BAUSCH & LOMB SURGICAL KERACOR®116 EXCIMER LASER SYSTEM

PHOTOREFRACTIVE KERATECTOMY (PRK) PROFESSIONAL USE INFORMATION

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed practitioner. U.S. Federal Law restricts this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical management and treatment of refractive errors.

This document provides information concerning the intended clinical use of the KERACOR®116 Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the KERACOR®116 Excimer Laser System *Operator's Manual.*

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.

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SECTION 1

DEVICE DESCRIPTION

The specifications for the KERACOR 116 Excimer Laser System are provided below.

Laser Type:	Argon Fluoride
Laser Wavelength:	193 nanometers
Laser Pulse Duration:	18 nanoseconds
Laser Head Repetition Rate	10 Hz
Effective Corneal Repetition Rate	10 Hz
Fluence (at the eye):	120 mJ/cm^2
Range of Ablation Diameter	0.8 to 7.0 mm

Features and Components of the Excimer Laser System:

Laser Unit	Contains the laser head, the high voltage system. and the gas system necessary to generate the desired laser energy.
Control Unit	Contains the control electronics and a standard MS-DOS based personal computer with menu-driven software program.
Bridge /Tower Unit	Contains the optical elements that condition the laser beam to the appropriate characteristics. It also contains the visualization optics (operating microscope), and the positioning and fixation optics for properly locating and monitoring the progress of the ablation.
Operating Elements	Multifunction joystick unit for manual actuation of the lasing and aiming beams; power switch for the laser diode in the operating microscope; variable resistor for controlling intensity of the coldlight; footswitch; on/off switch; footswitch connector; remote interlock connector; and external operating indicator.
Patient Bed and Chair	Operation of the bed (both direction and speed) is controlled via a multifunctional joystick. The operating chair supplied with the laser has a pneumatic height adjustment for surgeon positioning at the operating microscope.

SECTION 2

INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EVENTS

2.1. INDICATIONS FOR USE

The Bausch & Lomb Surgical KERACOR 116 Excimer Laser System is intended for use:

- In Photorefractive Keratectomy (PRK) treatments for the reduction or elimination of myopia between -1.50 and -7.00 D of sphere and less than or equal to -4.50 D of astigmatism.
- In patients with documented evidence of a change in manifest refraction of less than or equal to 0.50 diopters (in both cylinder and sphere components) for at least one year prior to the date of the pre-operative examination.
- In patients who are 18 years of age or older.

2.2. CONTRAINDICATIONS

PRK surgery is contraindicated in:

- Patients with collagen vascular, autoimmune, or immunodeficiency diseases;
- Pregnant or nursing women;
- Patients with signs of keratoconus;
- Patients who are taking one or both of the following medications: isotretinoin (Accutane), or amiodarone hydrochloride (Cordarone).

2.3. WARNINGS:

- The decision to perform PRK surgery in patients with systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease or an immunocompromised status should be approached cautiously. The safety and effectiveness of the KERACOR Excimer Laser System has not been established in patients with these conditions.
- PRK is not recommended in patients with a known history of *Herpes simplex* or *Herpes zoster*.

PRK treatment of myopia above 7.00 D with this device has demonstrated risk of a loss of 2 lines or more of BSCVA approximately twice that below 7.00 D. For treatment of myopic sphere between 8.00 and 12.00 D. effectiveness is also reduced compared to treatments less than 8.00 D. No safety and effectiveness data above 12.00 D is available.

2.4. PRECAUTIONS

2.4.1. GENERAL

The effects of PRK on visual performance under poor lighting conditions have not been determined. It is possible, following PRK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.

The safety and effectiveness of the Bausch & Lomb Surgical Excimer Laser System have not been established:

- In patients with progressive myopia or astigmatism, ocular disease, corneal abnormality, and previous corneal surgery or trauma in the ablation zone;
- In patients with corneal neovascularization within 1.0 mm of the ablation zone;
- In patients under 18 years of age:
- Over the longer term (more than two years after surgery);
- In patients with a history of keloid formation;
- In patients who are taking sumatripin (Imitrex);
- In patients taking hormone replacement therapy or antihistamines who may have delayed re-epithelialization of the cornea following surgery.

2.4.2. PATIENT SELECTION

Consideration should be given to the following in determining the appropriate patients for PRK:

- Complete examination, including, but not limited to, cycloplegic evaluation, must be performed. The lens must be evaluated, especially in the older patient, to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery. Myopic patients will have a higher incidence of retinal pathology, and indirect ophthalmoscopy through a dilated pupil and a clear crystalline lens is essential.

- To obtain accurate refractive information, contact lens wearers must be examined after a period of not wearing contact lenses for at least 2 weeks for soft lenses and at least 3 weeks for hard (PMMA) and gas-permeable lenses. Prior to treatment and after at least 3 weeks of not wearing contact lenses, patients who wear rigid gas permeable or hard lenses must have 3 central keratometry readings and manifest refraction taken at one week intervals, the last 2 of which must not differ by more than 0.50 diopter in either meridian. All mires must be regular.

- Glaucoma is more common in myopic patients than in the general population. Evaluation of the optic nerve and measurement of the intraocular pressure are necessary. If there are any concerns regarding the appearance of the optic nerve, a threshold test of the visual field should be performed. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should only be used with careful medical supervision or the patient should not undergo PRK surgery.

- Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. This is especially important when astigmatism or steep keratometry readings are present, which may indicate the presence of keratoconus or other irregularities.

- Baseline evaluation of patients requesting refractive surgery should be performed within 30 days of the PRK surgery.

- The patient should have the ability to lie flat without difficulty.

- The patient should be able to fixate steadily and accurately for the duration of the PRK procedure.

- The patient must be able to understand the surgery and give informed consent.

- The patient should be clearly informed of all alternatives for the correction of his/her myopia including, but not limited to, spectacles, contact lenses, and other refractive surgeries.

2.4.3. PROCEDURE

The output of the laser is potentially hazardous only to the skin and the surface layers of the cornea. This radiation has not been shown to pose a threat to retinal structures or to the crystalline lens. The area of potential hazard (Nominal Hazard Zone) for the production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam. All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist further than 40 cm from the beam, the use of protective eyewear is recommended if the possibility exists that healthcare personnel will approach closer than this distance to the primary beam.

Prior to initiating epithelium removal. the physician should perform the fluence test to ensure that the laser is ready to deliver laser energy.

2.4.4. POST-PROCEDURE

A slit-lamp examination should be performed on postoperative day one and as needed thereafter to ensure that healing of the cornea is complete. After re-epithelialization. the following examinations are recommended at a schedule of at least 1. 3. and 6 months.

- Uncorrected visual acuity (UCVA or VA-sc)
- Manifest refraction with best spectacle-corrected visual acuity (BSCVA or VA-cc)
- Intraocular pressure (IOP)
- Slip-lamp examination, including corneal clarity evaluation

2.5. ADVERSE EVENTS. COMPLICATIONS. AND PATIENT SYMPTOMS

2.5.1. ADVERSE EVENTS AND COMPLICATIONS

Table 1 presents the cumulative key safety. adverse events, and complications for all treated eyes.

Other adverse events and complications not listed in the table that occurred at a rate of less than 0.3% included: acne. allergies. astigmatism. blepharitis. central island, conjunctivitis. corneal abrasion. corneal edema, corneal infection/ulceration. decentered treatment, discharge. edema of the eyelid. epistaxis. eyestrain, filamentary keratitis. floaters. foreign body, Herpes zoster. IOP fluctuation. itching. keratitis, keratoconus. lagophthalmos. laser malfunction, overcorrection, pingueculitis. ptosis. recurrent erosion. retinal detachment. SPK. starburst. subepithelial opacity. and tight contact lens.

Other events that did not occur in this study that could occur following PRK include: corneal perforations. hyphemas. hypopyon, post-treatment lens abnormalities with vision loss. persistent corneal decompensation/edema. or cystoid macular edema.

Table 1
Cumulative Key Safety, Adverse Events, And Complications
All Treated Eyes

Key Safety, Adverse Events, and Complications	n	N	N not available on CRF	%
Key Safety Events				
Loss of ≥ 2 lines BSCVA at 6 months or later*	53	714	0	7.4
Loss of > 2 lines BSCVA at 6 months or later*	7	714	0	1.0
BSCVA worse than 20/40 at 6 months or later*	5	714	0	0.7
BSCVA worse than 20/25 at 6 months or later if 20/20 or better preoperatively*	21	617	0	3.4
Haze ≥ trace with loss of BSCVA > 2 lines at 6 months or later*	4	714	0	0.6
Increased manifest refractive astigmatism > 2.0 D†	2	419	0	0.5
Postoperative IOP increase from preop > 10 mmHg	16	707	7	2.3
Postoperative IOP > 25 mmHg	23	711	3	3.2
Complications at Any Postoperative Visit (Rate ≥ 0.3%)				
Blepharitis	2	714	0	0.3
Blurry vision	5	714	0	0.7
Burning	12	714	0	1.7
Conjunctivitis	7	714	0	1.0
Corneal epithelial defect	3	714	0	0.4
Corneal scarring	8	714	0	1.1
Dry eye	7	714	0	1.0
Foreign body sensation	29	714	0	4.1
Ghosting/double image	15	714	0	2.1
Glare	81	714	0	11.3
Halos	34	714	0	4.8
Haze	2	714	0	0.3
Headaches	4	714	0	0.6
IOP increase	8	714	0	1.1
Iritis	29	714	0	4.1
Light sensitivity	17	714	0	2.4
Night driving	32	714	0	4.5
Pain	4	714	0	0.6
Patient discomfort	23	714	0	3.2
Recurrent erosion	3	714	0	0.4
Redness	6	714	0	0.8
Tearing	5	714	0	0.7
Undercorrection	5	714	0	0.7

n = # of eyes with the corresponding safety event. N = # of eyes with non-missing measurement. N (not available on CRF) = # of eyes without measurement. % = n / N x 100. No "n" value means no occurrence.

2.5.2. PATIENT SYMPTOMS

At each scheduled postoperative visit, patients were asked to complete a questionnaire that allowed them to report any symptoms or complaints they had regarding their vision or ocular comfort following the surgery. Results for the subjective responses to these questionnaires at 12 or more months postoperative are provided in Table 2. This table presents the changes in each reported symptom compared to the baseline value for that symptom for all treated eyes.

Table 2

Change in Patient Symptoms at ≥ 12 Months Postoperative from Baseline All Treated Eyes

Patient Symptoms	n/N (%)		
	Better	No Change	Worse
Light sensitivity	91/597 (15.2%)	391/597 (65.5%)	115/597 (19.3%)
Headaches	76/597 (12.7%)	470/597 (78.7%)	51/597 (8.5%)
Pain	15/597 (2.5%)	520/597 (87.1%)	62/597 (10.4%)
Redness	53/597 (8.9%)	496/597 (83.1%)	48/597 (8.0%)
Tearing	19/597 (3.2%)	541/597 (90.6%)	37/597 (6.2%)
Burning	33/597 (5.5%)	508/597 (85.1%)	56/597 (9.4%)
Gritty feeling	20/597 (3.4%)	484/597 (81.1%)	93/597 (15.6%)
Glare	45/597 (7.5%)	369/597 (61.8%)	183/597 (30.7%)
Halos	39/597 (6.5%)	392/597 (65.7%)	166/597 (27.8%)
Night driving vision	87/597 (14.6%)	278/597 (46.6%)	232/597 (38.9%)
Allergies	4/597 (0.7%)	592/597 (99.2%)	1/597 (0.2%)
Astigmatism	0/597 (0.0%)	590/597 (98.8%)	7/597 (1.2%)
Blurry vision	8/597 (1.3%)	534/597 (89.4%)	55/597 (9.2%)
Conjunctivitis	0/597 (0.0%)	596/597 (99.8%)	1/597 (0.2%)
Corneal abrasion	0/597 (0.0%)	595/597 (99.7%)	2/597 (0.3%)
Depth perception	1/597 (0.2%)	596/597 (99.8%)	0/597 (0.0%)
Discharge	1/597 (0.2%)	592/597 (99.2%)	4/597 (0.7%)
Double vision	0/597 (0.0%)	582/597 (97.5%)	15/597 (2.5%)
Dry eye	10/597 (1.7%)	540/597 (90.5%)	47/597 (7.9%)
Edema	1/597 (0.2%)	596/597 (99.8%)	0/597 (0.0%)
Eye strain	1/597 (0.2%)	593/597 (99.3%)	3/597 (0.5%)
Floaters	6/597 (1.0%)	588/597 (98.5%)	3/597 (0.5%)
Ghosting	1/597 (0.2%)	588/597 (98.5%)	8/597 (1.3%)
Hordeolum	0/597 (0.0%)	596/597 (99.8%)	1/597 (0.2%)
Infection	0/597 (0.0%)	595/597 (99.7%)	2/597 (0.3%)
Involuntary eye movement	1/597 (0.2%)	596/597 (99.8%)	0/597 (0.0%)
Itching	3/597 (0.5%)	587/597 (98.3%)	7/597 (1.2%)
Monocular double vision	2/597 (0.3%)	593/597 (99.3%)	2/597 (0.3%)
Night vision	1/597 (0.2%)	592/597 (99.2%)	4/597 (0.7%)
Starburst	0/597 (0.0%)	592/597 (99.2%)	5/597 (0.8%)
Twitch	1/597 (0.2%)	596/597 (99.8%)	0/597 (0.0%)

N = Number of received Self-evaluation Forms with non-missing values at both preop. & ≥ 12 months visits.

Those symptoms that were reported more frequently as having gotten worse compared to baseline than had gotten better compared to baseline and that were reported at a frequency of at least 1% were light sensitivity, pain, tearing, burning, gritty feeling, glare, halos, night driving vision, astigmatism, blurry vision, double vision, dry eye, and ghosting.

SECTION 3

CLINICAL RESULTS

3.1. STUDY OBJECTIVES

A prospective, non-randomized, multicenter clinical study of 714 eyes was conducted to evaluate the safety and effectiveness of the KERACOR 116 Excimer Laser System.

3.2. DATA ANALYSIS AND RESULTS

3.2.1. SAFETY AND EFFECTIVNESS RESULTS

Tables 3 and 4 present the summary of the key safety and effectiveness variables for the 714 eyes at all available postoperative visits for eyes treated for spherical myopia only and for astigmatic myopia, respectively.

Table 3
Summary of Key Safety and Effectiveness Variables
All Eyes Treated for Spherical Myopia Only

Key Safety & Effectiveness Variables	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	12 Months n/N (%)	≥ 12 Months* n/N (%)
Effectiveness Variables						
UCVA 20/20 or better	86/383 (22.5%)	153/374 (40.9%)	172/368 (46.7%)	156/333 (46.8%)	140/324 (43.2%)	172/381 (45.1%)
UCVA 20/40 or better	292/383 (76.2%)	313/374 (83.7%)	331/368 (89.9%)	288/333 (86.5%)	279/324 (86.1%)	332/381 (87.1%)
MRSE† ± 0.50 D	213/384 (55.5%)	200/374 (53.5%)	210/367 (57.2%)	190/333 (57.1%)	192/326 (58.9%)	227/380 (59.7%)
MRSE† ± 1.00 D	301/384 (78.4%)	307/374 (82.1%)	299/367 (81.5%)	262/333 (78.7%)	255/326 (78.2%)	305/380 (80.3%)
MRSE† ± 2.00 D	369/384 (96.1%)	359/374 (96.0%)	356/367 (97.0%)	322/333 (96.7%)	313/326 (96.0%)	367/380 (96.6%)
Safety Variables						
Loss of ≥ 2 lines BSCVA	90/382 (23.6%)	19/376 (5.1%)	10/367 (2.7%)	12/334 (3.6%)	4/327 (1.2%)	12/381 (3.1%)
Loss of > 2 lines BSCVA	31/382 (8.1%)	5/376 (1.3%)	2/367 (0.5%)	0/334 (0.0)	0/327 (0.0)	0/381 (0.0)
BSCVA worse than 20/40	13/382 (3.4%)	3/376 (0.8%)	1/367 (0.3%)	0/334 (0.0)	0/327 (0.0)	0/381 (0.0)
Increase > 2 D cylinder‡	3/386 (0.8%)	1/376 (0.3%)	3/368 (0.8%)	0/335 (0.0)	0/328 (0.0)	2/382 (0.5%)
BSCVA worse than 20/25 if 20/20 or better preoperatively§	44/339 (13.0%)	8/333 (2.4%)	3/324 (0.9%)	2/302 (0.7%)	0/291 (0.0)	2/340 (0.6%)

N = Number of received CRFs with non-missing values at each visit.

* The first non-missing response reported from 12 to 24 months for the effectiveness variables, and the worst response reported from 12 to 24 months for the safety variables.

† MRSE = Manifest Spherical Equivalent.

‡ For eyes treated for spherical myopia only.

§ For eyes with BSCVA 20/20 or better preoperatively.

Table 4
Summary of Key Safety and Effectiveness Variables
All Eyes Treated for Astigmatic Myopia

Key Safety & Effectiveness Variables	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	9 Months n/N (%)	12 Months n/N (%)	≥ 12 Months* n/N (%)
Effectiveness Variables						
UCVA 20/20 or better	78/282 (27.7%)	104/283 (36.7%)	118/260 (45.4%)	104/246 (42.3%)	107/238 (45.0%)	118/269 (43.9%)
UCVA 20/40 or better	219/282 (77.7%)	234/283 (82.7%)	225/260 (86.5%)	213/246 (86.6%)	199/238 (83.6%)	225/269 (83.6%)
MRSE† ± 0.50 D	145/281 (51.6%)	143/281 (50.9%)	125/261 (47.9%)	100/246 (40.7%)	110/239 (46.0%)	121/270 (44.8%)
MRSE† ± 1.00 D	227/281 (80.8%)	215/281 (76.5%)	196/261 (75.1%)	179/246 (72.8%)	173/239 (72.4%)	195/270 (72.2%)
MRSE† ± 2.00 D	274/281 (97.5%)	273/281 (97.2%)	253/261 (96.9%)	235/246 (95.5%)	227/239 (95.0%)	258/270 (95.6%)
Safety Variables						
Loss of ≥ 2 lines BSCVA	45/279 (16.1%)	19/281 (6.8%)	6/260 (2.3%)	13/244 (5.3%)	8/236 (3.4%)	12/268 (4.5%)
Loss of > 2 lines BSCVA	12/279 (4.3%)	2/281 (0.7%)	2/260 (0.8%)	1/244 (0.4%)	0/236 (0.0)	1/268 (0.4%)
BSCVA worse than 20/40	7/279 (2.5%)	0/281 (0.0)	0/260 (0.0)	1/244 (0.4%)	0/236 (0.0)	0/268 (0.0)
Increase > 2 D cylinder‡	NA	NA	NA	NA	NA	NA
BSCVA worse than 20/25 if 20/20 or better preoperatively§	21/235 (8.9%)	11/234 (4.7%)	3/218 (1.4%)	8/203 (3.9%)	2/197 (1.0%)	5/227 (2.2%)

N = Number of received CRFs with non-missing values at each visit.

* The first non-missing response reported from 12 to 24 months for the effectiveness variables, and the worst response reported from 12 to 24 months for the safety variables.

† MRSE = Manifest Spherical Equivalent.

‡ For eyes treated for spherical myopia only.

§ For eyes with BSCVA 20/20 or better preoperatively.

3.2.2. SAFETY AND EFFECTIVENESS RESULTS AT THE POINT OF STABILITY

Tables 5 and 6 present the results for key safety and effectiveness at the point of refractive stability (9 months) stratified by the preoperative myopia.

Table 5
Summary of Key Safety and Effectiveness Variables
At the Point of Stability (Month 9) Stratified by Preoperative MRSE/MRSPH*
All Eyes Treated for Spherical Myopia Only

Key Safety & Effectiveness Variables	0.50 to 2.00 D† n/N (%)	2.01 to 3.00 D n/N (%)	3.01 to 4.00 D n/N (%)	4.01 to 5.00 D n/N (%)	5.01 to 6.00 D n/N (%)	6.01 to 7.00 D n/N (%)
Effectiveness Variables						
UCVA 20/20 or better	9/12 (75.0%)	25/43 (58.1%)	14/33 (42.4%)	27/68 (39.7%)	41/94 (43.6%)	40/83 (48.2%)
UCVA 20/40 or better	11/12 (91.7%)	39/43 (90.7%)	27/33 (81.8%)	65/68 (95.6%)	83/94 (88.3%)	63/83 (75.9%)
MRSE* ± 0.50 D	11/12 (91.7%)	27/43 (62.8%)	16/33 (48.5%)	38/68 (55.9%)	55/94 (58.5%)	43/83 (51.8%)
MRSE* ± 1.00 D	11/12 (91.7%)	37/43 (86.0%)	29/33 (87.9%)	56/68 (82.4%)	71/94 (75.5%)	58/83 (69.9%)
MRSE* ± 2.00 D	12/12 (100.0%)	43/43 (100.0%)	33/33 (100.0%)	66/68 (97.1%)	90/94 (95.7%)	78/83 (94.0%)
Safety Variables						
Loss of ≥ 2 lines BSCVA	0/12 (0.0%)	2/43 (4.7%)	1/33 (3.0%)	5/67 (7.5%)	1/94 (1.1%)	2/83 (2.4%)
Loss of > 2 lines BSCVA	0/12 (0.0%)	0/43 (0.0%)	0/33 (0.0%)	0/67 (0.0%)	0/94 (0.0%)	0/83 (0.0%)
BSCVA worse than 20/40	0/12 (0.0%)	0/43 (0.0%)	0/33 (0.0%)	0/67 (0.0%)	0/94 (0.0%)	0/83 (0.0%)
Increase > 2 D cylinder‡	0/12 (0.0%)	0/43 (0.0%)	0/33 (0.0%)	0/68 (0.0%)	0/94 (0.0%)	0/83 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively§	0/11 (0.0%)	0/38 (0.0%)	0/30 (0.0%)	0/61 (0.0%)	1/86 (1.2%)	1/74 (1.4%)

N = Number of received CRFs with non-missing values at each visit.

* Preoperative MRSE (manifest spherical equivalent) was used for eyes treated for spherical myopia only, and preoperative MRSPH (manifest sphere) was used for eyes treated for astigmatic myopia.

† Two eyes treated for astigmatic myopia and back for the 9-month visit had a preoperative sphere less than -1.00 D (-0.50 & -0.75 D).

‡ For eyes treated for spherical myopia only.

§ For eyes with BSCVA 20/20 or better preoperatively.

Table 6
Summary of Key Safety and Effectiveness Variables
At the Point of Stability (Month 9) Stratified by Preoperative MRSE/MRSPH*
All Eyes Treated for Astigmatic Myopia

Key Safety & Effectiveness Variables	0.50 to 2.00 D† n/N (%)	2.01 to 3.00 D n/N (%)	3.01 to 4.00 D n/N (%)	4.01 to 5.00 D n/N (%)	5.01 to 6.00 D n/N (%)	6.01 to 7.00 D n/N (%)
Effectiveness Variables						
UCVA 20/20 or better	13/18 (72.2%)	7/28 (25.0%)	16/35 (45.7%)	14/40 (35.0%)	22/52 (42.3%)	32/73 (43.8%)
UCVA 20/40 or better	18/18 (100.0%)	24/28 (85.7%)	32/35 (91.4%)	31/40 (77.5%)	45/52 (86.5%)	63/73 (86.3%)
MRSE* ± 0.50 D	11/18 (61.1%)	11/28 (39.3%)	17/35 (48.6%)	14/40 (35.0%)	22/52 (42.3%)	25/73 (34.2%)
MRSE* ± 1.00 D	16/18 (88.9%)	20/28 (71.4%)	28/35 (80.0%)	23/40 (57.5%)	39/52 (75.0%)	53/73 (72.6%)
MRSE* ± 2.00 D	18/18 (100.0%)	28/28 (100.0%)	33/35 (94.3%)	38/40 (95.0%)	48/52 (92.3%)	70/73 (95.9%)
Safety Variables						
Loss of ≥ 2 lines BSCVA	0/18 (0.0%)	0/28 (0.0%)	2/35 (5.7%)	3/40 (7.5%)	2/52 (3.8%)	7/73 (9.6%)
Loss of > 2 lines BSCVA	0/18 (0.0%)	0/28 (0.0%)	0/35 (0.0%)	0/40 (0.0%)	0/52 (0.0%)	1/73 (1.4%)
BSCVA worse than 20/40	0/18 (0.0%)	0/28 (0.0%)	0/35 (0.0%)	0/40 (0.0%)	0/52 (0.0%)	1/73 (1.4%)
Increase > 2 D cylinder‡	NA	NA	NA	NA	NA	NA
BSCVA worse than 20/25 if 20/20 or better preoperatively§	0/15 (0.0%)	0/23 (0.0%)	1/28 (3.6%)	1/35 (2.9%)	1/40 (2.5%)	5/64 (7.8%)

N = Number of received CRFs with non-missing values at each visit.

* Preoperative MRSE (manifest spherical equivalent) was used for eyes treated for spherical myopia only, and preoperative MRSPH (manifest sphere) was used for eyes treated for astigmatic myopia.

† Two eyes treated for astigmatic myopia and back for the 9-month visit had a preoperative sphere less than -1.00 D (-0.50 & -0.75 D).

‡ For eyes treated for spherical myopia only.

§ For eyes with BSCVA 20/20 or better preoperatively.

3.2.3. STABILITY OF THE MANIFEST REFRACTION

Results for stability of the manifest refraction as determined by the manifest spherical equivalent refraction are presented for those eyes that had data at all scheduled follow-up visits during the study (the "consistent cohort"). Stability is defined as a change in the spherical equivalent manifest refraction of 1.00 diopter or less between successive visits at least 3 months apart for 95% of the treated eyes. Table 7 presents the results for those eyes treated for spherical myopia only. Table 8 presents the results for those eyes treated for astigmatic myopia.

Table 7
Stability of Manifest Refraction Spherical Equivalent
Eyes Treated for Spherical Myopia Only
Consistent Cohort (N = 225 Eyes)

Change in Spherical Refraction	Between 1 & 3 Months	Between 3 & 6 Months	Between 6 & 9 Months	Between 9 & 12 Months
Change of MRSE by ≤ 1.00 D				
N/N† (%)	197/225 (87.6%)	207/224 (92.4%)	211/224 (94.2%)	212/225 (94.2%)
95% CI for %	(83.3%, 91.8%)	(88.8%, 96.0%)	(91.2%, 97.2%)	(91.2%, 97.2%)
Change of MRSE (Paired-Differences) in Diopters				
Mean	-0.157	-0.068	-0.026	0.022
SD	0.766	0.626	0.545	0.511
95% CI for Mean	(-0.256, -0.057)	(-0.148, 0.013)	(-0.096, 0.044)	(-0.046, 0.089)

The 95% confidence interval was adjusted for the correlation between eyes.
* Eyes examined at all postoperative visits (1, 3, 6, 9, & 12 months).
† Smaller N = some missing values.

Table 8
Stability of Manifest Refraction Spherical Equivalent
Eyes Treated for Astigmatic Myopia
Consistent Cohort (N = 204 Eyes)

Change in Spherical Refraction	Between 1 & 3 Months	Between 3 & 6 Months	Between 6 & 9 Months	Between 9 & 12 Months
Change of MRSE by ≤ 1.00 D				
N/N† (%)	177/201 (88.1%)	195/203 (96.1%)	196/204 (96.1%)	193/204 (94.6%)
95% CI for %	(83.7%, 92.5%)	(93.4%, 98.7%)	(93.3%, 98.9%)	(91.6%, 97.7%)
Change of MRSE (Paired-Differences) in Diopters				
Mean	-0.246	-0.016	-0.088	0.006
SD	0.746	0.478	0.484	0.578
95% CI for Mean	(-0.349, -0.143)	(-0.077, 0.046)	(-0.152, -0.023)	(-0.074, 0.085)

The 95% confidence interval was adjusted for the correlation between eyes.
* Eyes examined at all postoperative visits (1, 3, 6, 9, & 12 months).
† Smaller N = some missing values.

For both treatment groups, the refraction was demonstrated to be stable by 6 months postoperative based upon the upper limit of the 95% confidence interval. However, in Table 10, the upper 95% confidence limit for the period between 3 and 6 months is marginal. Therefore, taking a more conservative approach, stability was determined to occur at 9 months.

3.2.4. RETREATMENTS

Effectiveness and safety data (including postoperative adverse events/complications) for eyes that underwent PRK retreatment are presented. Patients were eligible for retreatment after 12 months of follow-up for the initial treatment with the KERACOR 116 Excimer Laser System. Table 9 presents the retreatment rate and the outcomes after retreatment for the 714 eyes, stratified by treatment for spherical myopia only and for astigmatic myopia. Among the 66 eyes (9.2%) that were retreated, 29/419 (6.9%) were originally treated for myopia only and 37/295 (12.5%) were treated for astigmatic myopia.

Table 9
Retreatment Summary
All Retreated Eyes

Summary Endpoints	Eyes Treated for Spherical Myopia Only N/N (%)	Eyes Treated for Astigmatic Myopia n/N (%)
Retreatment Rate, N/All Treated Eyes (%)	29/419 (6.9%)	37/295 (12.5%)
Key Effectiveness at the Last Available Postoperative Exam After Retreatment		
UCVA 20/20 or better	12/29 (41.4%)	16/37 (43.2%)
UCVA 20/40 or better	25/29 (86.2%)	33/37 (89.2%)
MRSE* ± 0.50 D	16/29 (55.2%)	24/37 (64.9%)
MRSE* ± 1.00 D	24/29 (82.8%)	33/37 (89.2%)
MRSE* ± 2.00 D	27/29 (93.1%)	37/37 (100.0%)
MRCYL* ± 0.50 D	NA	22/37 (59.5%)
MRCYL* ± 1.00 D	NA	33/37 (89.2%)
MRCYL* ± 2.00 D	NA	37/37 (100.0%)
Cumulative Key Safety After Retreatment		
Loss of ≥ 2 lines BSCVA at 6 months or later†	2/29 (6.9%)	3/37 (8.1%)
Loss of > 2 lines BSCVA at 6 months or later†	0/29 (0.0%)	0/37 (0.0%)
BSCVA worse than 20/40 at 6 months or later†	0/29 (0.0%)	0/37 (0.0%)
BSCVA worse than 20/25 at 6 months or later if 20/20 or better preoperatively†	2/28 (7.1%)	2/30 (6.7%)
Haze ≥ trace with loss of BSCVA > 2 lines at 6 months or later†	0/29 (0.0%)	0/37 (0.0%)
Increased manifest refractive astigmatism > 2.0 D‡	0/29 (0.0%)	NA
Postoperative IOP increase from preop > 10 mmHg	0/26 (0.0%)	1/37 (2.7%)
Postoperative IOP > 25 mmHg	0/29 (0.0%)	1/37 (2.7%)
Adverse Event Reports/Complications at Any Postoperative Visits After Retreatment		
Central island	0/29 (0.0%)	1/37 (2.7%)
Dry eye	0/29 (0.0%)	1/37 (2.7%)
Glare	0/29 (0.0%)	1/37 (2.7%)
Patient discomfort	1/29 (3.4%)	0/37 (0.0%)

N = Number of retreated eyes.

* MRSE = Manifest sphere. MRCYL = Manifest cylinder (for eyes treated for astigmatic myopia).

† For eyes without visits ≥ 6 months or eyes with visits ≥ 6 months but missing BSCVA, the last non-missing BSCVA was carried forward.

‡ For eyes treated for spherical myopia only. The timeframe is "6 months or later".

Following retreatment, the effectiveness outcomes for both the spherical myopia and astigmatic myopia groups were similar in terms of uncorrected visual acuity and deviation from emmetropia, although there was a somewhat higher success rate for the astigmatic myopia group in terms of deviation from emmetropia within ±0.50 D. Safety outcomes were very similar, and there were no eyes in either group that lost more than 2 lines of best spectacle-corrected visual

acuity following retreatment. There were few adverse events or complications reported following the retreatments.

SECTION 4

SURGICAL PLANNING AND PROCEDURES

4.1. INTRODUCTION

PRK is a procedure that uses the energy of the excimer laser to create a superficial keratectomy of a shape designed to correct or reduce a specific refractive error. The intent is to properly focus visible light entering the eye to provide improved vision. It is essential that the refractive information upon which this surgical procedure is based is accurate and correctly transmitted to the laser. It is the sole responsibility of the surgeon to ensure that the information for each individual patient is accurate.

4.2. PRE-OPERATIVE PROCEDURES

A complete examination, including, but not limited to, cycloplegic evaluation, must be performed. Direct and indirect ophthalmoscopy through a dilated pupil are essential. Evaluation of the optic nerve and measurement of IOP are necessary. If there are any concerns regarding the appearance of the optic nerve, a threshold test of the visual field should be performed. Pre-operative corneal mapping (topography) is essential on all patients to exclude topographical abnormalities. Baseline evaluation of patients with myopia desiring refractive surgery should be performed within 30 days prior to PRK surgery.

4.3. PERI-OPERATIVE PROCEDURES

ANESTHESIA

Extensive clinical experience has shown that PRK excimer surgery is well tolerated and rarely causes significant pain. For this reason, systemic sedatives and injected local anesthetics are not required. Topical anesthesia applied just before insertion of the lid speculum should provide adequate control of pain during surgery. For those patients with a high degree of anxiety, appropriate medication may be given pre-operatively.

4.4. INTRA-OPERATIVE PROCEDURES

4.4.1. REMOVAL OF EPITHELIUM - INITIAL TREATMENT

The recommended technique for epithelium removal in initial PRK surgery is mechanical removal. A blunt instrument such as a Paton spatula or a #64 Beaver blade can be gently used to remove the epithelial layer mechanically. The region of epithelium removal should be at least 7.0 mm in diameter. After the stromal bed is cleaned of debris, removal of remaining epithelial cells and associated debris can be accomplished using a nonfragmenting surgical sponge wetted with sterile balanced salt solution and wiped over the ablation bed. The PRK treatment can then