Seven-year Follow-up of LASIK for Myopia

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ABSTRACT

PURPOSE: To assess the long-term refractive results, subjective parameters, and late sequelae of LASIK.

METHODS: A retrospective follow-up study was conducted on 38 eyes of 21 patients (17 with bilateral treatment and 4 with unilateral treatment) who had LASIK surgery between 1999 and 2000. Laser ablations were done with an excimer laser (VISX STAR and STAR S2). Follow-up was 2 months, 2 years, and >7 years postoperatively. Uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, indirect ophthalmoscopy, and wavefront analysis were measured at the last follow-up and a questionnaire was answered.

RESULTS: Postoperatively, BSCVA ≤0.0 (logMAR) was obtained in 91%, 100%, and 89% of eyes at 2 months, 2 years, and at last follow-up, respectively. Postoperative spherical equivalent refraction within ±0.50 diopters (D) was obtained in 75%, 63%, and 42% of eyes at 2 months, 2 years, and 7 to 8 years, respectively. At 2 months and 2 years, 83% of eyes were within ±1.00 D, which decreased to 42% at 7 to 8 years. Mean spherical equivalent refraction at 2 months was −0.41 D, at 2 years −0.57 D, and at 7 to 8 years continued to decrease to −1.38 D. Patient satisfaction was high—100% of patients would have LASIK again.

CONCLUSIONS: LASIK outcomes tend to shift toward undercorrection over time. Postoperative ectasia was not noted 7 to 8 years after LASIK. All patients were satisfied with the postoperative results although emmetropia was not reached. [*J Refract Surg*. 2009;25:312-318.]

Although excimer laser refractive surgeries are well documented procedures, there is a paucity of long-term follow-up studies after LASIK. However, long-term studies after photorefractive keratectomy (PRK)[1,2] have shown the safety and stability of this procedure for up to 12 years.

Currently, 4 studies with a combined total of 206 eyes have been published on postoperative LASIK results for myopia with follow-up >5 years.[3-6] Two studies[4,5] with 6-year (33 eyes) and 11-year (11 eyes) follow-up focused on outcomes in high myopic corrections that could explain the modest results in intended correction with approximately 50% of eyes within ±1.00 diopter (D) at the end of these studies. A recent study[6] reported the long-term risk for ectasia following LASIK for high myopia after 5 (78 eyes), 7 (68 eyes), and 9 (15 eyes) years. Results of intended correction or visual acuity after the procedure are unable to be compared as a deliberate undercorrection was planned to preserve corneal tissue, yet they reported a stable refraction 5 years after LASIK. O'Doherty et al[3] studied all levels of myopia 5 years after LASIK in 94 eyes. Twenty-two eyes had a spherical equivalent refraction >−6.13 D, showing similar results as those reported in high myopic corrections.[4-6] Better results were achieved in mild (23 eyes) and moderate (49 eyes) myopia, with 100% and 96% of eyes, respectively, within ±1.00 D at 5 years.

Our aim was to study the long-term refractive results, subjective parameters, and late sequelae of postoperative LASIK corneas. We analyzed the results of eyes treated with LASIK followed for at least 7 years.

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PATIENTS AND METHODS

Between 1999 and 2000, 101 patients (142 eyes) underwent LASIK in a private clinic (Silmäkeskus Laser, Helsinki, Finland) by three different surgeons (T.T., K.T., A.V.). These patients were invited for a free-of-charge ophthalmological examination 7 to 8 years after surgery. Thirty-eight eyes of 21 patients (17 with bilateral treatment and 4 with unilateral treatment; unilateral treatment was performed because of unilateral high myopia) were available to attend follow-up after LASIK. Reasons for failure to attend follow-up were inability to contact patients due to a change of address, inability of patients to attend appointments, and no interest in a follow-up examination.

The study protocol was approved by the Ethical Review Committee of Helsinki University Eye and Ear Hospital and followed the tenets of the Declaration of Helsinki. All patients signed an informed consent and filled out a questionnaire to assess patient overall satisfaction at the last postoperative follow-up.

PREOPERATIVE ASSESSMENT

Preoperative examination included slit-lamp microscopy to exclude any pathology that could affect the wound healing process, visual acuity, manifest and cycloplegic refraction, corneal pachymetry, videokeratography, and mydriatic funduscopy.

LASIK PROCEDURE

A standard LASIK technique was performed in all cases. The flap was created using a Hansatome microkeratome (Bausch & Lomb Surgical Inc, San Dimas, Calif) with a superior hinge technique (thickness 160 µm, diameter 8.5 or 9.5 mm). Laser ablations were done with an excimer laser (VISX STAR (2 eyes) and VISX STAR S2 (36 eyes); VISX, Santa Ana, Calif) equipped with 2.5 (6 eyes) or 3.1 (32 eyes) software.

POSTOPERATIVE ASSESSMENT

Average follow-up was 2 months (range: 1 to 3 months [36 eyes]), 2 years (range: 1 to 3 years [35 eyes]), and >7 years (38 eyes). Each postoperative evaluation included sit-lamp microscopy, measurement of uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA), manifest refraction, and indirect ophthalmoscopy. At last follow-up, a questionnaire and wavefront analysis (version 2.0 software; iTrace Technologies, Houston, Tex) were performed.

QUESTIONNAIRE

The aim of the study was to determine visual and refractive results in the long term. A questionnaire to assess patient satisfaction at last follow-up included 8 questions, graded on a scale of 1 to 5, with 1 being very unsatisfied and 5 being very satisfied.

TABLE

Preoperative Demographics of 38 Eyes That Underwent LASIK With 7- to 8-year Follow-up

Parameter	Preoperative Value
No. of eyes	38
Mean age (y)	30±6.8
No. of female eyes	20
No. of male eyes	18
Right eye	20
Left eye	18
Sphere (D)	−6.55±1.74
Maximum sphere (D)	−11.00
Minimum sphere (D)	−3.25
Cylinder (D)	−0.63±0.55
Maximum cylinder (D)	−2.25
Minimum cylinder (D)	0
Keratometry 1 (D)	43.22±1.40
Keratometry 2 (D)	44.03±1.53
Laser	
VISX STAR	2
VISX STAR S2	36

STATISTICAL ANALYSIS

Statistical calculations were performed with Statview (version 5.0.1; SAS Institute Inc, Cary, NC) using analysis of variance with Bonferroni adjustment for repeated measures and non-paired *t* test. A *P* value <.0001 and <.05, respectively, was considered statistically significant.

RESULTS

Twenty eyes of 12 women and 18 eyes of 9 men were included in this study. Mean patient age at the time of LASIK was 30±6.8 years (range: 18 to 47 years). Mean follow-up was 7.45±0.37 years (range: 6.7 to 8.2 years). Preoperative patient demographics are given in the Table.

VISUAL OUTCOMES AND CHANGE IN LINES OF BEST SPECTACLE-CORRECTED VISUAL ACUITY

Uncorrected visual acuity before LASIK was counting fingers in all eyes. Uncorrected visual acuity 0.0 (logMAR scale) was achieved postoperatively in 55% of eyes at

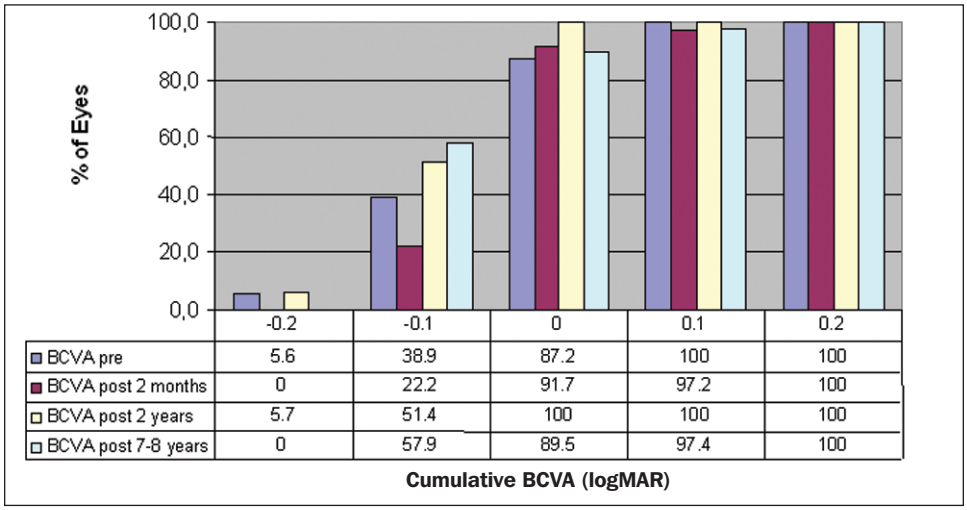


Figure 1. Cumulative best spectacle-corrected visual acuity (BCVA) (logMAR).

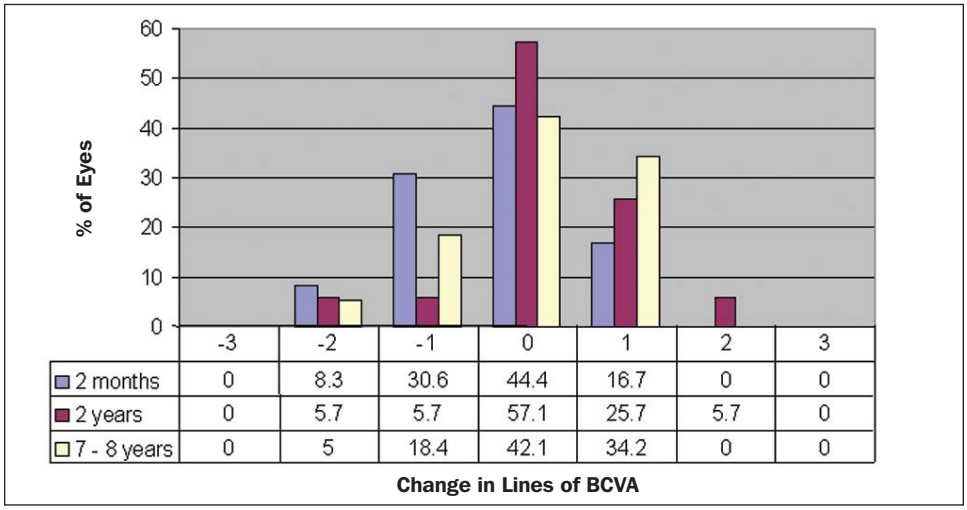


Figure 2. Change in lines of best spectacle-corrected visual acuity (BCVA) (logMAR).

2 months, 54% at 2 years, and 29% at last follow-up (7 to 8 years). This decrease in postoperative UCVA was statistically significant when last follow-up was compared with 2 months and 2 years. Preoperatively, mean BSCVA was 0.0±0.1 (range: 0.1 to −0.2). Postoperatively, BSCVA ≤0.0 was found in 91%, 100%, and 89% of eyes at 2 months, 2 years, and at last follow-up, respectively (Fig 1). Compared to preoperative BSCVA, no statistically significant changes were noted postoperatively ($P>.10$). At 2 months, 44% of eyes maintained the preoperative BSCVA, 17% gained 1 line of logMAR visual acuity, 31% lost 1 line, and 8% lost 2 lines. After 2 years, 57% showed no change in BSCVA compared to before LASIK, 32% showed an increase of 1 to 2 lines, 6% lost 1 line, and 6% lost 2 lines. At last follow-up, 42% of eyes maintained preoperative BSCVA, 34% gained 1 line, 18% lost 1 line, and 5% lost 2 lines (Fig 2).

Refractive Outcomes and Predictability

The mean spherical equivalent refractive error in the treated eyes was −6.80±1.70 D (range: −3.80 to −11.50 D; mean astigmatism: −0.60±0.50 D [range: 0 to −2.25 D]). Emmetropic correction was intended in 63% (24/38) of eyes. Spherical equivalent refraction correction within ±0.50 D, ±1.00 D, and ±2.50 D was intended in 95% (36/38), 97% (37/38), and 100% (38/38) of eyes, respectively. The intended refractive correction was −6.70±1.70 D (range: −3.80 to −10.60 D; mean astigmatism: −0.60±0.50 D [range: 0 to −2.25 D]). Mean spherical equivalent refraction at 2 months postoperatively was −0.41±0.74 D (range: 0.375 to −3.00 D), at 2 years −0.57±0.82 D (range: 0.625 to −3.50 D), and at last follow-up −1.38±1.03 D (range: 0.125 to −3.875 D).

Predictability of spherical equivalent refraction at 2 months showed that 75% of eyes were within ±0.50 D and 83% of eyes were within ±1.00 D of the intended correction. After 2 years these values were 63% and 83%, respectively. At 7 to 8 years, 34% of eyes were within ±0.50 D and 42% were within ±1.00 D of the intended correction (Fig 3).

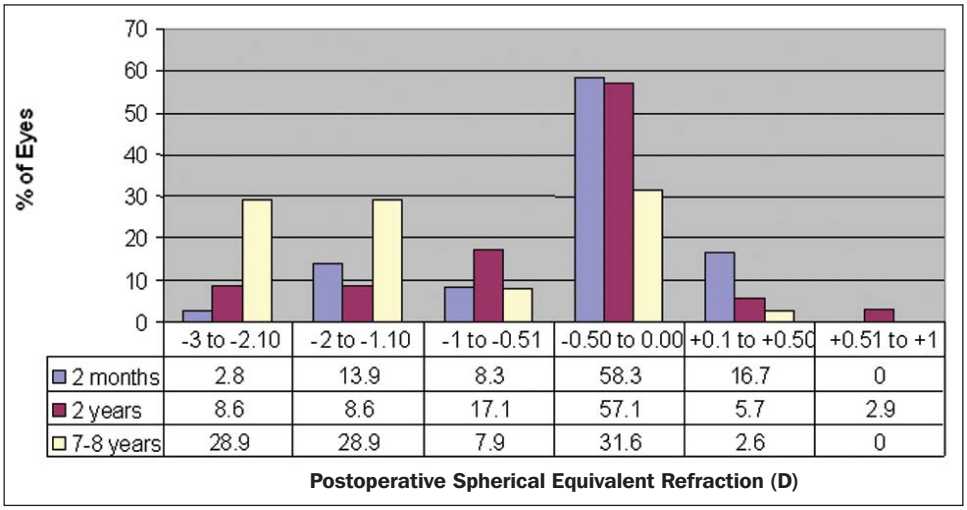
The scattergram of attempted versus achieved spherical equivalent refraction correction obtained at 2 months after LASIK showed good results in all ranges of correction, but at the follow-up (2 years and 7 to 8 years) it shifted progressively towards regression (Fig 4). Myopic regression was more evident in higher corrections (>6.00 D) and persisted during follow-up.

Stability

Spherical equivalent refraction over time is shown in Figure 5A. Two months after LASIK, spherical equivalent refraction was −0.41 D, at 2 years −0.57 D, and at 7 to 8 years continued to decrease to −1.38 D. Change in spherical equivalent refraction was not statistically sig-

nificant up to 2 years, whereas at last follow-up it was significantly lower compared to spherical equivalent refraction at 2 months ($P<.001$).

To study the rate of regression, we used the mean spherical equivalent refraction achieved at 2 months and compared that to the mean spherical equivalent refraction achieved at 2 years and 7 to 8 years. We found that spherical equivalent refraction regressed −0.13 D per year in the first 2 years and −0.16 D annually thereafter.



	-3 to -2.10	-2 to -1.10	-1 to -0.51	-0.50 to 0.00	+0.1 to +0.50	+0.51 to +1
2 months	2.8	13.9	8.3	58.3	16.7	0
2 years	8.6	8.6	17.1	57.1	5.7	2.9
7-8 years	28.9	28.9	7.9	31.6	2.6	0

Figure 3. Predictability. Percentage of eyes within ±spherical equivalent refraction postoperatively.

To study the regression pattern in more detail, patients were divided into three comparative groupings: 1) those who had a preoperative spherical equivalent refraction ≤6.00 D and those with >6.00 D (Fig 5B); 2) patients aged ≤30 years and those aged >30 years (Fig 5C); and 3) according to gender. In the first comparison, the groups did not differ in the amount of regression at 2 years ($P=.07$). However, at 7 to 8 years those patients who had a preoperative spherical equivalent refraction >6.00 D presented with significantly higher regression ($P<.0001$). In the second comparison, younger patients showed significantly more regression at 2 years ($P=.05$), and this difference became more evident at 7 to 8 years ($P<.0001$). In the third group, no difference between men and women was found. Accordingly, spherical equivalent refraction intended correction >6.00 D and patient age <30 years seem to show higher rates of regression in the long term.

Wavefront Analysis

All eyes underwent wavefront analysis at final follow-up. No major wavefront errors were induced. Because wavefront analysis was not available in 1999 to 2000, no preoperative measurements could be used for comparison. At final follow-up, mean root-mean-square values for coma and spherical aberrations were 0.342±0.307 µm (range: 0.014 to 1.51 µm) and 0.279±0.289 µm (range: 0.017 to 1.170 µm), respectively. We performed an analysis to compare eyes with changes of one or more lines of BSCVA with the aberration profiles obtained by wavefront. No correlation was found.

Questionnaire

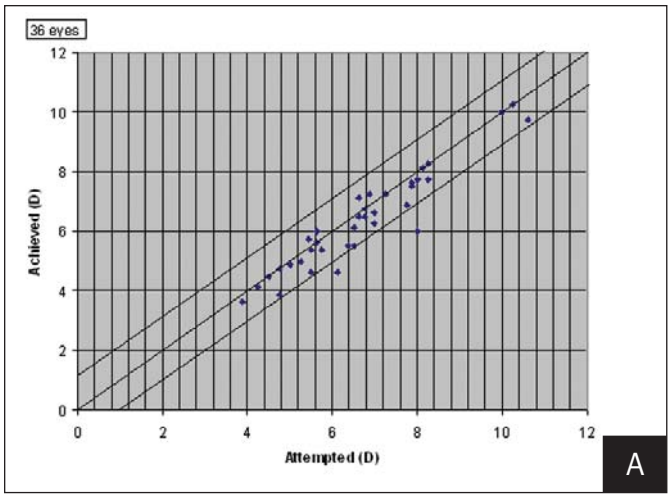
The response rate to the questionnaire was 86%. Of those who responded, 100% reported that they would have LASIK surgery again and LASIK improved their quality of life substantially. Eighty-nine percent were very satisfied with the surgery but only 55% were currently happy with their refractive status.

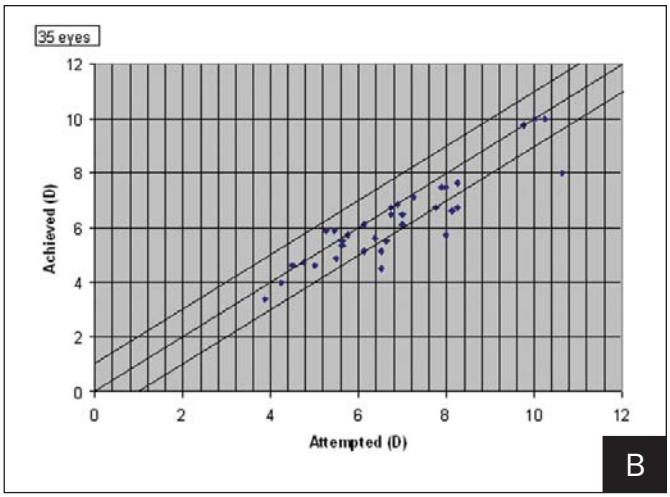
Regarding visual performance, 11% complained of problems in daylight and 39% in dim light. Thirty-three percent reported "tired eyes" in the past month and 33% reported dry eye. Regarding the use of spectacles, 54% did not wear corrective spectacles, 16% used them occasionally, and 27% wore spectacles every day.

DISCUSSION

Although LASIK is the most common laser refractive surgery performed currently in the world,[7] long-term safety is poorly studied.[8] Laser in situ keratomileusis is virtually painless, allows fast visual rehabilitation, and is able to correct high myopia. Yet, acceptance of this technique should be supported by long-term studies. Recently, the lack of long-term LASIK safety data was acknowledged.[9]

Numerous studies have focused on short-term results after LASIK.[10-15] To our knowledge, however, only four studies report follow-up >5 years[3-6]; three focus on results after high myopic correction[4-6] and one[3] includes all levels of myopia with an intended correction close to emmetropia. The present study shows visual and refractive outcomes in eyes subjected to myopic LASIK 7 to 8 years postoperatively. In this study, the eyes presented with spherical equivalent refraction between −3.875 and −11.50 D (mean −6.86 D) and were treated by LASIK using a VISX STAR or STAR S2 excimer laser. The maximum limit of correction approved to treat eyes with LASIK by the US Food and Drug Administration varies from one laser to another, but is close to −12.00 D.[16] None of the eyes had peri- or postoperative





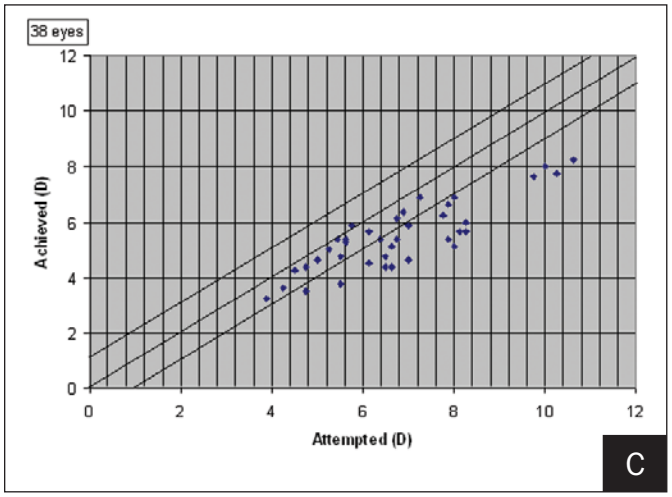


Figure 4. Intended versus achieved correction at **A)** 2 months, **B)** 2 years, and **C)** 7 to 8 years.

complications, and none underwent retreatment. All eyes included in this study had preoperative corneal topography, preoperative corneal thickness >500 µm, intended correction <−12.00 D, and a calculated postoperative residual stromal bed thickness >250 µm. Accordingly, the lack of keratectasia in this study may be due to the fact that the preoperative and operative parameters in these cases fulfill the parameters that were established years later to avoid postoperative LASIK ectasia.[17] However, ectasia has been reported after LASIK, even in the absence of the known preoperative risk factors.[18]

In the present study, 63% of eyes were within ±0.50 D and 83% were within ±1.00 D of the intended correction at 2 years. This is consistent with the results of O'Doherty et al[3] at 5 years. However, at last follow-up 7 to 8 years postoperatively, 34% of eyes were within ±0.50 D and 42% were within ±1.00 D. Similar to earlier results, myopic regression of the spherical equivalent refraction was noted. At 2 months, an undercorrection of −0.41 D was found; at 2-year follow-up, a minimal myopic regression to −0.57 D was noted, which continued to regress to −1.38 D at last follow-up. This trend toward myopic regression was noted in all 38 eyes, but it was more pronounced in eyes with preoperative spherical equivalent refraction >6.00 D and in patients aged <30 years.

These results show that although refractive results after LASIK are relatively good in the short term, they tend to decline over time. Interestingly, the mean spherical equivalent refraction regression was constant per year. The incidence of myopic regression after LASIK has been explained by both corneal and non-corneal causes.[19-21] Corneal alterations have been related to changes in the biomechanics of the cornea,[22] which could lead to a progressive ectasia or are secondary to an increase in the corneal epithelium thickness.[19] Non-corneal causes have been associated with some preoperative parameters.[23] Axial length[24] and vitreous chamber elongation[25] have been associated with increase of myopia and adult-onset myopia. Kinge and Midelfart[26] reported increased myopia of at least −0.37 D in 73% of myopic students during 3-year follow-up; similar results were reported by Jorge et al[27] among science students in Portugal. On the other hand, McBrien and Adams[25] reported that eyes with higher levels of myopia tend to become more myopic with time. These findings could explain the statistical difference between patients younger and older than 30 years and also why patients with higher intended corrections tend to show more regression. Accordingly, long-term follow-up studies should consider that regression may be related to changes in the axial dimensions of the eye. A recent study on long-term results after PRK[28] found a continuous small regression through 10-year follow-up. The authors concluded that higher corrections and age-related refraction

should be considered when assessing refractive stability after PRK.

Considering long-term safety, at 2 years every third eye gained lines of visual acuity whereas approximately 1 in 10 eyes lost lines. Interestingly, compared to 2 years postoperatively the number of eyes that gained one or more lines of visual acuity slightly increased at last follow-up, yet the number of eyes that lost lines of visual acuity doubled from 2 years to 7 to 8 years. This might be related to subclinical opacities in the lens or secondary to higher order aberrations. The last postoperative follow-up included a funduscopy examination to rule out possible pathologies that could decrease visual acuity. Evidence of retinal pathologies was not found in any eye.

Similar to other studies,[3,5] patient satisfaction was high, with 100% of patients declaring to be satisfied with the surgery and stating they would have LASIK surgery again.

Finally, this study—similar to others reporting long-term follow-up after LASIK[3-6]—suffers from some limitations. The most important is the small number of eyes at final follow-up. We believe postoperative results may be better than demonstrated in the current study. Patients with better results are satisfied with their current vision and refraction and therefore our impression is that they tend to decline to participate in further follow-up. Some parameters, which could provide more information such as contrast sensitivity and aberration profile, were not available when these LASIK procedures were done, and therefore no comparisons could be made. The lack of preoperative and long-term follow-up postoperative axial length and corneal curvature in this and other studies limits the possibility of drawing conclusions about regression after LASIK.

In summary, whether the observed myopic regression was due to a change of corneal curvature/power, lens power and/or axial elongation of the eye could not be verified. We were able to show that progressive regression continues even 7 years after LASIK. Severe or late

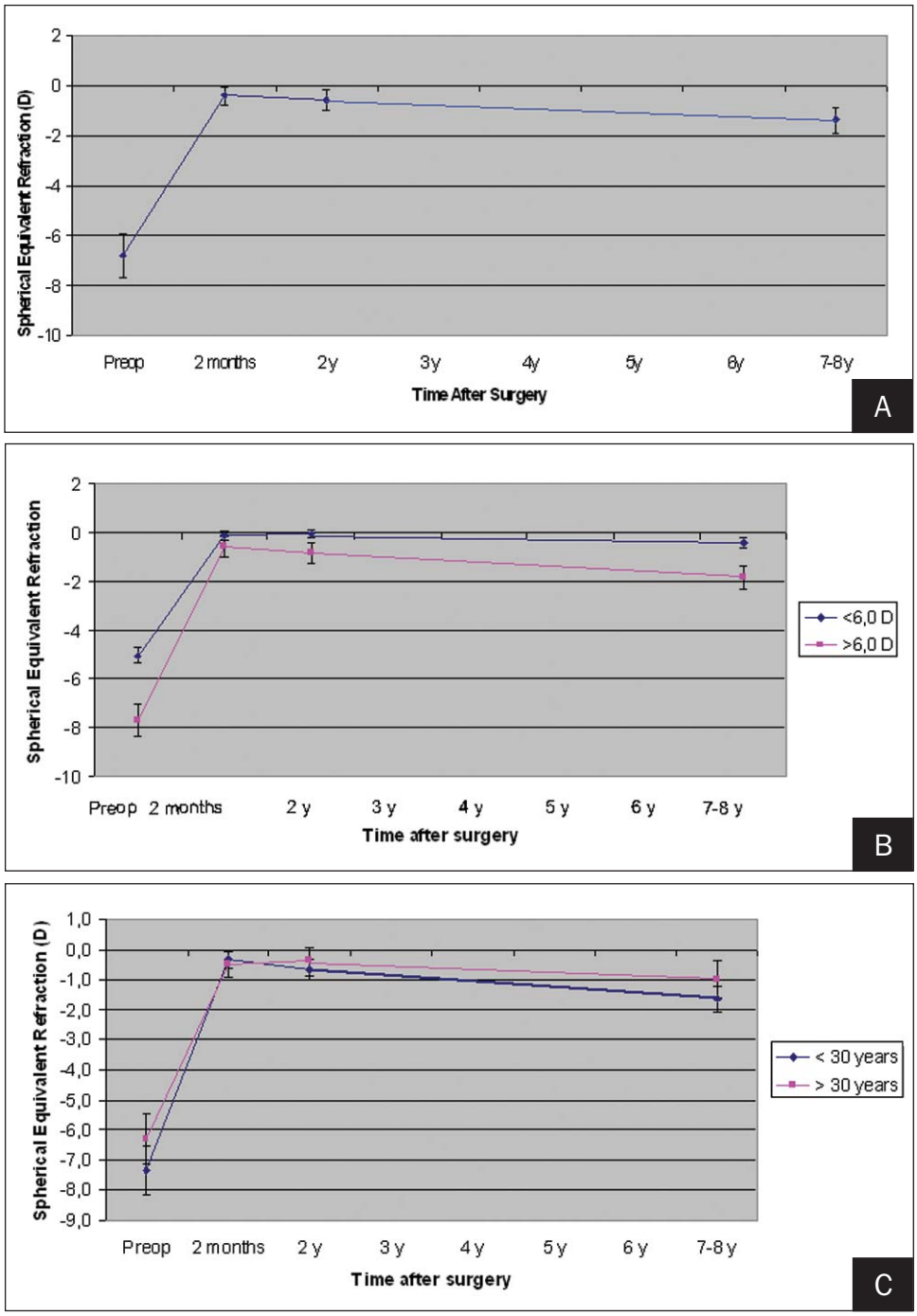


Figure 5. A) Stability, **B)** stability related to preoperative spherical equivalent refraction, and **C)** stability related to age.

postoperative complications such as ectasia were not found and the postoperative satisfaction rate was high despite the fact that emmetropia was often not reached.

AUTHOR CONTRIBUTIONS

Study concept and design (W.N.Z., T.M.T.T., J.M.H.); data collection (W.N.Z., J.M.H.); analysis and interpretation of data (W.N.Z., T.M.T.T., J.M.H.); drafting of the manuscript (W.N.Z., J.M.H.); critical revision of the manuscript (T.M.T.T., J.M.H.); statistical expertise (W.N.Z., J.M.H); obtained funding (W.N.Z., J.M.H.); administrative, technical, or material support (T.M.T.T.)

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