Intracorneal Ring Segment in Keratoconus: A Model to Predict Visual Changes Induced by the Surgery

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PURPOSE. We detected keratoconus cases with a significant potential for poor outcomes following intracorneal ring segment implantation (ICRS). We attempted to predict the potential of a case in terms of gain or loss of corrected distance visual acuity (CDVA).

METHODS. In this retrospective and prospective, consecutive, nonrandomized, multicentric study, 58 keratoconic eyes (aged 17–56) were implanted with the Keraring using the femtosecond laser technology. The follow-up period was 6 months. Keratometric, biomechanical, aberrometric, refractive, and visual variables were measured for two different groups: Group A included eyes that gained 0.2 or more in corrected distance visual acuity (CDVA, decimal scale) and group B included eyes that lost more than 0.15. Correlations between clinical parameters and changes in visual acuity were investigated. In addition, a linear regression model was developed using CDVA, apical keratometry (AK), and a new keratometric parameter defined and named by us as K-factor (KF).

RESULTS. Significant differences between groups preoperatively were found for CDVA (P = 0.002), AK (P = 0.013), and KF (P = 0.025). The following predictive model was obtained using these variables: \( \text{CDVA} = -0.511 + 0.0007\text{AK} + 0.849\text{CDVA}_0 + 0.0084\text{KF} \). Predictability of the model was 0.797. Sensitivity was 88.1% and specificity 83.3%.

CONCLUSIONS. The mathematical model predicts that this surgery is very effective in patients with preoperative CDVA (decimal scale) in the range of 0.01 to 0.3, predicting a gain of 3, 4, or even 5 lines. Gains are predicted and confirmed for CDVA between 0.3 and 0.5. For preoperative CDVA between 0.5 and 0.75 visual outcomes are doubtful. Higher values of CDVA often are related to a decrease in CDVA. This model may help surgeons to select the best cases for ICRS implantation and exclude the worst in terms of visual outcomes. (Invest Ophthalmol Vis Sci. 2012;53:8447–8457) DOI:10.1167/iovs.12-10659

Keratoconus is described in the literature as a corneal alteration related to a progressive thinning and protrusion of this tissue.1 The causes of this disease are not known completely yet, but its ocular effects clearly are identifiable, such as high keratometric values, irregular astigmatism, and, in general, high order aberration values compared to normal eyes.

Keratoconus treatment has improved greatly in the last 20 years. Nonsurgical methods, like rigid gas permeable (RGP) lenses adaptation, have experienced an important improvement in the last years, and can provide good visual results in low and medium grades of keratoconus.2 In the field of surgery, several techniques, like intracorneal ring segment (ICRS) implantation, are used for the treatment of keratoconus. The variety of implants currently available (Intacs, Keraring, or Ferrara rings) are examples of recent advances. Finally, we also must consider emerging techniques, like corneal collagen cross-linking.3 In addition, keratoplasty4 surgery can be performed when it is considered necessary, but usually only for the most advanced grades of keratoconus. However, the predictability of these treatments still must be improved.5–7

Nowadays, intracorneal ring segment implantation has become a widely used technique, and has proved to be a safe and useful tool to manage different kinds of corneal ectasia.8–19 This technique, mainly based on the topographic characterization of the anterior corneal surface, allows remodeling of the shape of the cornea.8–19 The main goal of this surgery is to achieve an improvement in visual acuity and, if possible, an increase in the stability of the cornea to stop the progression of the keratoconus. It seems clear that an improvement in the geometric quality of the cornea should be correlated with an improvement in visual acuity, but until now the relation between these two aspects has been quantified poorly in patients with keratoconus.20,21

The aim of our study was to provide quantitative factors to determine the suitability of ICRS surgery, by detecting potentially bad cases. For this purpose, a mathematical model based on visual and keratometric parameters was performed to understand the effect of this surgery in the gain or loss of corrected distance visual acuity (CDVA), and to make quantitative predictions about the number of lines gained or lost in each keratoconus surgery case.

METHODS

This retrospective, prospective, consecutive, nonrandomized, multicentric study was done on 58 eyes (27 left and 31 right eyes) of 50 patients (58.6% men and 41.4% women) diagnosed with keratoconus.
A bilateral implantation was performed in 8 patients. The mean age of the patients was 30.23 ± 10.24 years, ranging from 17 to 56 years.

All patients were diagnosed and implanted at Vissum Corporacion, Alicante (48) and Centro de Oftalmología Barraquer in Barcelona (10), Spain. More than 600 cases of ICRS implanted were analyzed, but only 58 of them fulfilled the restrictive inclusion criteria.

Inclusion criteria were patients implanted with a Keraring (Mediphacos, Belo Horizonte, Brazil) with femtosecond laser technology, and the presence of characteristic signs of keratoconus based on topography and slit-lamp observation. Corneal topography revealing an asymmetric bowtie pattern with or without skewed axes and one or more common keratoconus signs on slit-lamp examination, such as stromal thinning, conical protrusion of corneal apex, Vogt striae, anterior stromal scars, or Fleischer ring, also were considered inclusion criteria.1 In our study all grades of keratoconus under the Alion-Shabayek22 scale were included. Exclusion criteria were patients with previous ocular surgery or previous ocular pathology, and eyes with corneal opacities. Eyes with replaced rings, or explanted previously or during the follow-up were excluded from the study to avoid bias.

As two centers were involved in this study, two different topography systems were used. In the cases corresponding to Vissum Corporacion, Alicante (48) the CSO topograph (CSO, Firenze, Italy) was used. In these cases the topographic study also included the corneal aberrometric analysis and apical keratometry as the CSO system calculates this information directly. Ten cases corresponding to Centro de Oftalmología Barraquer in Barcelona, Spain, were analyzed with the Orbscan II system (Bausch & Lomb, Rochester, NY). The Orbscan II and CSO have proved to have a similar accuracy and precision on calibrated spherical tests surfaces.23

Data for the whole group of 58 cases were used to identify interesting keratometric variables, like a new keratometric parameter defined and named by us as K-factor (Ks, defined as K2(K2 - K1)) or visual variables, like CDVA, but for the rest of the analysis (before and after evolution, and the development of the mathematical model) we preferred to focus only on the 48 cases measured with the CSO to have a more homogeneous group, and include the information for corneal aberrations and apical keratometry (AK) not provided by the Orbscan. Similar results for the evolution of Ks and CDVA, and their correlations with the visual changes were obtained for the group of 58 cases and a less predictive model was obtained without using AK.

Patients were divided into two groups according to the changes in their visual acuity 6 months after the surgery. Group A (n = 56) was composed of eyes that gained two or more lines in CDVA (decimal scale) and group B (n = 12) was composed of eyes that lost 1.5 lines or more.

All patients were informed adequately and signed a consent form. The study adhered to the tenets of the Declaration of Helsinki and Ethical Board Committee approval was obtained from the institutions involved.

Pre- and Postoperative Examination Protocol

A complete ophthalmologic examination of each case was done. The clinical history of the patients was reviewed carefully to check the systemic state of each individual. Variables, including visual acuity, refractive status, corneal biomechanical data, corneal topography, slit-lamp biomicroscopy, Goldman tonometry, ultrasonic pachymetry, fundus eye evaluation, and surgical parameters, were studied. Biomechanical data were measured using the Ocular Response Analyzer (ORA) from Reichert (Buffalo, NY). The ORA investigates the biomechanical behavior of the cornea by providing three parameters: intraocular pressure, corneal hysteresis (CH) and corneal resistance factor (CRF). These last two parameters are related to the corneal viscosity and the elastic properties of the cornea, respectively.

Postoperative visits at 1 day, and 1, 3, and 6 months were done. On postoperative day 1 the most important aspects examined were the anatomic location and stability of the ICRS, and the general aspect and integrity of the cornea using slit-lamp. Uncorrected distance visual acuity also was evaluated. More detailed examinations were performed at the posterior follow-up visits, including corneal keratometry and corneal aberrometry.

Surgical Technique

All the implantations were performed in keratoconus-diagnosed patients presenting with reduced CDVA, intolerance to contact lenses, and/or lack of motivation to wear them. Surgeries were performed by two experienced surgeons (JLA from Vissum Corporacion, Alicante, Spain, and RIB from Centro de Oftalmología, Barraquer, Spain). All the interventions were done with the femtosecond laser-assisted surgical procedure and the 30 kHz IntraLase femtosecond system was used (IntraLase Corp., Irvine, CA). A suction ring was applied, and then the disposable glass lens of the laser system was applied to appmate the cornea, fix the eye, and help to maintain an adequate distance from the laser head to the focal point.21 A continuous circular stromal tunnel was created at approximately 80% of the corneal depth. The tunnel diameters in all surgeries were 4.8 mm for the inner and 5.7 mm for the outer diameter. Keraring nomograms were applied to determine the number, thickness and length of the segments required depending on the topographic profile and manifest refraction of the patient.

The medication protocol was the same in all cases: antibiotic prophylaxis before surgery using topical ciprofloxacin (Oftalcilox; Alcon Cusi, Barcelona, Spain) every 8 hours for 2 days. The interventions only required topical anesthesia. The postoperative topical medication was tobramycin and dexamethasone eye drops (TobraDex; Alcon Laboratories, Inc., Fort Worth, TX) every six hours for one week. Topical lubricants also were prescribed every six hours for one month (Systane; Alcon Laboratories, Inc.).

Statistical Analysis

For the statistical treatment of the data, the program used was version 17.0 of SPSS for Windows (SPSS, Chicago, IL).

The Kolmogorov-Smirnov test was applied for all data samples to check normality. When parametric statistical analysis was possible, Student’s t-test for paired data was applied to assess the significance of differences between preoperative and postoperative data. However, the Wilcoxon rank sum test was applied when it was not possible. The Mann-Whitney U test was used to compare parameters between groups. The level of significance always used was the same (P < 0.05).

Bivariate correlations were evaluated using Pearson or Spearman correlation coefficients, depending on whether normality could be assumed.

For the development of the predictive model, variables related to the visual outcomes were included in the multiple regression analysis. The analysis was done using different methods (backward, forward, and stepwise) with the purpose of contrasting the reliability of the obtained model, not depending on the method used. Selected variables by the three methods mentioned always were the same. Finally, we applied the method “enter.”

RESULTS

All the variables provided by the examination protocol that could be related to visual outcomes were analyzed before and after ICRS implantation. The main intention was to find preoperative differences between groups A and B to identify prognostic variables related to the visual outcomes following the surgery. Evolution of all variables present in the study also was investigated by the comparison of their values at different moments of the follow-up period to find differences in the progression of the two groups. Differences between groups and their evolution are shown in Table 1.
## TABLE 1.
Comparative between Groups before and after Surgery, Showing Evolution before and after Surgery for Each Group

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>Pre-Post</th>
<th>Post-Post</th>
<th>Pre-Post</th>
<th>Post-Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bp-B6m</td>
<td>3.89</td>
<td>47.14</td>
<td>6</td>
<td>3.82</td>
<td>0.8</td>
<td>0.505</td>
</tr>
<tr>
<td>K2</td>
<td>50.63</td>
<td>54.10</td>
<td>3.47</td>
<td>53.65</td>
<td>4.29</td>
<td>0.001</td>
</tr>
<tr>
<td>K1</td>
<td>4.29</td>
<td>4.10</td>
<td>0.11</td>
<td>4.29</td>
<td>4.10</td>
<td>0.1</td>
</tr>
<tr>
<td>K2-K1</td>
<td>47.62</td>
<td>50.00</td>
<td>2.39</td>
<td>49.36</td>
<td>3.61</td>
<td>0.046</td>
</tr>
<tr>
<td>CDVA</td>
<td>2.29</td>
<td>6.10</td>
<td>3.81</td>
<td>2.29</td>
<td>6.10</td>
<td>3.81</td>
</tr>
<tr>
<td>Corneal astigmatism RMS</td>
<td>1.63</td>
<td>4.49</td>
<td>2.86</td>
<td>1.63</td>
<td>4.49</td>
<td>2.86</td>
</tr>
<tr>
<td>Primary coma RMS</td>
<td>1.35</td>
<td>3.70</td>
<td>2.35</td>
<td>1.35</td>
<td>3.70</td>
<td>2.35</td>
</tr>
<tr>
<td>Spherical-like RMS</td>
<td>1.05</td>
<td>1.01</td>
<td>0.04</td>
<td>1.05</td>
<td>1.01</td>
<td>0.04</td>
</tr>
<tr>
<td>Residual RMS</td>
<td>0.87</td>
<td>2.14</td>
<td>1.27</td>
<td>0.87</td>
<td>2.14</td>
<td>1.27</td>
</tr>
</tbody>
</table>

**Corneal Aberrometric Analysis**

After 6 months, a significant decrease in corneal astigmatism root-mean-square (RMS, \( P = 0.04 \)) and in primary coma RMS (\( P = 0.045 \)) was found for group A. In group B, there was a significant decrease in corneal astigmatism RMS (\( P = 0.048 \)), but an increase in spherical-like RMS (\( P = 0.046 \)). No significant improvement in primary coma RMS or coma-like RMS was found, thus confirming the worse visual results for this group.

Regarding total corneal aberrations, statistically significant higher values for group B were obtained preoperatively: 7.59 \( \mu \)m of mean difference between groups A and B (\( P = 0.028 \)). No significant differences were found for the evolution of each group. Figures 1 and 2 show the change in aberrations over time.

**Keratometric Analysis**

Keratometric variables were studied within a wide range of values: mean keratometry (\( K_m \)) 47.87 ± 4.25 diopters (D), ranging from 42.75 to 57.79 D. After 6 months, the positive effect of the surgery was noted on the corneal profile for group A. A significant decrease was detected for \( K_2 (P < 0.001) \), \( K_1 (P < 0.001) \), and \( K_c (P < 0.001) \). For group B, a statistically significant improvement was found only for \( K_2 (P < 0.046) \), but not for \( K_1 - K_2 (P < 0.074) \) or \( K_c (P = 0.068) \). Preoperative differences between groups were found for \( K_2 (P = 0.025) \) and corneal cylinder (\( P = 0.039 \)). However, differences after 6 months were found only for \( K_c (P = 0.033) \).

For \( A \), differences between groups A and B were found in the preoperative (\( P = 0.013 \)) and postoperative (\( P = 0.006 \)) cases, with higher values for group B in both cases. The change of keratometric parameters is shown in Figures 3 to 6. The surface asymmetry index (SAI) showed a greater effect of the surgery in the regularization of the corneal shape for group A. No preoperative differences were detected for SAI (\( P = 0.245 \)), but postoperative significant differences at 6 months were found for this index (\( P = 0.021 \)). A slight worsening in SAI for group B during the follow-up is shown in Figure 7.

**Biomechanical Analysis**

No significant differences were found between groups for CH and CRF before (\( P = 0.753 \)) and after (\( P = 0.659 \)) the surgery. Only a significant increase of 0.53 units for the difference CH – CRF for group A (\( P = 0.017 \)) was noted 6 months after the surgery, but with no relevant correlation between this parameter and change of corrected visual acuity (ΔCDVA; \( r = -0.089, P = 0.752 \)).

**Visual and Refractive Analysis**

Preoperatively, no significant differences were found in sphere (\( P = 0.133 \)), cylinder (\( P = 0.086 \)), or spherical equivalent (\( P = 0.481 \)) between groups, nor were they found for postoperative sphere (\( P = 0.542 \)), cylinder (\( P = 0.509 \)), or spherical equivalent (\( P = 0.421 \)) at 6 months. However, a significant decrease in cylinder of –1.04 D (\( P = 0.025 \)) for group A was observed. In group B cylinder decrease was at the limit of statistical significance (–1.493 D, \( P = 0.050 \)) six months after surgery.

The CDVA preoperative values ranged from 1.70 to 0 (logMAR), with a mean value of 0.36 ± 0.32. The mean preoperative CDVA for group A (0.27 ± 0.25) was significantly worse than that in group B (0.14 ± 0.11, \( P = 0.002 \)). However, at 6 months the CDVA for group A (0.11 ± 0.11) was clearly better than in group B (0.38 ± 0.17, \( P < 0.001 \)).
Correlation Analysis

Correlations between the ΔCDVA after 6 months and preoperative variables were evaluated. The most notable correlations were found for ΔCDVA-preoperative CDVA \((r = -0.831, P < 0.001)\), ΔCDVA-preoperative \(K_p\) \((r = -0.391, P = 0.015)\), and ΔCDVA-preoperative \(AK\) \((r = -0.444, P = 0.012)\), Figs. 8-10). Correlations for the corneal aberrations and different variables also were investigated. The most relevant correlations were preoperative \(K_p\)-preoperative corneal astigmatism RMS \((r = 0.618, P < 0.001)\), preoperative \(K_p\)-6 months coma-like RMS \((r = 0.370, P = 0.048)\), and preoperative \(AK\)-preoperative coma-like RMS \((r = 0.358, P = 0.048)\). These correlations showed that greater values of \(K_p\) are related to greater values of corneal astigmatism RMS and steeper cones produce higher values of coma-like RMS. Other interesting correlations were found for postoperative variables at 6 months: \(K_p\)-corneal astigmatism RMS \((r = 0.380, P = 0.042)\) and \(K_p\)-coma-like RMS \((r = 0.524, P = 0.003)\).

Therefore, variables with preoperative and/or postoperative differences between groups, with different evolution in both groups, and with strong mathematical correlation were investigated in more depth. All of these interesting variables were introduced in a linear regression model and different techniques were compared (stepwise, backward, forward, and enter). Three variables always were present (preoperative CDVA, \(K_p\), and \(AK\)), and were evaluated finally with the option “enter” (most reliable in our opinion).

Predictive Model for the ΔCDVA after 6 Months

To complete the information provided by the nomograms, in a more quantitative form, a mathematical model was performed using the most relevant factors related to the changes in visual acuity.

A predictive model using linear regression was obtained:

\[
\Delta CDVA = -0.511 + 0.0007K_p - 0.849CDVA_p + 0.008AK_p
\]

Subindex “p” means preoperative. \(\Delta CDVA\) is the gain or loss in CDVA in the logMAR scale, that is the difference between

![Figure 1. Aberrometric evolution after surgery for group A.](https://iovs.arvojournals.org/pdfaccess.ashx?url=/data/journals/iovs/933249/ on 12/03/2018)

![Figure 2. Aberrometric evolution after surgery for group B.](https://iovs.arvojournals.org/pdfaccess.ashx?url=/data/journals/iovs/933249/ on 12/03/2018)
visual acuity at 6 months minus preoperative visual acuity. KF, was defined previously as K-factor ($K_F = K_2/[K_2 - K_1]$). CDVA is corrected distance visual acuity in logMAR. The term $AK$ denotes the apical keratometry of the cone in diopters. The $\Delta$CDVA is correlated significantly with previous CDVA, $K_F$, and $AK$ ($P < 0.001$). All coefficients present in the model were statistically significant, with $P \leq 0.001$.

Predictability ($R^2$) was 0.797 and adjusted $R^2$ was 0.774. No influential points or outliers were detected: Mean Cook distance $= 0.064 \pm 0.081$.

The statistical validity of the model was checked. The unstandardized residuals were distributed normally ($P = 0.200$), confirming homoscedasticity of the model. Moreover, 75% of unstandardized residuals were lower than 0.07 with a 95% confidence interval (CI) ranging from $-0.043$ to $0.043$. All residuals were lower than 0.21. The value provided by the Durbin-Watson test was 1.773, showing the independence of the residuals. Multicollinearity tests also were examined, providing variance inflation factors (VIFS) ranging from 1.013 to 1.058, and values of tolerance were 0.987 to 0.952, respectively. Low values for the condition indexes were confirmed with a maximum value of 15.613.

Figure 11 shows the results predicted by the model. Due to the importance of CDVA, the most direct and accessible parameter, the values for the term $-0.511 + 0.0007K_F + 0.0084AK$ were computed and a 95% CI for this term (0.098, 0.203) was obtained. This interval corresponded to the space between the red and green lines, and the mean expected gain is represented by the blue line.

Results for visual acuity at 6 months versus those predicted by the model are presented in Table 2. The correlation between both variables in logMAR scale can be seen in the equation below:

$$CDVA(\text{6 months}) = -0.05 + 0.989CDVA(\text{predicted})$$

The significance was $P < 0.001$ and $r^2 = 0.607$.

The following conclusions can be derived from text above:

1. Linear regression coefficients showed that the most important factor is CDVA; however, the real weight of each factor is not considered. Values for CDVA (logMAR)
ranged from 1.70 to 0.00, while values for the $K_F$ ranged from 21.5 to 661.5 D$^2$ in our study. AK ranged from 48.24 to 97.03 D. More relevant information is provided by the standardized coefficients (“beta coefficients”) for the regression, showing that the combined influence of the keratometric parameters was comparable to that related with CDVA (Table 3).

2. As shown in Equation 1, the effect of each factor is as follows: Patients with higher values of CDVA (logMAR) experienced a greater improvement in their visual acuity, and lower previous values for the $K_F$ and AK imply higher improvement in CDVA.

**DISCUSSION**

The keratometric analysis showed that the surgery resulted in a flatter cornea for group A, with significantly lower values postoperatively for $K_1$, $K_2$, corneal cylinder, and $K_F$. So, in good cases an important flattening in the central cornea was confirmed as described by others.8–12,24–28 Instead, for group B only $K_F$ had a significant decrease.

Regarding the SAI, no significant differences between groups were detected preoperatively, but 6 months after the surgery the value of the SAI was significantly lower for group A. This effect in group A was positive for the refractive compensation. It is important to note that the main problem for the correction of ametropia in keratoconus patients is the lack of regularity of the cornea.

The corneal aberrometric analysis showed that in mean terms, a significant decrease for corneal astigmatism RMS was obtained for both groups. However, the evolution of the primary coma proved to be more important for the final visual result. A significant decrease of primary coma was detected for group A, but not for group B. Moreover, a significant increase of the spherical-like aberrations was confirmed in group B.

Biomechanical analysis of the cornea is another important issue in the study of keratoconus.29,30 However, no significant correlations of biomechanical variables with changes in visual acuity were found after 6 months, as noted by others.21
The analysis into linear regression model allows further
comments. As noted above, higher values of CDVA (logMAR),
or lower values of $K_p$ and $AK$ resulted in greater improvement
of CDVA. So, if a greater evolution of keratoconus is permitted
before the surgery, we will have on one hand higher
preoperative values of $K_p$ and $AK$ but, on the other hand,
higher values of CDVA (logMAR), and these two effects will
compete opposingly in the model for visual acuity changes.

However, this effect will depend on each individual case. For
example, the speed of the evolution of these competing factors
will be different for each patient. So, the balance of the three
factors will be very important to decide the optimal moment
for the surgery.

Taking into account that each case is different, we propose
the following protocol: For initial keratoconus grades, a
periodic and very restrictive evaluation of the progression of

![Figure 7. SAI evolution after surgery for groups A and B.](https://iovs.arvojournals.org/pdfaccess.ashx?url=/data/journals/iovs/933249/)

![Figure 8. Correlation between ΔCDVA and preoperative corrected distance visual acuity (CDVAp).](https://iovs.arvojournals.org/pdfaccess.ashx?url=/data/journals/iovs/933249/)
the pathology must be performed to check the location of the case (Fig. 11) over time to develop a curve of evolution to determine the most suitable moment for the surgery.

As can be seen from Figure 11, in a considerable number of cases with previous values of CDVA lower than 0.12, this surgery would result in a worsening of CDVA. Therefore, the most advisable protocol is to make the decision whether to perform the surgery at a later date, except in cases of a rapid and very negative evolution of the patient.

For CDVA in the narrow interval 0.24 to 0.12 (Fig. 11) variations of visual acuity can be positive or negative depending on the case. So, the application of the model will be more relevant.

CDVA preoperative values in the range of 0.30 to 0.40 can be considered, in general, as reasonable values to carry out this surgery. For 0.40 a notable improvement is predicted even when we consider the red line, corresponding to the worst cases. We highly recommend, as a safety factor, to consider this line to be sure of the benefits of the surgery when this formula is applied.

As shown in Figure 11, for previous CDVA values around 0.50 or higher, very important improvements are predicted. These results coincide with the fact that patients suffering a severe form of keratoconus experience a better improvement of their visual acuity.6,8,9,12,15,26,27,31

Evidently, ICRS implantation is a technique that depends on many factors, so it would not be logical to perform this procedure only using mathematical criteria. However, the model represents a new and important tool of decision that should be considered to complete the information provided by the nomograms, which are effective, but subjective. The model is useful particularly for the detection of potentially bad cases.

As in the case of keratoconus, it would be interesting to find new parameters for the prediction of visual changes after different kinds of surgeries and in particular for the implantation of ICRS.

A very large number of variables, measured or constructed were investigated, resulting in a new and interesting variable, related to the visual outcomes: $K_F$. This factor included in the model, possesses major advantages with respect to other keratometric parameters used previously in predictive models for ICRS implantation. This index can be considered to be very useful, at least, with the purpose of differentiating good cases from potentially bad ones. As an example, we can consider an extreme case to illustrate this point: A patient is diagnosed with keratoconus and keratometric values $K_1 = 30$ D and $K_2 = 60$ D. The calculation of $K_m$ results in 45 D. This value is more or less normal. On the other hand, a cornea with a better shape (normally related to lower $K_m$ values) will be more predictable, and could have a better prognosis than a deformed and damaged cornea.32 So, in a case like this, we could even make positive predictions about the effects of the ICRS surgery if we only consider $K_m$ to describe this case from a mathematical point of view. However, we can see that the example mentioned previously is clearly a difficult case for predicting any result. To avoid wrong mathematical interpretations of cases as mentioned before, we created a variable that is related to visual changes ($r = 0.391, P = 0.015$) and can differentiate pathologic cases corresponding to different causes: Very large values of $K_2$ will be considered clearly as potentially bad cases, and the same could be said for those cases with very large values of corneal cylinder ($K_2 - K_1$) or those with high values of $K_2$ and ($K_2 - K_1$) at the
same time, giving very high values of the product $K_2(K_2 - K_1)$.

As shown above, significant differences were found for this index for groups A and B preoperatively ($P = 0.025$) and postoperatively ($P = 0.033$).

It also is interesting to mention the role of the other parameters present in the regression. With $K_F$, the topographic shape of 3 mm of the central cornea is characterized, involving the visual axis, and therefore a very important zone for this study centered on visual outcomes. $AK$ is very important to characterize the zone related to the cone where the surgeon is going to act during the surgery. Finally, CDVA always must be a very important factor to determine the necessity of the surgery.

Until now, several characterizations of the degree of severity of keratoconus have been performed. Most of them have taken into account the keratometric values, using $K_2$ or $K_m$ among other parameters. Recent severity degree scales have started to consider CDVA as an important factor to catalogue keratoconus. The problem has been to unify these two different approaches as patients frequently can be found with a high degree of severity under the Krumeich scale criteria, but still having an acceptable CDVA. If we are making predictions about the ICRS surgery, evidently related to the preoperative degree of severity of the keratoconus, we would have to use one of the above described approaches. However, we consider that it is better if visual and keratometric parameters are taken into account as they compete in importance when the predictive model is used.

We concluded that cases with higher values of CDVA (logMAR) can improve more than those with lower values. Taking into account that the initial state of the patient could
limit the final result, an encouraging finding is that this surgery is effective even for patients with very poor CDVA.

As shown in Figures 1 to 7, a smooth and continuous evolution of the variables involved in the model was observed in group A. However, group B proved to be very unpredictable, with a significant improvement in corneal shape in the immediate postoperative period, but deteriorating quickly after 3 months. These abrupt changes could be due to the presence of more deformed corneas, with higher keratometric power, in this group.

The numeric calculation derived has been extracted for the femtosecond-laser technology and Keraring implants in all cases. However, we considered that these results could be similar for the mechanical procedure or for other kinds of implants, such as Intacs.27

In conclusion, we considered that ICRS is a safe and suitable technique for the treatment of keratoconus. Moreover, this surgery seems to improve the tolerance to contact lenses as reported by others.9,35 but its main problem at present is its poor predictability regarding visual outcomes when performed only taking into account the nomograms. To improve the predictability and outcomes the present mathematical model is proposed.

References


