Changes in ABCD keratoconus grade following intracorneal ring segment implantation

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Running head: ABCD keratoconus grading system following the ring implantation

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ABSTRACT

Purpose: To assess the changes in the ABCD keratoconus staging system 6 months following intracorneal ring segment implantation.

Methods: Fifty eyes of 50 keratoconic patients who were implanted with Keraring (Mediphacos, Belo Horiztone, Brazil) using the femtosecond laser were included in this study. Pre- and post-operative assessments included determination of distance uncorrected and corrected visual acuity (UCVA & BCVA), refraction, and Scheimpflug tomography with Pentacam HR. In the ABCD kerartoconus staging system A, B, C and D elements stand for the anterior and back/posterior radiuses of curvature in 3.0mm zone centered on the thinnest point, corneal thickness at thinnest point and distance corrected visual acuity (DCVA), respectively.

Results: Keraring implantation produced significant flattening changes (pre- vs. post-operatively) in the anterior (6.60±0.48 vs. 7.22±0.57mm) and posterior (4.99±0.47 vs. 5.16±0.53mm) radius of curvature of the 3mm zone centered on the corneal thinnest point associated with statistically significant improvement in the corrected distance visual acuity (0.56±0.24 vs. 0.70±0.22 in decimal notation) ($p<0.05$) with no significant change in the corneal thickness at the thinnest point ($p>0.05$). The most changes occurred in element A of the ABCD keratoconus classification. Also, one stage change was observed for element B while elements C and D did not show changes in their stages pre- and post-operatively. The ABCD keratoconus staging before ring implantation was A2B3C2D1 and changed to A1B2C2D1 six months after surgery.

Conclusion: the ABCD staging system provides a more comprehensive guide that better illustrates the structural changes and visual acuity as one aspect of visual performance following the implantation of the intra-stromal corneal ring segments.

Key Words: Keratoconus; Staging; Intracorneal ring segments; Keraring; Corneal tomography.

INTRODUCTION

Keratoconus is a bilateral and usually asymmetrical condition characterized by progressive para-axial thinning and corneal steepening.[1, 2] One suggested option for rehabilitation of visual performance in the eyes with keratoconous is implantation of intra-stromal corneal ring segments (ICRSs), which are effective in improving vision, reducing refractive errors and mean corneal curvature.[3] ICRSs' implantation creates a flattening effect while maintaining the corneal prolateness. Unlike subtraction techniques, such as excimer laser corneal refractive surgery, ICRS preserve tissue, modifying the cornea without removing tissue or contact with the cornea center.[4]

Several classification systems have been proposed for keratoconus staging based on various parameters such as keratometry readings, spectacle refraction, apical corneal thickness, and high-orders aberrations, but until recently there was no grading system to provide an integrated approach for combining multiple morphological parameters along with visual related factors such as visual acuity.[5]

Two most widely used grading systems in the literatures are the Amsler-Krumeich (AK) and the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study classification systems. The AK system consists of four stages (stages 1-4) and uses four variables (mean keratomety reading, central corneal thickness, spectacle refraction and presence/absence of corneal scarring) for grading purpose.[6, 7] The CLEK study system is based on changes in visual acuity, mean keratometry, slit-lamp biomicroscopic signs, presence or absence of corneal scarring, and visual-related quality of life.[8]

There are significant limitations to the existing staging systems. The AK classification is over 70 years old and was based on optical pachymetry and keratometry. The CLEK classification is over 20 years old and did not utilize any corneal imaging technologies and does not take into account the posterior corneal surface data or corneal thickness map analysis, which have significant importance in detecting early or subclinical keratoconus.[9] Recently, a grading system known as Belin ABCD keratoconus staging (Topometric/KC-Staging) has been presented based on the tomographic data and visual acuity consideration to better describe both anatomical and functional changes seen in keratoconus.[10] In this system “A”, “B”, “C” and “D” respectively stand for the anterior radius of curvature in 3.0mm zone centered on the thinnest point, posterior (back) radius of curvature in 3.0mm zone centered on the thinnest point, corneal thickness at thinnest point, and distance corrected visual acuity (DCVA). It also has another variable that shows the presence or absence of corneal scarring.[11] This system consists of five stages (stages 0-4) where each component is independently graded. For the anterior corneal curvature stages 1-4 are closely in agreement to the AK classification. The 3.0mm zone used in this staging system corresponds to the exclusion zone utilized in the Belin-Ambrosio Enhanced Ectasia Display (BAD) screening program for keratoconus and other corneal ectatic diseases. The philosophy behind the choice of this region is that this zone contains the most ectatic areas compared to a single parameter such as the point with the highest elevation or point with the maximum curvature value (e.g. Kmax).[12]

Although several studies have evaluated the effect of ICRSs on some visual performance and structural parameters [2, 13-18], to the best of our knowledge, there is no study to evaluate the effect of corneal ring segments on the visual and corneal morphological status using a more comprehensive grading system. This study was designed to assess changes in the ABCD parameters 6 months following ring implantation.

METHODS

50 eyes of fifty keratoconic patients who were implanted with Keraring segments (Mediphacos, Belo Horiztone, Brazil) were included in this prospective clinical study. Diagnosis of keratoconus was based on corneal topo/tomography and slit-lamp observation and confirmed by an experienced corneal specialist.[19] The study followed the tenets of the Declaration of Helsinki and informed consent was obtained from all patients after an explanation of the nature and possible consequences of the study. The study was approved by the local ethics committee.

Inclusion criteria were clear central cornea without any scar or other complications; no history of kerato-refractive surgery; no previous history of corneal cross-linking: no history of other eye diseases except keratoconus; contact lens intolerance; corneal thickness at least 450 μm at the insertion site and 350 μm micron at the thinnest point; no history of atopy, allergy, autoimmune disorders and herpetic disease.[17] Pre- and port-operative assessments included determination of uncorrected visual acuity (UCVA) and corrected distance visual acuity (CDVA), refraction and Scheimplfug tomography with Pentacam HR (Oculus; Wetzlar, Germany). Only patients with anterior corneal changes were included in the study.

Included variables

The used variables for analysis were visual acuity (UCVA & BCVA measured in decimal notation) and refractive error data (sphere, cylinder, axis and spherical equivalent (SE)). Pentacam derived variables were keratometry in the flat and steep meridians and mean keratometry in the central 3 mm of the front and back corneal surfaces; the magnitude and axis of front and back corneal astigmatisms (CA); maximum keratometry (K-Max) in front corneal surface and corneal asphericity expressed as the Q-value in the central 8-mm of the cornea in both surfaces; corneal thickness at the apex (CCT) and the thinnest point (TP). In addition to the above recorded variables, the Belin ABCD keratoconus staging parameters which are the radius of curvature for the anterior surface (ARC) and posterior surface (PRC) for a 3.0 mm zone centered on the thinnest point, corneal thickness at the thinnest point and distance corrected visual acuity, were recorded pre- and post-ring implantation. This classification system is currently available on the Pentacam HR on the Topometric/Keratoconus Staging display and on the Belin ABCD Progression display. Corneal tomography using Pentacam were performed by the same experienced and qualified technician to avoid any bias.

The studied eyes were divided post-operatively into two groups, the group with successful results and those with unsuccessful results 6 months following the ring implantation. The criterion used was based on the DCVA, a post-operative VA improvement a least two lines was considered as a success and otherwise was recognized as a failure.[20]

Used intrastromal ring segments (ICRS)

Keraring (Mediphacos, Belo Horiztone, Brazil) was implanted for all patients, these ICRSs made of PMMA material (polymethylmethacrylate). The SI-5 model of these segments has been used in this study which is characterized by an optic zone 5 mm, isosceles triangular cross-section (base 600 μm and truncated apex 40 μm), thickness 150-350 μm by step range 50 μm, and arc lengths of 90, 120, 160, and 210 degrees.

Surgical Technique

The manufacture's proposed nomogram was used for rings' selection and the surgical plan. Selecting one or two and symmetrical or asymmetrical segments were based on the distribution of the ectatic zone on the sagittal curvature map. Segment thickness was selected according to the ectatic area's distribution, spherical and cylindrical components of refractive errors. The corneal topographic steep meridian determined the incision location.[21] A complete ophthalmic assessment was done by an experienced corneal specialist and also Kerarings were implanted by the same surgeon (MRS).

Femtosecond laser-assisted implantation was used to create the tunnel ring (Ziemer FEMTO LDV Z6) at a depth of approximately 80% of the corneal thickness at the thinnest point in the implantation area (5 mm diameter around the pupil center). The inner and outer diameters of channels were set to 4.8 and 5.4 mm, respectively. No sutures were utilized in any of the studied eyes. Postoperative treatment regimen was combination of topical corticosteroid (fluorometholone) and antibiotic (levofloxacin) 4 times daily for 2 weeks. Preservative-free artificial tear (artelac advanced) was used for 4 weeks, 8 times daily for the first two weeks and then 4 times daily for the second two weeks. In addition, a bandage contact lens (Biofinity, Cooper vision care, USA) which is a silicon hydrogel (Comflicon A) contact lens approved for up to 6 nights/7 days of continuous wear with water content 48%, Dk = 128, base curve of 8.6 mm and overall diameter of 14 mm, was used for 2 weeks.

Statistical Analysis

Data were analyzed in SPSS.22 software using the paired-samples T test and its non-parametric equivalent (Wilcoxon signed ranks test) for variables with no Gaussian distribution. The Chi-square test was used for categorical variables. A p-value<0.05 was considered as significant in all tests.

RESULTS

Fifty eyes implanted with Keraring (Mediphacos, Belo Horiztone, Brazil) of 50 keratoconic patients were included in this study. Mean age was 29.10±8.50 years (range: 18-60 years). Mean and standard deviation of visual acuity and refraction (sphere, cylinder, axis and spherical equivalent (SE)) before and 6 months after operation are presented in Table 1.

Post-operative assessment showed an improvement in refractive and acuity data with no significant cylinder axis shift. There was significant difference in all parameters except the axis of refractive astigmatism.

(P=0.434) The pre- and post-operative mean difference in sphere, refractive cylinder and SE was 0.54 D, 3.36 D, 2.22 D, and in UCVA and BCVA was 0.26 and 0.13 in decimal notation, respectively. Mean and standard deviation of studied corneal shape indices obtained with the Pentacam are shown in Table 2.

All keratometry-readings (K1, K2, mean K and Kmax) and corneal astigmatism on both corneal surfaces were significantly lower post-operatively compared to the pre-operative values (P<0.05) except the back mean keratometry. (P=0.520) The post-operative reduction in mean front keratometry, maximum front keratometry and front corneal astigmatism were 2.12, 3.36 and 2.74 D, respectively. The asphericity expressed as Q-value showed significantly decrease in the front surface prolateness (0.44) post-operatively while the back Q-value showed a more negative but non-significant change following the ring implantation. The corneal thickness at the apex and the thinnest point and the ART maximum did not show significant change after operation statistically. (P>0.05)

The mean and standard deviation of each element of the ABCD keratoconus classification pre- and post-ring implantation separately in different stages of keratoconus are shown in Table 3. The most post-operative change occurred in element A of the ABCD keratoconus classification so that the number of eyes with stage 0 increased from 3 to 23 eyes post-operatively.

Regarding the number of eyes in each stage of keratoconus, for element A, the following sequences in a decreasing trend were observed for the anterior radius of curvature (ARC) before (A2, A4, A3, A1, and A0) and after (A0, A2, A1, A4 and A3) operation. The posterior radius of curvature (PRC) showed nearly similar sequence pre- and post-operatively (B4>B2>B3>B0=B1). For the thickness at the thinnest point (TP), the preoperative sequence was C2>C1>C0=C3 and the post-operative one was C2>C1>C0>C3. The observed pre- and post-operative sequences for distance corrected visual acuity (DCVA) were D1>D2>D0>D3=D4 and D1>D0=D2, respectively. The mean and standard deviation of each element of the

ABCD keratoconus classification pre- and post-ring implantation with attention to the surgical outcomes are presented in Table 4.

There was significant difference in the numerical values of elements A, B and D of the ABCD keratoconus classification system following ring-implantation compared to the pre-operative status separately in all eyes and in the eyes with successful results, while the element C, which refers to the corneal thickness at the thinnest point, did not show significant changes. The group with unsuccessful outcomes did not show significant difference in all elements other than element A. Although the ARC showed significant flattening but it was not great enough to make a change in stage. The mean change in ARC, PRC and DCVA were 0.62 mm, 0.17 mm and 0.13, respectively. The highest change occurred in element A of the ABCD keratoconus classification system. The observed changes in each element are illustrated in Figure 1. Frequency distribution of the eyes in various stages of each element of the ABCD keratoconus classification system pre- and post-operation is shown in Figure 2.

The largest distribution of changes in the anterior surface occurred in the pre-operative stage 2, so improvement to stage 0 was observed in 30.0% of the eyes in this stage. Regarding element A, the most frequency of the eyes in the pre- and post-operative conditions was seen in stages 2 and 0, respectively. Considering element B, the highest frequency was seen in stage 4 before and after operation. However, the most changes occurred in stages 0 and 4 with a six percent change in an increasing and decreasing trends, respectively. Tbhe frequency distribution was similar pre- and post-ring implantation in stage 2. (34.0%) The distribution of the eyes in difference stages of the element C showed a slight increase in stages 0 and 1 and a subtle decrease in stages 2 and 3 post-operatively. Regarding element D, stages 0 and 1 were seen in 68% of keartoconic eyes before operation and this value increased to 84% after operation. The highest changes were observed in stages 0 and 2 with 10% increase and 12% decrease in the frequency, respectively.

The chi square test showed a significant difference in the distribution of different stages before and after ring implantation for A (X^2=31.408, df=16, P=0.012), B (X^2=52.999, df=16, P<0.001), C (X^2=62.853, df=9, P<0.001) and D (X^2=16.224, df=8, P=0.039) elements.

DISCUSSION

The global consensus of keratoconus and ectatic disorders highlighted the limitations of the prior classification systems.[9] The ABCD keratoconus staging system depicts both structural and functional changes in the cornea, grades the anterior and posterior corneal surfaces individually,b and may better reflect changes in the entire cornea compared to the previous systems.

This study showed that kerarìng implantation produces significant changes in the anterior and posterior radius of curvature of 3mm zone centered on the corneal thinnest point associated with statistically significant improvement in the corrected distance visual acuity with no significant change in the corneal thickness at the thinnest point. Considering the ABCD keratoconus classification system, the most change occurred in element A (anterior corneal surface) of this system in the group with successful outcomes. Distribution of the eyes in the different stages highlights these changes in element A, so 14% of the eyes were in the stages 0 and 1 pre-operatively and this value increased to 60% after ring implantation. The changes made to the anterior surface are more remarkable than the posterior surface.

Independent of tunnel creation method, the corneal ring segments are usually implanted in deep stroma at an approximate depth of 70-80% in the corneal midperiphery.One might also expect a significant change in the posterior corneal curvature; while, the observed changes showed the most flattering effect in the anterior corneal surface in the group with successful results. This flattening effect is explainable based on the arc shortening model which supposes the ring segments act as spacers between the corneal lamellae and consequently will reduced the arc length of the central lamellae.[14] These findings are confirming Pérez-Merino et al. (2013) and Ortiz et al. (2012) studies.[22, 23]

Comparison of the B element before and after surgery in the two groups based on the functional outcome showed a higher stage or steeper posterior curvature in the 3mm zone centered on the thinnest point in the eyes with unsuccessful results, while other elements were not significantly different. Ring implantation produced a significant posterior corneal flattening in the zone centered on the thinnest point which is in agreement with the previous studies although all earlier studies assessed changes in the central corneal zone.[2, 24] In contrast to the current findings, some studies reported a steepening of the posterior corneal surface following the ring implantation.[25]

C element of the ABCD keratoconus staging which refers to the corneal thinnest point did not show significant changes and no stage changes post-operatively compared to the pre-operative status, this is in contrast with the findings of Ortiz et al. (2012) and Muftuoglu et al. (2018).[23, 25]

Discrepancies between this study and the aforementioned studies may be related to the different parameters being measured. The “A” and “B” parameters are unique and have not been previously utilized and are centered on the thinnest point versus the corneal apex which is commonly utilized. Kmax is also a frequent end point parameter, but Kmax is a single point measurement, while the “A” and “B” parameters are taken from a 3.0 mm optical zone. Similarly, the “C” value is the thinnest point and would not be the same as an ultrasonic pachymetry reading which is typical taken at the corneal apex.

The D element of this staging system shows significant acuity changes in all eyes in the group with the successful results but these improvements did not change the stage, these findings are confirming the previous studies by Alfonso et al. (2011)[26], Piñero et al. (2009)[15], Coskunseven et al. (2008)[17], Shabayek & Alió (2007)[27].

CONCLUSION

Utilizing the Belin ABCD Classification system, we were able to document the different anatomical changes that occur with ICR implantation. Eyes which obtained improved DCVA showed significantly greater change on the anterior corneal surface as measured by the “A” parameter. While changes were also seen on the posterior corneal surface, these changes were relatively minor compared to the anterior corneal flattening. Compared to prior older classification systems which did not incorporate modern imaging technology, the ABCD classification may allow for better study designs and outcome analysis.

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Figure Legend:

Figure 1: Bar representation of the exact pre- and post-operative values of each element of the ABCD keratoconus classification system. (n=50 eyes)

Figure 2: Frequency distribution of the various stages of each element of the ABCD keratoconus classification system pre- and post-operation. (n=50 eyes)