Automated lamellar keratoplasty for the correction of hyperopia

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ABSTRACT

Hyperopic automated lamellar keratoplasty (H-ALK) is a refractive procedure that corrects low to moderate hyperopia of up to +5.00 diopters (D). In this retrospective series, we examined the efficacy, predictability, and safety of H-ALK in 85 eyes in 49 patients. Follow-up was from 4 to 34 weeks (mean 18 weeks). Eyes were divided into three subsets: those in which we attempted an emmetropic result (n = 45), those in which we attempted to reduce, but not eliminate, hyperopia greater than 5.00 D (n = 23), and those in which we attempted a monovision result of −1.50 D (n = 17). In the eyes in which we attempted emmetropia, 76% achieved uncorrected visual acuity of 20/40 or better and 78.6% were within a range of −1.00 to +0.87 D. In those in which we attempted monovision, 47% achieved a spherical equivalent result between −2.50 and −1.00 D because of a tendency toward undercorrection. In those in which we attempted to reduce hyperopia, there was a mean correction of 4.33 D (standard deviation 1.36 D), with a range of 2.12 to 6.75 D. The most significant complication was a reduction in best corrected visual acuity of one to three lines in 11 of 85 eyes; this was transient in six eyes. These preliminary results compare favorably with those of other procedures to correct hyperopia.

Key Words: automated lamellar keratoplasty, ectasia, hyperopia surgery, irregular astigmatism, monovision, predictability

Hyperopic automated lamellar keratoplasty (H-ALK) was developed by Luis Antonio Ruiz, M.D., of Bogotá, Columbia. The procedure induces a controlled ectasia of the central cornea (Figure 1) by thinning the cornea, using a 53% to 74% depth lamellar dissection, with an automated microkeratome (corneal shaper, Steinway Instruments, Chiron Vision, Boca Raton, FL). The resulting corneal steepening causes a myopic shift that neutralizes hyperopia of up to +5.00 diopters (D).

Hyperopic automated lamellar keratoplasty is among the refractive procedures for hyperopia that increase central corneal curvature. These procedures work through one of two mechanisms: they bend the native cornea, or they add substance to the cornea or remove tissue from it. Included in the former are keratomileusis,[1] thermokeratoplasty,[2,3] hexagonal keratotomy,[4–6] and other forms of circumferential corneal dissection such as partial thickness trephination.[7] Included in the latter are keratophakia,[8] epikeratophakia,[9] and hyperopic photorefractive keratoplasty (stromal and surface). Hazing of the central cornea,[1,9] irregular astigmatism,[4–6] glare, unstable refractions, and regression have been seen with these procedures.

This retrospective study was undertaken to assess the efficacy, safety, and predictability of H-ALK. We report the results of the procedure and the complications encountered and suggest some modifications.

SUBJECTS AND METHODS

Eighty-five eyes in 49 patients that had H-ALK were retrospectively studied. The cohort represents a consecutive series of eyes, operated on by a single surgeon (G.M.K.) under similar conditions at one institution (SurgiVision, Atlanta, GA). Surgery was performed between May 1, 1993, and December 31, 1993.

All patients were evaluated preoperatively with cycloplegic refractions, slitlamp biomicroscopy, direct

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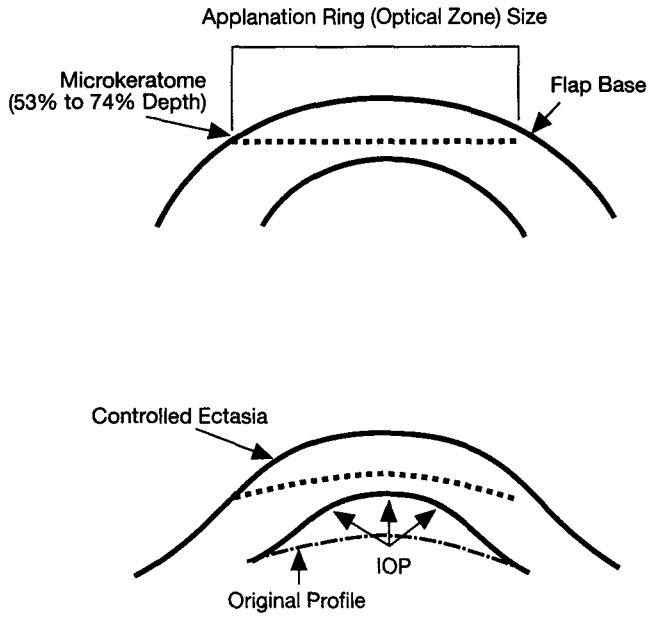

Fig. 1. (Kezirian) Mechanism of action of H-ALK. No tissue is added or removed and no sutures are used to hold the flap in place.

and indirect ophthalmoscopy, applanation tonometry, and computerized corneal topography. Eyes with surface keratitis, evidence of compromised endothelial function, cataracts, retinal disease, ocular hypertension, or other conditions that might threaten a successful outcome were excluded.

All patients were symptomatic for hyperopia or, in the case of those seeking a monovision correction, for presbyopia. They were offered alternative treatments for their hyperopia or presbyopia, such as spectacle correction. All patients were informed of the investigational nature of the procedure and were presented with an appropriate informed consent acknowledging their awareness of potential complications.

Surgical planning of applanation ring size was done using the Ruiz nomogram for hyperopia (Table 1). Forty-five eyes were targeted for plano results, using the spherical equivalent to determine the amount of correction. Seventeen eyes were targeted for −1.50 D, a monovision correction, as detailed under the Results section. Only patients who were successful wearers of monovision contact lenses were offered this option. Twenty-three eyes were targeted for a 5.00 D reduction of hyperopia greater than 5.00 D. Simultaneous astigmatism correction was planned in eyes with more than 1.00 D of preoperative astigmatism. In these eyes, arcuate keratotomy was performed using the Casebeer nomogram.

Surgery was performed as follows: Patients were given diazepam 20 mg, by mouth, and one drop of pilocarpine 4% to the operative eye one hour before surgery. Topical anesthesia of lidocaine 2% mixed 1:1 with bupivacaine 0.5% was administered four times at 15 minute intervals, and the patients were brought into the procedure room. A gentle lid prep using povidone–iodine swabs was performed; no ocular irrigation was performed. Surgeon and assistant were scrubbed, masked, and gloved in a sterile manner. The microtome head, plates, and motor portions of the ALK unit were cleaned with alcohol. (The manufacturer recommends against autoclaving the unit.)

Lids were draped with a 1035 drape, capturing the lashes under the drape, and a Barraquer wire lid speculum was placed. Pachymetry was performed 1.5 mm temporal to the central corneal reflex using a Sonogauge ultrasonic pachymeter, and plate selection was made using the Ruiz nomogram. The cornea was

Table 1. The Ruiz nomogram for H-ALK. Higher levels of correction are achieved by using a deeper dissection of a smaller diameter (optical zone). The maximal depth used is 74% of corneal thickness.

		Temporal–Paracentral Corneal Thickness									
Diopters (SE)	Dissection Diameter (OZ)	490–525 μm (Mean: 507 μm)		526–550 μm (Mean: 538 μm)		551–575 μm (Mean: 563 μm)		576–600 μm (Mean: 588 μm)		>600 μm	
		Micron	% Depth	Micron	% Depth	Micron	% Depth	Micron	% Depth	Micron	% Depth
1.0	6.6	300	59	300	56	300	53	325	55	325	<54
1.5	6.5	300	59	300	56	325	58	325	55	350	<58
2.0	6.4	300	59	325	60	350	62	375	64	400	<67
2.5	6.3	300	59	325	60	350	62	375	64	400	<67
3.0	6.2	300	59	325	60	350	62	375	64	400	<67
3.5	6.1	300	59	325	60	350	62	375	64	400	<67
4.0	6.0	300	59	325	60	350	62	375	64	400	<67
4.5	5.8	350	69	375	70	375	67	400	68	400	<67
5.0	5.6	375	74	375	70	400	71	400	68	400	<67

SE = spherical equivalent; OZ = optical zone

marked using the ALK marker (Chiron Vision). The constricted pupil was used for centration.

The suction ring was placed, and intraocular pressure (IOP) was checked to confirm pressure of 65 mm Hg or greater. The appropriate applanation ring was applied. Ring height was adjusted to match corneal apposition to the applanation ring meniscus. The applanation ring was removed, and the microkeratome was introduced into the track. Balanced saline solution was used to wet the corneal surface. The microtome was driven across the cornea from the temporal to the nasal side and manually stopped approximately 0.5 mm short of the nasal edge of the flap. The instrument was removed, suction broken, and the rings removed. The diameter of the dissection achieved was measured using a caliper, under the microscope, and compared with the diameter attempted. Intraoperative pachymetric measurement of the depth of dissection was not performed. If astigmatism correction was done, it was performed at this point in the operation.

The operative field was irrigated with balanced saline solution, including the stromal bed under the flap. Excess fluid was expressed from the interface using a dampened Merocel sponge (Merocel Corporation, Mystic, CT), and compressed air was used to lightly dry the surface. Flap adhesion was checked by moving the lids over the cornea. Then, one drop of ciprofloxacin 0.3% was instilled and a Fox shield was placed over the eye.

Patients were instructed to keep both eyes closed, except during ambulation. The operative eye was not patched. They were given ketorolac tromethamine (Toradol®) 10 mg by mouth every six hours for discomfort and triazolam (Halcion®) 0.25 mg for sleep. They were requested to wear the Fox shield to bed, to refrain from swimming, and not to use makeup for two weeks.

Patients were seen postoperatively at one day, one week, one month, three months, and six months. On each visit, visual acuity, manifest refraction, corneal topography, and slitlamp examination were performed. Patients who did not complete their follow-up were included in analysis for the visits for which they did come in. Data from eyes that had subsequent procedures were included up to the point of the second procedure.

RESULTS

A total of 85 eyes in 49 patients were studied. Forty three of the eyes were from female patients, 42 from male patients. The average age was 47 years (range 28 to 64 years; standard deviation 9 years). Follow-up ranged from 4 to 34 weeks; the mean follow-up was 18 weeks, with a standard deviation of 12 weeks. All eyes completed the one day and the one month examinations. Fifty-five eyes completed the one week examination, 65 completed the three month examination, and 46 completed an examination six to eight months following the procedure.

The mean preoperative spherical equivalent of the 45 eyes targeted for emmetropia was +2.70 D (range +1.37 D to +5.00 D; standard deviation 1.10 D). The postoperative value was +0.20 D (range −1.25 D to +2.50 D; standard deviation 0.90 D) ($P < .0001$). In all eyes, hyperopia was reduced. The one day refractions were typically 0.50 to 1.00 D more myopic than the one, three, and six month refractions. Patients reported stabilization of vision by the one month visit.

The visual acuity results in these eyes are presented in Table 2. Preoperatively, 21% had a visual acuity of 20/40 or better without correction; postoperatively, 76% did ($P < .001$). Uncorrected visual acuity improved in all eyes.

In all 85 eyes, there was a statistically insignificant effect ($P = 0.42$) on best corrected acuity at the one month visit. Eleven of the eyes decreased one line or more; two eyes decreased three lines. Six of these eyes improved to the preoperative level by the six month visit, two remained the same, and three were lost to follow-up. Corneal topography sometimes demonstrated smoothing to coincide with this improvement.

Table 2. Visual acuity results in the 45 eyes targeted for emmetropia; 76% achieved uncorrected distance acuity of 20/40 or better.

Mean Preoperative SE (Diopters)	Number of Eyes	Visual Acuity							
		20/20–20/25		20/30–20/40		20/50–20/80		20/100 or Worse	
		Number	%	Number	%	Number	%	Number	%
1.00 to 2.00	16	6	38	8	50	2	13	0	0
2.12 to 3.00	16	4	25	6	38	5	31	1	6
3.12 to 4.00	5	2	40	2	40	1	20	0	0
4.12 to 5.00	8	1	13	5	63	1	13	1	13
All eyes: 2.70	45	13	29	21	47	9	20	2	4

SE = spherical equivalent

Table 3. Postoperative spherical equivalents (SE) of the 45 eyes targeted for emmetropia, stratified by preoperative SE. Eyes with less preoperative hyperopia were less likely to undercorrect.

Mean Preoperative SE (Diopters)	Number of Eyes	Mean Postoperative SE (Diopters)	Standard Deviation	Postoperative SE							
				−2.00 to −1.12		−1.00 to −0.12		Plano to +0.87		+1.00 to +2.50	
				n	%	n	%	n	%	n	%
1.00 to 2.00	16	0.01	0.67	1	6.3	6	37.5	8	50.0	1	6.3
2.12 to 3.00	16	0.05	0.83	1	6.3	6	37.5	7	43.8	2	12.5
3.12 to 4.00	5	0.88	0.99	0	0.0	0	0	4	80.0	1	20.0
4.12 to 5.00	8	1.15	1.19	1	12.5	0	0	3	37.5	4	50.0
All eyes: 2.70 (SD 1.24)	45	0.20	0.09	3	6.7	12	26.7	22	48.9	8	17.8

In 15 eyes, the best corrected acuity improved from one to three lines at the one month visit.

Twenty-five eyes had more than 1.00 D of preoperative astigmatism, and these eyes had simultaneous astigmatism correction with the H-ALK procedure. The average preoperative astigmatism in these eyes was 2.71 D (range 0 to 5.00 D; standard deviation 1.44 D), the average postoperative astigmatism, 1.14 D (range 0 to 2.50 D; standard deviation 0.97 D). None of these eyes was overcorrected for their astigmatism. Fifteen eyes (60%) corrected to less than 1.00 D of remaining astigmatism and required no further surgery. The remaining 10 eyes had between 1.00 D and 5.00 D of astigmatism and required a subsequent procedure to correct residual astigmatism. In four eyes, no measurable astigmatism correction was achieved, despite the placement of arcuate incisions.

Sixty eyes did not have more than 1.00 D of astigmatism preoperatively, and therefore did not have simultaneous astigmatism correction. In these eyes, there was a slight tendency to induce a change in astigmatism in the against-the-rule orientation; that is, to add plus cylinder within 30 degrees of axis 180 or reduce plus cylinder within 30 degrees of axis 90. Changes in astigmatism were calculated by subtracting the preoperative from the postoperative values. In eyes in which the new astigmatism axis was not exactly on the pre-existing axis, or 90 degrees from it, simple vector analysis was used to quantify the change.

Overall, in these 60 eyes (that had H-ALK without astigmatism correction and that had less than 1.00 D of pre-existing astigmatism at any axis), the mean change in astigmatism was 0.27 D, standard deviation 0.72 D, with an overall reduction of astigmatism with the rule or, alternatively, an overall increase in astigmatism against the rule. There were three subsets within this group: those that followed this tendency, those that did not change in their cylinder, and those that went against this tendency. In the first subset (32 eyes), against-the-rule cylinder increased or with-the-rule cylinder decreased (range of cylinder change 0.25 D to 2.00 D). In the second subset (9 eyes), the cylinder remained unchanged. In the third subset (19 eyes), against-the-rule cylinder decreased or with-the-rule cylinder increased (range of astigmatism change 0.25 D to 1.00 D).

Table 3 presents the preoperative refractions in the 45 eyes targeted for emmetropia, against the amount of correction achieved, and shows a significant tendency toward undercorrection in the higher ranges. There was a wide scatter of results in eyes with more than 5.00 D of hyperopia (Figure 2), in which a reduction of hyperopia of 5.00 D was attempted. In these eyes, the mean correction was 4.33 D (range 2.12 D to 6.75 D; standard deviation 1.36 D).

The results in monovision eyes show a similar trend of undercorrection (Table 4). The average amount of correction attempted in these eyes was 3.42 D; the average obtained was 2.59 D, with a standard deviation of 0.85 D. The range of attempted correction was 1.50 to 5.00 D; the range achieved was 1.13 to 3.88 D, reflecting the trend toward undercorrection in the higher ranges. While these eyes were targeted for 1.50 D of myopia, functional success was achieved with any result between −1.00 D and −3.00 D, which was obtained in 47% of eyes.

The intraoperative measurement of the diameter of dissection achieved was within 0.1 mm of attempted diameter in all eyes. Complications included delayed

Table 4. Results in the 17 eyes targeted for monovision eyes. Targeted spherical equivalent was −1.50 D, with functional success between −1.00 D and −2.50 D. Note tendency for undercorrection.

Range (Diopters)	Number of Eyes	Percentage
−2.50 to −1.00	8	47
−0.88 to plano	7	41
> +0.12	2	12

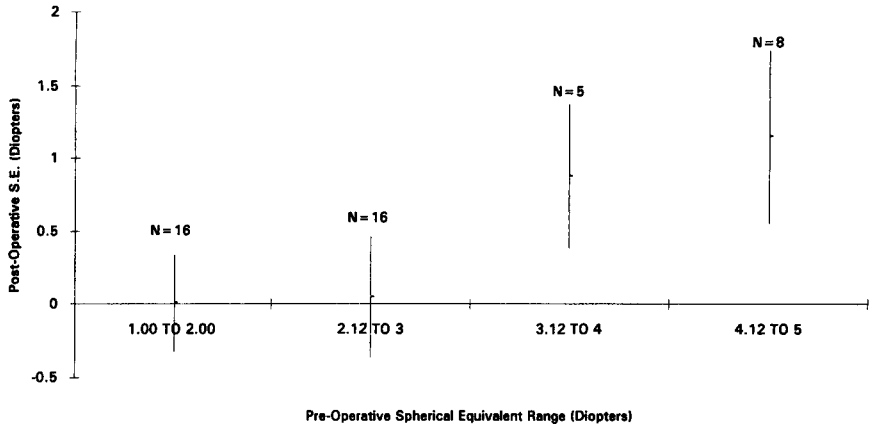

Fig. 2. (Kezirian) Postoperative versus preoperative mean spherical equivalents, plotted with 1 standard deviation, for 45 eyes targeted for emmetropia. Note the increased tendency for undercorrection and increased scatter, with higher levels of preoperative hyperopia.

epithelialization in two eyes, with eventual healing and full recovery. Interface debris was present in almost all eyes to some extent, although it was not deemed enough to cause symptoms in any. Most patients with over 3.00 D of correction complained of nighttime glare when driving. This generally improved between the one and six month visits, by history. Glare complaints were not objectively quantified. Diurnal fluctuation was not reported after the first month. Initial irregular astigmatism (astigmatism associated with asymmetric topography and with decreased best corrected visual acuity of one line or more) improved between one and six months. However, insufficient data were recorded to quantify this observation further. There were no dislocated caps or infections in this series.

DISCUSSION

This preliminary report presents the results of H-ALK in a retrospective consecutive series of 85 eyes. It shows that H-ALK is effective in the treatment of low to moderate hyperopia, although concerns about long-term stability, predictability, and irregular astigmatism remain.

Hyperopic ALK makes a deep, lamellar dissection in the cornea, which permits the posterior lamellae to bow forward under the IOP of the eye. The ectasia produced is immediate and visibly apparent at the time of surgery. In this study, the ectasia was stable, with no observed tendency for myopic progression beyond the original correction. The amount of correction achieved is determined by the cut's diameter and depth. Ruiz's nomogram (Table 1) calls for a depth between 54% and 74% of thinnest pachymetry, increasing the amount of correction by decreasing the diameter of the applanation ring (optical zone) and increasing the depth of the dissection.

In this series, 76% of the 45 eyes targeted for emmetropia achieved uncorrected visual acuities of 20/40 or better. Spherical equivalents correlated well with these results, with 78.6% of eyes falling in the range of −1.00 to +0.87 D. In eyes targeted for a −1.50 D (monovision) correction, only 47% achieved a successful result of a spherical equivalent between −2.50 and −1.00 D, with a majority of eyes undercorrected. In both these groups, the eyes in which we attempted more correction were the ones most likely to be undercorrected. However, these data must be interpreted with one limitation in mind: They compare preoperative cycloplegic refractions with postoperative manifest refractions. In future studies, to understand the refractive effects better, cycloplegic refractions should be done on all postoperative examinations.

These data compare favorably to the results of other procedures for hyperopia. With hexagonal keratotomy, Casebeer and Phillips[6] achieved a spherical equivalent result between −1.00 and +0.50 D in 52.2% of cases. In our series we achieved this result in 78.6% of eyes with similar preoperative refractions. With thermokeratoplasty, Neumann[10] reports a 60% rate of correction within 1.00 D of emmetropia at 2 months postoperatively; this fell to 17% by 9 to 12 months.

Beyond demonstrating the predictability and efficacy of H-ALK, this series illustrates some strengths and weaknesses of the Ruiz nomogram. Table 3 and Figure 2 describe good predictability and little scatter of results in corrections up to 3.00 D, with increased tendency toward undercorrection and increased scatter with corrections beyond this range. Thus, in a 2.50 D hyperope, the surgeon can be confident that surgery will bring the patient to a +1.00 to −1.00 D correction of emmetropia, within one standard deviation, or approximately two thirds of the time. On the other hand, in an attempted 5.00 D correction, the average eye will remain approximately 1.50 D hyperopic, with a 1.50 D standard deviation, using the Ruiz nomogram.

It would be desirable to increase the amount of correction in higher levels of hyperopia. Table 1 shows that Ruiz already calls for a depth of up to 74% in the correction of a 5.00 hyperope, which limits the available options. In our practice, we limit H-ALK to eyes with less than 4.00 D of desired correction, which

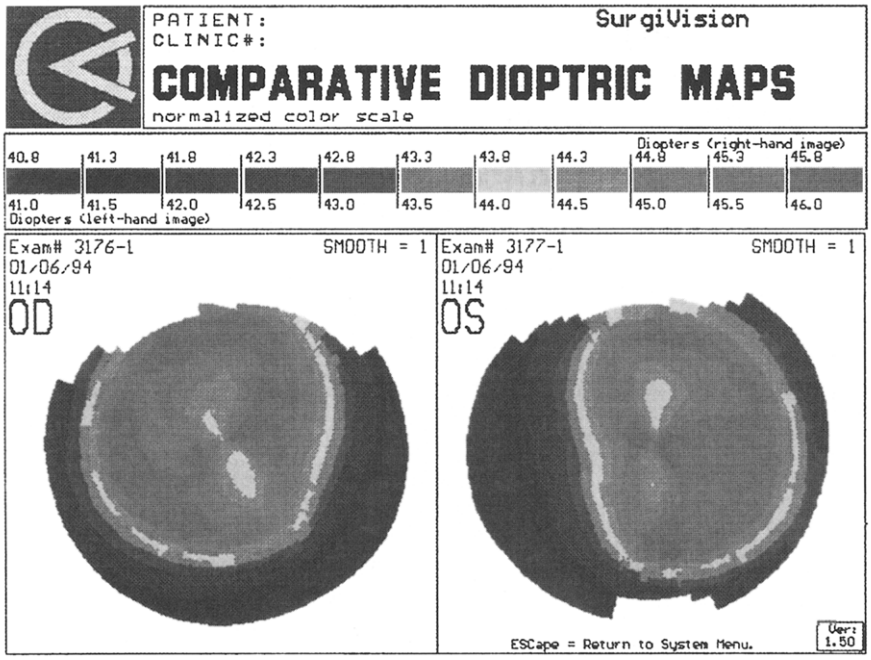

Fig. 3. (Kezirian) Corneal topography of a patient who had bilateral H-ALK. In the left eye, too large a flap base (hinge) was made because the dissection did not proceed far enough in the nasal direction. This led to a nasal squaring of the ectasia, which was noticed by the patient as glare and distortion. Note the well-defined central ectasia in both eyes.

has resulted in a more satisfied patient population overall. Monovision eyes, in which over 3.00 D of correction is desired, are now targeted for −2.50 D spherical equivalent, instead of −1.50 D as reported in this series, to compensate for the tendency of these eyes to be undercorrected. If less than 3.00 D correction is desired, the eyes are targeted for −2.00 D final refraction.

It would also be desirable to decrease the scatter of results. The issue of second or enhancement procedures for these eyes remains unsettled. We are currently performing a series of enhancements on undercorrected eyes by making a second, deeper pass with the microkeratome at an optical zone size 0.2 mm larger than the original. This presents the potential complication of layer separation during surgery, which would be difficult to correct. The risks of uncontrolled ectasia and irregular astigmatism are also of concern. In eyes that correct into the myopic range, radial keratotomy can reportedly be performed,[11] although the long-term stability of RK over H-ALK has yet to be established.

These eyes are among the first in North America to have H-ALK using a flap technique, leaving the cap attached by a hinge located in the nasal quadrant.[12] Two observations regarding the use of a flap in this procedure may be helpful to other surgeons. First, no caps dislocated postoperatively. However, this successful rate of cap adhesion may be more related to preoperative screening of patients than to use of the flap. All patients were examined clinically for evidence of epitheliopathy, especially from dry eyes, and for evidence of compromised endothelial function, such as guttata. Patients with these findings were disqualified for surgery. In two subsequent eyes, cap dislocations occurred, despite the presence of the hinged flap. These eyes had had previous intraocular surgery and both had polymorphism and polymegathism on preoperative examinations of the endothelium. During surgery, both experienced epithelial loss, thought to be related to the subsequent development of stromal edema, and cap dislocation. The use of a flap does not guarantee against dislocation, and extra caution should be exercised when performing H-ALK in eyes that have had previous surgery.

Second, too large a flap base (hinge) can lead to a nasal squaring of the ectasia, which can be noticed by the patient as glare and distortion (Figure 3) and appears to induce against-the-rule astigmatism. Should this occur, the dissection can be extended by hand, using a #65 Beaver blade or a Suarez spreader. In this series, the ideal size of the hinge was 30 arc degrees of the dissection.

Glare was subjectively reported to be associated with higher amounts of correction and usually became less bothersome with time, usually four to eight weeks. However, since this study did not quantitate glare complaints, the extent of glare cannot be ascertained. Future studies may provide further information about this complaint and should measure glare quantitatively.

Finally, the issue of simultaneous astigmatism correction remains unresolved. In this series, 10 of the 25 eyes (40%) that had simultaneous astigmatism correction were undercorrected for astigmatism. None were overcorrected. There was no noted effect on the hyperopic correction caused by performing astigmatism correction. Many hyperopic eyes have significant coexisting astigmatism, and reducing, if not eliminating, that astigmatism can greatly improve the visual results

of surgery. The astigmatism correction is performed at the same setting as the H-ALK, but after the suction rings are removed from the eye and IOP normalized. One possible reason for the astigmatic undercorrections was the use of paracentral pachymetry for setting the knife, since on re-operation many of these eyes were observed to have peripheral pachymetries more than 150 μm thicker than the paracentral readings used in setting the blade in the initial procedure. A study is now underway to determine the efficacy of using peripheral pachymetry to determine knife setting during the primary correction. While simultaneous astigmatism correction may have benefitted some eyes in this series, predictability was not adequate to recommend this practice to all surgeons.

This study was limited by its retrospective design and because it was performed when the technique was just being introduced into the United States (May to December 1993). Therefore, some of the techniques introduced later, such as the use of intraoperative pachymetry to measure the depth of dissection, were not used. Because glare was not clinically measured, it could not be compared against glare encountered with other techniques. Follow-up was variable and would be expected to be better with a prospective study. These considerations might be applied in the design of future investigations of the procedure.

Hyperopic ALK shows much promise in the correction of low to moderate hyperopia. With the equipment modifications that have been made since this series was performed, such as the stop to assist in flap creation, the procedure has become easier to perform. Long-term stability and improvements in predictability remain to be established.

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