Hyperopic Automated Lamellar Keratoplasty

Complications and Visual Results

W. Andrew Lyle, MD; George J. C. Jin, MD

Objective: To examine the long-term safety and efficacy of hyperopic automated lamellar keratoplasty (H-ALK) for correction of primary hyperopia and for consecutive hyperopia following overcorrected myopic refractive surgery.

Methods: A prospective study was done on 67 eyes of 50 consecutive patients who underwent H-ALK between March 17, 1993, and August 18, 1995. Hyperopic automated lamellar keratoplasty was performed for primary hyperopia in 25 eyes (group 1) and for consecutive hyperopia after myopic refractive surgery in 42 eyes (group 2, radial keratotomy, 41 eyes, and myopic automated lamellar keratoplasty, 1 eye). The eyes were followed up for a mean±SD of 19.2±12.8 months (range, 3-49 months), 58 (87%) of them with 6 months’ follow-up, and 45 (67%) of them with at least 1 year’s follow-up. Twenty-one eyes were followed up for 2 to 4 years.

Results: The overall mean±SD preoperative spherical equivalent was +2.87±1.28 diopters (D). The mean±SD postoperative spherical equivalent was −0.03±1.42 D at 3 months, −0.42±2.25 D at 6 months, −0.55±3.00 D at 1 year, −1.58±1.53 D at 2 years, and −0.35±1.79 D at the last follow-up. A mean myopic shift of 0.50 D was noted between 3 months and 1 year, and of 1.00 D between 1 and 2 years. Hyperopia was meaningfully reduced and visual acuity was improved by H-ALK, especially for patients with primary hyperopia. Long-term refractive instability, however, is a serious problem with this procedure. In this series, 11 (26%) of 42 eyes in which H-ALK was performed for consecutive hyperopia developed iatrogenic keratoconus.

Conclusion: Based on this study, the long-term instability of H-ALK and the high incidence of iatrogenic keratoconus following the procedure should discourage its use, especially for consecutive hyperopia following radial keratotomy.


From The Eye Institute of Utah, Salt Lake City.
PATIENTS AND METHODS

Sixty-seven eyes of 50 patients were treated between March 17, 1993, and August 18, 1995. The age of the patients ranged from 26 to 61 years (mean, 43.6 years). Thirty-one men and 19 women participated in the study. Seventeen patients had bilateral surgery. Hyperopic automated lamellar keratoplasty was performed for primary hyperopia in 25 eyes (group 1) and for consecutive hyperopia after myopic refractive surgery in 42 eyes (group 2, radial keratotomy [RK], or laser in situ keratomileusis) 3 months after H-ALK.

SURGICAL PROCEDURE

All surgical procedures were performed with an automated corneal shaper (Steinway Instruments, Chiron Vision, Boca Raton, Fla) using the Ruiz nomogram for hyperopia. Preoperative sedation with diazepam, the patients were given anesthesia with topical proparacaine hydrochloride (Alcaine). The eye was prepared and draped, and a speculum was placed. The center of the entrance pupil was marked with a small, blunt hook and the temporal cornea was marked with a 2-circle marker. The central corneal thickness was measured with ultrasonic pachymetry. The suction ring was then centered on the cornea and the intraocular pressure verified with an applanation tonometer. The Ruiz nomogram was used to select an appropriate plate, which ranged from 300 to 425 µm. The microkeratome then was introduced into the track and driven across the cornea leaving the nasal edge hinged. The suction ring and microkeratome were removed from the eye, and the flap was left in place untouched. The gutter around the flap was dried using a Merocel sponge (Merocel Corp, Mystic, Conn) until the flap was seen to be firmly adhered, then the flap adhesion was checked. Topical antibiotic was instilled, half-inch Steri-Strips (3M Medical-Surgical Division, St Paul, Minn) were applied to close the lids, and an eye shield was placed. On the first postoperative day, the Steri-Strips were removed and the patient was instructed to begin treatment with a combination of dexamethasone, neomycin sulfate, and polymyxin B sulfate (Maxitrol) 4 times daily for 1 week. The hinged-flap technique as described earlier was used for 34 eyes. In 13 eyes, the surgery was performed with the nonhinged-cap technique, which has been described in detail elsewhere.1

PREOPERATIVE AND POSTOPERATIVE EVALUATION

Preoperatively, each patient underwent a complete ophthalmologic examination that included uncorrected and spectacle-corrected visual acuity, manifest and cycloplegic refraction, keratometry, corneal topography, slitlamp microscopy, and fundus examination. Patients were seen postoperatively at 1 day, 1 week, 1, 3, and 6 months, 1 year, and then yearly. At each postoperative visit, an uncorrected and a corrected visual acuity, a manifest refraction, keratometry, corneal topography, slitlamp microscopy were performed. Last follow-up data, as well as data at each follow-up, were used for analysis and the SPSS 6.1 program for Windows (SPSS Inc, Chicago, Ill) was used for data entry and analysis.

at 6 months, −0.55 D ± 3.00 D at 1 year, −1.58 ± 1.53 D at 2 years, and −0.35 ± 1.79 D at the last follow-up visit. A mean myopic shift of 0.50 D was noted between 3 months and 1 year, and of 1.00 D between 1 and 2 years after surgery. The percentage of eyes within ±1.00 D of emmetropia was 65% at 3 months, 64% at 6 months, 58% at 1 year, 47% at 2 years, and 67% at the last follow-up visit.

In the eyes in which H-ALK was done for primary hyperopia (group 1), the mean±SD preoperative SE was +3.20±1.23 D compared with a postoperative SE of +0.46±1.00 D at 3 months, +0.39 D ± 1.03 D at 1 year, and +0.27±1.07 D at the last follow-up. Seventy-eight percent had an SE within ±1.00 D of emmetropia at 3 months, 88% at 6 months, 76% at 1 year, and 84% at the last examination. The mean±SD refractive astigmatism was 0.94±0.99 D preoperatively and 0.94±0.83 D at 3 months, 1.16±1.09 D at 6 months, 1.07±1.00 D at 1 year, and 1.11 D±1.00 D at last follow-up. There was no significant difference in refractive astigmatism between the preoperative and postoperative examinations (P > .09).

In those patients who underwent H-ALK for consecutive hyperopia after RK or myopic automated lamellar keratoplasty (group 2), the mean±SD preoperative SE was +2.68±1.28D and the postoperative SE was −0.39±1.57 D at 3 months, −1.13±3.63 D at 1 year, −1.42±3.09 D at 2 years, and −0.71±2.03 D at the final follow-up (Figure 1). The percentage of eyes within ±1.00 D of emmetropia was 55% at 3 months, 48% at 6 months, 46% at 1 year, 38% at 2 years, and 56% at the last follow-up. The mean±SD preoperative refractive astigmatism was 1.28±1.15 D, and postoperatively it was 1.88±1.52 D at 3 months with 29% more than 2.00 D; 2.12±0.97 D at 6 months with 41% more than 2.00 D; 1.88±1.73 D at 1 year with 32% more than 2.00 D; and 2.55±1.96 D at 2 years with 50% more than 2.00 D. At the last follow-up, refractive astigmatism was 1.57±1.40 D with more than 26% over 2.00 D. A significant difference was noted between refractive astigmatism preoperatively and at both 3 months and 6 months postoperatively (P < .01).

STABILITY OF REFRACTION

There was a trend toward myopia after H-ALK surgery, especially in the eyes that had had previous RK. In group 2, the mean myopic shift was 0.74 D between 3 months and 1 year and 1.03 D between 3 months and 2 years. In group 1, there was a 0.07 D myopic change between 3 months and 1 year (Figure 1). The variability in refraction was larger in group 2. At 1 year the SD was 3.63 D in group 2 compared with 1.03 D in group 1.
VISUAL ACUITY

Overall, uncorrected visual acuity was 20/40 or better in 46 (69%) of 67 eyes at the last follow-up (84% and 61% in group 1 and group 2, respectively). At the last visit, 20 (80%) of 25 eyes in group 1 had a spectacle-corrected visual acuity that was unchanged or improved from baseline, and 1 (4%) of 25 eyes lost 2 lines of best-corrected visual acuity (BCVA). In group 2, 26 (62%) of 42 eyes had unchanged BCVA and 3 (7%) of 42 eyes lost 2 or more lines (2-5 lines) (Figure 2).

COMPLICATIONS

A high incidence of an unexpected condition was noted among our cases of H-ALK following previous RK. Iatrogenic keratoconus occurred in 11 eyes 3 to 25 months postoperatively. These eyes displayed a progressive myopic shift with no trend toward stabilization, and demonstrated inferior steepening on corneal topography. Mean±SD surface regularity index (SRI) and surface asymmetry index (SAI) increased from 1.08±1.07 and 0.80±0.26 before surgery to 1.53±0.93 (P=.38) and 1.72±0.49 (P=.005), respectively, at the examination after their laser in situ keratomileusis procedure and prior to penetrating keratoplasty (PKP) (Figure 3). Mean±SD simulated keratometry (Sim K) measurements increased from 35.7±3.01 D to 44.43±3.73 D (P<.001). A mean increase of myopia of 3.00 D was observed in these eyes between 3 months and 2 years after surgery. Ten eyes in this series required PKP and 1 eye was on the waiting list for PKP. All of the 11 eyes except 1 had lost 2 to 9 lines of BCVA before PKP; the 1 eye had lost 1 line.

Other complications included epithelial ingrowth requiring removal in 2 eyes, and folds in the corneal cap in 2 eyes. One patient experienced loss of the corneal cap 6 months after surgery due to trauma. This required a homoplastic lamellar keratoplasty. One eye developed retinal detachment 10 months after H-ALK. All of these complications were observed in group 2.

CORNEAL THICKNESS AND CUT DEPTH

To evaluate the relationship between the occurrence of iatrogenic keratoconus and corneal thickness and cut depth, we compared these measurements in 2 groups of patients with and without iatrogenic keratoconus. The mean±SD pachymetry reading was 547±43 µm in the eyes with iatrogenic keratoconus and 560±47 µm in the eyes without it (P>.7). The average depth of cut was 63% (range, 50%-72%) of the corneal thickness in the eyes without iatrogenic keratoconus and 65% (range, 52%-70%) in those with keratoconus (P>.8). Ten eyes (19%) in the group without iatrogenic keratoconus and 3 eyes (27%) in the group with keratoconus had a cut depth of more than 70% of the corneal thickness. There was no
significant difference in these percentages between the 2 groups (P > .5).

**COMMENT**

The major problem with H-ALK is long-term instability, with increasing effect of the procedure over time causing a progressive myopic shift. After initial success, the patient may develop iatrogenic keratoconus, which occurred at 3 to 25 months postoperatively in one third of eyes in which H-ALK was performed for overcorrected RK. All patients with this problem required PKP. The mechanism of action of the H-ALK procedure is a “controlled” ectasia with steepening of the central cornea. In eyes with previous RK surgery, the results are unpredictable. It is generally believed that when the cut is made at a depth exceeding 70% of corneal thickness, ectasia can result. In this study, however, we found there was no significant difference in the corneal thickness and the depth of cut in eyes with or without iatrogenic keratoconus. Even when the cut did not exceed 70% of thickness, iatrogenic keratoconus developed in some eyes with previous RK. This indicates that RK weakens the cornea substantially. As we show in this study, the efficacy, predictability, stability, and safety of H-ALK outcome are much less reliable in the treatment of consecutive hyperopia than of primary hyperopia.

**CONCLUSIONS**

Hyperopic automated lamellar keratoplasty meaningfully reduced hyperopia and improved visual acuity, especially for patients with primary hyperopia. However, long-term refractive instability is a serious problem with this procedure. In the present series, 26% of eyes in which H-ALK was performed for consecutive hyperopia developed iatrogenic keratoconus. Based on this study, the long-term instability and high incidence of iatrogenic keratoconus following H-ALK should discourage its use, especially for consecutive hyperopia following RK.

Accepted for publication December 17, 1997.

**REFERENCES**


**Notice to the Authors of Clinical Trials**

The *Journal of the American Medical Association* (JAMA) and the *Archives of Ophthalmology* function as an editorial consortium. With one submission and one set of reviews, your clinical trial manuscript will be considered for publication in both JAMA and the *Archives of Ophthalmology*. Submit your paper to the journal of your choice according to the appropriate “Instructions for Authors” and the following guidelines will apply:

1. If your manuscript is accepted by JAMA, it will be considered for an editorial or commentary in JAMA. Your abstract will also be published in the *Archives of Ophthalmology* with a commentary or editorial.
2. If your manuscript is accepted by the *Archives of Ophthalmology*, it will be considered for an editorial or commentary in the *Archives of Ophthalmology*. Your abstract will also be considered for publication in JAMA and may be accompanied by a commentary or editorial in JAMA.