Results of Photorefractive Keratectomy for Hyperopia Using the VISX Star Excimer Laser System

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ABSTRACT

PURPOSE: To evaluate safety, efficacy, and predictability of photorefractive keratectomy (PRK) for hyperopic astigmatism of +1.75 to +5.00 D manifest refractive sphere and up to -2.50 D manifest refractive astigmatism using the VISX Star excimer laser system, version 2.5 software.

METHODS: Treatment was performed on 32 eyes of 21 patients. Eighteen of 21 patients were 45 years of age or older. Manifest and cycloplegic refraction together with Pelli-Robson contrast sensitivity assessment was performed prior to surgery and 1, 3, 6, 12, and 24 months after treatment.

RESULTS: Twenty-seven of 32 surgical procedures were reviewed 1 year after treatment (84%). Corneal epithelial healing was complete between day 4 and 10. Twelve months after treatment, 25 of 27 eyes (93%) achieved 20/40 or better uncorrected visual acuity and 19 eyes (70%) achieved 20/20. No patient lost two or more lines of Snellen visual acuity assessed 6 months and later after treatment. The mean spherical equivalent refraction was reduced from +2.90 D at baseline to +0.10 D at 1 year and +0.40 D at 2 years; 65% of eyes had a refraction within ±0.50 D. Four patients had further treatment by laser in situ keratomileusis for undercorrection in three eyes and overcorrection in one eye. Pelli-Robson contrast acuity was significantly reduced 12 months after treatment from a mean 1.72 before to 1.66 after PRK (P=0.02, t-test).

CONCLUSIONS: PRK for hyperopia using the VISX Star excimer laser system was effective in the treatment of hyperopic astigmatism. Although no patient lost two or more lines of high contrast best spectacle-corrected Snellen visual acuity 1 year after treatment, there was a significant decrease in Pelli-Robson contrast acuity. [J Refract Surg 2002;18:30-36]

Excimer laser photorefractive keratectomy (H-PRK) for hyperopia has been performed since the early 1990s using the Meditec MEL60 excimer laser system. Other laser systems including the Summit laser, Nidek system, and the VISX Model C Star laser have also been used. Early results have demonstrated reasonable efficacy for treatment of low to moderate hyperopia. All excimer laser systems perform such correction by steepening the anterior corneal stromal surface by removal of a paracentral meniscus of tissue (Fig 1). To avoid a high rate of change of curvature on the corneal surface, the VISX Star excimer laser system employs a transition zone beyond the central refractive treatment zone. The intended refractive treatment zone may be between 5.0 and 6.0 mm and the peripheral blend zone extending peripheral to the intended refractive treatment zone to between 8.0 and 9.0-mm diameter.

Previous studies have documented the safety of hyperopic PRK treatment and its effectiveness; there is an early myopic overcorrection followed by a slower stabilization of the refraction. This prospective study was approved by an investigative review board to perform PRK using the VISX excimer laser system to treat compound hyperopic astigmatism, with long-term follow-up.

PATIENTS AND METHODS

This research was approved by the Moorfields Eye Hospital institutional review board and informed consent was obtained from all patients prior to entering the study.

Thirty-two eyes of 21 patients were enrolled in this prospective study of excimer laser photorefractive keratectomy for hyperopic astigmatism.
The corneal epithelium was removed using an Amoils rotary epithelial brush. Treatment was centered over the undilated pupil, not the corneal vertex. The first 17 treatments were performed using a 5.0-mm refractive treatment zone and 9.0-mm peripheral zone, and the remaining 15 treatments were performed using a 6.0-mm refractive treatment zone and a 9.0-mm peripheral zone. Following surgery, either a bandage contact lens or an eye-patch was applied, depending on patient preference. Following treatment, patients were examined until epithelization was complete and then at specific time points. All patients were seen 1 week after treatment and were administered further preservative-free chloramphenicol QDS and dexamethasone 0.1% QDS for 2 weeks. Patients were also issued preservative-free hyromellose PRN for use in the first 2 weeks and then Liquifilm up to 3 months, as required.

Full refractive and visual assessment was performed 1, 3, 6, 12, and 24 months after treatment. No patient underwent any further retreatment until after at least 12 months and where documented refractive stability had occurred. Refractive stability was defined as spherical equivalent refraction within 0.50 D between two consecutive refractive assessments.

RESULTS

There were 10 male and 11 female patients with an age range of 21 to 65 years and a mean age of 49 years. Eighteen of the 21 patients were over 45 years.

Follow-up Examination

Thirty-two treatments were performed: 31 eyes (97%) had 1-month follow-up, 28 (88%) had 3 months, 27 (84%) had 6 and 12 months, and 9 (28%) had 2 years of follow-up. Four eyes of four patients (13%) underwent retreatment after 12 months, such that the total follow-up at 2 years after the primary treatment was 13 of 32 eyes (41%). All patients not attending were sent recall requests or telephoned. All patients completed at least 6 months of postoperative follow-up. No patient formally withdrew from the study.

Epithelial Healing

Corneal epithelial healing was complete between days 4 to 10. During the time to complete epithelial healing, patients underwent multiple follow-up assessments. No patient had placement of punctal plugs.
Preoperative Keratometric Power
The intended postoperative maximum keratometric power was set by protocol to be less than a mean 50.00 D. The range of preoperative keratometry was 39.50 to 46.00 D. Mean preoperative keratometric power for the group as a whole was 42.40 D. The maximum intended curve after treatment using a simple summation of preoperative keratometry added to the intended corneal plane power refractive change created a range of intended curvature of 42.40 to 49.80 D.

Distance Uncorrected Visual Acuity
Prior to treatment, six eyes (19%) had 20/40 or better uncorrected visual acuity and this improved to 20 of 31 eyes (65%) after 1 month and 27 of 29 eyes (93%) after 3 months. One year after treatment, 25 of 27 eyes (93%) achieved 20/40 or better uncorrected visual acuity and 19 eyes (70%) achieved 20/20 uncorrected (Fig 2). Two years after treatment, 8 of 9 eyes (89%) with only primary treatment achieved 20/40 or better and 3 of 9 eyes (33%) achieved 20/20 or better. For the nine primary treatment eyes with 2-year follow-up, five eyes achieved 20/20 or better uncorrected at 12 months. The reason for the change in uncorrected visual acuity between year 1 and year 2 for these patients was residual refractive errors of both sphere and astigmatism.

Unaided visual acuity assessed at last follow-up, including the four eyes that underwent retreatment, is a useful measure of results at last examination because all patients had been examined to at least 6 months after surgery. There were 30 of 32 eyes (94%) with 20/40 or better visual acuity and 21 of 32 eyes (66%) with 20/20 or better uncorrected visual acuity.

Distance Best Spectacle-corrected Visual Acuity (BSCVA)
Prior to treatment, 21 of 32 eyes (68%) were refracted to 20/12 BSCVA and 27 (84%) to 20/15 BSCVA. All were 20/30 or better prior to treatment by protocol requirement. One month after treatment, 7 of 31 eyes (23%) lost two or more lines of BSCVA, but by 3 months this had recovered to 2 of 28 eyes (7%). Review at 6, 12, and 24 months after primary treatment recorded no patient having lost two or more lines of best spectacle-corrected visual acuity (Fig 3). Twelve months after treatment, 30% of patients lost one line of visual acuity and 7% gained one line. At last follow-up, no patient had lost two or more lines of visual acuity, 8 of 32 eyes (25%) had lost one line of visual acuity, 18 eyes (56%) had no change in visual acuity, and 6 eyes (18%) gained one line.

Near Uncorrected Visual Acuity
Uncorrected near visual acuity depended on age and refractive error. Prior to treatment, 5 of 32 eyes (16%) achieved N8 uncorrected near visual acuity and 1 month after treatment this improved to 28 of 31 eyes (90%). Three months after treatment, 22 of 28 eyes (79%) and 1 year after treatment 16 of 27 eyes (59%) achieved N8 uncorrected visual acuity.

Refractive Results
The mean corneal plane power preoperative sphere was +2.90 D (range, +1.80 to +5.10 D) and mean manifest refractive astigmatism was -0.60 D (range, 0 to -2.70 D). The mean corneal plane corrected autorefractive preoperative sphere was +2.80 D (range, +1.30 to +4.80 D) and mean astigmatism was -0.50 D (range, 0 to -2.20 D). The mean corneal plane corrected cycloplegic preoperative sphere was +3.40 D (range, +1.80 to +5.60 D) and mean astigmatism was -0.50 D (range, 0 to -2.20 D). The mean difference (absolute) between the manifest and the cycloplegic refractive spherical equivalent refraction was 0.20 D (SD, 0.29 D) and the range was 0 to 1.10 D.

The target refractive outcome was emmetropia in 17 eyes, -0.25 D in 8 eyes, and -0.50 D in 7 eyes. One year after treatment, 65% of eyes were within ±0.50 D and 88% within ±1.00 D of the intended refractive target (Fig 4).

One month after treatment, there was a mean over-correction beyond intended (P<.01, t-test) with a mean spherical equivalent refraction of -1.00 D (SD, 1.13 D) (Fig 5). Between 1 and 3 months after treatment, there was a significant regression of effect and the mean spherical equivalent refraction was -0.10 D (SD, 0.73 D, change between month 1 and month 3, P<.01). Forty-eight percent of eyes regressed by ≥1.00 D between 1 and 3 months. Between month 3 and month 6, there was no statistical difference in the mean from spherical equivalent refraction of -0.10 to 0 D, and 13% of eyes changed by ≥1.00 D. Between 6 and 12 months, there was again no statistical difference in the mean spherical equivalent refraction and 5% of eyes changed by ≥1.00 D.

One year after treatment, mean spherical equivalent refraction was +0.10 D (SD, 0.71 D) and 2 years after treatment, it was +0.40 D (SD, 1.00 D) with 1 of 9 eyes (22%) changing by ≥1.00 D between
Figure 2. Uncorrected visual acuity 12 months after treatment. The graph compares the preoperative best spectacle-corrected visual acuity (gray bars) with the uncorrected visual acuity (black bars). Prior to treatment, 66% achieved 20/12 best spectacle-corrected visual acuity and 19% achieved this uncorrected.

Figure 3. Change in best spectacle-corrected visual acuity compares preoperative to 12 months postoperative. No patient lost two or more lines of visual acuity.

Figure 4. Postoperative spherical equivalent refractive error 12 months after treatment; 65% of eyes were within ±0.50 D and 66% ±1.00 D of intended refractive target.

Figure 5. Stability of refractive change over time. The spherical equivalent refraction has an apparent overcorrection at 1 month after treatment, and 48% of eyes changed by ≥1.00 D between 1 and 3 months after treatment.

Figure 6. Intended and achieved spherical equivalent refraction 12 months after treatment. There was no refractive difference between the 5.0-mm and 6.0-mm refractive treatment zones.

Figure 7. Defocus equivalent refraction error assessed 12 months after treatment; 37% of eyes were within ±0.50 D, 74% within ±1.00 D, and 100% within ±2.00 D.
year 1 and year 2 (Fig 5). The apparent regression of effect between year 1 and 2 for the nine eyes assessed at 2 years was not statistically significant (P<.37) for the small follow-up numbers at year 2 within this series.

Figure 6 plots the scattergram of the intended and achieved spherical equivalent refraction change 12 months after treatment. Four eyes underwent treatment of less than +2.00 D, 24 eyes +2.00 to +3.90 D, and four eyes +4.00 to +5.00 D. There was no difference between the 5-mm and 6-mm refractive treatment zone in the spherical equivalent refraction. For spherical equivalent refraction up to +2.50 D, mean spherical equivalent refraction at 1 year was -0.10 D; for +2.50 to +3.40 D, mean at 1 year was +0.10 D; and for +3.50 to +5.00 D, the mean at 1 year was +0.30 D.

The defocus equivalent (absolute spherical equivalent added to half the absolute astigmatism magnitude) plots defocus by refractive error (Fig 7). Using this measure, 12 months after treatment 57% of eyes were within ±0.50 D and 74% were within ±1.00 D defocus equivalent.

Four treatments were for astigmatism 1.00 D or more and this manifest refractive astigmatism was reduced from a mean -1.80 to -0.80 D at 12 months follow-up; the mean vector magnitude was 96% of that intended. There was a mean 7° absolute vector axis error from intended. All preoperative manifest refractive astigmatism was treated using the VISX software. For preoperative astigmatism 0.50 to 0.90 D (n=11, mean 0.60 D) at 1 year, the mean was 0.60 D. For this small preoperative astigmatism, the mean vector magnitude was 227% of intended comparing preoperative to 1 year postoperative and the mean absolute vector axis error was 11°. Seventeen eyes had 0.25 D or no preoperative astigmatism (mean, 0.16 D); at 1 month after treatment, mean astigmatism magnitude was 0.71 D, and at 1 year was 0.45 D. Residual astigmatism induced in eyes without previous astigmatism was small (mean, 0.45 D) but one eye had 0.75 D astigmatism assessed 1 year after treatment and another eye had 1.75 D residual astigmatism.

**Contrast Sensitivity**

Pelli-Robson contrast acuity was assessed at each time point. The mean preoperative Pelli-Robson score was 1.72 (SD, 0.13) and 1 month after treatment this decreased to 1.64 (P=.03, t-test). One year postoperative, Pelli-Robson contrast acuity remained significantly decreased at a mean 1.66 (P=.02, t-test) compared to the preoperative score (Fig 8).

**Haze**

Only one eye developed grade 2 haze when assessed 6 months after treatment and when further assessed 12 months after treatment, this had completely resolved.
Retreatment

Four eyes of four patients underwent retreatment no less than 1 year after the primary treatment. All four patients underwent laser in situ keratomileusis (LASIK) as the method of retreatment rather than PRK. All four retreated eyes had unremarkable treatments for moderate hyperopia without significant astigmatism. LASIK treatments were performed with parameters chosen by the surgeon, as there were no protocol requirements for retreatment. Three eyes had a 6.0-mm refractive treatment zone and one eye had a 5.0-mm-diameter refractive treatment zone. Three eyes were undercorrected and one eye was overcorrected as the reason for further treatment (Table). Three months after LASIK retreatment, two patients had 20/20 or better uncorrected visual acuity, one patient had 20/30 uncorrected, and the remaining patient had 20/60 due to residual hyperopic astigmatism (patient 3, Table).

Refractive Treatment Zone Size

Treatments were performed as either a 5.0 or 6.0-mm intended refractive treatment zone and a blend out to a 9.0-mm-diameter peripheral zone (Fig 1). For a given intended refractive spherical change, the 6.0-mm refractive treatment zone involved a greater depth of ablation than the 5.0-mm refractive treatment zone. For a radially symmetric sphere-only treatment, the contour created was identical for the central 5.0-mm diameter. There was a difference between 5.0-mm and 6.0-mm treatments more peripheral to this (Fig 1). There were 17 eyes that underwent a 5.0-mm refractive treatment zone ablation and 15 eyes were treated with a 6-mm refractive treatment zone. The mean spherical equivalent refraction prior to treatment for the 5.0-mm refractive treatment zone group was +2.80 D and for the 6.0-mm refractive treatment zone group was +3.00 D. There was no statistical difference between the means (P=.48) prior to treatment. One month after treatment, the 5.0-mm group mean spherical equivalent refraction was -0.80 D and for the 6.0-mm group, was -1.20 D. This did not reach statistical significance (P=.26). The 6.0-mm refractive treatment zone group mean overcorrection resolved when assessed 3 months after treatment and was stable until 24 months. Between 12 and 24 months, the 5.0-mm refractive treatment zone group appeared to regress with the mean at month 12 being +0.20 D for the 5.0-mm group, and this increased to +0.90 D at 12 months, although this was not statistically significant (P=.37) with the limited statistical power of this study.

Loss of best spectacle-corrected visual acuity in both groups was similar, with no patient losing two or more lines of visual acuity assessed 1 year after treatment. Three of 14 eyes (21%) lost one line of visual acuity in the 5.0-mm group and five of 13 eyes (38%) lost one line of visual acuity in the 6.0-mm group.

There was no difference in the mean Pelli-Robson contrast acuity prior to treatment for the two groups (5.0-mm group was 1.71, 6.0-mm group was 1.72) and no difference 1 year after treatment. The 5.0-mm group mean score was 1.65 and the 6.0-mm group mean was 1.68 (P=.29).

DISCUSSION

All treatments resulted in significant correction of hyperopia with 70% of eyes achieving 20/20 or better uncorrected visual acuity 12 months after treatment. Patients considering hyperopic refractive surgery tend to be older than comparable patients undergoing myopic treatment, and in this group 18 of the 21 patients were over 45 years old. Many in this patient group were experiencing presbyopia prior to treatment and the return of some intermediate and near uncorrected vision was welcome. One year after treatment, 59% of patients could read N8 uncorrected monocular with the treated eye. In spite of this, patients have high expectations, and detailed counseling was performed prior to treatment to advise that treatment of presbyopia was not the aim of the surgery. Many patients elected to target a slight amount of residual myopia, aiming to maximize depth of focus after surgery.

There were no problems with corneal epithelial healing in this group, with all eyes healed by day 10 after treatment. Continued review during the period of corneal epithelial healing was considered onerous by both patients and medical staff, but this was considered necessary to minimize risk of wound healing complications. Compared to LASIK for hyperopia, PRK for hyperopia is more involved during the early postoperative period. This study did not formally assess pain following treatment, but it is well documented that excimer laser PRK treatment can be uncomfortable in spite of administering pain relief.

The issue of corneal curvature after hyperopic refractive surgery is currently under investigation and debate, since optical quality has a relationship to corneal curvature. Hyperopic excimer laser application, whether by PRK or LASIK, causes a steepening of the curve of the central cornea. This
leads to a decreased tear film break-up time\textsuperscript{11} and issues of irregular astigmatism. It is unknown whether a simple summation of the preoperative keratometry and the intended refractive change is appropriate and what the maximum allowable corneal surface curvature should be.

The safety of PRK for hyperopia using the VISX excimer laser system was good, with no eye losing two or more Snellen lines of visual acuity 6 months and beyond. Thirty percent of eyes lost one line of Snellen visual acuity 12 months after surgery and this may be partly due to the loss of linear magnification that a spectacle lens previously provided, but also there is likely to be a subtle loss of some overall optical quality. Support for this is provided by Pelli-Robson contrast acuity assessment where the preoperative mean of 1.72 was significantly decreased to a mean of 1.66 at 1 year after treatment. Slit-lamp visible haze was not a factor in decreased contrast sensitivity since only one patient developed significant (grade 2) haze, assessed 6 months after treatment. Further wavefront assessment and assessment of the point spread function for these patients is planned to assess higher order aberrations.

The four eyes of four patients that underwent retreatment had LASIK rather than further PRK. Retreatment technique was not part of the original study protocol, since it was assumed that any patient requiring retreatment should have such treatment based on individual need, rather than any restriction by research protocol. LASIK for hyperopia was chosen due to the rapid recovery of vision and the ability to refine the refractive outcome, if necessary, by performing a flap lift. No patient experienced any complication with the LASIK retreatment procedure and no patient required a flap lift. All four patients achieved a satisfactory outcome following the LASIK procedure.

There was no statistically significant difference in the results of 5.0 or 6.0-mm refractive treatment zones but due to the small number of treatments in this study, it has a relatively low statistical power. The authors felt that an intended treatment zone of 6.0 mm with a peripheral blend zone to 9.0 mm may offer an improvement in optical result compared with a 5.0-mm intended treatment zone with a 9.0-mm peripheral blend zone. However, the larger intended treatment zone results in greater ablation depth and therefore a greater rate of change in curvature over the peripheral blend zone of the cornea (Fig 1). This did not affect Pelli-Robson contrast acuity when the 5.0-mm and 6.0-mm treatment zone groups were compared. However, these vision tests were performed in bright light conditions and tests of mesopic vision may provide greater information.

Many patients are now undergoing excimer laser surgery for hyperopia, but this is primarily LASIK\textsuperscript{10} rather than PRK. Although the limited numbers in this study found PRK for hyperopia to be effective and safe, the issues of the long time to epithelial healing, and the time taken to refractive stability has led to LASIK for hyperopia being the current preferred procedure.

REFERENCES