Excimer laser keratomileusis on the stromall side of the disc for correction of miopia of 5.00 to 12..00 diopters: one year follow up.

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Summary

Excimer laser myopic keratomileusis has recently been in clinical use. In this study we present our experience in applying this technique for the correction of myopia of 5.00 to 12.00 Diopters. Autoplastic excimer laser keratomileusis was performed on 30 eyes of 15 consecutive patients with myopia (range -525 D to -11.75D. The surgical technique used the OmniMed Excimer Laser (Summit Technology, Inc. Waltham, Mass) for the refractive photoablation on the stromal side of a corneal disc previously resected with the Automatic Corneal Shaper (Steinmay Co. San Diego, Ca). All patients were followed for one year. The mean preoperative spherical equivalent refraction was -7.72 ± 1.91 D. After a mean follow up of 12 months, the mean postoperative spherical equivalent refraction was -0.01 ± 0.54 D (range, +1.25 to -1.25). At the end of follow up, 23 eyes (76.6%) were within ±0.50 D of emmetropia and 27 eyes (90%) achieved 20/40 or better uncorrected visual acuity. Between 1 and 3 months postoperatively, there was a regression of the surgical effect of 0.58 D. between 3 and 6 moths postoperatively, regression was 0.12 D; between 6 and 12 moths postoperatively, regression was 0.04 D. One eye (3.3%) lost one line of best corrected Snellen visual acuity and theree eyes (10%) presented with irregular astigmatism at one year postoperatively. Excimer laser myopic keratomileusis performed on the disc is a safe, effective and predictable technique for correcting myopia of 5.00 to 12.00 diopters with fast recovery of vision and early stability of the surgical effect.

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Introduction

The argon fluoride (193 nm) excimer laser with its sub-micron precision in ablating corneal stroma is a new alternative for correction of refractive errors.Photorefractive keratectomy was first suggested by Marshall and trokel in 1986. (1) numerous studies have established its efficacy in correcting low and moderate myopia (2,3) Conversely, other authors have reported poor predictability, regression from persistent corneal haze and lack of stability of the procedure in correcting myopia over 6.0 D. (4,5).

In an attempt to avoid these complications, Pallikaris first suggested the «corneal flap technique for laser in situ keratomileusis» (Lasik) in 1990. (6) Buratto's study in 1992 concluded that keratomileusis with the excimer laser was effective for high myopia (7) and safer than other mechanical lamellar refractive surgical techniques, including cryolate keratomileusis, (8) nonfreeze planar lamellar refractive keratoplasty (9) and keratomileusis in situ. (10) Both new modalities of treatment are variations of Barraquer's original procedures. (11) The first technique susbstitutes the excimer laser for the in situ procedure after lifting a flap; in the second technique the cryolathing and molding are replaced by photoablation.

In this study we present our experience in performing excimer laser keratomileusis on the corneal disc for the correction of myopia of 5. 00 to 12.00 Diopters.

Subjects and methods

During the period of 5th to 10th february 1994, 30 eyes of 15 consecutive patients underwent autoplastic excimer laser keratomileusis to correct moderate and high myopia. Entry criteria included patients who were at least 18 years old with a preoperative myopia of -5.00 D or more, and 4.00 D or less of astigmatism. All patients had a stable manifest refraction. A corneal thickness of at least 520 microns was required and patients wearing contact lenses were requested to discontinue their use for at least 4 days prior to surgery. No patient had a history of systemic disease or active ocular pathology. All patients signed an informed consent before undergoing surgery.

Preoperative evaluation included a noncycloplegic manifest refraction, keratometry, slit-lamp micropscopy, optical pachymetry (Haag-Streit, Bern, Switzerland), corneal topography using the TMS (Topographic Modeling System, TMS-1 Computed Anatomy, Inc, New York City) and Goldmann applanation tonometry. Visual acuity measurement, both preoperatively and postoperatively, was performed under standard conditions by an independent observer (JTS) other than the surgeon.

Surgical Technique

One drop of 1% pilocarpine was administered 30 minutes preoperatively. Bilateral surgery was conducted in a sterile operating room with topical anesthetic eyedrops for all patients with the exception of one who elected to have general anestesia. Several drops of 0.4 % Oxybuprocaine Hydrochloride were instilled in the operated eye and a Barraquer eyelid speculum was inserted. A para-radial reference line was drawn with a disposable needle. The patients was then asked to fixate on the filament of the operatining microscope, and a gentian violet pen was used to mark the patient's cornea over the center of the constricted pupil. The globe was then fixated with the adjustable suction ring with its wrench already attached, the size of the desired disc diameter was checked with a Barraquer applanation lens and a keratectomy was performed usig the Automatic Corneal Shaper. The thickness of the corneal disc was measured with the Mitutoyo micrometer and

then placed and flattened onto the cover of the antidesiccation chamber, epithelium side down. During the laser treatment on the corneal disc, the exposed recipient cornea was covered with a sterile, plastic thimble. Before the ablation, The Helium-Neon aiming beams were aligned with the gentian violet spot previously marked on the corneal disc. The refractive photo-ablation was then performed on the stromal side of the corneal disc with an ArF(193 nm) OmniMed Lasser (Summit technology Inc, Waltham, Mass), usig a frequency of 10 Hz, an energy fluence at the cornea of 180 mJ cm^2 and an assumed ablation rate of 0.25 u/pulse. The ablation depth and diameter were preselected based on the spectacle sperical equivalent refraction using a nomogram. The myopic photorefrective keratectomy program was used in a all cases in an attempt to achieve emmetropia (SER). The ablation consisted of a single-step procedure for corrections of 9.90 D or less, and a two-step procedure (-9.90+ the remainder by reprograming) for corrections of 10.00 D or more. In both cases, a single zone was used. The time between the keratectomy and starting of ablation was standardized (less than one minute)and no fluid was allowed to reach the corneal disc in an attempt to maintain the original hydration state of the cornea. Following the laser sculpting, the lenticule was rinsed with normal saline, removed from the antidessication chamber with a Barraquer spatula, placed and sutured onto the recipient cornea, matching the reference marks, using a single-running, three-bite, antitorque 10-0 nylon suture. At the end of the surgery, one drop of tobramycin (0.3%) was instilled, and the eye was patched for 4 hours.

Postoperative Care

The sutures were removed between 4 and 24 hours after surgery. Examination schedules then continued at 1, 3, 6 and 12 months. Postoperative medication included tobramycin (0.3%) drops four times daily for 4 days, and prednisolone acetate 1% twice daily for 10 days. At each posto operative visit, all eyes had visual acuity measure ment, keratometry, corneal topography, noncy cloplegic manifest refraction, slit-lamp micros copy and Goldman applanation tonometry.

The manifest refraction (strongest plus or weak est minus lens needed to give maximum visua acuity) began with phoropter placed retinoscopy compared to the videokeratographic cylinder modified by Javal's rule (refractive cylinder = 1.25 corneal cylinder + (-0.50 axis 90)). The manifest refraction endpoint resulted from the «fogging techique» as described by Gartry et al. (12).

In an attempt to evaluate the regression of the refractive effect, normalized post-operative videokeratographs were compared to manifest refractions at intervals. The flattest power within a 1.5 mm. radius from the fixation cross was located in a searching fashion by an observer without acces to the patient's other recorded data. The amount of decentration of the center of the ablation zone relative to corneal vertex was also measured.

Results

The study included 30 eyes of 15 consecutive patients, 10 females and 5 males, with a mean age of 25 ± 3.7 year (range, 20 to 33 years). The mean preoperative spherical equivalent refraction was -7.72 ± 1.91 D (range, -5.25 to 11.75 D), and the mean preoperative astigmatism was 0.95 ± 0.94 (range, 0.00 to 4.00 D). Preoperatively, the mean corneal radius of curvature was 7.70 mm, and the mean preoperative pachimetry was 0.56 mm. The operative parameters are displayed in (table 1). After the refractive photoablation, 46.6% of the lenticules had a remaining thickness of 160 µm or less. (Table 2) presents the preoperative and postoperative spherical equivalent refraction correlated with the operative parameters for the 30 eyes. Postoperatively, all patients were followed

Table 1
Oerative Data for 30 eyes undergoing Eximer Laser Myopic Keratomileusis

OPERATIVE PARAMETER	MEAN	STANDARD DESVIATION	MINIMUM	MAXIMUM
Diameter of the disc (mm)	7.8	0.07	7.00	7.20
Thickness of the disc (µm)	248.00	26.20	200.00	289.00
Depth of the ablation (µm)*	75.90	15.30	55.75	110.00
No. of pulses	303.60	61.30	223.00	444.00
Diameter of ablation (mm)	4.94	0.12	4.70	5.00
Thickness after ablation (µm)**	162.30	25.70	125.50	204.25

* Assumes 0.25 microns per pulse
** Subtraction of depth of ablation from measured thickness of disc.

TABLE 2
Preoperative and one year postoperative spherical equivalent refraction compared with surgical paramaters in 30 eyes treated with excimer myopic keratomileusis

EYE	PREOPERATIVE SPHERICAL EQUIVALENT REFRACTION (D)	POSTOPERATIVE SPHERICAL EQUIVALENT REFRACTION(D)	OMNIMED CORRECTION SETTING(D)	No.of PULSES	ABLATION DEPTH (µm)	ABLATION ZONE DIAMETER (mm)	THICKNESS AFTER ABLATION (µm)
1	-6.75	Plano	-6.00	251	62.75	5.00	137.25
2	-6.75	+0.12	-6.00	251	62.75	5.00	137.25
3	-9.12	Plano	-8.50	339	84.75	5.00	135.25
4	-8.62	+0.25	-8.00	322	80.50	5.00	149.50
5	-7.50	Plano	-7.50	304	76.00	5.00	134.00
6	-8.87	+0.25	-8.50	339	84.75	5.00	145.25
7	-5.87	-0.50	-6.00	251	62.75	5.00	142.25
8	-5.87	Plano	-6.00	251	62.75	5.00	167.25
9	-11.00	Plano	-9.90	340	85.00	4.70	155.00
10	-11.00	+1.12	-11.00	409	102.25	4.70	137.75
11	-7.87	-0.50	-6.80	279	69.75	5.00	170.25
12	-5.62	-0.75	-5.60	237	59.29	5.00	175.75
13	-5.50	-1.25	-5.50	233	58.25	5.00	176.75
14	-6.25	Plano	-6.20	258	64.50	5.00	188.50
15	-6.00	-0.12	-6.00	251	62.75	5.00	189.25
16	-7.62	Plano	-7.60	307	76.75	5.00	174.25
17	-8.25	-0.12	-8.20	329	82.25	5.00	160.75
18	-5.75	0.87	-5.70	240	60.00	5.00	182.00
19	-6.00	-0.87	-6.00	251	62.75	5.00	179.25
20	-5.25	+0.25	-5.20	223	55.75	5.00	166.25
21	-6.25	-0.12	-6.20	258	64.50	5.00	166.50
22	-6.37	+0.12	-6.90	283	70.75	5.00	204.25
23	-7.00	Plano	-7.50	304	76.00	5.00	199.00
24	-9.00	-0.25	-9.50	328	82.00	4.70	140.00
25	-11.00	+1.25	-11.50	422	105.50	4.70	125.50
26	-11.25	+1.12	-11.70	429	107.25	4.70	145.75
27	-11.75	+0.25	-12.20	444	111.00	4.70	159.00
28	-6.75	-0.25	-6.70	276	69.00	5.00	174.00
29	-8.25	+0.25	-8.70	346	86.50	5.00	151.50
30	-3.37	+0.25	-8.90	353	88.25	5.00	200.75

for 1 year. (Figure 1) summarizes the preoperative and postoperative refractive results at regimented intervals. At 1 month, the mean spherical equivalent refraction was +0.73±1.02 D (range, +3.12 to -1.12D), representing 109.4% of the attempted correction; at the last examination, the mean spherical equivalent refraction was -0.01± 0.54 D (range, +1.25 to -1.25D). Between 1 and 3 months postoperatively, there was a regression of the surgical effect of 0.58 D (7.51 %); between 3 and 6 months postoperatively, the regression was 0.12 D (1.56%) between 6 and 12 months postoperatively, the regression was 0.04 D (0.51%), indicating a minimal loss of surgical effect. Twenty-nine eyes (96.6%) had stable refraction (±0.50) between 6 and 12 months. The refractive outcome is shown in (table 3).

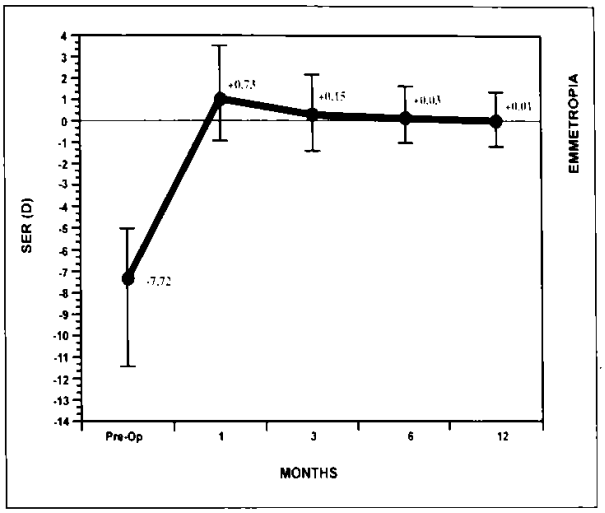

Figure 1. The mean spherical equivalent refraction (D) over time for 30 eyes treated with excimer laser keratomileusis. the error bars schw the ranges at different intervals.

TABLE 3
Distribution of refraction in 30 eyes following excimer laser myopic keratomileusis

Spherical equivalent Refraction (D)	Time after surgery (Mo) 1 No. of eyes	%	12 No. of eyes	%
-1.12 to -2.00	1	3.3	1	3.3
-0.62 to -1.00	2	6.7	3	10.0
+0.50 to -0.50	11	36.7	23	76.7
+0.62 to 1.00	5	16.6	0	0
+1.12 to +2.00	8	26.6	3	10.0
+2.12 to 3.00	2	6.7	0	0
+3.12 to +4.00	1	3.3	0	0
TOTAL	30	100	30	100

At the last follow-up examination, 23 eyes (76.7%) were within ±0.50D of emmetropia and 26 eyes (86.6%) were within ±1.00 D of

emmetropia (Fig. 2). No significant change was seen in the amount of refractive astigmatism after surgery. The mean preoperative astigmatism was 0.95 ± 0.94 D and the mean postoperative astigmatism at the end of the follow-up period was 1.04 ± 0.71 D.

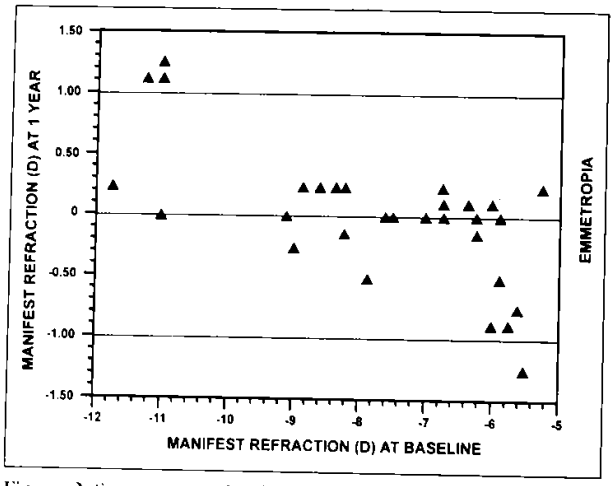

Figure 2. Scattergram display the spherical equivalent refraction (D) after 12 months following excimer laser keratomileusis, compared to the preoperative refraction at baseline for 30 eyes

Visual acuity

Preoperatively, all eyes were correctable to 20/40 or better with spectacles. Postoperatively, all eyes had improvement of uncorrected visual acuity. The number of eyes with uncorrected visual acuity of 20/40 or better was 24 (80%) at 6 months, improving to 27 (90%) at the last examination, with 16 eyes (53.3%) achieving 20/20 uncorrected acuity (Table 4). At one month postoperatively, all eyes were within one line of preoperative Snellen best spectacle-corrected acuity.

Best spectacle-corrected visual acuity of 20/40 or better was achieved in all eyes examined at the 1 year follow-up visit, with one eye (3.3%) losing one line of best spectacle-corrected visual acuity from 20/25 to 20/30. Two eyes (6.6%) experienced improvement of three Snellen lines from their preoperative best spectacle-corrected visual acuity from 20/40 to 20/20. The remaining 27 eyes maintained their preoperative best spectacle-corrected visual acuity.

	1			
Snellen visual acuity	No. of eyes	%	No. of	
20/20 to 20/25	13	43.4	24	80.0
20/30 to 20/40	11	36.7	3	10.0
20/50 to 20/100	5	16.6	3	10.0
20/160 or worse	1	3.3	0	0
TOTAL	30	100	30	100

Corneal transparency

Between four and 24 hours following surgery, most corneal lenticules showed some degree of «granular» stromal infiltration. No epithelial defect was observed in any cornea. At 1 month postoperatively, most lenticules presented with Bowman's layer folds (fingerprint-like lines that look like wrinkles), which gradually attenuated thereafter. At the end of follow-up, fine Bowman's layer striations were observed in eyes (53.3%). Corneal haze was not grade in this study; however, some lenticules presented with a mild degree of transient central haze within the lamellar bed, corresponding to the location of the laser treatment. In some cases, tha ablation zone was still discernable biomicroscopically as late as one year after surgery. All lenticules showed a brown epithelial iron spot, which gradually increased in density between 3 and 12 moths postoperatively. At 1 year follow-up, the iron deposit was well defined, and its location was generally well correlated with the flattest curvature found within a radius of 1.5 mm from the fixation cross, as studied by computerized videokeratography (Fig. 3 and 4).

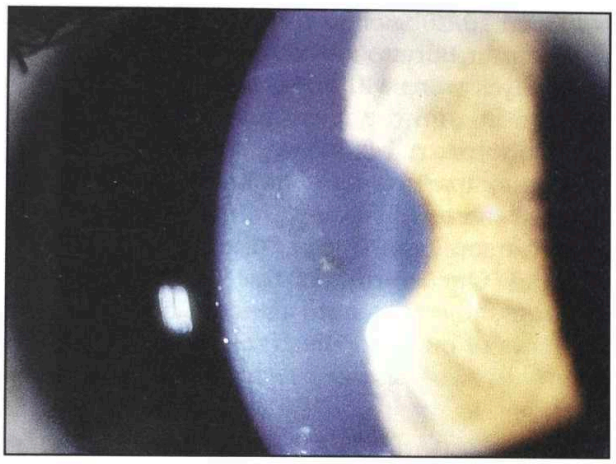

Figure 3. Microphotograph shows the brown ephithelial iron spot (arrow) at 12 months postoperative.

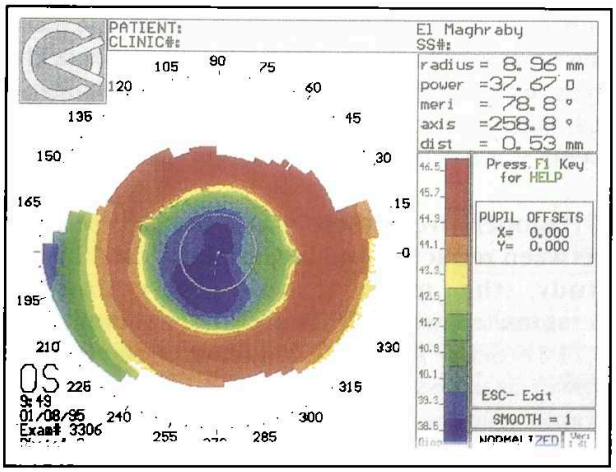

Figure 4. Videokeratograph of the same eye in figure 3 shows good correlation of the location of the iron spot and the flattest curvature found within a radius of 1.5 mm trom corneal apex (cursor cross).

Computer-Assited Topographic Analysis

The mean decentration of the ablation zone relative to the corneal apex was 0.55 ± 0.25 mm. (range, 0 to 1.00 mm), with thirteen eyes (43.3%) centered within 0.5 mm. The decentration measurements did not vary with time postoperatively. (Table 5) compares the regression of the surgical

TABLE 5
Summary of topographic analysis at different intervals for 30 eyes treated with exciomer laser myopic keratomileusis

	Time after surgery (Mo)				
	Preoperative	1	3	6	12
Mean spherical equivalent refraction (D)	-7.72	+0.73	+0.15	+0.03	0.01
Mean keratometry (D)	43.80	37.90	37.60	37.55	37.85
Mean videokeratographic flattest curvature (D)	42.90	34.62	3 5.31	35.65	35.88

effects as studied by computerized topography, keratometry and manifest refraction. After a follow up of 12 months, the mean myopic correction by keratometry was 5.95 D, and by manifest refraction was 7.71 D. The mean decrease of the corneal power assessed by computerized videokeratography (flattest point within 1.5 mm. of radius from the corneal vertex) was 7.02 D.

Complications

No serious intraoperative complication was reported in this series of patients. (Table 6) lists the postoperative refractive complications. No cases of infection, loss of lenticule, opacification of the cornea, or increase in intraocular pressure occurred. Five eyes had induced regular, refractive astigmatism of 1 diopter or more, and three eyes (10.0%) had irregular astigmatism (principle meridians separated by an angle of other than 90 degress) at 1 year postoperatively, as evaluated

TABLE 6
Postoperative refractive complications in 30 eyes undergoing excimer laser myopic keratomileusis

	No. of Eyes	*%*
Undercorrection (≥100 D)	1	3.3
Overcorrection (≥1.00 D)	3	10.0
Induced astigmatism (≥1.00 D)	5	16.6
Irregular astigmatism keratometry and videokeratography	3	10.0
Loss of one sellen line of best spectacle-corrected visual acuity	1	3.3
Loss of two snellen lines of best spectacle-corrected visualacuity	0	0.0

by both keratometry and videokeratography. All three eyes with irregular astigmatism were in the higher myopic group (-9.00 to -11.75D), and had an ablation diameter of 4.7 mm. One of the eyes with irregular astigmatism lost one line of best spectacle-corrected visual acuity. At the end of the follow-up period, one patient (6.6%) complained of persistent perception of halos at night.

Discussion

Excimer lase myopic keratomileusis has recently been in clinical use. Results on sighted human eyes have been reported by Buratto and Pallikaris perfoming the excimer laser ablation either on the stromal side of a corneal disc previously resected with a microkeratome, (13) or on the corneal bed following the creation of a truncated, disc shaped corneal flap. (14) Both studies documented the efficacy and safety of the techinique, but revealed limited refractive accuracy for cases of high amount of myopia. Since we have previously observed that predictability of cryolathe myopic keratomileusis is better in eyes with moderate myopia, (15) we elected to report results of this series of patients with a mean preoperative spherical equivalent refraction of -7.72 D (range - 5.25 to -11.75 Diopters). The mean refraction of this series is less than the mean preoperative refraction reported in other studies: -17.87 D (range, -11.20 to -24.50 Diopters) by Burrato et al; (13) and -16.61 D (range, -10.62 to -25.87 Diopters) by Pallikaris and Siganos. (14). The results obtained in this group of patients are encouraging. At one month postoperatively, all eyes were within one line of preoperative Snellen best spectacle corrected visual acuity. After a follow up of one year , the mean postoperative sperical equivalent refraction was -0.001 D, representing an average correction of 99.8%, with 76.7% of eyes within ± 0.50 D of emmetropia. All eyes had an improvement in their uncorrected visual acuity after surgery. Ninety percent of the eyes achieved 20 -40 or better, and 16 eyes (53.3%) achieved 20/20 Snellen visual acuity without correction. In Buratto's study , fifty-seven percent of the eyes were within ±1.00 D of the intended correction, and the mean postoperative spherical equivalent refraction was -2.30 D. Certainly, such a comparison must be taken with caution, because Buratto's study was limited to eyes with higher amounts of myopia (mean -17.87) Diopters). (13) Our improved refractive results may be attributed to having used a revised nomogram on the basis of our experience using the Omnimed laser with two previous unpublished series of patients,

This study showed that over correction and subsequent regression occurred in the first three months, followed by relative stability of refraction. Bettween 6 and 12 months postoperatively, there was a mean regression of 0.04 D and 96.6% of the eyes were stable within ±0.50. Buratto and Pallikaris also reported stability of refraction bet ween 3 and 6 months after surgery. (13,14).

Postoperatively, there was a poor correlation between refractive and keratometric data. In this study, the mean myopic correction by keratometry was 5.95 D and by refraction was 7.71 D (SER). The mean decrease of the corneal power as assessed by computerized videokeratography (flattest point within a radius of mm from the corneal vertex) was 7.02 D, indicating a better correlation between refractive and topographic data. Centration of ablation was satisfactory. For cases of laser assisted in situ keratomileusis (LASIK), Pallikaris reported a mean deviation of the ablation center of 0.96 mm. (range 0.49 to 1.64 mm) using a suction ring for stabilization. We agree with Buratto et al, that ablating the corneal disc has the advantage of more accurate centration on a non-moving target. In our study, the mean decentration of the ablation zone relative to corneal apex was 0.55 mm, with 100% of the eyes centered within 1.0 mm. No serious operative or postoperative complications were reported in this series. The presence of fine

Bowman's layer striations, found in 53.3% of the eyes at the end of follow-up, may be atrributed to the remaining thickness of the lenticules after the refractive photo-ablation (an average of 162 u). The Bowman's layer folds apparently did nor reduce visual acuity and therefore did not need management. Three eyes, out of six with high myopia, who received an ablation zone of 4.7 mm. persisted with a moderate degree of irregular astigmatism 12 months after surgery. Larger optical zones lead to greater ablation depths, and therefore, demand thicker initial keratectomies. In this series of patients, we strictly avoived keratectomies deeper than 300 microns as they may increase the potential for ectasia of the deep non- resected corneal bed.

In summary, we found excimer laser myopic keratomileusis performed on the disc to be a safe , effective and predictable technique for correcting moderate and high myopia with fast recovery of vision and early stability of the surgical effect.

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