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Long-Term Follow-Up of Excimer Laser Phototherapeutic Keratectomy

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Purpose: To evaluate long-term follow-up results of excimer laser phototherapeutic keratectomy (PTK) in a Japanese population.

Methods: Twenty-six patients (31 eyes) with corneal opacity were treated with excimer laser PTK. Preoperative diagnoses included 16 eyes with band keratopathy, 10 with granular dystrophy, and 5 with corneal scar. Mean postoperative follow-up was 27 months.

Results: Corneal opacity was reduced in all patients. At postoperative month 12, best spectacle-corrected visual acuity (BSCVA) improved from the preoperative level in 22 eyes of 28 eyes, did not change in 3 eyes, and declined in 3 eyes. BSCVA at month 24 was better than the preoperative acuity in 17 eyes of 23 eyes, similar in 1 eye, and worse in 5 eyes. Eyes with granular dystrophy showed significantly better BSCVA improvement than those with band keratopathy. A hyperopic shift of +1.0 diopter or more occurred in 14 eyes of 28 eyes at month 12 and in 12 eyes of 23 eyes at month 24. No serious adverse effects were encountered during the 3-year follow-up period.

Conclusions: Excimer laser PTK is a safe and effective procedure for the treatment of Japanese patients with superficial corneal opacity. **Jpn J Ophthalmol 1999;43:513–516** © 1999 Japanese Ophthalmological Society

Key Words: Band keratopathy, excimer laser, granular dystrophy, phototherapeutic keratectomy.

Introduction

The 193-nm excimer laser has been used to remove superficial corneal opacity, to smooth the irregular corneal surface, and to correct refractive errors since its first clinical application in 1988.[1] Previous reports[2–8] indicated that phototherapeutic keratectomy (PTK) was effective in treating cornea with superficial opacity. The long-term efficacy and safety of PTK, however, has not been well assessed.[7,8] Moreover, wound healing response in the ocular tissue differs among races,[9] and thus the efficacy and safety of the PTK procedure should be evaluated in each racial population. We have participated in the clinical trial of the VISX 20/20 excimer laser system (VISX, Santa Clara, CA, USA) in Japan, and the report at the end of a 1-year follow-up at three institutions has been published.[10] We herein report the long-term results of excimer laser PTK in additional Japanese patients.

Materials and Methods

Entry criteria for this study conformed to the guidelines approved by the institutional review board in the University of Tokyo School of Medicine. Nine eyes of 9 men, and 22 eyes of 17 women underwent PTK. Patient age ranged from 37 to 85 years (mean = 64 years). Preoperative diagnoses included 16 eyes with band keratopathy, 10 with granular dystrophy, and 5 with corneal scar. The averages of best spectacle-corrected visual acuity (BSCVA) in the diagnostic subgroups of band keratopathy, gran-

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Table 1. Scoring of Corneal Haze

Score	Quality of Opacity
0	Clear
0.5	Barely detectable opacity
1	Mild opacity not affecting retinoscopy
1.5	Opacity slightly affecting retinoscopy
2	Moderate opacity interfering with retinoscopy
3	Marked opacity making retinoscopy impossible but visualization of anterior chamber details possible
4	Anterior chamber details obscured by opacity
5	Marked opacity with visualization of anterior chamber impossible

ular dystrophy, and corneal scar were 0.05, 0.17, and 0.15, respectively. There was no significant difference between these averages (analysis of variance [ANOVA], $P \geq .05$). All patients were informed of the investigational nature of the laser procedure and provided written consent. The patients were treated using the VISX 20/20 excimer laser system with an average energy density of 160 mJ/cm^2 and a pulse repetition rate of 5 Hz. The ablation depth was set from 60 μm to 250 μm (mean = 109 μm), depending on the preoperative evaluation of the thickness of the corneal opacity. The ablation zone was 5.0–6.0 mm (mean = 5.9 mm) in diameter. After surgery, patients received topical 0.1% fluorometholone and 0.3% ofloxacine four times daily initially, with tapering of the dosage over 24 weeks. The follow-up period was 6–36 months (mean = 27 months).

Preoperative and follow-up examinations included visual acuity, refraction, and slit-lamp biomicroscopy. Improvement or worsening of visual acuity was defined as a change of one or more lines of visual acuity in decimal notation. The degree of corneal opacity was scored as indicated in Table 1. Evidence of recurrence of underlying pathology in the treated area was determined by slit-lamp biomicroscopy. All data reported here are mean ± standard deviation unless otherwise specified.

Results

The numbers of eyes examined at each interval were 31 preoperatively, 28 at month 12, 23 at month 24, and 11 at month 36. Because the number of eyes examined at month 36 was small, statistical analyses were not performed on their data. For the evaluation of the safety of the procedure, data at month 36 were included. At month 12, BSCVA improved from the preoperative level in 22 of 28 eyes, did not change in 3 eyes, and deteriorated in 3 eyes (Figure 1). The BSCVA at month 24 was better than the preoperative acuity in 17 of 23 eyes, similar in 1 eye, and worse in 5 eyes. Comparing improvement among the preoperative diagnostic subgroups, improvement of BSCVA at month 12 was achieved in 10 of 14 eyes with band keratopathy, in 8 of 9 eyes with granular dystrophy, and in 4 of 5 eyes with corneal scar.

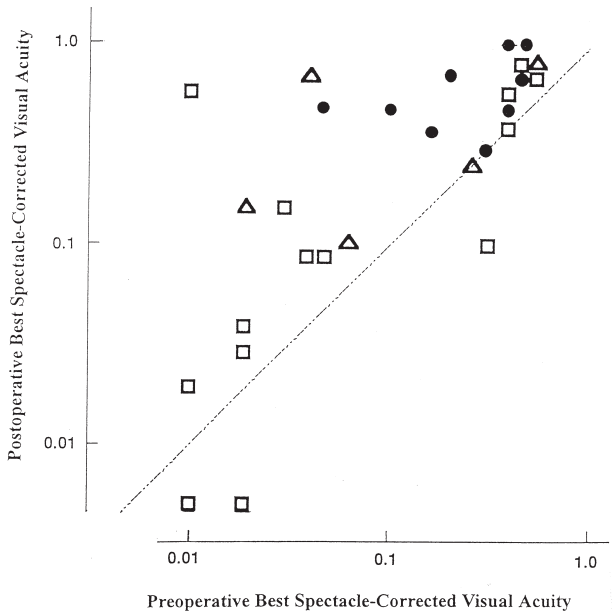

Figure 1. Relationship between preoperative and postoperative best spectacle-corrected visual acuity at postoperative month 12. □: band keratopathy, ●: granular dystrophy, △: corneal scar.

The averages of BSCVA were calculated by means of the logarithm of minimum angle of resolution. The averages of BSCVA are shown in Table 2. Both at months 12 and 24, the BSCVA in the granular dystrophy group was significantly better than that in the band keratopathy group ($P < .02$, ANOVA and Scheffe's multiple comparison).

At month 12, uncorrected visual acuity improved from the preoperative acuity in 13 eyes of 28 eyes, did not change in 6 eyes, and decreased in 9 eyes (Figure 2). At month 24, uncorrected visual acuity improved in 14 eyes of 23 eyes, did not change in 3 eyes, and declined in 6 eyes. The mean spherical equivalent changed from −0.33 ± 4.94 diopters (D) to 0.84 ± 5.98 D at month 12, and 0.28 ± 5.22 D at month 24. A hyperopic shift of +1.0 D or more was observed in 14 eyes of 28 eyes at month 12 and in 12 of 23 eyes at month 24. A myopic shift of −1.0 D or more occurred in 2 eyes at month 12 and in 1 eye at month 24.

Corneal opacity was reduced in all patients. The mean scores of corneal haze are shown in Table 3.

Table 2. Averages of Best Spectacle-Corrected Visual Acuity

	Preoperative	1-Year Postoperative	2-Years Postoperative
Total	0.09	0.22	0.23
Band keratopathy	0.05	0.11*	0.11*
Granular dystrophy	0.17	0.55*	0.45*
Corneal scar	0.15	0.32	0.41

* $P < .02$.

There were no significant differences among the three diagnostic subgroups at each follow-up occasion (ANOVA, $P > .05$). Corneal reepithelization was attained in all eyes within 1 week. There was no adverse effect of the surgery, such as infection and intraocular pressure elevation (>21 mm Hg). Recur rence of the original pathological condition was not observed during the follow-up period.

Discussion

In the current study, BSCVA improved in 79% of the eyes after PTK. This result is comparable with those of previous studies, which ranged from 45% to 78%.[2–6] Worsening of BSCVA has been reported in 9%–19% of the eyes after PTK.[2–5] The visual impairment was attributed to several factors, such as irregular astigmatism and excessive scarring induced by the laser treatment, and aggravation of preexisting glaucoma or cataract. In the current study, in 3 of 31 eyes (10%) there was deterioration of BSCVA at month 12. All were band keratopathy cases. In 2 eyes, progression of preexisting glaucoma appeared to have caused BSCVA loss, and it seemed that laser treatment itself was not responsible for the decrease in visual acuity.

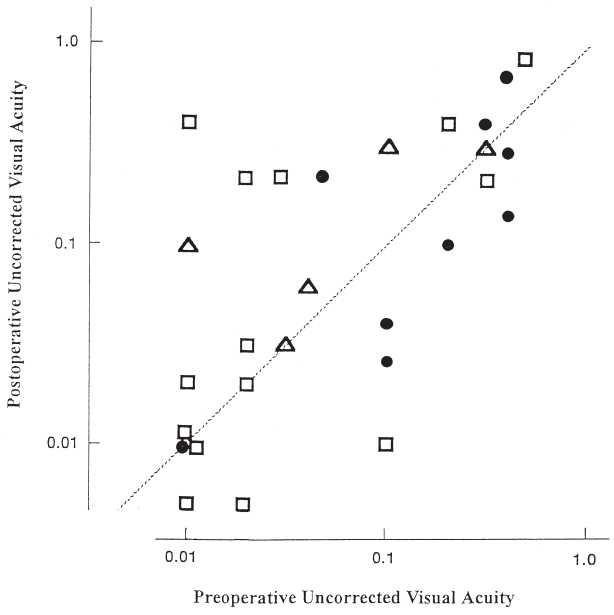

Figure 2. Relationship between preoperative and postoperative uncorrected visual acuity at postoperative month 12. □: band keratopathy, ●: granular dystrophy, △: corneal scar.

Comparing the diagnostic subgroups (band keratopathy, granular dystrophy, and corneal scar), the corneal opacity scores did not vary significantly either preoperatively or postoperatively. Preoperative BSCVA also did not vary significantly between diagnostic subgroups. Postoperatively, however, BSCVA was significantly better in the granular dystrophy group than in the band keratopathy group. This discrepancy may be explained by the different mechanism of the corneal disorders. Whereas granular dystrophy is a primary disease of the cornea, band keratopathy often develops secondarily to chronic uveitis and glaucoma. Accordingly, damage of the retina and optic nerve can exist more often in eyes with band keratopathy, where increased corneal clarity may not necessarily lead to the improvement of visual acuity. On the other hand, the disorder is mostly localized in the cornea in eyes with granular dystrophy, and then improved corneal clarity more likely results in better postoperative visual acuity.

Some authors reported the recurrence of lattice dystrophy, granular dystrophy, and Salzmann's nodular degeneration in the laser-treated area after PTK.[4,8] In the current study, the evidence of recurrence was determined by slit-lamp biomicroscopy, which may not be suitable for the detection of a minimum recurrence. Photographs of the corneas may be required to see the time-course of corneal clarity and detect a minimum recurrence of the underlying pathology.

Recent studies showed that the classic form of granular dystrophy associated with the R555W mutation in the *βig*-h3 gene is rare in Japanese patients,

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Table 3. Mean Score of Corneal Haze

	Preoperative	1-Year Postoperative	2-Years Postoperative
Total	2.8 ± 1.1	0.62 ± 0.52	0.63 ± 0.51
Band keratopathy	2.8 ± 1.3	0.42 ± 0.34	0.44 ± 0.46
Granular dystrophy	3.1 ± 0.74	0.72 ± 0.53	0.64 ± 0.35
Corneal scar	2.4 ± 0.80	1.0 ± 0.61	0.80 ± 0.68

whereas corneal dystrophy associated with the R124H mutation in the *βig*-h3 gene, Avellino corneal dystrophy, is more common.[11] In the current study, the diagnosis of granular dystrophy was determined by slit-lamp examination, which may be insufficient for the proper diagnosis of corneal dystrophy. Thus, it is probable that some of the cases diagnosed as granular dystrophy in this study are actually Avellino dystrophy.

Previous studies[2–5,12] reported the occurrence of a hyperopic shift in 29%–56% of the eyes. Removing the central corneal tissue is expected to lessen the corneal curvature and induce a hyperopic shift. In the current study, the mean spherical equivalent changed from −0.33 D to 0.84 D at month 12 and 0.28 D at month 24. A hyperopic shift of +1.0 D or more occurred in approximately 50% of these eyes after surgery. Postoperative hyperopic shift can disturb uncorrected visual acuity and compromise the otherwise favorable surgical outcomes. Further study to minimize the hyperopic shift is needed.

Between month 12 and month 24, there were no fluctuations in visual acuity and the degree of corneal opacity in each eye, indicating the continued effectiveness of PTK even after 12 months postoperatively. In the current series of patients, no serious adverse effects were encountered during the follow-up period. Considering the fact that efficacy and safety were as good as in previous studies conducted in the United States and Europe, it is concluded that excimer laser PTK is a safe and effective procedure for the treatment of superficial corneal opacity in the Japanese population.

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