfied (Fig. 2).

4. Discussion

The findings in this prospective, single-center cohort study help to elucidate the long-term PRO postrefractive surgery for patients who attend regular medical checkup. The total S, and some subscale items of RSVP were improved at 6 months postoperative period, and the mean scores were approximately equal over the following 5 years. During the same postoperative period, the refractive errors became slightly myopic, although the rate of patient satisfaction regarding the surgical outcome remained the same.

Schein showed that from 2 to 6 months postoperatively, S improved to "13" from the preoperative number of "24,"[10] and that the scores of RSVP were correlated with the refractive error of worse-outcome eyes.[7] In their study on long-term PRO, Pasquali et al[16] performed a physician-initiated questionnaire survey on patients who underwent refractive surgery, and their findings indicated that 19 months postoperatively, 95.3% (mean percentage) of the patients were satisfied with the surgical outcome. Our study shows that at 1-year-interval follow-ups from 6 months until 5.5 years postoperatively the mean RSVP score did not change, that is, the mean total score S was "36" before surgery, "19" at 6 months postoperative, and "20" at 5.5 years postoperative.

The eyes in this study that underwent surgery were found to become slightly myopic at 5.5 years postoperative period compared to the 6 months after surgery. This change, however, does not influence the mean RSVP scores. Alio et al[1] examined myopic LASIK patients up to 10 D until 10 years postoperatively. Their finding showed that from 3 months to 10 years post-LASIK the eyes became 1 D myopic, and that there was a little refractive change from 5 to 10 years postoperative period. O'Brart et al[2] examined moderate myopic PRK patients for 20 years postoperatively, and reported that no change in corneal shape was observed after 6 months postoperatively. Thus, they concluded that the cause of myopia was axial elongation. Although the cases in our study had myopic progression from 6 months to 5.5 years postoperatively, there was less myopic change (i.e., 0.3 D) than it was reported in previous studies.[1,2,17,18] Contrary to the findings in Schein's study, the PRO in our study did not change as a result of the slight myopic progression. Further study is needed to analyze detailed visual functions (i.e., contrast sensitivity, higher-order aberration, etc) and help elucidate the causes.

One drawback of the current study is the decrease of the number of patients with time. In our facility, we recommend follow-up examinations every 6 months for surgical patients. Although our best efforts to encourage the patients to participate, the number decreased gradually. No cases were intentionally excluded. It is widely accepted that obtaining responses from >200 patients, 5 or more years after surgery is significant. Although, in our study 232 patients responded at 5.5 years postoperatively the results stayed stable at all time points.

Another limitation of this study is that our findings are only the results of a single-center study in Japan. The cause of the different pre- and postoperative RSVP scores in this study and those in previously reported studies conducted in the United States[10,12] most probably is the differences in cultural traits. In future, we hope that long-term PRO results will be reported in other studies to enhance the reproducibility and reliability of our results.

The patients of this study reported that LASIK, surface ablation, and phakic IOL implantation corrected refractive error and improved their overall quality of vision (QOV). The PROs were found to be stable and consistent for approximately 5 years postoperative, thus indicating that refractive surgery improved the patients' QOV in both mid- and long term.

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Author contributions

Involved in the design of the study (O.H., S.K.); conduct of the study (O.H., S.K.); collection, management, analysis, and interpretation of the data (O.H., Y.N., K.Y., K.W.); preparation, review (O.H., Y.S., S.K., C.S.); and approval of the manuscript (O.H., Y.N., K.Y., K.W., Y.S.,S.K., C.S.).

Statement about Conformity with Author Information: This retrospective review of patient data was approved by the Human Studies Committee of Kyoto Prefectural University of Medicine.

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