Intrastromal corneal ring segments: Effect of relationship between alignment and topographic keratometric meridians

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PURPOSE: To determine whether the keratometric and refractive surgical effects of paired intrastromal corneal ring segments (ICRS) depend on their alignment relative to steep and flat topographic meridians.

SETTING: St. Paul's Eye Unit, Royal Liverpool University Hospital, Liverpool, United Kingdom.

DESIGN: Comparative case series.

METHODS: Keratoconic patients who had two 0.3 mm Intacs ICRS inserted were retrospectively grouped depending on alignment of segments within 30 degrees either side of the steep (meridional group) or the flat (perpendicular group) topographic meridians, respectively, with the rest in the oblique group. Principal outcome measures were changes in visual acuity, refractive surgical effect, and keratometric surgical effect 4 months postoperatively.

RESULTS: Forty eyes of 40 patients were included. There was a significant reduction in keratometric power (flattening) (P<.01) but not in refractive error in all 3 groups. The reduction in keratometric astigmatism was significantly greater in the perpendicular group (-2.67 diopters [D]) than in the meridional group (-0.65 D) (P=.03), with the oblique group (-0.9 D) in between (P=.12). The principal reduction was flattening orthogonal to the incision site, with relative steepening in the axis of ICRS alignment. In all groups, variations in the refractive surgical effect and keratometric surgical effect were very high.

CONCLUSIONS: Placement of two 0.3 mm ICRS had a variable effect with limited predictability. There was predominant flattening of the cornea orthogonal to the axis of ICRS alignment. Irrespective of the location of preoperative steep and flat keratometric meridians, the maximum reduction in astigmatism occurred when the incision and the segments were placed along the flat topographic meridian.

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A good surgical procedure should have an accurate and precise outcome. In terms of a refractive procedure, accuracy may be viewed as closeness to the intended target and precision as the variability or reproducibility of the effect. We recently determined in patients with keratoconus the surgically induced refractive and keratometric surgical effects of two 0.3 mm vertically aligned intrastromal corneal ring segments (ICRS) (Intacs, Addition Technology, Inc.) inserted through an incision at 90 degrees. Overall flattening of the cornea occurred, with more flattening orthogonal to the incision site irrespective of the stage of keratoconus. The variability of the effect, however,

was very high. Several factors likely contribute to this variability, such as the relationship of the incision site to the steep and flat topographic keratometric meridians.

The aim of this study was therefore to determine whether the keratometric and refractive surgical effects of paired ICRS are dependent on the location of incision relative to the steep and flat topographic meridians. The refractive analysis was based on the complete refractive and keratometric error without the need to treat the components (sphere, cylinder axis, or meridian) as independent variables, as previously described.²⁻⁶

PATIENTS AND METHODS

Consecutive patients who had insertion of two 0.3 mm Intacs ICRS between November 2007 and January 2011 and had measurable preoperative and postoperative refractive and corneal topography were included. Collection of outcome data was limited to 4 months postoperatively in an attempt to isolate as much as possible the effect of ICRS from the possibility of keratoconic progression. Patients were excluded from the study if data at 4 months were incomplete. If a patient had ICRS in both eyes, only 1 eye was included based on the toss of a coin.

The following parameters were measured preoperatively and postoperatively: uncorrected, pinhole, contact lens-corrected, and spectacle-corrected distance visual acuities; manifest refractive error; simulated keratometric and mean corneal power in the central 3.0 mm and 5.0 mm zones; pachymetry; and location of the cone using topography (Orbscan IIz, Bausch & Lomb). The main outcome measures were changes in refractive error and keratometric power.

A standard surgical procedure was performed in all cases as previously described. The incision site was placed at 90 degrees or according to the manufacturer's recommended nomogram. After intraoperative ultrasonic pachymetry was performed at the incision site, a calibrated diamond knife was set at 70% to 80% of the mean measured corneal thickness and a 1.8 mm to 2.0 mm radial incision was made 7.0 mm from the optical zone. Stromal dissection was performed at the full depth of the incision, and a pocket was extended along its full length by the aid of a semiautomated device before 2 symmetrical ICRS (0.3 mm) were inserted. The incision was closed with a single 10-0 nylon suture.

Postoperatively, topical antimicrobial and steroidal agents were prescribed for 14 days. Postoperative follow-up visits were at 2 weeks, 6 weeks (when the corneal suture was removed), and 4 months and then at the clinician's discretion.

Classification of Patients

Patients were retrospectively placed in 1 of 3 groups depending on the location of the incision site relative to the topographic simulated keratometric steep meridian as follows: meridional if within 30 degrees either side of the steep meridian, perpendicular if within 30 degrees either side of the flat meridian, and oblique if more than 30 degrees away from either meridian.

The topographic keratometric steep meridian was determined according to the meridian of the simulated steep keratometry value in the preoperative Orbscan map in all

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cases, including those that had a skew between the steep astigmatic meridians.

Data Analysis

Refractive and keratometric data were transformed into Long's matrix formalism⁹; that is, $f_{11} = S + C \sin^2 a$, $f_{12} = -C \sin a \cos a$, and $f_{22} = S + C \cos^2 a$, where a is the axis. As opposed to the codependency of sphere (S) and cylinder (C), these equations transform the data into the independent variables f_{11}, f_{12}, f_{22} as defined, which then enables statistical analysis of the refractive data. This is statistically valid; leaving the data in spherocylindrical notation is not, that is, the sphere and cylinder cannot be treated as independent variables. ^{2,3,10} The subscripts define the cell in the matrix; that is, f_{11} is the first row and first column, f_{12} is the first row and second column, and f_{22} is the second row and second column. The data were then analyzed according to the methods of Kaye and Harris.³ and then transformed back into spherocylinder notation using Keating's method.¹¹ The standard deviation (SD) and 95% confidence intervals (CIs) were calculated on the independent variables f_{11}, f_{12}, f_{22} of the row matrix and then transformed back into spherocylinder notation. The data are therefore presented in standard notation as the mean, $SD_{\rm s}^{12}$ and 95% CI (S/Caxis) in the text, tables, and Figure 1. Keratometric data are similarly presented as k1/(k2 - k1) @ meridian; for example, k1: 43 diopters (D), k2: 45 D @ 90 is presented as 43/3 @ 90.

Differences between the preoperative and postoperative refractive and keratometric data— that is, the refractive surgical effect and keratometric surgical effect of the 3 groups (oblique, perpendicular, and meridional)—were tested for a significant difference from zero (no effect) and for a difference in effect between the 3 groups using analysis of variance with Minitab software (version 15, Minitab, Inc.). Visual acuity data were converted into logMAR units for calculation of the means and differences of the preoperative and postoperative visual acuities.

RESULTS

Forty patients with a mean age of 29.14 years \pm 9.7 (SD) and a female-to-male ratio of 29:11 were included. There were 21 patients, 7 patients, and 11 patients in the meridional group, perpendicular group, and oblique group, respectively. Table 1A and Table 1B show the preoperative topographic parameters in the 3 groups of patients. There was no significant difference in mean keratometric power (P=.37), simulated keratometric power (P=.13), or irregular astigmatism (P=.74) between the 3 groups (Table 1A). There were, however, significant differences in central corneal thickness (P=.05) and thinnest corneal pachymetry between the 3 groups (P=.049) (Table 1B).

Visual Acuity

There were significant preoperative to postoperative improvements in uncorrected distance visual acuity (P<.01) and spectacle-corrected distance visual acuity (P=.03), but not in pinhole visual acuity

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