Laser in situ keratomileusis to correct post-keratoplasty astigmatism: 1-step versus 2-step procedure

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Purpose: To investigate the correction of post-penetrating keratoplasty (PKP) astigmatism using laser in situ keratomileusis (LASIK). Visual and refractive outcomes were evaluated after LASIK was performed in 1 step (lamellar cut and ablation in 1 procedure) or 2 steps (lamellar cut then ablation in 2 successive procedures).

Setting: Department of Cornea and Refractive Surgery, Vissum–Instituto Oftalmológico de Alicante, University of Miguel Hernández, Alicante, Spain.

Methods: In this prospective observational study, 22 consecutive eyes were divided into 2 groups depending on the LASIK procedure performed to correct post-PKP astigmatism. Group 1 (1-step LASIK) included 11 eyes and Group 2 (2-step LASIK), 11 eyes. The patients were followed for 6 months.

Results: A statistically significant improvement was obtained in Group 2 with a mean vector analysis result of the cylinder of –4.37 diopters (D) ± 1.79 (SD) (P = .018). In Group 1, the mean astigmatism correction was 2.38 ± 1.71 D. The number of reoperations and residual refractive defects were significantly better in Group 2.

Conclusion: The 2-step technique improved the accuracy of excimer laser correction of post-PKP astigmatism.

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The outcome of penetrating keratoplasty (PKP) has improved with advances in microsurgical techniques. However, 8% to 20% of eyes have regular or irregular postoperative high astigmatism that cannot be corrected by spectacles or contact lenses,[1–5] resulting in astigmatic anisometropia.[6,7] Contact lenses are an alternative associated with problems of corneal topography, neovascularization, tear-film instability, and intolerance.[8,9] Because of the limitations of contact lens correction,[10] several surgical options for correcting post-PKP astigmatism have been described; these include incisional surgery[11] and postoperative suture manipulation.[12–14] The results with incisional procedures have been unsatisfactory and unpredictable, frequently leading to the development of irregular astigmatism.[15–17]

Excimer laser surgery's successful correction of corneal astigmatism[18] soon led to its application in PKP cases.[19] Because of the complications observed after photorefractive keratectomy,[20] laser in situ keratomileusis (LASIK) has been used for the correction of post-PKP astigmatism.[21,22] The hinged lamellar keratotomy performed in LASIK induced biomechanical changes in PKP corneas.[23] Such changes might have a significant

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effect on the predictability of the LASIK outcome. Hence, it seems reasonable to perform LASIK in PKP eyes as a 2-step procedure, first to create the hinged flap and later to perform refractive excimer laser ablation based on the corneal stromal surface after the changes have occurred.

This study investigated the most appropriate method for correcting post-PKP astigmatism: 1-step LASIK or 2-step LASIK.

Patients and Methods

A prospective consecutive observational multicenter study was conducted. Two institutional centers participated using identical excimer lasers and microkeratome technology and following an almost identical investigational protocol. After the ethical committee approved the study protocol, 22 consecutive cases were selected. Eleven eyes were treated at the Instituto Oftalmológico de Alicante, University of Miguel Hernandez, Spain, and the other 11 eyes were treated at Clinica Arila Lull-Fundacion Oftalmológico de Santander, University of Santander, Burcaramanga, Colombia. Selection criteria for inclusion in the study included a follow-up of 12 to 18 months after PKP and a minimum of 3 months after removal of all sutures with stable refractive and corneal topographic patterns for at least 2 consecutive visits within 1 month.

The only difference in the investigational protocol was the LASIK technique used to correct astigmatism. In 1-step LASIK (Group 1), flap creation and ablation were performed in 1 procedure. In 2-step LASIK (Group 2), they were performed in 2 procedures.

Preoperative Examination Protocol

The preoperative examination included uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA) with spectacles and contact lenses (rigid and gas permeable), and pinhole visual acuity to diagnose the presence of irregular astigmatism. The refraction was stable in the 2 months before LASIK treatment as ascertained in 2 consecutive examinations that included manifest and cycloplegic refractions, slitlamp biomicroscopy, measurement of intraocular pressure (IOP), and fundoscopy. Corneal topography (Orbscan® II, Orbtek) and pachymetry (DGH-500) were also performed.

Graft Evaluation

All sutures were removed from the corneal graft at least 3 months before LASIK. The diameter of the corneal button was measured, and signs of wound integrity and neovascularization were evaluated. Cases with fewer than 800 cells/mm^2 in the central cornea by specular microscopy were excluded. Peripheral and central ultrasonic pachymetry at the graft–recipient interface was also carried out to measure 8 to 16 corneal points using the topographic map as a guide, especially at the wound level and at sites where the cornea appeared thinner on slitlamp examination, to avoid perforation of undetected ectasia. Corneas with fewer than 400 μm of corneal thickness at any level of corneal topography were also excluded.

Surgical Procedure

After topical anesthesia (oxibuprocaine 0.4%) was administered, the Hansatome® microkeratome (Bausch & Lomb Surgical) was used to perform the lamellar cut with a flap diameter of 9.5 mm and a superior hinge. The tentative flap thickness was 160 μm. Large-diameter flaps were attempted to avoid interruption of the graft–host junction and to avoid bleeding from neovascularization at the graft–bed interface.

Group 1. In Group 1 (n = 11), surgery was performed by 2 surgeons (V.G., A.T.). After the flap cut was made, the suction ring was released, the flap was lifted using a blunt spatula, and excimer laser ablation was performed using the Technolas® 217C excimer laser (Bausch & Lomb Surgical).

Group 2. In Group 2 (n = 11), the surgery was performed by the same surgeon (J.L.A.). The hinged flap was created as in Group 1. The interface was carefully irrigated and then repositioned. The flap edges were dried for 15 seconds using a continuous surgical air stream at 1.0 L/min flow. One month later, refraction and corneal topography were reevaluated and laser ablation was performed using the Technolas 217C laser.

Postoperative Treatment

In both groups, the postoperative treatment consisted of topical tobramycin 0.3% and dexamethasone 0.1% (TobraDex®) 3 times daily for the first 5 days and then discontinued. Preservative-free artificial tears (sodium hyaluronate 0.18%) were used up to 3 months in each case.

All cases completed a follow-up of 6 months. Examinations were performed at 1 day, 1 week, and 1, 3, and 6 months. Uncorrected visual acuity, BCVA, manifest and cycloplegic refractions, IOP measurement, slitlamp biomicroscopy, and corneal topography were performed at each examination.

Statistical Analysis

Statistical analysis was performed with SPSS/PC + 8.0 for Windows (SPSS Inc.). Statistically significant differences between data sample means were determined by a paired-sample Student *t* test. A *P* value less than 0.05 was considered significant for between-group differences.

Visual data were analyzed statistically by transforming Snellen chart data into logMAR data. Results were expressed as means ± SDs. Vector analysis was used to analyze the

Table 1. Preoperative data.

Patient/Sex/Age (Y)	UCVA (LogMAR)	BSCVA (LogMAR)	Refraction
Group 1			
11/F/40	1.2	0.6	−2.00 −6.00 × 55
12/M/21	0.6	0.3	−1.75 −2.00 × 20
13/M/30	0.9	0.3	−2.25 −2.75 × 45
14/M/30	0.7	0.3	−1.50 −7.00 × 15
15/F/47	1.2	0.4	−5.50 −3.50 × 70
16/F/29	1.2	0.4	−1.00 −6.00 × 165
17/M/41	1.2	0.3	−2.50 −5.00 × 150
18/M/14	1.2	0.3	−1.75 −3.75 × 10
19/M/35	1.2	0.6	+1.50 −4.50 × 100
20/M/27	1.2	0.5	+.50 −7.00 × 10
21/F/51	1.2	0.5	+3.50 −5.00 × 135
Group 2			
1/M/31	1.0	0.5	+1.00 −7.00 × 170
2/F/68	1.2	1.2	−7.50 × 102
3/F/68	0.7	0.4	+1.00 −11.00 × 65
4/M/53	0.5	0.3	+5.00 −6.00 × 110
5/M/66	1.2	0.7	+1.00 −4.00 × 30
6/F/78	1.2	1.0	−5.00 × 90
7/M/44	1.2	0.7	−6.50 −11.00 × 50
8/F/68	1.0	0.4	−1.00 −6.00 × 120
9/M/50	0.7	0.4	+0.50 −5.00 × 90
10/M/50	0.7	0.4	+0.50 −5. 00 × 90

BSCVA = best spectacle-corrected visual acuity; UCVA = uncorrected visual acuity

changes in corneal astigmatism before and after the procedures. The standards for reporting refractive surgical data were followed.[24]

Results

The mean interval between the initial PKP and the LASIK treatment was 7.53 years ± 9.01 (SD) in Group 1 and 5.81 ± 5.17 years in Group 2.

Group 1 (1-Step LASIK)

The preoperative UCVA, BCVA, and refraction are shown in Table 1. The mean preoperative cylinder value was −4.80 ± 1.70 D (range −7.00 to −2.00 D) and the mean spherical equivalent (SE), −3.50 ± 2.20 D (range −7.25 to 1.00 D). At the 6-month follow-up, the mean refractive cylinder was −2.40 ± 2.10 D and the mean SE, −0.60 ± 1.60 D (Table 2).

Safety. The safety index was 1.27. One eye (9.09%) gained 3 lines of BCVA, 3 eyes (27.2%) gained 2 lines, 4 eyes (63.36%) gained 1 line, 1 eye (9.09%) retained the preoperative BCVA, and 2 eyes (18.18%) lost 1 line of preoperative BCVA (Figure 1, *A*).

Efficacy. The efficacy index was 0.72. The mean UCVA (logMAR) was 1.07 ± 0.22 preoperatively and 0.61 ± 0.32 at 6 months. The change was statistically significant ($P = .009$) The mean BCVA (logMAR) was 0.40 ± 0.12 preoperatively and 0.30 ± 0.13 at 6 months ($P = .026$). In 4 eyes (36.36%), the UCVA was 0.4 (20/50) or better (Figure 1, *B*).

Predictability. Eight eyes (72.7%) were within ±1.0 D of the attempted correction (Figure 1, *C* and *D*).

No major complications were reported intraoperatively, and all corneal grafts remained clear. No case of graft rejection was observed during the 6-month follow-up.

Figure 2 shows the topographical changes in 1 patient at 6 months.

Group 2 (2-Step LASIK)

The preoperative UCVA, BCVA, and refraction are shown in Table 1. Preoperatively, the mean cylinder was −6.80 ± 2.50 D (range −11.00 to −4.00 D) and the mean SE, −3.20 ± 3.60 D (range −12.00 to 2.00 D). One month after the lamellar cut, the mean SE was −2.20 ± 2.30 D and 6 months after the ablation, it was −1.10 ± 1.03 D.

One month after the lamellar cut, the mean refractive cylinder was −2.80 ± 1.90 D. The reduction induced in the cylinder by the lamellar cut was statistically significant ($P<.001$). Six months after the ablation, the cylinder was −2.30 ± 1.50 D, a statistically significant difference ($P<.001$) (Table 2).

Vector analysis showed that after the lamellar cut (ie, the first stage), 1 case (10%) achieved a refractive cylinder correction of 1.0 D; 4 cases (40%), a correction of 2.0 D; 3 cases (30%), a correction of 3.0 D; and 1 case (10%) each, a correction of 4.0 D and 5.0 D.

In 1 eye, the ablation procedure was canceled because of marked improvement from the lamellar cut

Table 2. Postoperative data.

Patient	Refraction 1 Mo Post Cut	Final		Refraction at 6 Mo
		UCVA (LogMAR)	BSCVA (LogMAR)	
Group 1				
11	—	0.5	0.3	+2.50 −3.50 × 60
12	—	0.6	0.2	+2.50 −2.50 × 50
13	—	1.0	0.3	−1.75 −1.50 × 50
14	—	1.0	0.4	+1.00 −5.00 × 180
15	—	0.4	0.2	−0.50 −0.5 × 180
16	—	0.4	0.3	+0.75 −1.50 × 160
17	—	0.2	0.1	+0.50 −0.50 × 160
18	—	0.2	0.2	+0.50 −0.75 × 10
19	—	0.5	0.4	+0.75 0.00 × 180
20	—	1.0	0.4	−1.00 −6.00 × 20
21	—	1.0	0.6	+1.25 −4.50 × 135
Group 2				
1	+1.00 −5.00 × 170	0.4	0.2	0.0 −1.75 × 160
2	0.0 −4.50 × 102	1.0	0.9	0.0 −4.25 × 103
3	+2.00 −6.00 × 63	0.4	0.3	+2.00 −5.50 × 63
4	+2.00 +3.00 × 180	0.2	0.1	−0.50 −0.75 × 110
5	0.00 −3.00 × 30	0.7	0.5	0.0 −1.75 × 55
6	−0.05 −1.00 × 90	0.7	0.4	+1.25 −0.50 × 30
7	−6.00 −9.00 × 50	1.0	0.6	0.00 −2.75 × 50
8	−1.25 −5.00 × 135	0.7	0.3	−1.75 −2.00 × 112
9	0.00 −3.75 × 80	0.5	0.2	0.00 −2.25 × 84
10	0.00 −3.75 × 80	0.5	0.2	0.00 −2.25 × 84

BSCVA = best spectacle-corrected visual acuity; UCVA = uncorrected visual acuity

(Figure 3). The preoperative UCVA (logMAR) in this case was 1.0 and the BCVA (logMAR), 0.4. One month after the lamellar cut, the UCVA was 0.7 and the BCVA, 0.3; at 6 months, the UCVA was 0.7 and the BCVA, 0.4.

After the ablation, vector analysis showed that 5 cases (50%) achieved a correction between 3.0 D and 4.0 D; 4 cases (40%), between 5.0 D and 7.0 D; and 1 case (10%), 8.0 D.

No major intraoperative complications other than bleeding at the neovascularization sites in some cases were observed. The bleeding was stopped mechanically and chemically by pressing a microsponge soaked in phenylephrine 10% at the site. No graft rejection occurred, and all corneal grafts were clear throughout the procedure and follow-up.

Safety. The safety index was 1.56. One eye (10%) gained 6 lines of BCVA, 1 eye (10%) gained 3 lines, 5 eyes (50%) gained 2 lines, and 3 eyes (30%) gained 2 lines (Figure 4, *A*).

Efficacy. The efficacy index was 0.9. The mean UCVA was 0.94 ± 0.26 preoperatively and 0.61 ± 0.26 at 6 months. This was statistically significant ($P = .002$). The mean BCVA was 0.60 ± 0.29 preoperatively and 0.37 ± 0.24 at the last visit ($P < .001$). Three eyes (30%) had a UCVA of 0.4 (20/50) or better (Figure 4, *B*).

Predictability. Eight eyes (80%) were within ±1.0 D of the attempted correction (Figure 4, *C* and *D*).

Between-Group Comparison

The UCVA, BCVA, SE, refractive cylinder, and achieved correction results in Groups 1 and 2 were

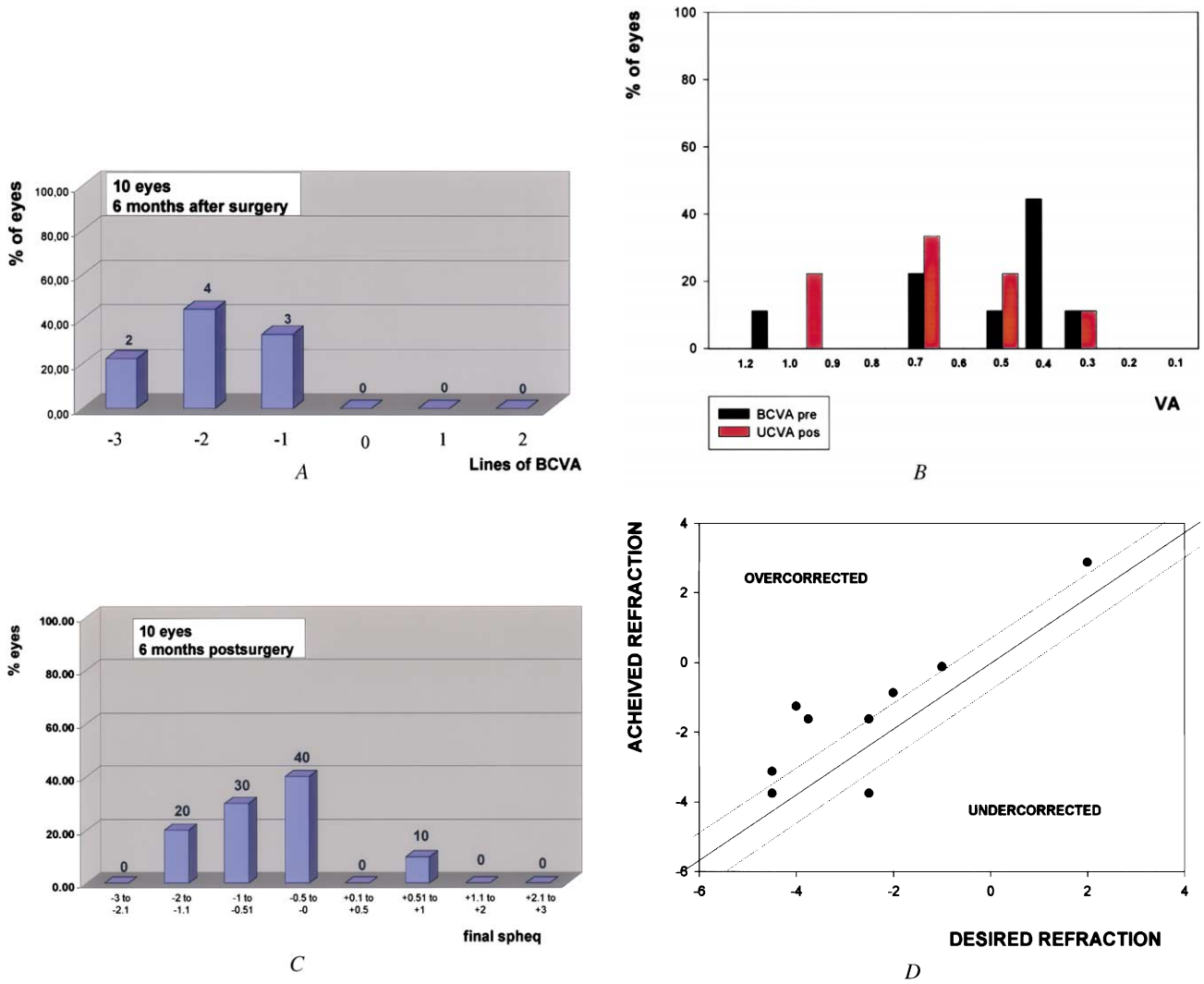

Figure 1. (Alió) *A*: Safety results in Group 1. *B*: Efficacy results in Group 1. *C* and *D*: Predictability results in Group 1.

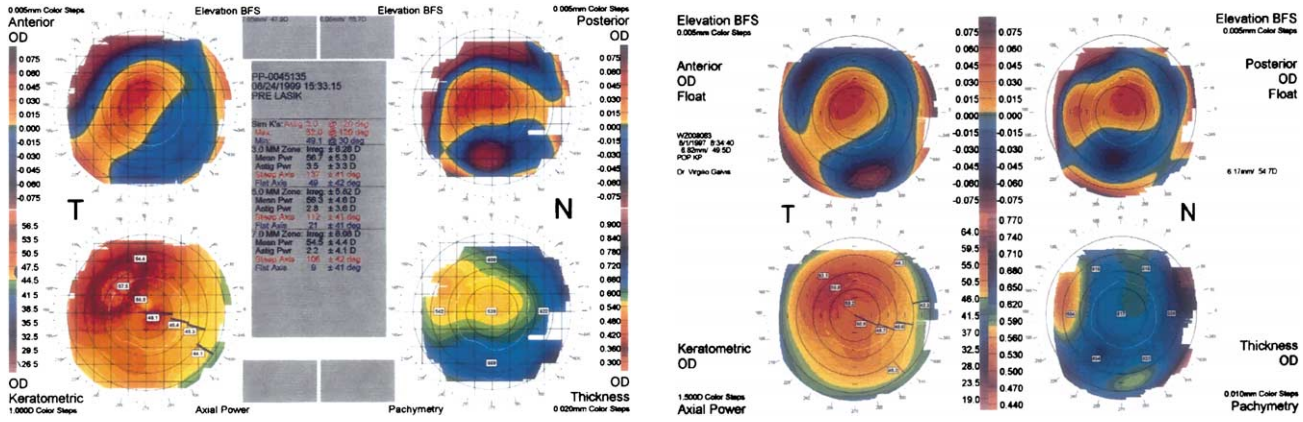

Figure 2. (Alió) *Left*: Preoperative corneal topography of a patient in Group 1. *Right*: Six-month corneal topography of the same patient.

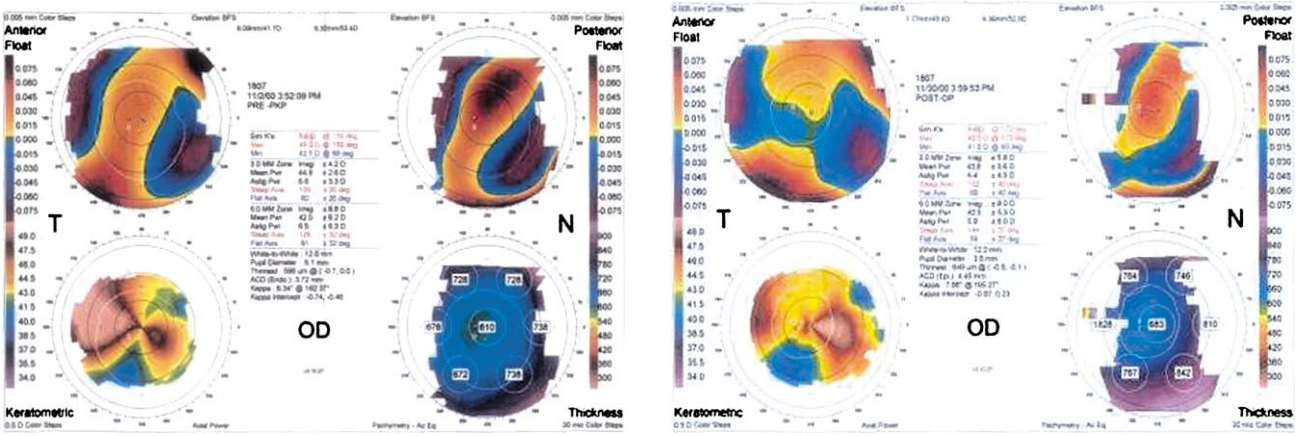

Figure 3. (Alió) *Left*: Preoperative corneal topography of a patient in Group 2. *Right*: Corneal topography 6 months after the lamellar cut in the same patient.

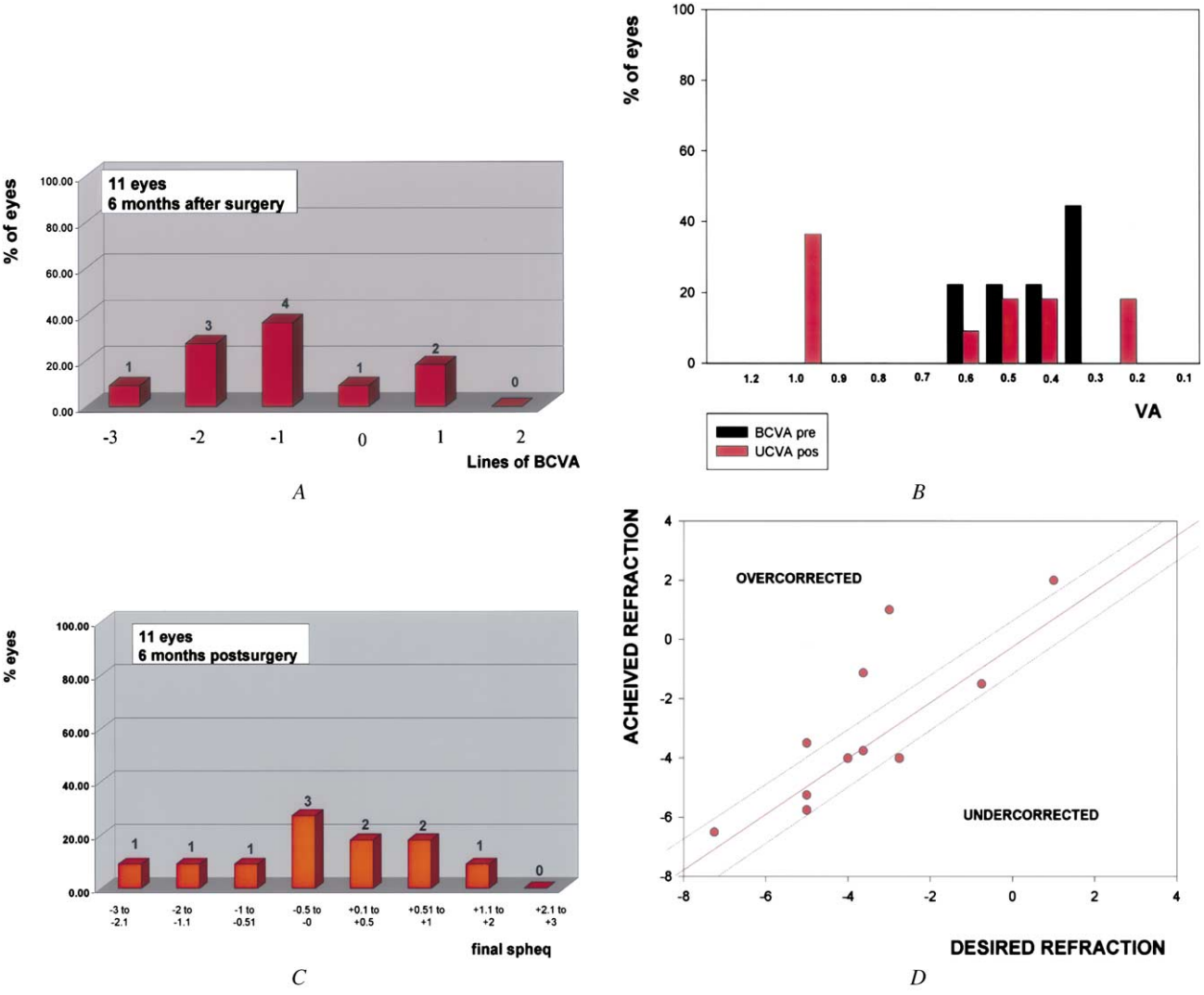

Figure 4. (Alió) *A*: Safety results in Group 2. *B*: Efficacy results in Group 2. *C* and *D*: Predictability results in Group 2.

Table 3. Between-group differences at 6-month follow-up.

Measurement	Group 1	Group 2	Between-Group Difference P Value
UCVA*			
Preoperative	0.09 ± 0.07	0.13 ± 0.09	.253
6 months	0.30 ± 0.20	0.30 ± 0.20	.944
P value	.009	.002	
BCVA*			
Preoperative	0.40 ± 0.10	0.30 ± 0.10	.07
6 months	0.50 ± 0.10	0.50 ± 0.20	.425
P value	.026	.001	
SE			
Preoperative	−3.50 ± 2.20	−3.20 ± 3.60	.806
6 months	−0.60 ± 1.60	−1.00 ± 1.00	.444
P value	.001	.001	
Cylinder			
Preoperative	−4.80 ± 1.70	−6.80 ± 2.50	.04
6 months	−2.40 ± 2.00	−2.40 ± 1.50	.989
P value	.002	.001	
Vector analysis of refractive cylinder	3.02 ± 1.4	4.70 ± 1.80	.024

Means ± SD
BCVA = uncorrected visual acuity; SE = spherical equivalent; UCVA = uncorrected visual acuity
*Snellen values

compared (Table 3). Statistically significant differences were found between the mean preoperative cylinders ($P = .04$) and the mean postoperative vector analysis of the refractive cylindrical change ($P = .024$), with a better cylindrical outcome in Group 2.

Discussion

Astigmatism is a frequent post-PKP finding.[1–6] Photorefractive keratectomy and LASIK have been used to treat PKP-induced refractive errors,[19–21] with LASIK achieving better results.[25,26]

Laser in situ keratomileusis requires the creation of a corneal flap made by a microkeratome lamellar-hinged cut. Lamellar cuts may induce substantial changes in the corneal shape, especially in PKP cases in which meridian and corneal stress caused by irregularities in wound shape and wound healing are present after suture removal. Reports consistently demonstrate substantial changes after flap creation in PKP eyes,[23] with changes of up to 4.0 D of astigmatism in corneal topography after the lamellar cut.

The 2-step approach appears to have an advantage over the 1-step procedure in eyes with PKP astigmatism, increasing the predictability of LASIK. It is important to note that 1 patient in the 2-step group achieved adequate correction with the lamellar cut and did not require laser ablation.

Factors that may influence the outcome of astigmatism treatment by LASIK in PKP cases other than the wound-healing process are the position of the hinge in relation to the location of the visual axis, flap diameter relative to the PKP donor button diameter, and flap thickness.[27,28]

Our results confirmed that the 2-step procedure with LASIK flap creation before ablation leads to a more precise and better refractive outcome in PKP eyes. The main change induced by hinged flap creation was found immediately after the lamellar cut during the first postoperative days. The appropriate time between the lamellar cut and the laser ablation has not been determined. However, this study indicates that a 3-month period, during which 2 successive corneal topographies performed 1 month apart are stable, is sufficient to im-

prove the outcome of LASIK. This is supported by the safety and efficacy indices, which were better in the 2-step group than in the 1-step group.

Although no significant between-group differences in the visual outcome were found, some degree of irregular astigmatism with a subsequent decrease in visual quality could be from ablating the unstable corneal surface in the 1-step LASIK procedure. The level of irregular astigmatism should affect the quality of vision that was evaluated in this study. This finding suggests that advanced, customized corneal ablation for the correction of the irregular part of the astigmatism in PKP eyes performed using 2-step LASIK may improve the visual outcome in eyes with post-PKP astigmatism having LASIK in the near future.

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