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RESEARCH ARTICLE

Individual Long-term Visual Stability after MyoRing Treatment of Keratoconus

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ABSTRACT

Purpose: The article aims to study the individual long-term stability of visual acuity after MyoRing treatment of keratoconus.

Materials and methods: This is a retrospective study of the individual visual acuity development for 5 years after MyoRing implantation for keratoconus.

Results: In no single case did uncorrected and corrected distance visual acuity lose one line or more during the first 5 years after MyoRing treatment for keratoconus. Moreover, visual acuity was even further ameliorated in most of the cases until the last follow-up period of 5 years after surgery.

Conclusion: The results indicate that MyoRing placement inside the cornea can achieve both visual rehabilitation and stop of progression of the disease.

Keywords: Corneal ring, Keratoconus, MyoRing, Stop of progression, Visual rehabilitation.

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INTRODUCTION

Keratoconus is a rare disease, i.e., characterized by progressive steepening and thinning of the cornea, thus resulting in progressive vision loss.[1] Corneal intrastromal implantation surgery (CISIS) with MyoRing implantation has been demonstrated to be an effective and safe treatment for visual rehabilitation in myopia and keratoconus.[2,3] Long-term results show statistically stable refractive and visual data.[4] This article presents the analysis of the individual development of visual acuity of the treated eyes during an average period of 5 years after MyoRing treatment of keratoconus.

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MATERIALS AND METHODS

As described elsewhere,[2,3] CISIS starts with the creation of an intrastromal corneal pocket of 9 mm in diameter at a depth of 300 µm by means of the PocketMaker Ultrakeratome (DIOPTEX GmbH, Austria), followed by the implantation of the MyoRing through a small lamellar incision of less than 5.5 mm using a particular implantation forceps. Finally, the MyoRing has to be centered using the real postoperative optical axis as a reference. The lamellar tunnel is self-sealing and requires no suture. The procedure is minimally invasive, which causes no pre- or postoperative pain and takes only 10 minutes when performed by a trained and experienced surgeon.

Postoperatively, the eye requires neither bandage lenses nor patching. The patient is advised to apply a combination of steroid and antibiotic eye drops hourly until undergoing the first follow-up exam on the first postoperative day. Two weeks after surgery, the patient is advised to reduce the application of the aforementioned combination of eye drops to merely five times a day. Thereafter, no further medical therapy is required. The next follow-up exam is usually performed 3 months after surgery to evaluate whether the result is already optimal or may be further enhanced. This is called the initial postoperative observation period.

According to the suggested visual potential of the individual eye, up to 20% of the patients draw a visual benefit from a simple postoperative enhancement.[4] The enhancement is performed either by optimizing the position in relation to the real postoperative optical axis or by exchanging the MyoRing for one with different dimensions. An enhancement is accomplished easily and usually takes less than 1 minute without causing intra- or postoperative pain for the patient. All surgeries were performed by one surgeon (Albert Daxer).

In this retrospective study, two postoperative follow-ups per patient have been included: The first one approximately 1 year after the last surgical intervention and the

second one approximately 5 years later. The examination performed at the end of both follow-up periods included Scheimpflug measurement for topography, pachymetry at the thinnest point (corneal thickness), and K-readings simulated keratometry (SIM) K1, SIM K2, and K=(SIM K1+SIM K2)/2 using the Pentacam (Oculus GmbH, Germany), uncorrected and corrected distance visual acuity (UDVA and CDVA). Visual acuity data are represented in logMAR. In this study, the individual long-term development of UDVA and CDVA after MyoRing implantation was analyzed and evaluated. Line improvement was calculated by the difference of the visual acuity measured in logMAR between two follow-ups multiplied by a factor of 10. Changes in visual acuity of less than one line over time are considered as being not significant. Average data were expressed either as median and range in the case of a non-Gaussian distribution or as mean and/or standard error in the case of Gaussian distribution. For statistical evaluation of the postoperative changes in visual acuity, the paired t-test was used. The p-values of less than 0.05 were considered as statistically significant.

RESULTS

Nineteen eyes of 15 patients fulfilled the criteria of having two independent follow-up exams within the selected follow-up periods with all required data. After surgery, the first follow-up exam performed in the eyes included in the study was between 3 and 24 months after surgery (9±2), and the second follow-up exam was between 36 and 90 months after surgery (56±5). Ten eyes were right eyes (oculus dexter), and 9 were left eyes (oculus sinister). Three patients (5 eyes) were female, and 12 patients (14 eyes) were male. At the time of surgery, the age of the patients ranged from 21 to 50 years (median 35 years). According to the grading of Alio et al,[5] of the 19 eyes, 4 (21%) had grade I, 4 (21%) had grade II, 5 (26.5%) had grade III, 4 (21%) had grade IV, and 2 (10.5%) had grade V. A minimum of 4 eyes (21%) experienced progression of the disease in the year prior to surgery.

After 3 months of the initial treatment, four of the 19 eyes (21%) had an enhancement intervention, during which, the implant was replaced by a stronger or weaker one according to the related treatment standard.[4] For these 4 eyes, the postoperative follow-up period started with the date when the enhancement was performed. No eye underwent more than one enhancement procedure. Figure 1 shows the individual visual acuity improvement during several postoperative periods. Uncorrected distance visual acuity and CDVA improved statistically significantly during all postoperative periods ($p < 0.05$). Line improvement was up to 19 lines in UDVA (average 12.1±1.3 lines) and up to 8.5 lines in CDVA (average 2.5±0.5 lines) between preoperative examination and 1-year postoperative follow-up. Between preoperative examination and 5-year postoperative follow-up, the improvement was up to 20 lines in UDVA (average 12.9±1.3 lines) and up to 8.5 lines in CDVA (average 3.3±0.5). It is important to note that even during the second postoperative period between years 1 and 5, there is not only just a stop of the progression but also a significant improvement (antiprogression) of both UDVA and CDVA. Uncorrected distance visual acuity improved up to 3 lines (average 0.8±0.2 lines), and CDVA improved up to 2.5 lines (average 0.7±0.2 lines) between 1-year and 5-year follow-up. No eye lost one line or more during any follow-up period. Preoperatively, UDVA was 1.50±0.04 logMAR, and CDVA was 0.44±0.06 logMAR in average. After 1 year of treatment, these values were 0.28±0.04 logMAR (UDVA) and 0.18±0.03 logMAR (CDVA). At the last average follow-up of 5 years, the treatment UDVA showed improvement to 0.20±0.04 logMAR and CDVA to 0.11±0.02 logMAR.

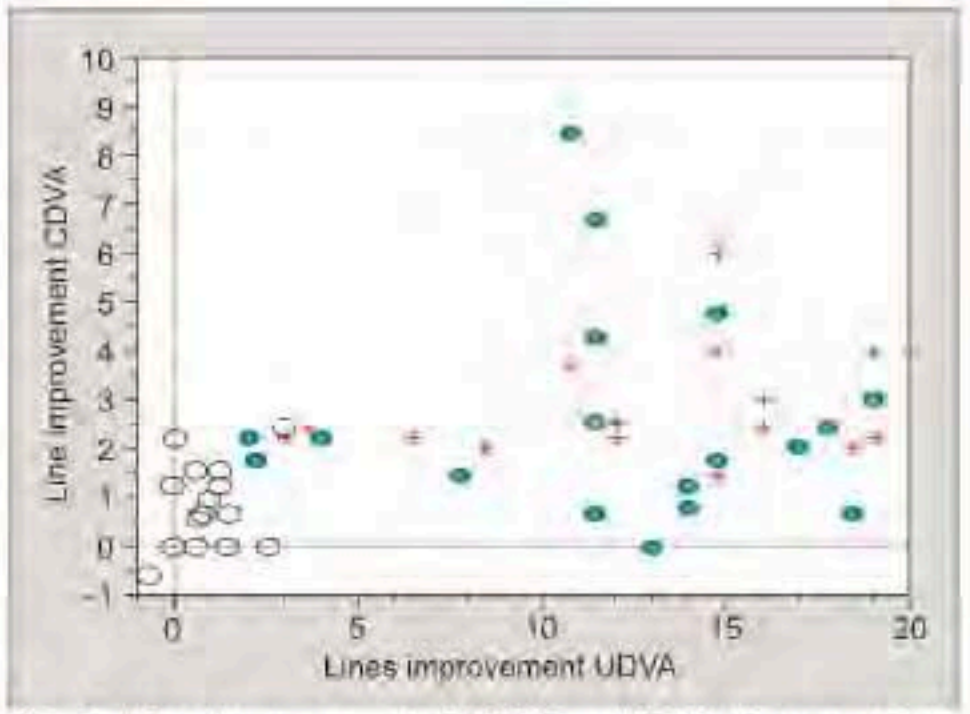

Fig. 1: Line improvement of CDVA *vs* UDVA of every single eye included into the study during different periods of time after MyoRing implantation. The black dots show the line improvement of UDVA and CDVA 1 year after treatment. The open circles show the improvement of UDVA and CDVA between 1 and 5 years after surgery. The crosses show the total line improvement 5 years after treatment. Some data points are hidden by others

No intra- or postoperative complication happened. In none of the treated eyes, an intervention resulting from postoperative progression was required. In 7 eyes, 37% of patients complained about halos that were disturbing night vision in a relevant dimension as side effect during the first 3 to 5 months after treatment. After 1 year of treatment, only 3 eyes reported halos, but these were not disturbing in a relevant dimension anymore. After 5 years of treatment, 2 eyes occasionally reported halos that did, however, not cause a relevant disturbance. No eye needed explantation of MyoRing for that side effect.

DISCUSSION

Previous studies have shown a significant improvement of K-reading, sphere, and cylinder as well as UDVA and CDVA after MyoRing implantation in keratoconus approximately 1 year after surgery.[3,4,6] While K-reading, sphere, and cylinder remain statistically unchanged between 1 and 5 years after surgery, UDVA and CDVA show a continued statistically significant improvement during this second postoperative period.[4]

The statistically significant improvement of UDVA and CDVA even during the long-term postoperative period does indicate not only visual rehabilitation but also a stabilization of the diseased cornea following MyoRing implantation.[4]

The results shown in Figure 1 demonstrate that there is no progression of the disease after MyoRing implantation on an individual level. Moreover, the visual acuity shows a continuous and statistically significant improvement during this late postoperative period (antiprogression). One of the reasons for this behavior is that, in contrast to intrastromal corneal ring segments (ICRS), the MyoRing can strengthen the cornea.[7] Many of the MyoRing-treated eyes show even further improvement of visual acuity in the long term between year 1 and year 5 after surgery (open circles in Fig. 1). Such a continuous improvement may result from "pushing" the cornea permanently against the regular and closed ring structure (MyoRing), which causes something like "ironing" of the postoperatively remaining irregularities of the central cornea over time.[8] In other words, the cornea centrally to the MyoRing gets smoother and smoother over time, which results in an improvement of visual acuity.

In contrast to MyoRing, ICRS have the disadvantage of resulting in a long-term postoperative loss of visual acuity.[9-11] This comes from the fact that ICRS can neither strengthen the cornea nor do they provide a regular and closed circular structure, which can "iron" the remaining postoperative irregularities over time.[7] Moreover, the constant pressing of the cornea against the ICRS results in a torque, which concentrates the forces against the anterior corneal lamella at the segment's endings. This may result in pressure atrophy of the anterior lamellae in front of the ICRS endings, commonly known as extrusion. Therefore, extrusion is very common after ICRS implantation and extremely rare after MyoRing implantation.[12,13]

The nomogram of MyoRing treatment is simple and depends only on the central average K-readings (SIM K's). Ring segments have a much more complicated nomogram; however, the predictability is nevertheless very limited.[14,15] The reason is because of the fact that not only the dimensions of the implants play a role for the predictability of the postoperative results but also material properties of the tissue are unfortunately not well known. There is also no way to measure these properties adequately.[7] The overall deformability in reaction to a corneal implant is therefore considered to show a significant variation among different individual corneas (Fig. 2). Under the circumstances, even the most detailed nomogram fails to give a 100% predictability. Under serious considerations, we estimate that it is possible to predict the optimal postoperative results by not more than 80 to 85% of the cases. This is reflected by the measured MyoRing enhancement rate of 21% measured in this study. In contrast to the treatment by ring segments, where the unsatisfactory results are usually accepted in order to avoid multiple interventions including opening and suturing of the radial cut, exchanging the MyoRing in the cases of over- and undercorrection is part of the treatment strategy.[4] The strategy is as follows: If it is not possible to get a 100% predictability, it is required to have a surgical technique which allows a simple, pain-free, and quick exchange of the implant as part of the procedure. The cases that require intervention for over- and undercorrection are those in Figure 2 which are outside the vertical borders. These cases may show overcorrection when located on the Gaussian curve right to the right vertical line in Figure 2. The opposite is true for corneas that show a deformability less than the normal range (e.g., high rigidity) to the left of the left vertical line. The cases in between the vertical borders are those which have a "average deformability" in

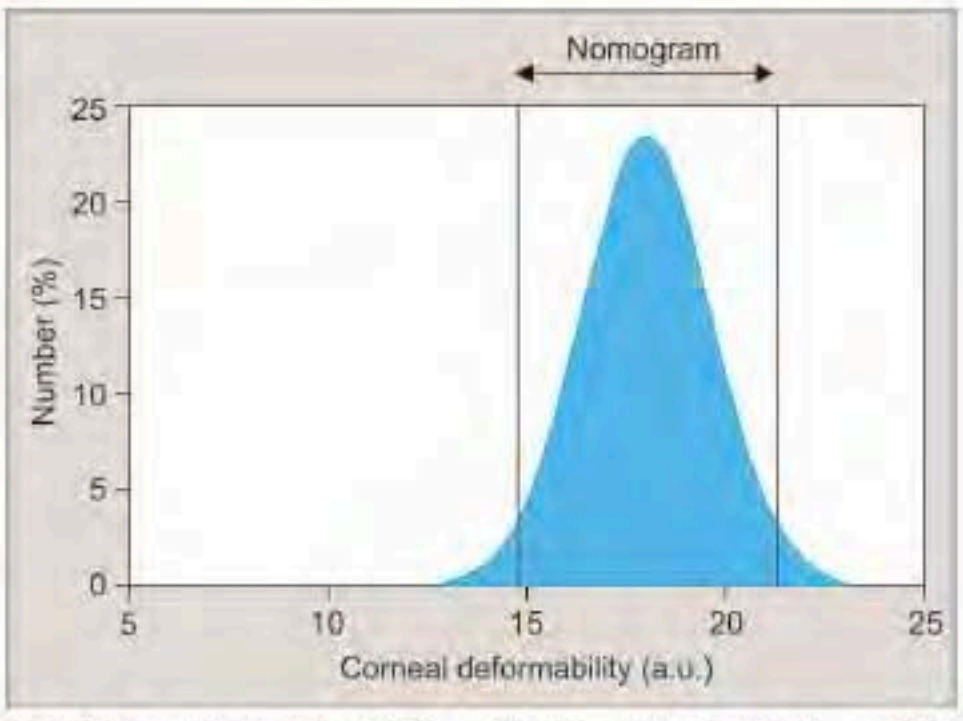

Fig. 2: The estimated distribution of the biomechanical "deformability" (e.g., inverse rigidity) of the corneas in arbitrary units among the individuals affected by keratoconus. The selection of a particular MyoRing dimension according to the nomogram depends on the SIM K's. The "deformability" of corneas showing a particular SIM K varies according to the Gaussian distribution curve among the affected eyes. If the "deformability" of the treated eye is outside a certain range (outside the vertical borders) the treatment result shows under- or overcorrection. If the treated cornea has a "deformability" which ranges in between the vertical borders (normal range where the nomogram works) the result of the treatment will be as predicted preoperatively. In the case of over- or undercorrection, the MyoRing has to be exchanged within the first 3 months after surgery

respect to an implant of a certain dimension. The results for that cases are as predicted.

In Figure 1, there is one case that shows a nonsignificant reduction of visual acuity of less than one line during the second follow-up period. After 1 year of treatment, the improvement of UDVA was 18.5 lines – from finger counting to 0.7 decimal. After 7 years of treatment, this value varied slightly over time and was 18 lines at the latest follow-up. After 1 year of treatment, the improvement of CDVA was 3.5 lines – from 0.3 to 0.7 decimal. After 7 years of treatment, the value varied slightly over time and was 3 lines at the latest follow-up. A variation within one line over time is considered to be nonsignificant and no reason for intervention. In none of the treated eyes, an intervention resulting from postoperative progression was required. If unexpectedly a progression in one of these cases should occur, it would be appropriate to use the corneal pocket for riboflavin instillation in order to bypass the epithelium and to perform cross-linking accordingly.[16,17]

A limitation of the study is that only 21% of the cases had a documented progressive disease. A further limitation is that the study population had an average age of 35 years – an age where progression is less common than in a much younger population. The fact, however, that the majority of the cases had a continuous improvement of visual acuity in the long-term may be a good clinical proof that the treatment is able to strengthen and stabilize the cornea.[4,7]

In agreement with the findings that visual acuity (UDVA and CDVA) statistically significantly improves between year 1 and year 5,[4] while no individual case showed a significant reduction in visual acuity during that postoperative follow-up period (Fig. 1), the biomechanical calculations[7] are very strong indicators that MyoRing implantation when performed according to the referenced standard[4] can achieve not only a visual rehabilitation but also a stop of progression.

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