

# Effect of laser in situ keratomileusis on vision analyzed using preoperative optical quality

Meritxell Vilaseca, PhD, Adenay Padilla, BSc, Juan C. Ondategui, MD, Montserrat Arjona, PhD, José L. Güell, MD, Jaume Pujol, PhD

**PURPOSE:** To evaluate the effect on vision of laser in situ keratomileusis (LASIK) based on preoperative optical quality.

**SETTING:** Universitat Politècnica de Catalunya, Terrassa, and Barcelona Institute of Ocular Microsurgery, Barcelona, Spain.

**DESIGN:** Comparative case series.

**METHODS:** The relative change in optical quality and visual acuity were evaluated in eyes that had LASIK for myopia. The optical quality was assessed before and 3 months after surgery using parameters provided by a double-pass system. Patients were classified into 4 groups by preoperative optical quality: low (Group 1), moderate (Group 2), high (Group 3), and very high (Group 4).

**RESULTS:** The study evaluated 25 patients (50 eyes). The optical quality parameters improved postoperatively in Group 1 and Group 2, with the improvement ranging from 15% to 21% and from 13% to 17%, respectively. The preoperative and postoperative optical quality in Group 3 was similar. The optical quality in Group 4 worsened significantly by percentages ranging from –20% to –26%. Although visual acuity had the same trend, there were no statistically significant changes.

**CONCLUSION:** The changes in optical quality after LASIK surgery depended on the patient's preoperative optical quality; visual acuity showed the same trend, although no change was significant.

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From the Centre for Sensors (Vilaseca, Arjona, Pujol), Instruments and Systems Development and the University Vision Centre (Padilla, Ondategui), Department of Optics and Optometry, Universitat Politècnica de Catalunya, Terrassa, and the Cornea-Refractive Surgery Unit (Güell), Barcelona Institute of Ocular Microsurgery, Barcelona, Spain.

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Corresponding author: Meritxell Vilaseca, PhD, Centre de Desenvolupament de Sensors, Instrumentació i Sistemes (CD6), Universitat Politècnica de Catalunya (UPC), Rambla Sant Nebridi 10, 08222 Terrassa, Barcelona, Spain. E-mail: [mvilasec@oo.upc.edu](mailto:mvilasec@oo.upc.edu).

Laser in situ keratomileusis (LASIK)<sup>1–5</sup> is the most widely used ophthalmic surgical technique to correct refractive errors. The technique is mainly used to treat myopia,<sup>6–16</sup> but can also be used to treat hyperopia<sup>17–19</sup> and astigmatism.<sup>16,19,20</sup> Laser in situ keratomileusis provides good results in most patients, with a reduced refractive error and acceptable vision postoperatively.<sup>21</sup> Although LASIK outcomes are usually very satisfactory if the correct tools are applied, complications have been reported.<sup>3,22–26</sup> These include infectious keratitis, dry eye, and diffuse lamellar keratitis. In addition, refractive complications, such as unexpected refractive outcomes, irregular astigmatism, decentering, visual aberrations, and loss of vision, can also occur. One advantage of LASIK is that most eyes can be retreated if necessary<sup>27–29</sup>; retreatment can resolve some refractive complications.

The follow-up clinical examination after LASIK is important. Many studies used subjective tests, such as standard visual acuity evaluations, and some used contrast sensitivity tests to assess postoperative LASIK patients.<sup>7,30-38</sup> Today, it is possible to objectively evaluate the eye's optical quality in clinical practice using aberrometers (usually based on the Hartmann-Shack wavefront sensor<sup>39,40</sup> or laser ray tracing<sup>41,42</sup>) and newer devices based on the double-pass technique.<sup>43,44</sup>

In the past decade, aberrometers have become widely used for determining ocular aberrations in clinical ophthalmology and vision research. Thus, many studies have evaluated aberrations in normal eyes,<sup>45,46</sup> in the elderly population,<sup>47</sup> and in eyes that have had refractive surgery, such as LASIK.<sup>41,42,48-53</sup>

In the double-pass technique, the image of a point-source object is recorded after reflection on the retina and a double pass through the ocular media. The technique has been shown to accurately estimate the eye's image quality. Although the clinical use of this technique is new, it has been used to analyze retinal image quality in the normal population as a function of age,<sup>54</sup> in contact lens wearers,<sup>55,56</sup> in patients with monofocal<sup>57,58</sup> or multifocal<sup>59</sup> IOLs, and in LASIK patients.<sup>57</sup>

One study<sup>60</sup> recently compared the optical quality results of a double-pass device with those of a Hartmann-Shack wavefront sensor. The study found that the double-pass technique characterized the eye's optical quality, including the effect of monochromatic higher-order aberrations (HOAs), and especially intraocular scattering. However, the study's findings indicate that wavefront sensors may overestimate retinal image quality in eyes with prominent HOAs and scattered light. Furthermore, because the double-pass technique provides complete information on aberrations and intraocular scattering, it is useful for evaluating optical quality in patients who have ocular conditions such as cataract as well as in older eyes and eyes that have had refractive surgery.<sup>61-64</sup>

In this study, we used a double-pass clinical system to analyze the changes in optical quality after LASIK. The changes in optical quality and the visual acuity were analyzed over time in patients with different preoperative optical quality.

## PATIENTS AND METHODS

The study evaluated patients who had bilateral LASIK at the Barcelona Institute of Ocular Microsurgery. The LASIK was performed to correct moderate to high myopia (spherical equivalent 4.25 to 10.50 diopters [D]) in patients younger than 40 years. All patients provided written informed consent in accordance with the Declaration of Helsinki.

Inclusion criteria included stable myopia for the past year and a preoperative corrected distance visual acuity (CDVA) better than 20/30. The last criterion was applied because in

some cases, a CDVA worse than 20/20 might be the result of a small degree of amblyopia.

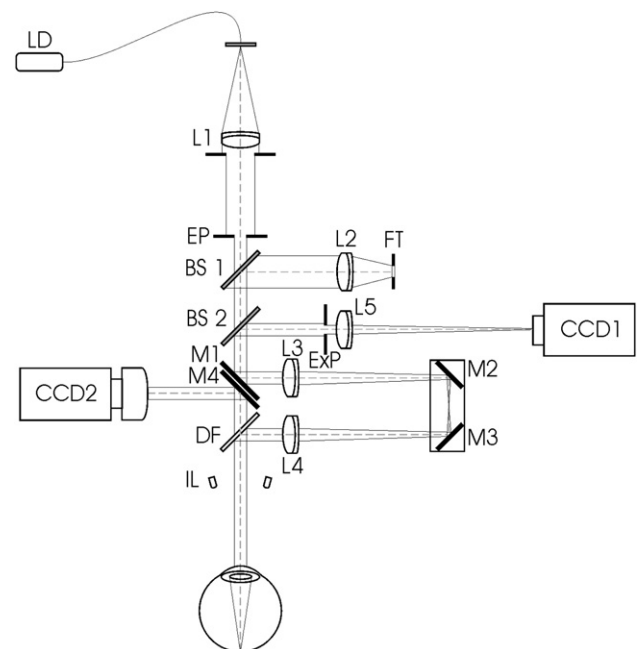
## Surgical Technique

The same surgeon (J.L.G.) performed all LASIK procedures using an MEL 80 excimer laser with the Aberration Smart Ablation optimized profile (Carl Zeiss Meditec), a 6.2 mm optical zone, and a standard 8.2 mm transition zone. The ablation profile corresponds to a wavefront-optimized treatment that mainly takes into account final asphericity to reduce the induction of spherical aberration. The flap was created with an Amadeus microkeratome (Ziemer Group AG) with a 140  $\mu\text{m}$  plate and 9.0 mm diameter.

Postoperatively, patients received tobramycin-dexamethasone (TobraDex) and timolol maleate 0.5% (Cusimolol) 4 times a day and dexamethasone sodium phosphate-chloramphenicol ointment (De Icol) at bedtime for 2 weeks and then tapered over 10 days. Patients were instructed to use artificial tears at least 5 times a day for 2 months.

## Patient Evaluation

Optical quality was assessed preoperatively and 3 months postoperatively using a commercially available double-pass system (Optical Quality Analysis System, Visiometrics S.L.). Artificial tears were instilled immediately before each measurement. The refractive error was corrected during measurements to obtain the best retinal image; the spherical refractive error was automatically corrected by the double-pass system, and astigmatism was corrected with an external



**Figure 1.** The double-pass experimental setup (BS1 and BS2 = beam splitters 1 and 2, respectively; CCD1 and CCD2 = charge-coupled-device cameras 1 and 2, respectively; DF = dichroic filter; EP = entrance pupil; ExP = exit pupil; FT = fixation test; IL = infrared light-emitting diode; L1, L2, L3, L4, and L5 = lenses 1, 2, 3, 4, and 5, respectively; LD = laser diode; M1, M2, M3, and M4 = mirrors 2, 2, 3, and 4, respectively).

**Table 1.** Preoperative refractive error by group.

Group	Sphere (D)	Cylinder (D)	SE (D)
1 (6 eyes)			
Mean $\pm$ SD	6.50 $\pm$ 1.33	1.36 $\pm$ 1.00	7.21 $\pm$ 1.83
Range	5.00 to 9.00	0.25 to 3.00	5.00 to 10.50
2 (15 eyes)			
Mean $\pm$ SD	6.01 $\pm$ 1.16	1.08 $\pm$ 0.89	6.55 $\pm$ 1.61
Range	4.25 to 7.75	0.00 to 3.00	4.25 to 9.25
3 (18 eyes)			
Mean $\pm$ SD	5.66 $\pm$ 1.04	0.68 $\pm$ 0.55	5.96 $\pm$ 1.28
Range	4.25 to 7.75	0.00 to 2.00	4.25 to 8.75
4 (11 eyes)			
Mean $\pm$ SD	5.73 $\pm$ 0.74	0.69 $\pm$ 0.55	6.08 $\pm$ 1.01
Range	4.50 to 7.50	0.00 to 2.00	4.50 to 8.50

SE = spherical equivalent

lens. Because the optical quality of the external lenses is much higher than the optical quality of the eye (in general, this is accomplished by other optical elements, such as intraocular lenses<sup>65</sup>), the final optical quality measurement is not affected by the external lenses.

Figure 1 shows a diagram of the double-pass system. Because of its asymmetric configuration, asymmetrical aberrations in retinal images can be captured. The instrument<sup>44,60</sup> records the retinal image corresponding to a point-source object in near-infrared light, which consists of a laser diode (wavelength 780 nm) coupled to an optical fiber. The image is captured after reflection on the retina and a double pass through the ocular media. Near-infrared light is used because it for patient comfort and it provides retinal image quality estimates comparable to those obtained with visible light.<sup>66</sup> A motorized optometer consisting of 2 lenses with a 100 mm focal length and 2 mirrors measures the patient's defocus correction. An infrared video camera with a pixel size of 8.4  $\mu$ m records the double-pass images after the light is reflected on the retina and on a beam splitter. Pupil alignment is controlled with an additional camera. A fixation test is used to help patients fixate during measurements. The

**Table 3.** Three-month postoperative refractive error by group.

Group	Sphere (D)	Cylinder (D)	SE (D)
1 (6 eyes)			
Mean $\pm$ SD	-0.50 $\pm$ 0.58	-0.71 $\pm$ 0.39	-0.86 $\pm$ 0.77
Range	-1.75 to 0.00	-1.25 to 0.00	-2.25 to 0.00
2 (15 eyes)			
Mean $\pm$ SD	-0.30 $\pm$ 0.29	-0.46 $\pm$ 0.47	-0.53 $\pm$ 0.53
Range	-0.75 to 0.25	-1.25 to 0.00	-1.25 to 0.25
3 (18 eyes)			
Mean $\pm$ SD	-0.20 $\pm$ 0.40	-0.23 $\pm$ 0.34	-0.31 $\pm$ 0.57
Range	-1.25 to 0.50	-1.25 to 0.00	-1.75 to 0.50
4 (11 eyes)			
Mean $\pm$ SD	-0.13 $\pm$ 0.30	-0.42 $\pm$ 0.43	-0.34 $\pm$ 0.51
Range	-0.75 to 0.25	-1.25 to 0.00	-1.25 to 0.25

SE = spherical equivalent

**Table 2.** Statistical comparison between groups of preoperative sphere and cylinder in the 4 groups.

Group	P Value*	
	Sphere	Cylinder
1 versus 2	.333	.488
1 versus 3	.110	.049
1 versus 4	.130	.053
2 versus 3	.289	.080
2 versus 4	.411	.136
3 versus 4	.796	.665

\*(Student *t* test)

entrance pupil has a fixed diameter of 2.0 mm. The instrument has an artificial and variable exit pupil controlled by a diaphragm wheel whose image is formed on the patient's natural pupil plane. In this study, optical quality measurements were performed using a standard pupil diameter of 4.0 mm.

Optical quality parameters<sup>67</sup> related to the monochromatic averaged modular transfer function (MTF) profile corresponding to all radial directions were assessed; these parameters were directly computed by the double-pass system. The MTF profile contains all information on the eye's optical quality with regard to monochromatic aberrations and scattered light. One optical quality parameter assessed was the Strehl ratio,<sup>68</sup> which is often computed in the frequency domain as the ratio between the volumes under the MTF curve of the measured eye and that of the aberration-free eye.<sup>69,70</sup> The double-pass computes the Strehl ratio in 2 dimensions (2D Strehl ratio) as the ratio between the areas under the MTF curve of the measured eye and that of the aberration-free eye, which is also accepted in the literature<sup>69</sup> and is related to a smaller computational cost in time, which makes this approach more suitable for the clinical practice.

The other optical quality parameters (called OV) represent normalized values for 3 spatial frequencies that correspond to MTF values. The values describe the optical quality under 3 contrast conditions (100%, 20%, 9%). Specifically, the 100% value is directly related to the MTF cutoff frequency; that is, the MTF cutoff frequency divided by 30 cycles per degree (cpd). It is normally given that a cutoff frequency of 30 cpd in contrast sensitivity function corresponds to a visual acuity

**Table 4.** Statistical comparison of 3-month postoperative sphere and cylinder in the 4 groups.

Group	P Value*	
	Sphere	Cylinder
1 versus 2	.239	.221
1 versus 3	.125	.051
1 versus 4	.058	.129
2 versus 3	.349	.064
2 versus 4	.069	.679
3 versus 4	.472	.172

\*Student *t* test

of 20/20.<sup>71</sup> In the double-pass system, the MTF cutoff is calculated as that corresponding to a MTF value of 0.01 because in the MTF profile computed from the real recorded double-pass image, there is some background noise. The 20% and 9% values are computed in the same way from smaller frequencies linked to MTF values of 0.05 and 0.10, respectively, that maintain the proportion of contrasts 20% and 9%, respectively. These frequencies are also normalized so that the values obtained are comparable to standard decimal visual acuity values.<sup>57</sup> Values higher than 1.00 are associated with high optical quality.

The eyes were divided into 4 groups based on the preoperative 100% values as follows: low optical quality (100% value  $\leq 0.6$ ; Group 1), moderate optical quality (100% value  $> 0.6$  to  $\leq 0.9$ ; Group 2), high optical quality (100% value  $> 0.9$  to  $\leq 1.2$ ; Group 3), and very high optical quality (100% value  $> 1.2$ ; Group 4).

The decimal CDVA was assessed with a standard Snellen test preoperatively and 3 months postoperatively. The uncorrected distance visual acuity (UDVA) was measured at 3 months.

### Statistical Analysis

Statistical analysis was performed using SPSS for Windows software (version 17.0, SPSS, Inc.). The results were expressed as the mean  $\pm$  the standard deviation. Statistically significant differences in mean values were determined using the Student *t* test and paired *t* test. A *P* value less than 0.05 was considered statistically significant.

### RESULTS

The study evaluated 50 eyes of 25 patients. There were no postoperative complications.

#### Refractive Error

Table 1 shows the number of eyes and preoperative refraction in each of the 4 groups. The degree of myopia was similar between the groups. Table 2 gives the *P* values for between-group comparisons of sphere and cylinder. Although there were no statistically significant differences, the differences in cylinder between Group 1 and Group 3 and between Group 1 and Group 4 approached statistical significance.

Table 3 shows the mean 3-month postoperative refractive error by group. There were no statistically significant differences between the groups in sphere or cylinder (Table 4).

#### Optical Quality

Figure 2 shows representative retinal images recorded preoperatively and 3 months postoperatively using the double-pass system. The images correspond to 4 patients, 1 in each optical quality group.

Figure 3 shows the mean preoperative and postoperative MTF profiles by optical quality group. The MTF for an aberration-free eye with a 4.0 mm size is also plotted.

Table 5 shows the mean optical quality parameters preoperatively and 3 months postoperatively by optical quality group. In Group 1, the change from preoperatively to postoperatively was statistically significant for the 2D Strehl ratio ( $P = .042$ ) and for all 3 contrasts (100%,  $P = .049$ ; 20%,  $P = .049$ ; and 9%,  $P = .083$ ; paired *t* test).

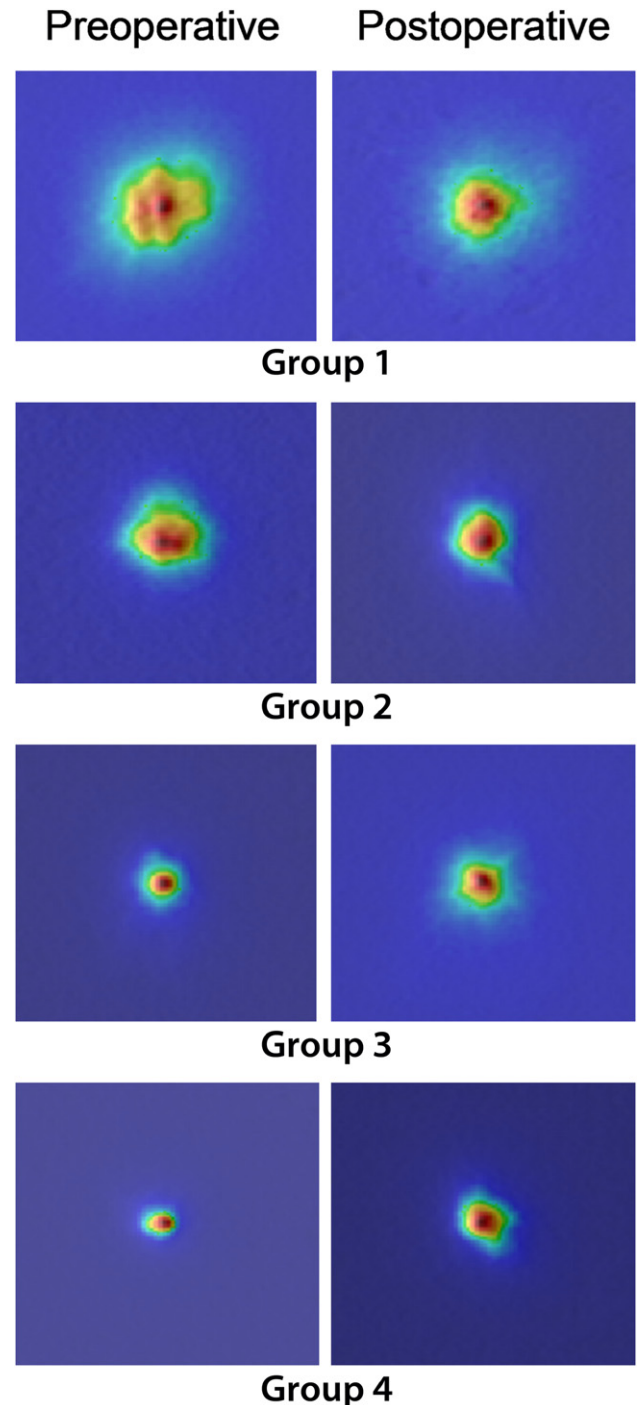


Figure 2. Representative retinal images.

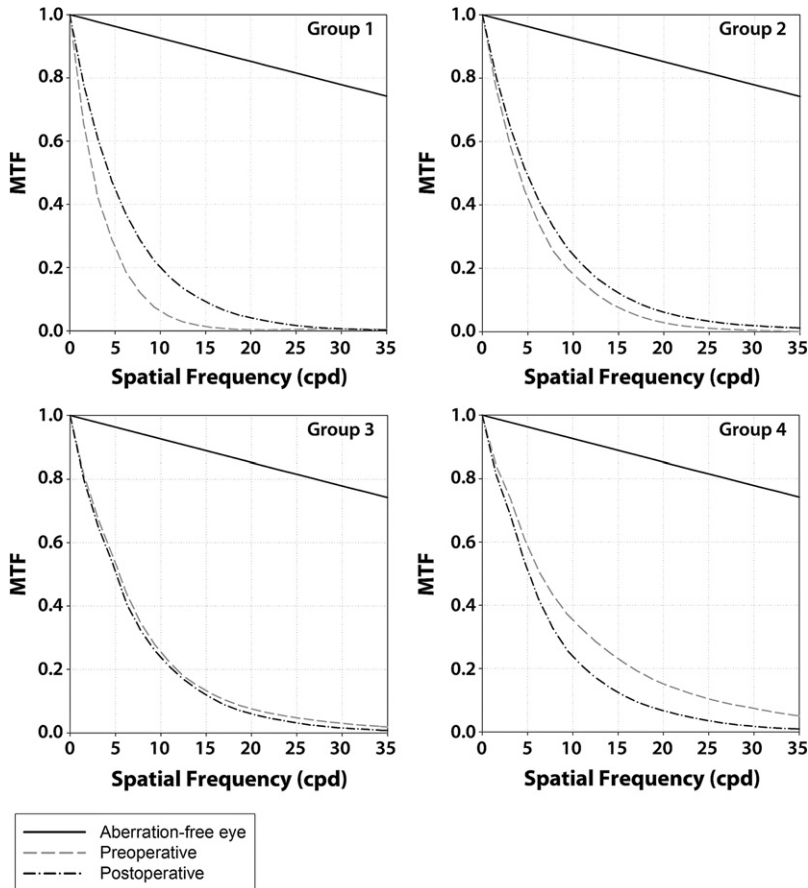


Figure 3. Mean preoperative and postoperative MTF results by group. The MTF corresponding to an aberration-free eye with a 4.0 mm pupil is also plotted (cpd = cycles per degree; MTF = modulation transfer function).

In Group 2, the change was statistically significant for the 2D Strehl ratio ( $P = .069$ ) and for all 3 contrasts (100%,  $P = .009$ ; 20%,  $P = .008$ ; and 9%,  $P = .049$ ; paired  $t$  test).

In Group 3, there were no statistically significant changes (2D Strehl ratio,  $P = .497$ ; 100% contrast,  $P = .107$ ; 20% contrast,  $P = .555$ ; and 9% contrast,  $P = .904$ ; paired  $t$  test).

In Group 4, the change was highly statistically significant for the 2D Strehl ratio ( $P = .0005$ ) and for all 3 contrasts (100%,  $P < .0001$ ; 20%,  $P < .0001$ ; and 9%,  $P < .0005$ ; paired  $t$  test).

### Visual Acuity

Table 6 shows the mean preoperative CDVA and the postoperative CDVA and UDVA by group. Although visual acuity had the same trend as the optical quality parameters, there were no statistically significant changes in CDVA from preoperatively to postoperatively (Group 1,  $P = .104$ ; Group 2,  $P = .054$ ; Group 3,  $P = .512$ ; and Group 4,  $P = .507$ ; paired  $t$  test).

Figure 4 shows the percentage of improvement in or worsening of the optical quality parameters and the CDVA, calculated as follows: Percentage = [(Postoperative/Preoperative) parameter - 1]  $\times$  100.

### DISCUSSION

As seen in our study, some eyes have better preoperative optical quality than others, possibly because of a combination of factors including the degree of ametropia, keratometry values, degree of irregular astigmatism, and corneal and intraocular HOAs. In our study, the spot size of the retinal images decreased after the LASIK in eyes with low optical quality (Group A) or moderate optical quality (Group B) preoperatively. In eyes with high optical quality (Group C) and very high optical quality (Group D) preoperatively, the spot size of the retinal images increased after LASIK. The same trend was seen in the mean MTF profiles. The mean MTF improved after LASIK in Group 1 and Group 2 and worsened in Group 3 and Group 4.

The 2D Strehl ratio calculated by the double-pass system evolved differently over time depending on the optical quality group. The ratio increased postoperatively in Group 1 and Group 2 and decreased in Group 3 and Group 4, especially the Group 4. Group 1 and Group 2 had an improvement of 21% and 13%, respectively, whereas Group 3 and Group 4 had a decrease of 4% and 20%, respectively. The differences were statistically significant in Group 1 and Group 4.

**Table 5.** Mean preoperative and 3-month postoperative optical quality values by group.

Group/Exam	Mean ± SD			
	Strehl 2D	Contrast		
		100%	20%	9%
<b>Group 1</b>				
Preop	0.099 ± 0.014	0.47 ± 0.04	0.46 ± 0.07	0.48 ± 0.10
3 mo postop	0.120 ± 0.016	0.56 ± 0.12	0.55 ± 0.11	0.55 ± 0.10
<b>Group 2</b>				
Preop	0.135 ± 0.026	0.74 ± 0.09	0.72 ± 0.11	0.74 ± 0.16
3 mo postop	0.152 ± 0.017	0.85 ± 0.10	0.84 ± 0.10	0.84 ± 0.12
<b>Group 3</b>				
Preop	0.163 ± 0.024	1.06 ± 0.06	1.01 ± 0.10	0.95 ± 0.15
3 mo postop	0.157 ± 0.030	0.98 ± 0.15	0.97 ± 0.16	0.95 ± 0.19
<b>Group 4</b>				
Preop	0.227 ± 0.022	1.41 ± 0.08	1.37 ± 0.13	1.34 ± 0.16
3 mo postop	0.181 ± 0.025	1.04 ± 0.14	1.01 ± 0.15	1.04 ± 0.16

Strehl 2D = Strehl ratio in 2 dimensions

The values of all 3 contrast values calculated by the double-pass system showed similar behavior and correlated well with the Strehl parameter; their evolution also varied by group. The mean 100% value increased postoperatively in Group 1 and Group 2 and decreased in Group 3 and Group 4, especially in the latter group. The mean improvement in the 100% value was 19% in Group 1 and 15% in Group 2. In contrast, the mean optical quality decreased by 7% in Group 3 and by approximately 26% in Group 4. The change was statistically significant in all groups except Group 3, in which the change was small.

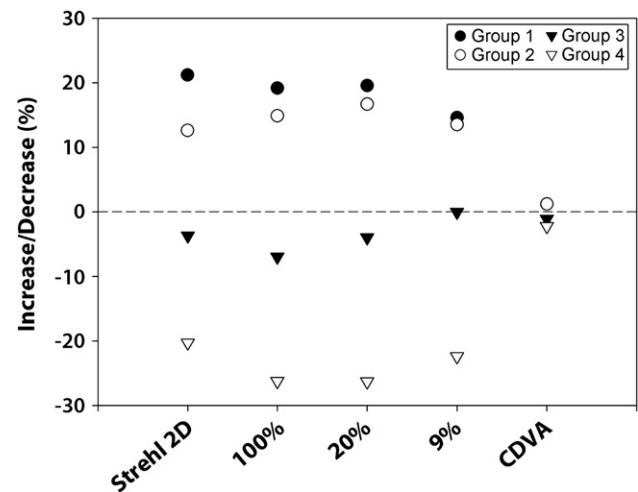
A similar evolution was seen for the 20% and 9% values. The 20% value improved by 20% and 17% in Group 1 and Group 2, respectively, and decreased by 4% and 26% in Group 3 and Group 4, respectively. Again, the only group that did not have a statistically significant change was Group 3. The 9% value improved by 15% in Group 1 and 14% in Group 2 and decreased by 22% in Group 4. The mean 9% value in Group 3 remained unchanged. The changes in the 9% value was statistically significant in Group 2 and Group 4.

The CDVA also changed over time in some groups, although it not as much as the 2D Strehl ratio and the 3 contrast values. This may be attributed to retinal or neural factors, which are not included in the optical

**Table 6.** Mean preoperative and 3-month postoperative CDVA and UDVA by group.

Group/Exam	Mean ± SD	
	CDVA	UDVA
<b>Group 1</b>		
Preop	0.82 ± 0.07	—
3 mo postop	0.83 ± 0.13	0.74 ± 0.13
<b>Group 2</b>		
Preop	0.84 ± 0.09	—
3 mo postop	0.85 ± 0.10	0.77 ± 0.12
<b>Group 3</b>		
Preop	0.90 ± 0.08	—
3 mo postop	0.89 ± 0.10	0.84 ± 0.10
<b>Group 4</b>		
Preop	0.91 ± 0.07	—
3 mo postop	0.89 ± 0.15	0.78 ± 0.13

CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity



**Figure 4.** Percentage improvement or worsening in mean optical quality and CDVA by group (CDVA = corrected distance visual acuity; Strehl D = Strehl ratio in 2 dimensions).

quality parameters. The CDVA improved by 1% in Group 1 and in Group 2 and was worse by 1% in Group 3 and 2% in Group 4. None of the changes was statistically significant.

The changes in the optical quality parameters show that the patients with low or moderate optical quality before surgery generally had a relative improvement in optical quality after LASIK. Patients with high optical quality before surgery had similar optical quality after LASIK. Finally, patients with very high optical quality before surgery had a decline in optical quality after surgery. The reason most eyes with low to moderate optical quality limited improvement in optical quality after LASIK might be a result of the small change in the asphericity and precise correction of the ametropic error. In some cases, the surgery may have compensated for a portion of the irregular astigmatism. The trend was not remarkable for CDVA. The objective optical quality parameters proved more useful in this case because they allowed better discrimination of the results in the different groups of patients.

Our study shows that the double-pass technique can be useful in determining the influence of refractive surgical procedures on the optical quality of the eye through a comparison of preoperative and postoperative images, including HOAs and intraocular scattering individually and over time. Furthermore, the changes in optical quality parameters probably explain why some patients with very high optical quality before surgery report being unsatisfied with their postoperative vision despite a good refractive result.

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First author:

Meritxell Vilaseca, PhD

*Centre for Sensors, Instruments and Systems Development, Department of Optics and Optometry, Universitat Politècnica de Catalunya, Terrassa, Spain*