Retinal Image Quality three months after Photorefractive Keratectomy for Myopia of up to -5.75 diopters

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PURPOSE: To assess changes in retinal image quality in myopic patients after photorefractive keratectomy with a double-pass instrument.

METHODS: Eighteen patients (34 eyes) with spherical equivalent of up to -5.75 diopters underwent excimer laser PRK. The patients were analyzed before surgery and three months after the procedure using a clinical double-pass-based instrument for a 4-mm pupil. The main outcome measures reflected the eye's optical quality, by means of parameters calculated from the double-pass images acquired. Preoperative and postoperative manifest refraction and visual acuity were also reported.

RESULTS: The results showed that PRK surgery has a noticeable impact on retinal image quality and that the differences between the preoperative and postoperative stages are statistically significant ($P < .05$). However, patients did not report a significant change in the best spectacle-corrected visual acuity after the surgery ($P = .56$).

CONCLUSIONS: Although a decrease in retinal image quality in PRK patients was reported, probably due to an increase in higher-order aberrations and to intraocular scattering, the final optical quality parameters assessed at the postoperative stage gave satisfactory results. This was consistent with visual acuity outcomes and subjective reports given by the patients, who did not complain about their final visual result.

KEYWORDS: intraocular scattering; myopia; photorefractive keratectomy; retinal image quality.

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INTRODUCTION

Photorefractive keratectomy (PRK)[1] was the first laser technique for corneal photoablation to be approved by the US Food and Drug Administration (FDA). Later, laser in situ keratomileusis (LASIK)[2-4] was developed, and made it possible to overcome some of the drawbacks reported by postoperative PRK patients, such as discomfort and pain, slow recovery of visual function, risk of corneal opacity, dry eye, and an increase in haze or halo phenomena around lights in night vision[5,6]. LASIK has become the most commonly used technique in refractive surgery in recent years. However, recent improvements to PRK, which include a new algorithm and profiles, have seen it regain popularity, particularly for patients who present specific conditions under which LASIK is contraindicated. These conditions include irregular or thin corneas[7,8], diseases on the corneal surface such as recurrent corneal erosions[9] and reluctance to undergo incisional surgery due to the risk of flap detachments (mainly in the case of contact sports players)[10,11]. PRK surgery is sometimes used as an alternative to LASIK to reduce the risk of complications such as corneal ectasia that have been observed in patients after laser surgery[12].

There are some follow-up studies[13-17] that analyze the long-term outcomes of PRK surgery, which in general conclude that it is a safe and effective procedure. Other authors[18-20] used standard clinical procedures such as visual acuity and contrast sensitivity tests to evaluate the technique and suggested that PRK induces loss of contrast sensitivity postoperatively. However, few studies consider the impact of this surgical technique on the optical quality of the eye, which can be assessed using commercial clinical instruments such as wavefront aberrometers, most of which are based on the Hartmann-Shack sensor[21,22], and newer devices based on the double-pass technique[23]. Authors of recent studies focused on wavefront aberration measurements reported very good optical quality in PRK patients,[24,25] although others[11,20,26,27] found that PRK

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significantly increases the presence of ocular higher-order aberrations, which compromise contrast sensitivity function (CSF) after surgery. However, the retinal image quality of PRK patients assessed using the double-pass technique has not been analyzed.

In the recent years, the double-pass method has proven to be a useful tool to completely evaluate the optical quality of the eye in the daily clinical practice. In a double-pass system, the image of a point source object is recorded after reflection on the retina and a double pass through the ocular media, which provides accurate estimates of the eye's image quality. Recent studies suggest that wavefront aberrometers may overestimate the optical quality of eyes when scattered light is prominent[28], whereas the double-pass technique can characterize retinal image quality including the effect of monochromatic higher-order aberrations but also intraocular scattering, which is often the main cause of postoperative visual deterioration. Therefore, the use of this technique can be of interest in the analysis of PRK outcomes. Recently, a double-pass clinical system (Optical Quality Analysis System, OQAS, Visiometrics S.L., Terrassa, Spain)[29] has been developed. This system has been widely used to assess retinal image quality in various situations, such as patients with keratitis[30], patients that have undergone LASIK surgery[31,32], patients with intraocular lens implants[31-34], and to evaluate presbyopia after photorefractive keratectomy[35] and the in vitro optical quality of foldable monofocal intraocular lenses[36].

In this study, this double-pass clinical system was used to assess the optical quality of patients following PRK surgery and any postoperative changes observed. The results are used to conduct an objective analysis of the impact of PRK surgery on visual quality. We also evaluate the refractive outcome, the best spectacle-corrected visual acuity (BSCVA) and the uncorrected visual acuity (UCVA) of each patient and analyze the corresponding safety and efficiency indexes.

PATIENTS AND METHODS

The study population consisted of 18 patients (34 eyes) with low to moderate myopia (up to -5.75 diopters) who underwent PRK surgery at the Instituto de Microcirugía Ocular de Barcelona (IMO), Spain, between September 2008 and July 2010.

Patients were aged between 22 and 45 years (31.1 ± 7.7 years, mean ± standard deviation). Patients were included in the study if they could both provide preoperative and postoperative data, if they had stable refractive error for at least one year before surgery, and if their preoperative BSCVA was better than 20/30. Patients were excluded from the study if they suffered from anterior segment diseases, if they gave abnormal posterior pole evaluation results during the preoperative or postoperative stages, and if their preoperative intraocular pressure was higher than 21 mmHg.

The PRK treatment was performed using a MEL 80 excimer laser system (Carl Zeiss Meditec, Jena, Germany) with aberration smart ablation (ASA) optimized profile treatment, a 6.2 mm optical zone and a standard 8.2 mm transition zone. This profile corresponds to a wavefront-optimized treatment that mainly takes into account final asphericity to reduce the induction of spherical aberration. It is mostly applied in myopic treatments. The same profile was used on all eyes. A standard corneal epithelial scraper (ALCON 681.01) was used to expose Bowman's membrane in a central area of 8 mm in diameter. Immediately after the surgery, a bandage contact lens (BCL) was applied. A broad spectrum antibiotic was administered t.i.d and artificial tears were prescribed every hour. Three days later, the BCL was removed and standard treatment with FML-FORTE was prescribed three times per day and then tapered over the next 12 weeks. Artificial tears were prescribed for at least five times per day for four months.

No postoperative complications were observed. All patients were properly informed and provided written informed consent before surgery and prior to any additional examinations, and the Declaration of Helsinki tenets of 1975 (as revised in Tokyo in 2004) were followed throughout the study.

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Patients were visited before surgery and approximately three months after surgery, when a routine patients' visit was available, assuming that subsequent changes of the optical quality would be relatively minor. Preoperative and postoperative examinations were conducted to measure manifest refraction, BSCVA, UCVA and retinal image quality. Visual acuity was measured using a standard logMAR acuity chart at 2 m, and the results were then transformed into decimal notation to calculate the correct safety and efficacy indexes. Optical quality was assessed using the double-pass system based OQAS for a 4 mm pupil. The patient's refractive error was corrected during these measurements: the spherical refractive error was corrected automatically by the double-pass system and the astigmatism was corrected with an external cylindrical lens to ensure the best possible optical quality, i.e., not affected by spherical or cylindrical residual refractive errors.

The double-pass system uses the experimental measurements to compute the modulation transfer function (MTF), which represents the loss of contrast produced by the eye's optics as a function of spatial frequency. The MTF is a two-dimensional function although an averaged profile corresponding to all radial directions is used to describe the complete eye's optical quality. The system also provides other parameters[37-39] related to the MTF, which were used in this study to produce a general measure of the eye's optical quality: the Strehl ratio[40], and the OQAS values (OVs) at contrasts of 100%, 20% and 9%. In the double-pass system the Strehl ratio is calculated as the ratio between the areas under the MTF curve for the measured eye and the MTF curve for the aberration-free eye, and therefore provides global information on optical quality. The OVs are normalized values of three specific spatial frequencies that are related to the MTF values that describe the eye's optical quality for the contrast values mentioned. Specifically, OV 100% is directly related to the MTF cut-off frequency and, therefore, to the patient's visual acuity, although it is not affected by retinal and neural factors. Furthermore, its normalization factor allows it to be within a range of values that are approximately equivalent to decimal visual acuity values. In general, OVs higher than 1 are associated with very high retinal image quality[39]. OVs can be used to obtain specific information (which may otherwise remain hidden) on the behavior of the eye at different contrasts, which can be very useful in the clinical setting.

OQAS also allows the quantification of intraocular scattered light by means of the objective scatter index (OSI)[41]. From the double pass images, OSI is computed as the ratio between the amount of light recorded inside an annular area between 12 and 20 minutes of arc and that recorded at the closer surroundings of the peak, specifically a circular area of a radius of 1 minute of arc from the central peak. This parameter has already been used to establish an objective gradation for cataracts, concluding that in general OSI values lower than 2 are usually recorded in eyes with low scattering, values from 2 to 5 correspond to eyes with moderate diffused light, and values higher than 5 are normally linked to eyes with very high scattering, such as eyes with mature cataract.

Statistical analysis of the data was performed using the SPSS software (version 17.0, SPSS Inc., Chicago, IL, USA) for Windows. Histogram plots and the Kolmogorov-Smirnov test were used to evaluate the distribution of all parameters analyzed (BSCVA, Strehl, OV 100%, OV 20%, OV 9%, and OSI), and if they were normally distributed. The mean (± SD), and the corresponding range (minimum and maximum) are given for each of them. The results obtained at the preoperative and postoperative stages were compared statistically using the paired sample *t*-test. Differences were considered to be statistically significant for *P* values of less than .05.

RESULTS

Figure 1 shows the double-pass images and the MTF curves for two representative patients before and after PRK surgery and the preoperative and postoperative BSCVA, UCVA, retinal image quality parameters analyzed (Strehl, OV 100%, OV 20%, OV 9%) and intraocular scattering measurement (OSI) associated with each image.

Table 1 shows the pre- and postoperative refractive error of PRK patients in terms of sphere, cylinder, and spherical equivalent.

Figure 2 shows the mean preoperative MTF for all eyes analyzed and the mean MTF corresponding to the

Table 1: Pre- and postoperative refractive error of eyes that underwent PRK (mean ± standard deviation (range), SE: spherical equivalent)

	Mean ± standard deviation (range) (D)	
	Preoperative	**Postoperative**
NSphere	-3.16 ± 1.39 (-5.50 to -0.25)	0.05 ± 0.53 (-1.00 to 1.50)
Cylinder	-0.72 ± 0.78 (-2.75 to 0.00)	-0.33 ± 0.41 (-1.50 to 0.00)
SE	-3.46 ± 1.38 (-5.75 to 0.00)	-0.12 ± 0.48 (-1.25 to 1.25)

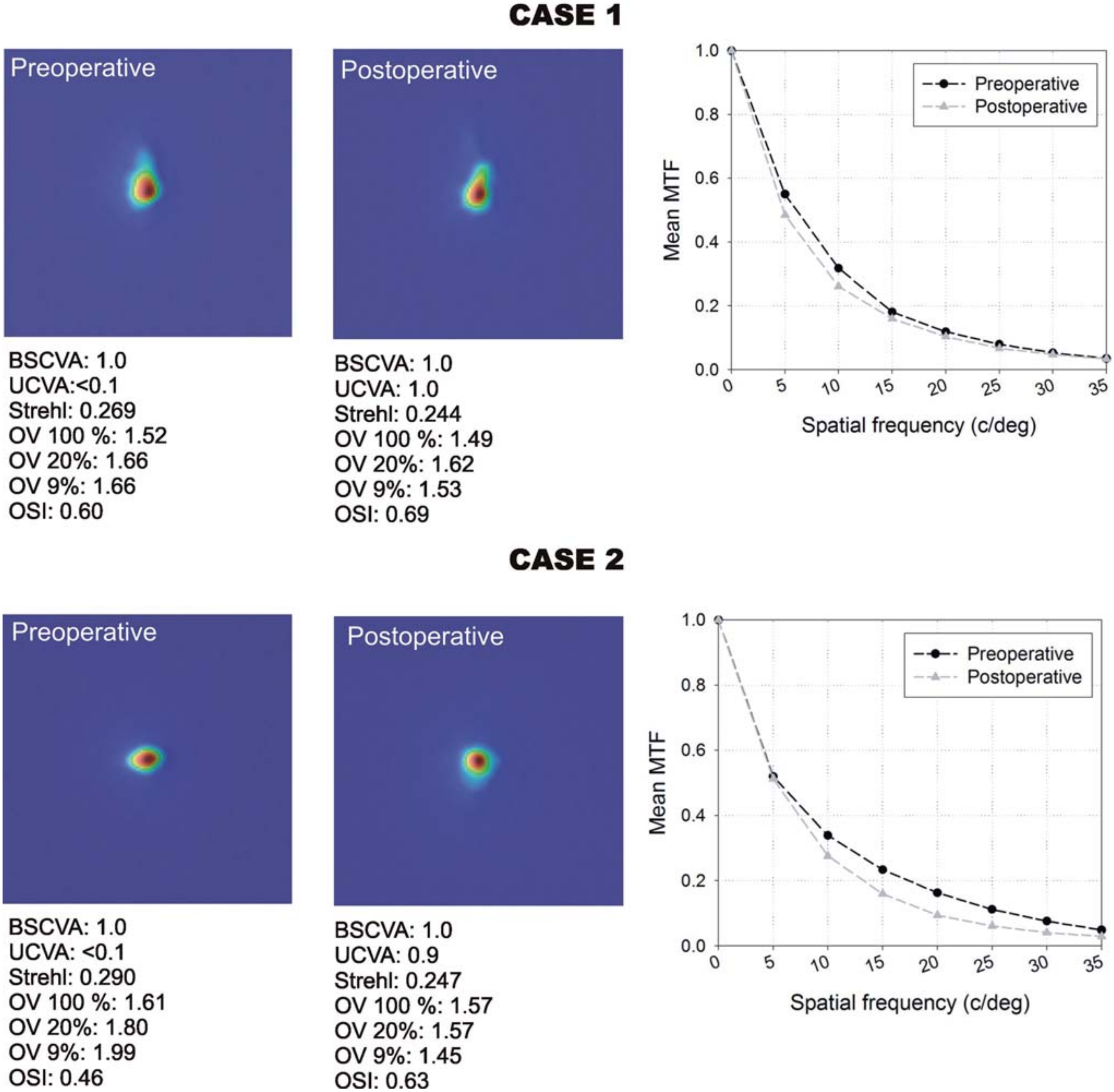

Figure 1. Preoperative and postoperative double-pass images, MTF curves and BSCVA, UCVA, and retinal image quality parameters (Strehl, OV 100%, OV 20%, OV 9%) and intraocular scattering measurement (OSI) corresponding to two representative cases of patients underwent PRK surgery. (c/deg = cycles per degree).

postoperative stage. Figure 3 shows the mean ratio between the postoperative and preoperative MTF curves. A loss of retinal contrast after surgery, especially for middle-high spatial frequencies, can be observed.

Table 2 contains the pre- and postoperative decimal BSCVA, UCVA, the values of the retinal image quality parameters (Strehl, OV 100%, OV 20%, OV 9%) and intraocular scattering measurement (OSI) for eyes treated with PRK. All of them were normally distributed ($P > 0.15$). The variations in BSCVA were not statistically significant (P = .56), and the averaged postoperative BSVCA was almost identical to the preoperative value. In contrast, the changes in the mean retinal image parameters were in general statistically significant [P = .02 (Strehl), P = .05 (OV 100%), P = .01 (OV 20%), P < .01 (OV 9%)] as well as the scatter measurement [P = .01 (OSI)]. The exception was the parameter OV 100%, for which the difference was just within the limit of statistical significance. Figure 4 shows the cumulative distributions of pre- and postoperative BSCVA, and OV at 100%, 20% and 9% contrasts equal to or higher than 0.7, 0.8 and 1, since all

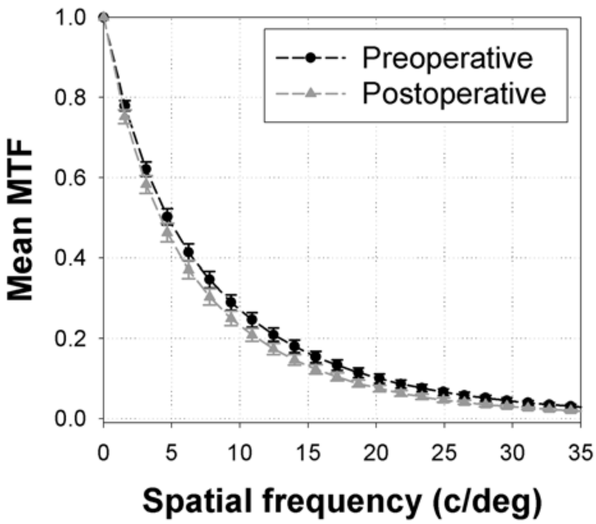

Figure 2. Mean preoperative modulation transfer function (MTF) of eyes that underwent PRK, as well as the mean MTF profile corresponding to the postoperative stage. Error bars represent standard error of the mean. (c/deg = cycles per degree).

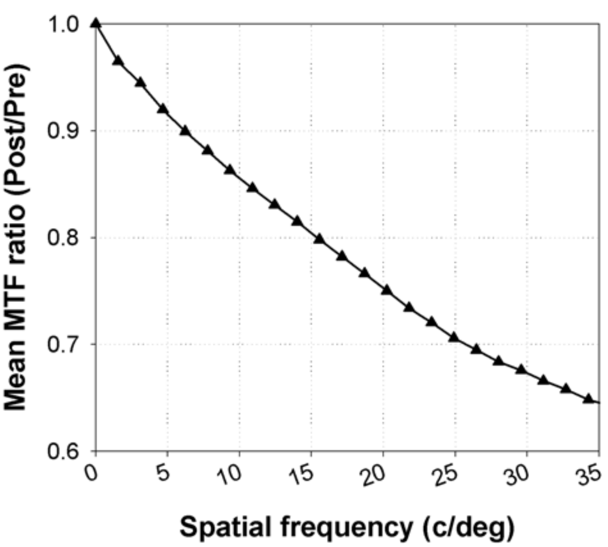

Figure 3. Mean decrease of the modulation transfer function (MTF) between the postoperative and preoperative stages corresponding to all eyes that underwent PRK. (c/deg = cycles per degree).

of these parameters have equivalent ranges, as stated above. Importantly, the final percentage of eyes in the 0.7 range does not reach 100% for the OV parameters, because there are some eyes with much lower values.

To quantify the postoperative variations in the parameters analyzed, we calculated the ratio between BSCVA three months post-surgery and the corresponding preoperative BSCVA (i.e., the safety index), and the ratio between postoperative UCVA and preoperative BSCVA (i.e., the efficacy index). We also calculated the ratios between the postoperative and preoperative values for all of the retinal image quality parameters and the intraocular scattering measurement. Table 3 shows the mean, the standard deviation and the range of the safety and efficacy indexes, and the mean, the standard deviation, and the range of the Strehl, OV 100%, OV 20%, OV 9% and OSI ratios for all patients treated with PRK.

Finally, Figure 5 shows the correlations between the preoperative spherical equivalent and postoperative retinal image quality parameters (Strehl, OV 100%, OV 20%, OV 9%) and intraocular scattering measurement (OSI) for the eyes that underwent PRK. As shown, the Strehl ratio and OV at 100%, 20% and 9% contrasts worsened in proportion to the preoperative refraction. The OSI parameter increased with the preoperative spherical equivalent. However, a significant correlation was only established in the case of OSI (r=.361, P=.046).

DISCUSSION

Figure 1 illustrates two specific examples of patients that underwent PRK surgery. Both cases show a decrease in the postoperative MTF curve, which is more marked in case 2, although the double-pass images obtained at the pre- and postoperative stages do not differ substantially. The figure also shows the pre- and postoperative BSCVA, UCVA, the retinal image quality parameters, and the intraocular scattering measurement. Values of BSCVA are similar at the pre- and postoperative stages, values of Strehl and OVs are

Table 2: Pre- and postoperative decimal BSCVA and UCVA, retinal image quality parameters (Strehl, OV 100%, OV 20%, OV 9%) and intraocular scattering measurement (OSI) of eyes that underwent PRK (mean ± standard deviation (range)

	Mean ± standard deviation (range)	
	Preoperative	Postoperative
BSCVA	1.00 ± 0.11 (0.71 to 1.20)	1.00 ± 0.09 (0.79 to 1.26)
UCVA	<0.1	0.89 ± 0.18 (0.67 to 1.26)
Strehl	0.248 ± 0.079 (0.099 to 0.463)	0.213 ± 0.070 (0.094 to 0.334)
OV 100%	1.38 ± 0.37 (0.46 to 1.90)	1.27 ± 0.37 (0.60 to 1.81)
OV 20%	1.47 ± 0.45 (0.46 to 2.35)	1.25 ± 0.43 (0.49 to 2.00)
OV 9%	1.54 ± 0.54 (0.49 to 3.00)	1.24 ± 0.46 (0.42 to 2.00)
OSI	0.78 ± 0.43 (0.34 to 2.45)	1.00 ± 0.46 (0.48 to 2.13)

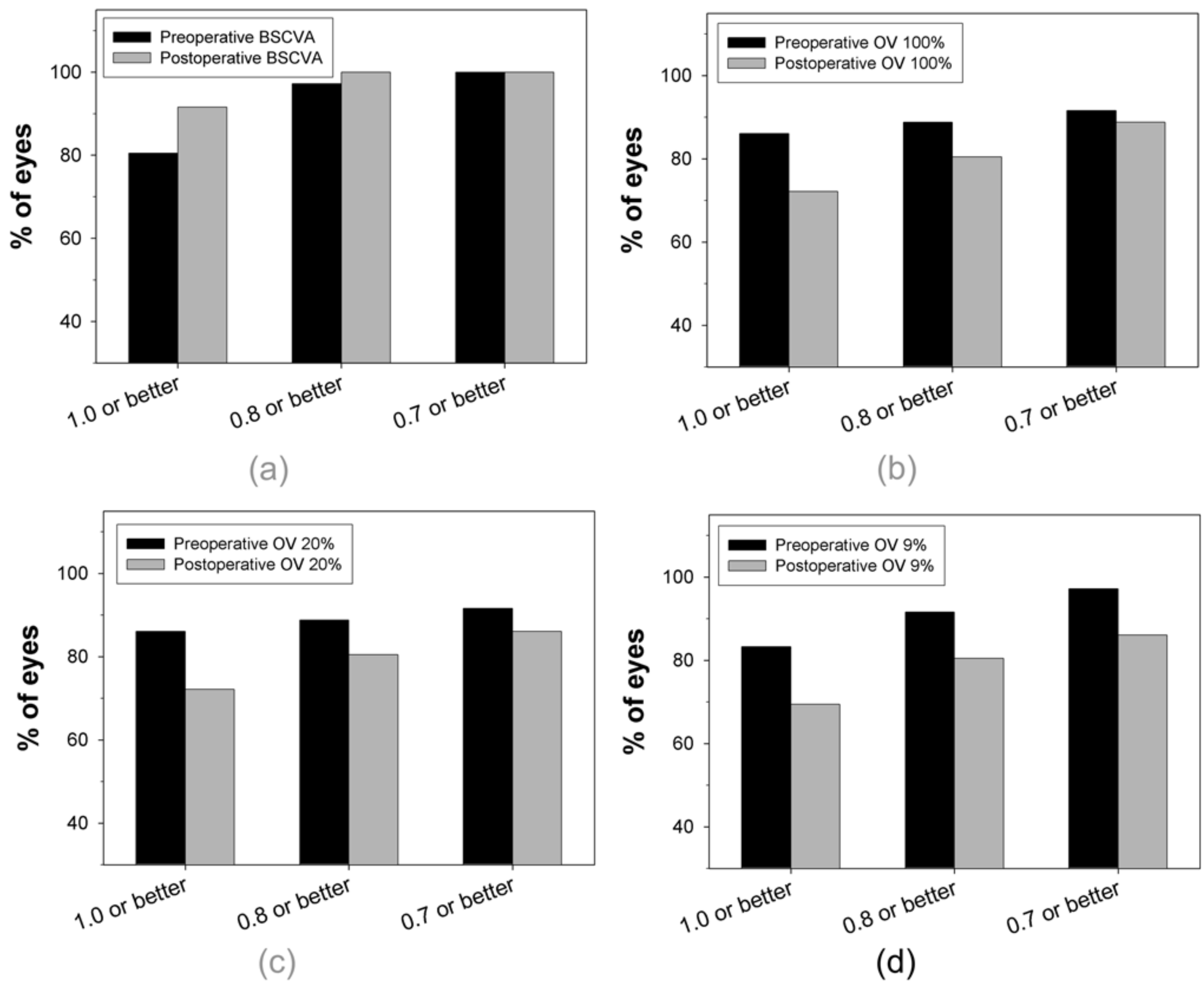

Figure 4. Bar graph showing the cumulative distributions of pre- and postoperative BSCVA (a), and retinal image quality parameters OV at contrasts 100% (b), 20% (c) and 9% (d). The percentages of eyes corresponding to values equal or higher than 0.7, 0.8 and 1 are shown.

slightly lower after surgery, and the postoperative value of OSI is higher in both cases.

Table 3: Safety and efficacy indexes, and post/preoperative ratio of the retinal image quality parameters (Strehl, OV 100%, OV 20%, OV 9%) and intraocular scattering measurement (OSI) of eyes that underwent PRK (mean ± standard deviation (range)

	Mean ± standard deviation (range)
Safety index	1.00 ± 0.14 (0.83 to 1.32)
Efficacy index	0.89 ± 0.16 (0.62 to 1.32)
Strehl	0.906 ± 0.317 (0.203 to 1.798)
OV 100%	0.96 ± 0.36 (0.36 to 2.02)
OV 20%	0.91 ± 0.36 (0.21 to 2.02)
OV 9%	0.87 ± 0.35 (0.14 to 2.06)
OSI	1.48 ± 1.06 (0.59 to 6.25)

As shown in the Results section, PRK surgery corrected most of the myopic refraction, although a small residual refractive error (particularly cylindrical) was still observed in some patients at three months post-surgery (Table 1). Long-term studies of the effect of PRK on low to moderate myopia report that refraction appears to be stabilized between one and three months after surgery in most patients[42], although in few cases the myopic regression may take six months[15,16,43] and a slight decrease in the mean topographical cylinder can be observed for a period of up to 10 years[16]. This may explain why refractive errors (mainly astigmatic) were still found in few patients.

The postoperative visual acuity is generally very good in the study population (Table 2). The BSCVA reported at three months post-surgery was as good as before or even still better in some patients as it is shown in Figure 4 (a), and the differences between preoperative and postoperative values were not statistically significant. After three months, all patients had a BSCVA

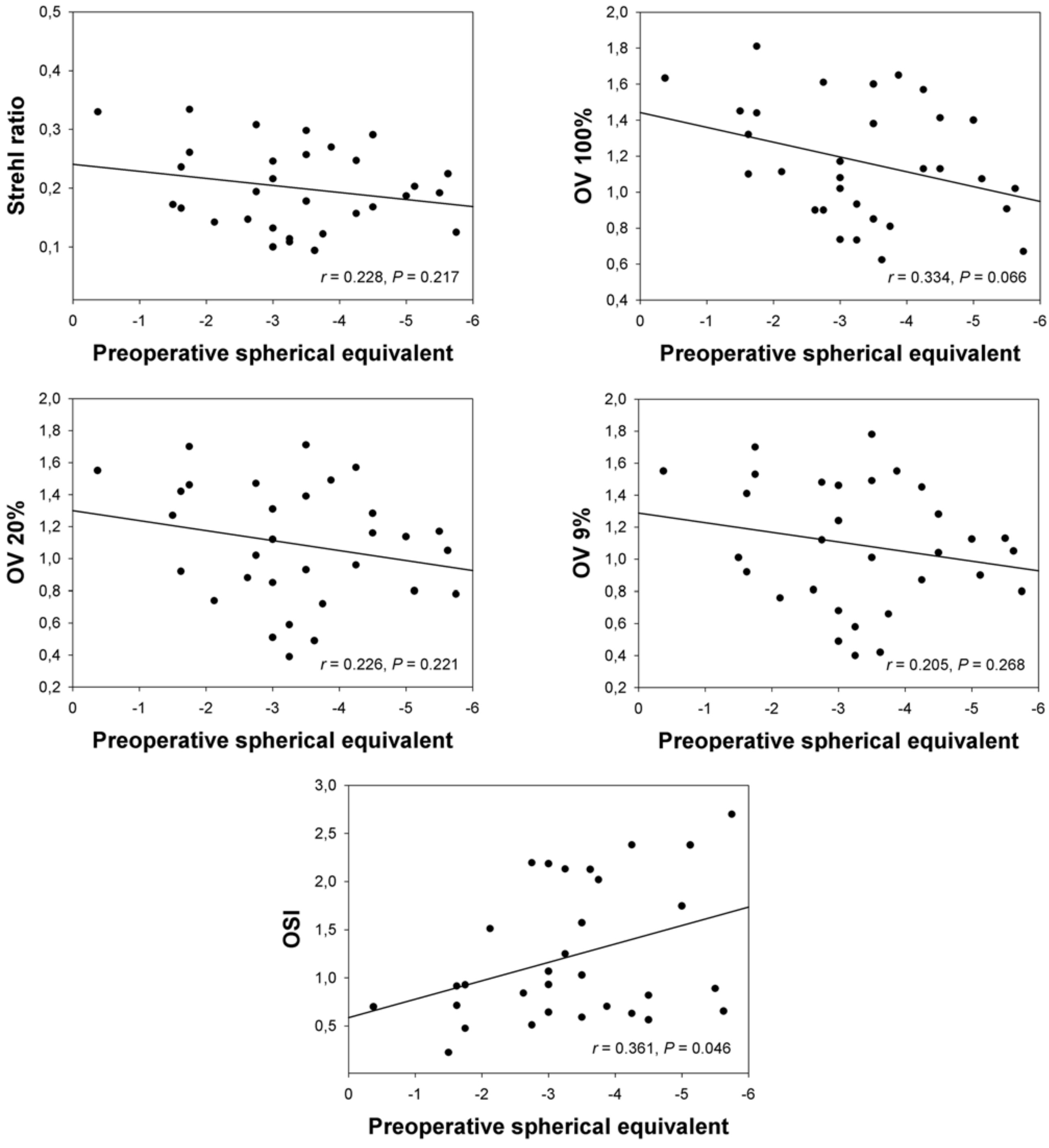

Figure 5. Correlation between the preoperative spherical equivalent and postoperative retinal image quality parameters (Strehl, OV 100%, OV 20%, OV 9%) and intraocular scattering measurement (OSI) (r: Pearson correlation coefficient; P: corresponding statistical significance).

equal to or higher than 20/30. Specifically, 79.4% of patients showed a BSCVA of 1 or higher (27/34), 97.1% of patients showed a BSCVA of 0.8 or higher (33/34), and only 2.9% (1/34) of patients achieved lower values. Postoperative UCVA was higher than 1 in 47.0% (16/34) of patients, at least 0.8 in 64.7% (22/34) of patients, and equal to or higher than 0.7 in all patients. The safety score obtained three months after PRK surgery was very high (1.00) and an efficacy index of 0.89 was obtained (Table 3). The differences between BSCVA and UCVA are mainly associated with the predominantly cylindrical postoperative refractive error, which was still present three months after PRK treatment, although they may also be caused by persistent corneal edema or slight inflammation. More time is probably needed to achieve perfect visual results.

The results for retinal image quality parameters differ from those obtained with BSCVA and UCVA. As shown in Figure 2, the mean values of MTF obtained preoperatively and postoperatively differ substantially. The mean MTF ratio (postoperative/preoperative) obtained between both curves for all patients underwent PRK is shown in Figure 3, and a clear worsening in the postoperative MTF values can be observed. Higher frequencies, which are related to the visual acuity, are associated with a greater reduction of MTF. In general, the MTF fairly correlates with the CSF, although the first one is not affected by retinal and neural factors. Therefore, it could be expected a degraded CSF after PRK from the obtained results, especially for high spatial frequencies. Actually, Marcos[44] found that both functions tended to decrease similarly with LASIK, with a more marked degradation at high spatial frequencies, too.

The MTF results correlate well with those obtained for the main retinal image quality parameters, i.e. Strehl, OV 100%, OV 20%, and OV 9% (Table 2). As can be seen, these parameters decreased significantly after surgery, with the exception of OV 100%, the change in which fell just within the limit of statistical significance. These results suggest that optical quality decreases after PRK surgery. The percentages of eyes with OV parameters at 100%, 20% and 9% contrasts equal to or higher than 0.7, 0.8 and 1 are shown in Figure 3 (b), (c) and (d), respectively. The behavior is different to that observed for BSCVA, and the number of eyes in the different optical quality ranges in the postoperative stage is always smaller than before surgery. In addition, the optical quality recorded by some patients corresponded to OV values lower than 0.7, so the total cumulative percentage does not reach 100%.

The mean decrease in the optical parameters after surgery (Strehl, OV 100%, OV 20% and OV 9%) is shown in Table 3. Specifically, the table contains the ratio for each parameter three months after surgery and the corresponding preoperative values. In most cases, the postoperative retinal image quality parameters are lower than in the preoperative stage. The mean ratio, and therefore the mean decrease, was 9% for the Strehl parameter, whereas the ratios for OV 100%, 20% and 9% were 4%, 9% and 13%, respectively. Since the Strehl value is obtained as an integrated parameter along all the spatial frequencies, it exhibits more moderate behavior as measured by the OV values at 100%, 20% and 9% contrast, which only account for specific frequencies related to MTF values that describe optical quality at the contrast values considered. Therefore, the results suggest that PRK affects the contrast parameters in different ways: a greater decrease in retinal image quality is observed at lower contrasts. This could explain the behavior observed in previous studies, in which PRK surgery was found to reduce the contrast sensitivity function[11,20,26,27].

Nevertheless, although the values for the retinal image quality parameters used so far decrease after PRK surgery, the final values are still acceptable, probably due to the MEL 80 aberration smart ablation (ASA) optimized profile treatment used. The mean Strehl value of 0.213 and the mean OV values of 1.27, 1.25 and 1.24 at 100%, 20% and 9% contrast, respectively, are associated with high optical quality which explains why patients do not complain about their final visual result.

On the other hand, no significant correlations were detected between the preoperative refraction and the Strehl ratio and OV at 100%, 20% and 9% contrasts. This indicates that even though there was a slight tendency for the postoperative retinal image quality to worsen by increasing the attempted refractive correction as other authors have already suggested[45], no significant relationships could be established in this study by means of the double-pass data.

To complete the analysis of the impact of PRK on retinal image quality, a separate analysis must be carried out for the OSI parameter, which accounts for intraocular scattering. The results of this study show a statistically significant increase in OSI after PRK surgery. The mean postoperative value of this parameter is 1.00 when all patients are taken into account (Table 2), which corresponds to an average increase in scattered light of 48% across the total study population (Table 3) and is probably the main reason for any postoperative visual deterioration observed. Although this is a substantial change, postoperative OSI in most patients was still lower than 2 which is within the normal range for this parameter. The results obtained in terms of intraocular scattering correlated with those previously found by some authors, who also reported a moderate increase in corneal haze using confocal microscopy and slit-lamp biomicroscopy that peaked at three months and gradually declined at one year after PRK as a consequence of anterior keratocyte loss[46,47]. Furthermore, Mohan et al. found that haze formation correlated with the level of PRK correction for myopia, which might be related to corneal wound healing[48].

Finally, we would like to highlight the fact that the OQAS clinical double-pass system uses infrared (IR) light of 780 nm instead of light coming from the visible range. Although this could be an issue of discussion, some studies have revealed that this is a good approximation to be used clinically[49-51], especially if one has in mind one of the most important aspects in this field: the comfort of the patient. The use of green light, where the human visual sensitivity has its maximum peak, usually causes lasting post-images in the patients. López-Gil et al.[49] compared estimates of the retinal image quality obtained by using light of different wavelengths, specifically green and IR, concluding that in average accurate estimates could be achieved using IR light. However, they reported a greater amount of diffused light with IR light. Nevertheless, it should be kept in mind that OSI is not intended for absolute measurements, but to relative ones, such as those carried out in the comparative analysis performed in this study, where pre- and postoperative measurements have been reported.

In conclusion, our findings indicate that PRK is a safe and effective technique for correcting low to moderate myopia (up to -5.75 diopters) that leads to high postoperative BSCVA and UCVA in most patients. However, PRK surgery had a noticeable impact on optical quality, with a slight decrease in MTF and the retinal image quality parameters such as the Strehl and OV values. These results highly correlate with other found in former studies[11,20,26,27], in which an increase of the ocular higher-order aberrations was found after PRK. Moreover, it was also shown that the scattered light present in the eye increased noticeably after PRK surgery. However, the final retinal image quality outcomes can be still considered good at three months, which explains why patients do not complain about their final visual result. This is consistent with results from previous clinical studies where measurements reported very good optical quality in PRK patients[24,25]. A follow-up study of the retinal image quality changes at larger times will be carried out in the future.

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