Intrastromal Corneal Ring Segments for Visual Rehabilitation of Keratoconus Patients

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ABSTRACT

Purpose: Visual rehabilitation is an important part of keratoconus treatment. Glasses or contact lenses are usually sufficient in mild cases. Advanced disease may require surgical treatment.
Intrastromal corneal ring segments (ICRS) implantation is an effective treatment. However, surgical planning is in constant evolution and the visual results are hard to predict.
We aim to assess predictive factors of the visual results, determining the best candidates for this treatment.

Material and Methods: Retrospective analysis of successful ICRS implantation in our hospital. Refractive and topographical data in pre and postoperative setting was analyzed in order to identify predictive factors for success.
INTACS-SK® ring segments were used, according to the plan recommended by the manufacturer.

Results: Sixty-five eyes were analyzed. Both uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) showed significant improvement after surgery (0.11±0.11 to 0.28±0.20 and 0.48±0.22 to 0.63±0.20, respectively). Refractive and keratometric values also improved significantly.
BCVA improved in 43 eyes (67%), with gain of at least 2 Snellen lines in 28 eyes (43%).
Post-operative BCVA was negatively correlated with pre-operative refraction, corneal thickness and corneal curvature. Visual improvement was negatively correlated with pre-operative corneal astigmatism and steep K.
Patients with steep K lower than 47.5D and corneal astigmatism lower than 3.75D had better results.

Conclusions: ICRS implantation is effective in improving visual acuity, refraction and corneal shape.
Eyes with more advanced disease (higher astigmatism and corneal curvature) have worse results, perhaps being better suited for other treatments, such as keratoplasty. It is possible that a different type of ring segment or improved surgical planning could improve the results.

Keywords: corneal ectasia, corneal surgery, corneal topography, keratoconus, ring segments.

INTRODUCTION

Keratoconus is a degenerative and progressive disease that causes important visual dysfunction. Besides irregular astigmatism, visual function of keratoconic eyes is also severely affected by high-order aberrations, with vertical coma having special relevance.[1,2]

Treatments include optical correction and surgical intervention, with implantation of intrastromal corneal ring segments (ICRS) being a popular choice. It is a safe and effective method for correcting refractive irregularities present in corneal ectasias, with an established place in the treatment algorithm.[3–6]

The implantation of intrastromal corneal ring segments in the peripheral cornea allows for a flattening and regularisation of the keratic surface. INTACS-SK are one of the available choices and are safe and effective in improving uncorrected (UCVA) and best corrected visual acuity (BCVA).[7–9] However, the nomogram suggested by the manufacturer only takes into account keratometry, corneal thickness, refraction and position of the cone. Other types of ICRS use more complex nomograms, including asphericity and the distribution of the cone into the calculation.[10]

This paper aims to identify predictive factors of success in INTACS-SK implantation in order to serve as a starting point in the improvement of surgical planning and to establish the cases that benefit more from this treatment.

METHODS

Design

Retrospective study reviewing characteristics and outcomes of consecutive successful ICRS implantation. Surgery was performed between 2013 and 2017.

The study was approved by the local ethics committee and followed the tenets of the Declaration of Helsinki. All patients signed an informed consent form.

Surgical decision

Keratoconus diagnosis was based on clinical history, objective and subjective refraction, biomicroscopy and corneal tomography (Galilei G2, Zeiss, Germany).

Indications for surgery included low BCVA with spectacles and intolerance to contact lenses. Exclusion criteria included advanced keratoconus, with maximum curvature over 56D, significant corneal opacity and corneal thickness below 400mm in the implantation zone.

Preoperative and postoperative examination

Complete ophthalmic examination was performed before surgery and 3 to 6 months after surgery. Data examined included UCVA, BCVA, manifest refraction and corneal tomography maps, including data on keratometry, corneal thickness and high-order aberrations.

Surgery

The implanted ICRS were INTACS-SK® (Addition Technology, Inc.). These are crescent shaped PMMA segments with a rounded design and an inner diameter of 6mm, with different thicknesses and arcs to choose from. Surgical plan, including place of incision and type of segment to be implanted, was decided following the manufacturers' calculator, which considered keratometry, refraction and location of the cone.

During surgery, incision was performed at the marked axis, 6 to 7mm off the center of the pupil. Corneal tunnels were created by manual mechanical dissection, with assistance of a suction device.

Grouping

In order to assess importance of the location of keratoconus in the ICRS implantation results, eyes were classified as having paracentral (thinner corneal point more than 0.6mm from the pupil center) or central (thinner corneal point less than 0.6mm from the pupil center) cones.

Statistical analysis

SPSS 23 was used for statistical analysis. Normality of data was tested with the Shapiro-Wilk test.

Related-Samples Wilcoxon Signed Rank Test was used to compare pre and post-operative data.

Independent-Samples Kruskal-Wallis Test was used for group comparison results.

Spearmann Rho Correlation test was used to assess relevant preoperative factors for the final result.

In all cases, a p value less than 0.05 was considered statistically significant.

RESULTS

We analysed 65 eyes from 52 patients. Population description is presented in Table 1.

	Average	SD	Min	Max
Age	38.72	10.63	24	67
	Male	**Female**		
Gender	30	22		
	OD	**OS**		
	Average	SD	Min	Max

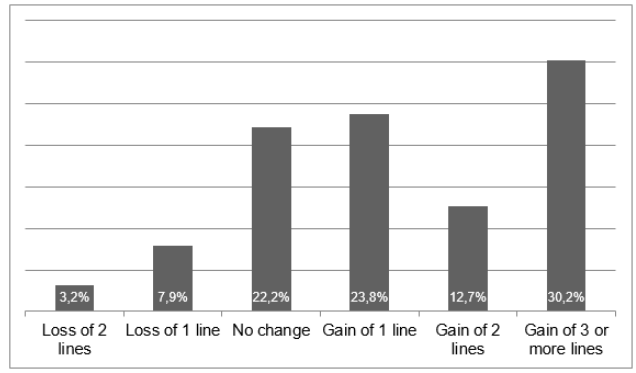
Table 1 - Population characteristics

Visual, refractive and topographical characteristics before and after the surgery are compared in Table 2. There was a statistically significant improvement in every analysed variable.

	Preoperative		Postoperative		*P* value
	Average ± SD	Min - Max	Average ± SD	Min – Max	
UCVA	0.10 ± 0.11	<0.05 - 0.5	0.28 ± 0.20	<0.05 - 0.8	<0.001
BCVA	0.48 ± 0.22	<0.05 - 0.8	0.63 ± 0.20	0.2 – 1.0	<0.001
Spherical Equivalent	-5.96 ± 3.82	-16.00 - +1.00	-2.11 ± 3.73	-16.25 - +4.00	<0.001
Cylinder	4.51 ± 1.89	0.00 - 10.00	-3.44 ± 1.46	1.00 - 8.00	<0.001
Corneal Astigmatism	3.31 ± 1.54	0.25 - 7.60	2.85 ± 1.41	0.29 - 8.12	0.026
Mean K	47.23 ± 2.56	42.20 - 53.77	43.60 ± 2.39	37.88 – 49.57	<0.001
Steep K	48.89 ± 2.69	43.95 - 55.48	45.05 ± 2.58	40.07 – 51.79	<0.001
Coma	2.48 ± 1.30	0.28 - 8.87	1.94 ± 1.03	0.50 - 6.38	<0.001

Table 2 - Comparison of visual, refractive and topographical characteristics before and after surgery (Related-Samples Wilcoxon Signed Rank Test was used to assess statistical significance)

Graph 1 shows the gain and loss of lines of BCVA. Two thirds of the eyes improved BCVA, with 30% improving 3 or more Snellen lines.



Graph 1 - Snellen lines change after surgery

Correlation tests (Spearman Rho) were performed in order to assess preoperative factors influencing the final visual acuity and visual acuity change. Variables with strongest correlation with final BCVA were pre-op BCVA ($p< 0.001$, $r= 0.594$), mean K ($p< 0.001$, $r= -0.534$), steep K ($p< 0.001$, $r= -0.507$), minimal corneal thickness ($p< 0.001$, $r= 0.455$), spherical equivalent ($p= 0.013$, $r= 0.312$), asphericity ($p= 0.013$, $r= 0.313$) and coma ($p= 0.023$, $r= -0.288$). Visual improvement was correlated with pre-op BCVA ($p< 0.001$, $r= -0.492$), corneal astigmatism ($p= 0.023$, $r= -0.29$) and steep K ($p= 0.034$, $r= -0.272$).

Postoperative coma did not seem to significantly influence the final result.

Patients were divided considering the pre-op steep K and corneal astigmatism (Table 3), with significant differences in terms of success between the groups.

Variable	Group 1	Group 2	P value
Steep K	>47.50D	≤47.50D	
BCVA difference	0.12 ± 0.18	0.25 ± 0.20	0.032
Corneal astigmatism	>3.75	≤3.75D	
BCVA difference	0.08 ± 0.20	0.20 ± 0.18	0.013

Table 3 - BCVA difference compared according Pre-operative Steep K and Pre-operative Corneal Astigmatism (Independent Samples Mann-Whitney U Test was used to assess statistical significance)

Patients were divided in two groups according to cone location (paracentral or central). Distribution and results are presented in Table 4. As we can see there is no statistically significant difference between the groups. However, there was a tendency for worse results in the group with central keratoconus.

	Paracentral	Central	*P* value
N (%)	51 (78.5%)	14 (21.5%)	
Final BCVA	0.65 ± 0.20	0.55 ± 0.22	0.516
VA change	0.17 ± 0.20	0.13 ± 0.24	0.280

Table 4 - Comparison of groups divided according to location (Independent Samples Mann-Whitney U Test was used to assess statistical significance)

DISCUSSION

Our results confirm that ICRS implantation is a safe and effective procedure to improve visual acuity and reduce the optical correction in patients with keratoconus. We observed a mean improvement of 1.5 Snellen lines both in UCVA and BCVA.

However, it proved to be a highly variable surgery in terms of visual improvement, with visual change varying between loss of 2 lines and gain of 6 lines.

The literature shows that INTACS-SK have good results in improving VA. Hashemian reported improvements of 1,5 lines of UCVA and 2 lines of BCVA.[11] Other studies show a significant improvement in UCVA (between 1,5 and 3,5 lines) but not in BCVA.[12,13] The safety of the procedure was also confirmed in the series of Ibrahim, with more than 80% of eyes improving at least 1 line of UCVA and BCVA and no loss of lines in any case.[14]

Studies evaluating implantation of Ferrara ring segments have reported different results according to the type of keratoconus. Ferrara reported improvements of about 2 Snellen lines of UCVA and BCVA in central keratoconus by implanting single segments with 210º of arc, with significant improvements in spherical equivalent and keratometry.[15] In paracentral keratoconus, improvements described were of 2 Snellen lines of UCVA and 3 lines of BCVA with the implantation of single segments with 160º of arc. It is also interesting to note that paracentral cones had better initial visual acuity in that study.

Our results with INTACS-SK are comparable to those described in other types of ICRS, with a mean improvement of almost 2 Snellen lines in BCVA after ICRS implantation. There was no statistical difference in results between central and paracentral cones, but central cones tended to improve less and achieve lower final visual acuity. It is unclear if this difference is due to implantation strategy not being adapted to the situation or a lack of response of these type of keratoconus to this treatment. It is possible that the results of a personalized implantation would provide better outcomes. Different types of ring segments and nomograms could improve the results in selected cases, as described previously.[16]

Post-op BCVA improved in 43 eyes (67%), with gain of at least 2 Snellen lines in 28 eyes (43%). Besides that, it is also important to remind that even patients with minimal to none visual acuity improvement may benefit from the surgery, because of the important reductions in the refractive correction and better tolerability to it.

As expected, initial visual acuity and corneal curvature were good predictors of the final outcome. That underlines the importance of diagnosing the disease early on, allowing for the evaluation of progression and intervention to stop progression with improvement of the chances for visual rehabilitation. It is also important to note that eyes with higher corneal curvature and corneal astigmatism show lower improvement, which could indicate that those patients might benefit from a different surgical approach, such as keratoplasty.

High-order aberrations have a complex association with visual acuity, affecting it in different manner. Symmetrical aberrations, such as spherical aberration, seem to influence VA to a larger extent.[17] Interestingly, combinations of astigmatism and coma appear to provide better VA than the astigmatism alone in certain conditions.[18] This shows that coma is hard use in order to predict VA loss. Besides, the difference in coma values in eyes with similar VA may cause differences in visual quality that are difficult to assess by common methods. This may explain why, although deemed relevant to visual quality, coma values did not seem to influence VA in our results.

Limitations of this study include its retrospective nature and a relatively long period of time during which the data was collected. Also, the number of eyes studied is not ideal for group analysis, as it may be insufficient to achieve statistical significance.

In conclusion, ICRS implantation is a very useful weapon in the visual rehabilitation of keratoconus. Its definite technique in terms of segment type and positioning is still under evaluation. More advanced cases are probably more suited for treatment with keratoplasty, although clear and consensual criteria are lacking.

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