

Intrastromal Femtosecond Laser Presbyopia Correction: 1-year Results of a Multicenter Study

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ABSTRACT

PURPOSE: To investigate functional outcomes of the INTRACOR femtosecond laser-based intrastromal procedure to treat presbyopia.

METHODS: Sixty-three eyes from 63 presbyopic patients (median age: 54 years) with mild hyperopia were enrolled in this prospective, ethics committee-approved, multicenter, nonrandomized clinical trial. The INTRACOR procedure was performed using the Technolas femtosecond laser (Technolas Perfect Vision GmbH) in the nondominant eye. Postoperatively, follow-up was performed at 1 day, 1 week, and 1, 3, 6, and 12 months and included near and distance visual acuity tests, slit-lamp examinations, and corneal topography.

RESULTS: All 63 surgeries were uneventful. Twelve months postoperatively, outcomes of 58 (92.1%) eyes were available for evaluation. Median uncorrected distance visual acuity (0.1 logMAR [range: 0.5 to 0.0 preoperatively and 0.5 to -0.1 postoperatively]) and corrected distance visual acuity (CDVA) (0.0 logMAR [range: 0.2 to -0.2 preoperatively and 0.3 to -0.1 postoperatively]) remained stable. Median spherical equivalent changed from +0.63 diopters (D) preoperatively to 0.00 D postoperatively. Median uncorrected near visual acuity increased significantly from 0.7 logMAR (range: 1.0 to 0.2) preoperatively to 0.2 logMAR (range: 0.8 to -0.1) postoperatively and eyes gained a median of 4 lines (range: 1 to 9 lines). Losses of 2 lines of CDVA were noted in 7.1% of eyes. Ring cuts were faintly visible at 12 months.

CONCLUSIONS: The INTRACOR presbyopia procedure showed good and stable visual acuity outcomes over 12-month follow-up but loss of CDVA occurred in 7% of eyes. Overall patient satisfaction with the procedure was approximately 80%. Short treatment time and maintained corneal surface integrity are advantages of this procedure. [*J Refract Surg.* 2012;28(3):182-188.] doi:10.3928/1081597X-20120203-01

Presbyopia treatment is performed mainly by prescribing reading glasses or contact lenses.¹ Surgical attempts to treat presbyopia include monovision procedures, removal of the crystalline lens and implantation of a multifocal or accommodative intraocular lens, intracorneal pinhole inlays, multifocal excimer laser corneal ablations with change in corneal asphericity, and scleral implants.²⁻¹¹ All of these procedures are invasive and potential risks such as infection remain a concern.^{12,13}

The introduction of femtosecond laser technology in the field of corneal surgery has drawn interest in research regarding correcting refractive errors in the corneal stroma without the need for cutting flaps or any other corneal incisions. Experimental studies have been conducted over the past few years investigating such treatment options.¹⁴⁻¹⁶ In October 2007, the first treatments of presbyopia using the Technolas 520F femtosecond laser (Technolas Perfect Vision GmbH, Munich, Germany) were carried out by Ruiz and colleagues. They reported initial results of a procedure called INTRACOR, which changes the biomechanical forces of the cornea leading to an increase in depth of focus and subsequently the increase of near visual acuity.¹⁷

This article presents our outcomes of the INTRACOR procedure in the treatment of presbyopia.

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PATIENTS AND METHODS

Sixty-three eyes from 63 patients were enrolled in this prospective, multicenter, nonrandomized, clinical trial including four sites within Germany: Heidelberg (n=25), Duisburg (n=21), Mannheim (n=16), and Munich (n=1). The study protocol was approved by the ethics committee of the University of Heidelberg, Germany. All patients were informed about the nature of the study and gave written informed consent prior to enrollment. Inclusion criteria for the study were presbyopia with a minimum near add of +2.00 diopters (D) at 40-cm distance to achieve best possible near visual acuity, hyperopia between 0.50 and 1.25 D, cylinder ≤ 0.50 D, no prior ocular surgery or any ocular pathology, corrected distance visual acuity (CDVA) of at least 20/25, and Scheimpflug corneal thickness of at least 500 μm (thinnest point).

Examinations were performed preoperatively as well as 1 day, 1 week, and 1, 3, 6, and 12 months postoperatively with the following parameters: uncorrected distance visual acuity (UDVA), CDVA, uncorrected near visual acuity (UNVA), distance-corrected near visual acuity (DCNVA), and corrected near visual acuity (CNVA). All near reading tests were performed at a fixed distance of 40 cm from the treated eye using Sloan ETDRS near charts (Precision Vision, La Salle, Illinois). Additionally, detailed slit-lamp examinations including digital photograph as well as corneal topographies preoperatively and 3, 6, and 12 months postoperatively (Pentacam; Oculus Optikgeräte GmbH, Wetzlar, Germany) were performed. A questionnaire was used to analyze subjective satisfaction.

In addition, a subgroup of patients at one study site (n=22) was analyzed with a Hartmann-Shack aberrometer (Ocular Wavefront Analyzer; SCHWIND eye-tech-solutions, Kleinostheim, Germany) preoperatively as well as 12 months postoperatively.

The preoperative examination was performed within 30 days prior to INTRACOR treatment. All patients were treated in their nondominant eye. Dominance/nondominance of the eyes was determined using the hole-in-the-card test and pointing test. On the day of surgery, eyes were anesthetized using oxybuprocaine hydrochloride 0.4% eye drops. Under the surgical microscope, the line of sight was marked using the first Purkinje image of a red fixation light, on which the patient was asked to fixate, to center the laser treatment and a suction ring was placed on the eye. Subsequently, the eye was connected to the femtosecond laser using a specific curved patient interface device and five consecutive rings around the marked line of sight were cut with the laser beam purely intrastromally with a distance of approximately 100 μm to the

corneal surface. The exact depth of these cuts, energy used, and spacing follows a proprietary nomogram, which is based, among other parameters, on pachymetry data. The treatment time was between 15 and 20 seconds in all cases.

Postoperatively, patients received dexamethasone 1% eye drops five times a day and artificial tears as needed. The steroid eye drops were discontinued after 1 week.

The Kolmogorov-Smirnov test revealed that the parameters investigated were not normally distributed ($P < .01$) and the paired Wilcoxon test was applied. A P value $< .05$ indicated a statistically significant difference.

RESULTS

Median age of the 63 patients (23 women and 40 men) who underwent the INTRACOR procedure was 54 years (range: 43 to 72 years). Twelve-month postoperative outcomes for 58 (92.1%) eyes were available for evaluation. No adverse event related to the treatment or classified as serious was reported.

REFRACTION

Refraction and visual acuity analysis revealed stable postoperative findings from 1 to 3 months up to 1 year after surgery with only minimal variations over time.

Median preoperative distance spherical equivalent was +0.63 D with a median sphere of +0.75 D and median cylinder of 0.25 D. The INTRACOR treatment induced a median myopic shift of -0.50 D regarding the spherical equivalent, which is mainly due to sphere changes compared to stable cylinder values (Table 1). This development was seen 1 month after surgery and did not show any further progression over time.

DISTANCE VISUAL ACUITY

No difference was noted regarding median UDVA of 0.1 logMAR before and 1 year after surgery (Table 2). Some eyes showed a slight improvement due to the myopic refraction shift closer to zero (emmetropia)—12 months after surgery, 32.8% of eyes achieved 20/20 or better compared to 22.2% before treatment (Fig 1). Regarding loss and gain of UDVA, 43.1% of eyes gained one or more lines, 24.1% were unchanged, and 32.7% lost one or more lines (Fig 2). No statistically significant difference was found (Wilcoxon test, $P > .5$).

Median CDVA remained stable for most eyes (Wilcoxon test, $P > .2$), 0.0 logMAR pre- and postoperatively (Table 2). All (100%) eyes achieved 20/40 or better (Fig 3). Regarding loss and gain of CDVA, 25% of eyes gained one to three lines, 21.4% lost one line, and 7.1% lost two lines (Fig 4).

TABLE 1

Refraction Results in Eyes That Underwent INTRACOR Femtosecond Laser Treatment of Presbyopia

Refraction	Median (Range)				
	Preop (n=63)	1 Month (n=61)	3 Months (n=61)	6 Months (n=60)	12 Months (n=56)
SE (D)	0.63 (-0.50 to 1.25)	0.00 (-1.25 to 1.00)	0.00 (-1.38 to 0.88)	0.00 (-1.38 to 1.00)	0.00 (-1.25 to 1.38)
Sphere (D)	0.75 (-0.25 to 1.50)	0.00 (-1.25 to 1.00)	0.00 (-1.25 to 1.00)	0.00 (-1.00 to 1.25)	0.25 (-0.75 to 1.75)
Cylinder (D)	-0.25 (-1.00 to 0.00)	0.00 (-1.50 to 0.00)	-0.25 (-1.50 to 0.00)	-0.50 (-1.25 to 0.00)	0.00 (-1.50 to 0.00)

SE = spherical equivalent

Note. At 12 months, only 56 of 58 patients received a subjective refraction; for the remaining 2, only uncorrected visual acuities were measured.

TABLE 2

Visual Acuity Results in Eyes That Underwent INTRACOR Femtosecond Laser Treatment of Presbyopia

Visual Acuity (logMAR)	Mean (Range)					P Value*
	Preop (n=63)	1 Month (n=61)	3 Months (n=61)	6 Months (n=60)	12 Months (n=58)	
UDVA	0.1 (0.5 to 0.0)	0.1 (0.7 to -0.1)	0.1 (0.7 to -0.1)	0.1 (0.7 to -0.1)	0.1 (0.5 to -0.1)	.52
CDVA	0.0 (0.2 to -0.2)	0.0 (0.2 to -0.1)	0.0 (0.2 to -0.1)	0.0 (0.2 to -0.1)	0.0 (0.3 to -0.1)†	.24
UNVA	0.7 (1.0 to 0.2)	0.3 (1.0 to 0.0)	0.3 (0.9 to -0.1)	0.2 (0.8 to -0.1)	0.2 (0.8 to -0.1)	<.01
DCNVA	0.6 (1.1 to 0.2)	0.3 (1.0 to -0.1)	0.2 (0.7 to -0.1)	0.3 (0.8 to 0.0)	0.2 (0.8 to -0.1)†	<.01
CNVA	0.0 (0.4 to -0.2)	0.0 (0.4 to -0.2)‡	0.0 (0.3 to -0.2)	0.0 (0.3 to -0.2)	0.0 (0.3 to -0.2)†	.60

UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, UNVA = uncorrected near visual acuity, DCNVA = distance-corrected near visual acuity, CNVA = corrected near visual acuity

*Comparing pre- vs 12-month postoperative results using the paired Wilcoxon test.

†Only 56 eyes were measured.

‡Only 60 eyes were measured.

Note. At 12 months, only 56 of 58 patients received a subjective refraction, for the remaining 2 only uncorrected visual acuities were measured.

NEAR VISUAL ACUITY

Median UNVA improved from 0.7 to 0.2 logMAR 1 year after treatment (Table 2). Snellen visual acuity of 20/40 or better was achieved in 70.7% of eyes compared to only 3.2% preoperatively (Fig 5). One year after surgery, all eyes gained UNVA, with a median of four lines; 3.4% achieved a gain of nine lines (Fig 6).

Median DCNVA improved from 0.6 to 0.2 logMAR (Table 2), with 75% of eyes achieving 20/40 or better and 89.3% 20/50 or better (Fig 7). One (1.8%) eye lost one line, two (3.6%) eyes neither lost nor gained lines, and 53 (94.6%) eyes gained between one and nine lines (median: 3 lines) (Fig 8). This gain in UNVA and DCNVA was statistically significant (Wilcoxon test, $P < .01$).

Median CNVA was 0.0 logMAR before and 12 months after surgery (Wilcoxon test, $P > .1$). Corrected near visual acuity of 20/25 was achieved in 93.4% of

eyes and 20/40 or better in 100% of eyes after treatment (Fig 9). Regarding gains and losses of CNVA, 26.2% of eyes gained between one and three lines, 29.5% lost one line, and 11.5% lost two lines (Fig 10). Median near addition was 2.50 D (range: 1.25 to 3.75 D) before and 1.50 D (range: 0.00 to 3.00 D) after surgery (Wilcoxon test, $P < .01$).

CORNEAL TOPOGRAPHY

Median maximum axial curvature (steepest keratometry reading within a central 4-mm zone) in the treated corneal area was 44.60 D (range: 40.90 to 49.10 D) preoperatively and 44.90 D (range: 40.60 to 50.20 D), 45.00 D (range: 40.70 to 50.00 D), and 45.30 D (range: 41.20 to 50.90 D) at 3, 6, and 12 months postoperatively, respectively. The curvature increase between pre- and 12 months postoperative was statistically significant ($P < .001$), the change be-

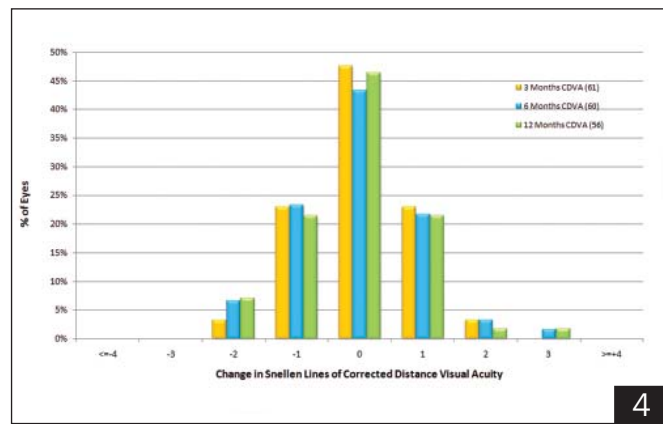
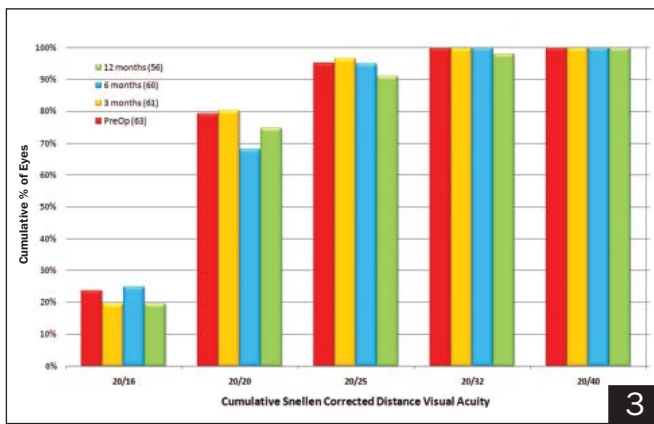
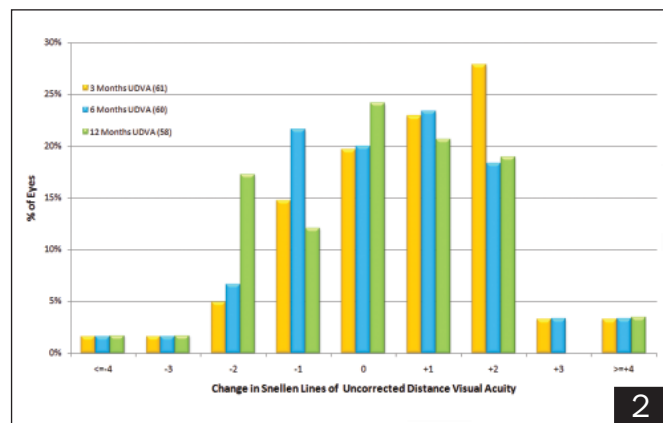
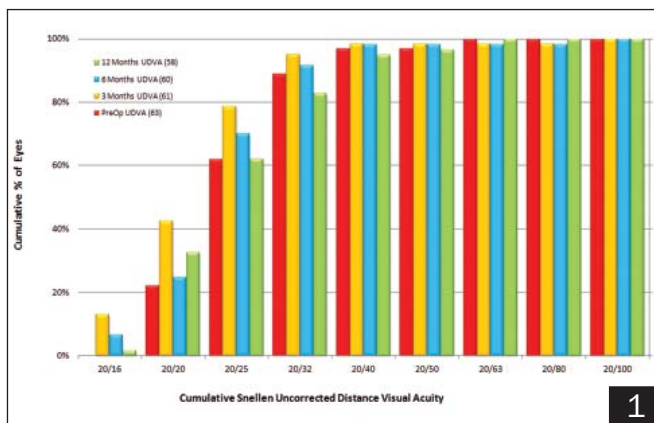


Figure 1. Cumulative Snellen distribution: uncorrected distance visual acuity (UDVA). **Figure 2.** Lines lost and gained: uncorrected distance visual acuity (UDVA). **Figure 3.** Cumulative Snellen distribution: corrected distance visual acuity (CDVA). **Figure 4.** Lines lost and gained: corrected distance visual acuity (CDVA).

tween 3 and 6 months was not significant ($P=.622$), and the change between 6 and 12 months was significant ($P=.037$).

Median anterior corneal asphericity (Q-value at 6 mm) changed from -0.17 (range: -0.69 to 0.32) preoperatively to -0.21 (range: -0.73 to 0.15) at 3 months, -0.20 (range: -0.73 to 0.07) at 6 months, and -0.18 (range: -0.94 to 0.12) at 12 months postoperatively. The change between pre- and 12 months postoperative was statistically significant ($P=.002$), but no significant change was noted between 3 and 6 or between 6 and 12 months postoperative ($P=.113$ and $P=.966$, respectively).

Median posterior corneal asphericity (Q-value at 6 mm) changed from -0.30 (range: -0.71 to 0.09) preoperatively to -0.41 (range: -1.15 to -0.07) at 3 months, -0.41 (range: -1.01 to 0) at 6 months, and -0.43 (range: -1.18 to -0.02) at 12 months postoperatively.

The change between pre- and 12 months postoperative was highly statistically significant ($P<.001$) whereas the change between 3 and 6 months was not ($P=.126$) and between 6 and 12 months was less significant ($P=.03$).

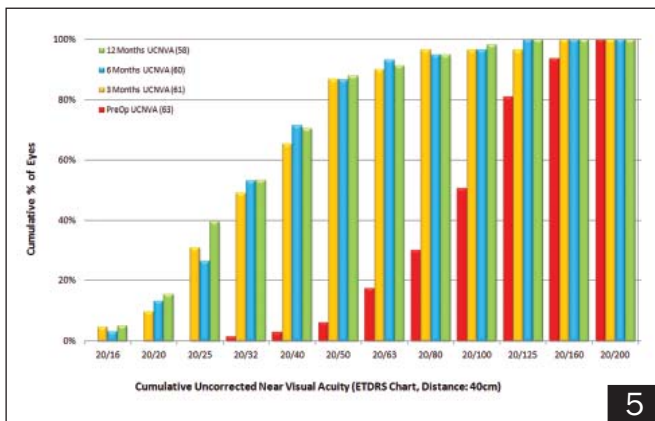
ABERROMETRY

The aberrometry measurements at one study site (22 eyes pre- and 21 eyes postoperatively) revealed a significant change ($P=.031$) in spherical aberrations induced by the INTRACOR procedure. Measured for a 6-mm pupil size, the median spherical aberrations were reduced from $0.202 \mu\text{m}$ (range: 0.084 to $0.627 \mu\text{m}$) preoperatively to $0.111 \mu\text{m}$ (range: 0.007 to $0.576 \mu\text{m}$) 12 months postoperatively.

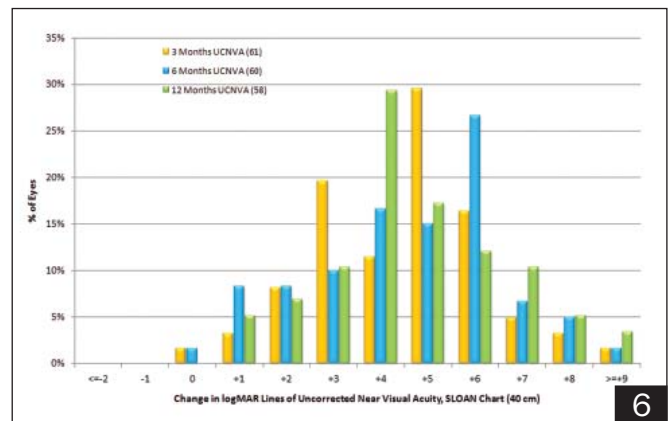
SUBJECTIVE QUESTIONNAIRE

Twelve months after surgery, 58 patients answered different questions regarding subjective satisfaction and visual acuity perception as well as photopic phenomena either on a scale from 0 to 4 or with “yes,” “no,” or “uncertain,” respectively.

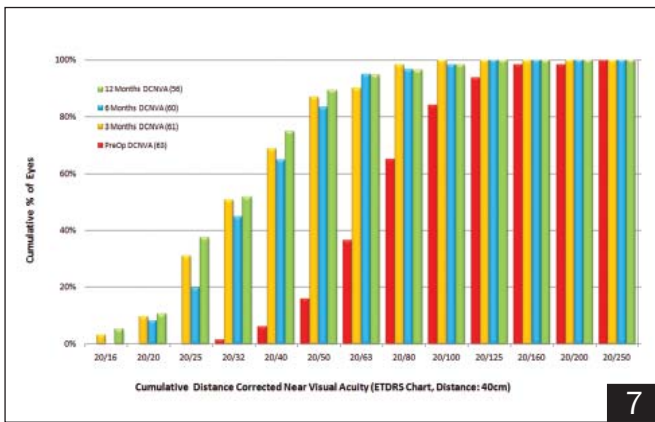
The median scores for glare and halos were 1.14 and 1.03, respectively, indicating a low perception of photopic phenomena. Noticeable vision problems (score >2.5) in dim light conditions were noted by 17.2% preoperatively vs 32.8% 12 months after surgery. Overall, 71.4% of patients were satisfied with



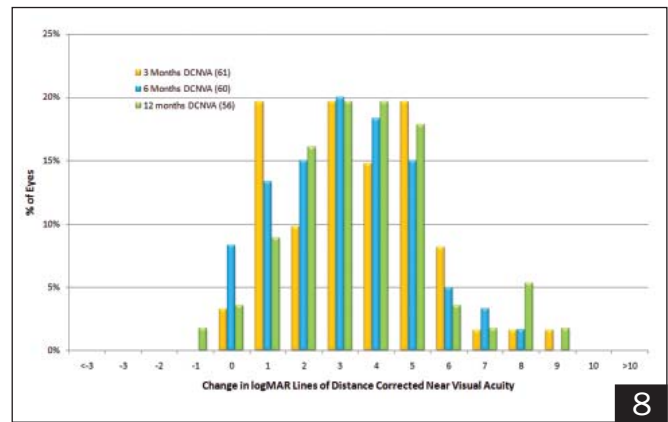
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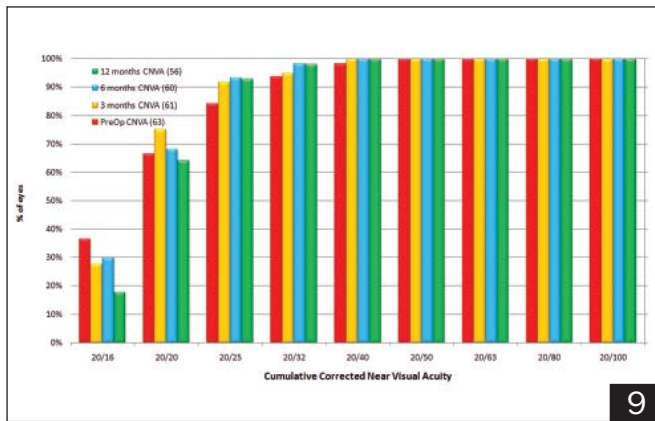
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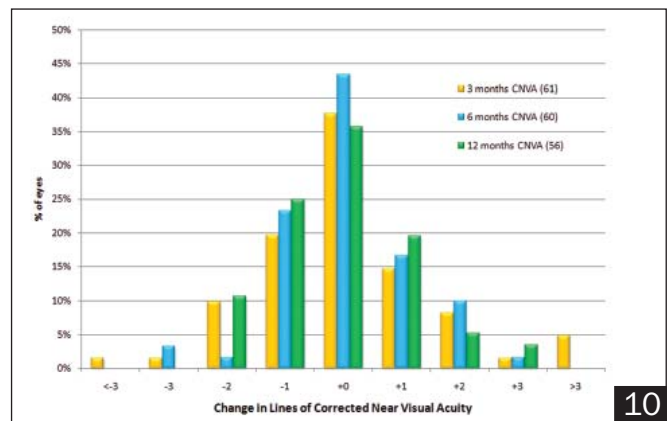
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Figure 5. Cumulative Snellen distribution: uncorrected near visual acuity (UCNVA). **Figure 6.** Lines gained: uncorrected near visual acuity (UCNVA). **Figure 7.** Cumulative Snellen distribution: distance-corrected near visual acuity (DCNVA). **Figure 8.** Lines lost and gained: distance-corrected near visual acuity (DCNVA). **Figure 9.** Cumulative Snellen distribution: corrected near visual acuity (CNVA). **Figure 10.** Lines lost and gained: corrected near visual acuity (CNVA).

the procedure, 19.6% were not, and 9% were uncertain (2 of 58 patients did not answer this question). In regards to undergoing the same procedure, 86% of patients would undergo treatment again whereas 12.3% answered “no” and 1.8% were uncertain (1 patient did not answer this question). In regards to treatment, 80.4% would recommend the procedure to a relative

or friend, 16% would not, and 3.6% were uncertain (2 patients did not answer).

DISCUSSION

Corneal presbyopia correcting procedures include excimer laser treatments either as monovision procedures or as multifocal corneal ablations and conduc-

tive keratoplasty.^{3,5,7,18-24} Laser in situ keratomileusis for myopic astigmatism and presbyopia using nonlinear, aspheric, micromonovision provided stable and effective results with 96% of eyes achieving binocular UNVA of J2.²³ Treating hyperopic astigmatism and presbyopia with this approach, Reinstein et al²⁴ reported 81% of patients could read J2 and 100% J5. Binocularly, 95% of patients achieved 20/20 and could read J5. No eyes lost two or more lines and contrast visual acuity was improved.²⁴ Epstein and Gurgos¹⁹ found peripheral presbyLASIK in the nondominant eye with distance-directed monofocal refractive surgery in the dominant eye a valuable option. With regards to hyperopic patients treated, 71.4% achieved UNVA of at least 20/20 at 40 cm and 89% reported complete spectacle independence.¹⁹ Pinelli et al²² published their findings regarding a center distance, paracentral near treatment of presbyopia and mild hyperopia up to +3.00 D with a mean binocular uncorrected visual acuity of 1.06 for distance and 0.84 for near. In regards to CDVA, 4.5% of eyes lost one line.²² Another multizone LASIK investigation using a center far algorithm was safe; however, only 33% of treated hyperopic patients achieved UNVA of 20/40 or better. Two percent of eyes lost two lines of CDVA and patients were satisfied in 54% of cases.¹⁸

In contrast to these excimer laser methods, the femtosecond laser offers the advantage of keeping the corneal surface intact and reducing the risk of microbial infections. Aside from the INTRACOR procedure to correct presbyopia clinically,^{17,25} experimental studies on regaining lenticular elasticity by treating the crystalline lens have been evaluated.²⁶

The laser-induced biomechanical response of the cornea, which subsequently leads to the refractive effect, mostly manifests itself in the first hours after surgery. The cut pattern induces a corneal curvature change with a central steepening with reduced spherical aberrations after surgery. The present multicenter trial has shown stable functional results 1 year after surgery. At least 20/40 uncorrected visual acuity was achieved by 94.8% of eyes regarding distance and 70.7% for near. All (100%) eyes gained near visual acuity; however, a wide distribution between one and nine lines was noted. The fact that some eyes only gained one to three lines indicates a certain number of "low-responders." To date, no factors, such as preoperative keratometry or corneal thickness as well as ring centration, have been found to have an impact on the predictability of the postoperative refractive result.

No patient lost more than two lines of CDVA and no adverse events related to the procedure have been reported. Regarding CDVA and CNVA, 100% of eyes achieved 20/40 or better. However, a loss of two lines

of CDVA occurred in 7.1% of patients. Patients also reported slight but noticeable vision problems in dim light conditions with low perception of photopic phenomena and limited near visual acuity in dim light conditions. As with many other presbyopia correction procedures, the improvement of near vision sometimes involves a compromise, which needs to be discussed and explained to the patient prior to treatment.

The preoperative manifest refraction is important in patient selection. The current recommendation of the manufacturer (Technolas) includes a minimum spherical equivalent of +0.25 D (sphere between +0.50 and +1.00 D and cylinder between 0.50 and 0.0 D). To achieve spectacle independence for distance and near, the myopic shift of approximately -0.50 D that can be seen in the majority of patients must be taken into account.²⁵ In this regard, it is highly recommended to also measure distance refraction after pharmacologic cycloplegia to detect cases of higher hyperopia. Furthermore, the myopic shift should be simulated either with glasses or contact lenses preoperatively.

Further aspects that need to be investigated in the future are different INTRACOR patterns to correct low degrees of myopia and astigmatism. The outcomes of binocular treatment are of interest to determine whether the refractive outcome can be further improved. Longer follow-up is needed to confirm the continuous stability of functional results as well as corneal integrity. Further studies are necessary that evaluate the feasibility and outcomes of retreatment patterns in patients who gained insufficient near visual acuity after the initial surgery.

The femtosecond laser offers a variety of new treatment possibilities in many fields of ophthalmic anterior segment surgery.²⁷⁻³¹ With regards to presbyopia correction, the intrastromal INTRACOR procedure significantly improved UNVA in most patients with only a few side effects. It presents an interesting option for the treatment of presbyopia.

AUTHOR CONTRIBUTIONS

Study concept and design (M.P.H., M.C.K., M.T., T.M.N., G.U.A.); data collection (M.P.H., M.C.K., M.T., T.M.N., G.U.A.); analysis and interpretation of data (M.P.H., M.C.K., M.T., T.M.N., G.U.A.); drafting of the manuscript (M.P.H.); critical revision of the manuscript (M.P.H., M.C.K., M.T., T.M.N., G.U.A.)

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