CLINICAL RESULTS AFTER CONTINUOUS CORNEAL RING (MYORING) IMPLANTATION IN KERATOCONUS PATIENTS

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SUMMARY

Purpose: to present one and two years clinical results after intrastromal continuous corneal ring implantation in keratoconus patients.

Methods: Retrospective evaluation of the results of patients with keratoconus, after MyoRing implantation for improving of visual functions. The uncorrected distance visual acuity (UDVA), best corrected distance visual acuity (CDVA), the residual subjective refractive error, pachymetry, keratometry and the size of corneal astigmatismus were evaluated. Peroperative and postoperative complications were investigated. The minimal follow-up time was 12 months.

Results: The study included 32 eyes of 30 patients with mean age of 30.08 (± 11.56) years. UDVA improved from 1.03 (± 0.41) logMAR to 0.36 (± 0.25) logMAR 12 months and 0.31 (± 0.27) logMAR 24 months after surgery. These changes were stastistically significant. The maxima value of corneal curvature (Kmax) was preoperatively 52.48 (± 6.35) D, 46.08 (± 4.44) D 12 months and 45.53 (± 5.52) D 24 months after surgery. Both changes were statistically significant (P < 0,00000). The mean value of corneal curvature (K mean) was preoperatively 50.10 (± 4.96) D, 44.25 (± 4.40) D 12 months and 44.11 (± 5.38) D 24 months after surgery. Both changes were statistically significant. In any of the patients we did not register any severe peroperative or postoperative complication.

Conclusion: The MyoRing implantation is an effective and safe method in improvement of visual functions in keratoconus patients. Clinical results are stable in one and two years follow-up time.

Key words: continuous corneal ring, MyoRing, keratoconus

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INTRODUCTION

Keratoconus remains one of the main indications for the performance of perforating transplantation of the cornea (7, 11, 16). Nevertheless, in recent years there has been ever increasing use of methods which can have a favourable influence on the course of the disease, and thus detect (or even eliminate) the necessity of transplantation. This primarily concerns the technique of corneal collagen crosslinking (CXL), thanks to which stabilisation of the progression of keratoconus is as a rule achieved (14, 15, 17). Another method is implantation of intrastromal segments, the purpose of which is to flatten the central part of the cornea and regularise it, which in its result may lead to an improvement of the patient's visual acuity (12). At present 3 types of segments are available on the market (ICRS – intracorneal ring segment) – Intacts (Addition Technology Inc.), Ferrara ring (Ferrara Ophthalmics Ltd.) and Keraring (Medicophacos Ltd.). Implantation of a full corneal intrastromal ring – MyoRing (Dioptex GmbH, Austria) is an alternative technique, which has been described by Daxer for use in the correction of keratoconus (6) (fig. 1). The ring is produced from polymethyl methacrylate, and is partially flexible. It is available in diameters of 5 and 6 mm, the thickness of the ring is 240, 280 and 320 µm. The type of ring is chosen according to the required effect according to the normogram recommended by the manufacturer (table 1). The ring is implanted into the corneal pocket with a diameter of approx. 9 mm, at a depth of 300 µm. As a rule, the inlet channel into the pocket is located temporally, and its width is approximately 4-5 mm, length approx. 2 mm. The intrastromal pocket can be created using a special microkeratome, in which the incision is made by a vibrating diamond knife following previous attachment of the head of the keratome to the cornea of the patient (PocketMaker, Dioptex GmbH, Austria). Another possibility is the use of a femtosecond laser (1, 9). The main advantage of the MyoRing in comparison with corneal segments is the possibility of postoperative adjustment of the position of the ring, thereby optimising the effect of the ring (4, 10), easy handling and the possibility of combination with intrastromal application of riboflavin in a procedure combined with CXL (5). One-year and two-year results in a group of patients with keratoconus and an implanted MyoRing form the content of this study.

METHOD

This represents a retrospective evaluation of patients undergoing outpatient corneal treatment at the Department of Ophthalmology at the Královské Vinohrady University Hospital with a diagnosis of keratoconus, in whom a MyoRing had been implanted in order to improve visual functions. The classification of keratoconus was determined on the basis of a division according to Amsler-Krumeich (2). The exclusion criteria were thickness of the cornea of less than 350 µm in the thinnest part, corneal scar, acute corneal hydrops and previous surgical procedure on the eye.

All the operations were performed by a single surgeon (PS). The procedure was always performed in outpatient care, under local anaesthesia. The corneal pocket was crea-

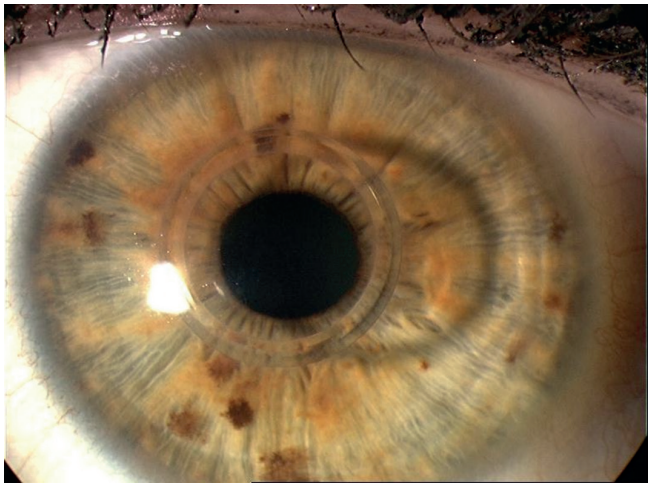


Fig. 1 Cornea with implanted MyoRing

ted using a PocketMaker, at a depth of 300 µm, the type of MyoRing was chosen according to the nomogram supplied by the manufacturer (see table 1). In the case that progression was determined in the preoperative period, the implantation of the MyoRing was combined with the CXL method. In the case of these patients, Riboflavin without Dextran (0.1% riboflavin, Mediocross-sine, Medio-HAUS Medizinprodukte GmbH, Germany) was injected into the stromal corneal pocket via an incision tunnel, in a quantity of approximately 0.5 ml. Irradiation of the cornea of the patient using a UV-A lamp (Peschke Meditrade GmbH, Switzerland) with a wavelength of 365 nm, intensity 3mW/cm2 for a period of 30 minutes was commenced within approximately 5 minutes following the application of riboflavin. During the course of irradiation, the application of riboflavin was continued also on the surface of the cornea with a retained epithelium. The corneal tunnel is self-closing, non-perforating and does not require suturing. After the end of the operation the cornea was covered by a contact lens for a period of approximately 3-4 days, and application of a combined preparation of antibiotics and steroids locally was recommended 5x daily for a period of 14 days.

During follow-up examinations within the first and second week after the operation, only the postoperative reaction was observed, and any complications were recorded. Within the framework of follow-up examinations in the 1st, 6th, 12th and 24th month, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) and size of the subjective refractive error were observed. Pachymetry, keratometry and size of corneal astigmatism were observed with the help of a Scheimpflug camera (Pentacam, Oculus). Any applicable peroperative and postoperative complications were registered. The minimum observation period was 12 months.

Unless otherwise stated, the average values are always stated with the standard deviation (SD) in brackets. A pair Student test was used for the statistical evaluation, we considered the value of $P < 0.05$ to represent the level of significance.

RESULTS

The study cohort comprised 32 eyes of 30 patients, of whom 23 were men and 7 women. The youngest patient in our cohort was 18 years old, the oldest 61. The average age in the cohort was 30.08 years (± 11.56). In 4 patients this concerned 1st degree keratoconus, in 11 cases 2nd degree keratoconus, in 14 cases 3rd degree and in 3 cases 4th degree. The average observation period was 21.9 (± 9.4) months. The shortest observation period was 12 months, the longest 48 months. In the case of 18 eyes the observation period was 24 months and longer. In 24 cases the implantation of the MyoRing was combined with intrastromal application of Riboflavin and CXL. We did not record any more serious peroperative or postoperative complications in any case.

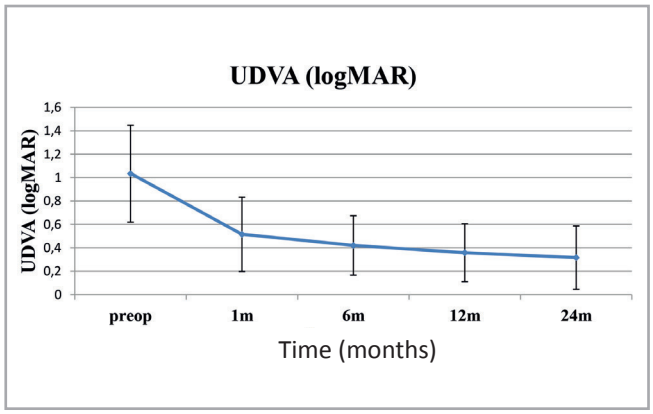
UDVA improved from 1.03 (± 0.41) log MAR preoperatively to 0.42 (± 0.25) log MAR 6 months after surgery, 0.36 (± 0.25) log MAR 12 months after surgery and to 0.31 (± 0.27) log MAR 24 months after surgery (see table 2, graph 1). In comparison with the preoperative values, the improvements were statistically significant in all the observed periods. We observed a further statistically significant improvement also in comparison between the value in the 1st month postoperatively and in the 6th, 12th and 24th month. Subsequent improvements were no longer statistically significant (table 3).

CDVA improved from 0.48 (± 0.19) log MAR preoperatively to 0.22 (± 0.18) log MAR 6 months after surgery, 0.20 (± 0.13) log MAR 12 months after surgery and to 0.18 (± 0.16) log MAR 24 months after surgery (see table 2, graph 2). In comparison with the preoperative values, the improvements were statistically significant in all the observed periods. We observed a further statistically significant improvement also in comparison between the value in the 1st month postoperatively and in the 6th, 12th and 24th month. Subsequent improvements were no longer statistically significant (table 4).

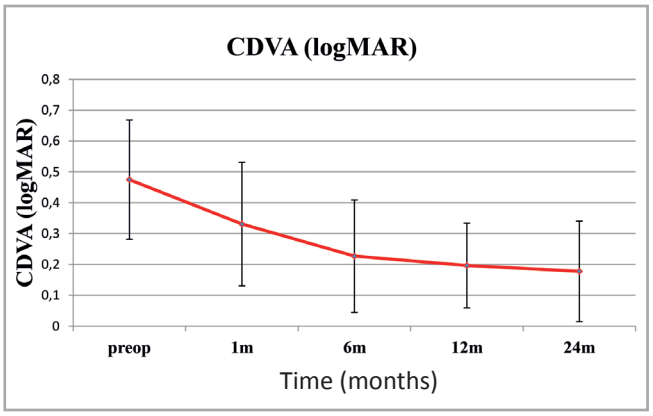
The maximum value of corneal curvature (Kmax) preoperatively was 52.48 (± 6.35) D. One month after surgery this was reduced to 45.77 (± 5.64) D, in subsequent obser-

Table 1 Nomogram for selection of type of ring.

Kmean (D)	Size of pupil (mm)	Diameter of ring (mm)	Thickness of ring (µm)
< 44		6	240
> 44 to < 48	< 4.5	5	240
	> 4.5	6	280
> 48 to < 52	< 4.5	5	280
	> 4.5	6	320
> 52		5	320



Graph 1 Uncorrected distance visual acuity (UDVA) (log MAR) following implantation of a MyoRing



Graph 2 Corrected distance visual acuity (CDVA) (log MAR) following implantation of a MyoRing

ved period it remained practically unchanged, in the 12th month 46.08 (± 4.44) D and in the 24th month after surgery 45.53 (± 5.52) (table 1). The differences between the preoperative value and the results in the 12th and 24th months were statistically significant (in both cases P < 0.00000). The mean value of corneal curvature (K mean) preoperatively was 50.10 (± 4.96) D. One month after surgery this was reduced to 44.13 (± 5.70) D. K mean also remained practically unchanged in the subsequent periods, in the 12th month 44.25 (± 4.40) D and in the 24th month 44.11 (± 5.38) (table 2). The differences between the preoperative value and the results in the 12th and 24th months were statistically significant (both values P < 0.00000).

Corneal astigmatism, calculated as the difference between minimum and maximum corneal curvature determined using a Pentacam, was preoperatively 5.05 (± 4.21) D, one month after surgery this was reduced to 3.36 (± 2.27) D. In the 6th month it was 1.55 (± 1.02) D, in the 12th month 3.41 (± 2.34) D and in the 24th month 2.96 (±2.22) D (table 2). In comparison with the preoperative values, the difference in the values in the 12th month was statistically significant (P = 0.0341). In comparison with the preoperative values, the difference in the values in the 24th month was not statistically significant (P = 0.34397).

Spherical equivalent (SE) preoperatively was -5.36 (± 4.38) D, one month after surgery it was -1.42 (± 2.71) D, and -0.97 (± 3.19) D, -1.46 (± 2.34) D and -0.42 (± 1.74) D in the 6th, 12th and 24th months respectively. In comparison with the preoperative value, the difference in the 12th and 24th months was statistically significant (P < 0.00000, P = 0.00023).

Corneal thickness in its thinnest part preoperatively was 431.7 (± 35.4) µm, postoperatively there was only a small reduction of corneal thickness, in the 12th month to 422.8 (± 44.5) µm, and in the 24th month 412.5 (± 37.6) µm (table 2). The differences were not statistically significant (P = 0.05896 and P = 0.96990).

DISCUSSION

Change of the shape of the cornea with the help of implantation of intrastromal segments may alter the curvature of the ectatic cornea and thus improve the patient's visual acuity (13). A range of studies have been published which demonstrate the effectiveness of the implantation of various types of intrastromal segments on visual functions. Colin describes an improvement of UDVA one year after implantation of Intacs from 1.05 (± 0.33) log MAR to 0.35 (± 0.16) log MAR and an improvement of CDVA from 0.38 (± 0.13) to

Table 2 Overview of results following implantation of a MyoRing over time.

	preoperatively	1 month	6 months	12 months	24 months
UDVA (logMAR)	1.03 (± 0.41)	0.52 (± 0.32)	0.42 (± 0.25)	0.36 (± 0.25)	0.31 (± 0.27)
CDVA (logMAR)	0.48 (± 0.19)	0.33 (± 0.20)	0.22 (± 0.18)	0.20 (± 0.13)	0.18 (± 0.16)
Kmax (D)	52.48 (± 6.35)	45.77 (± 5.64)	45.60 (± 4.87)	46.08 (± 4.44)	45.53 (± 5.52
Kmean (D)	50.10 (± 4.96)	44.13 (± 5.70)	43.95 (± 4.91)	44.25 (± 4.40)	44.11 (± 5.38)
Corneal astigmatism (D)	5.05 (± 4.21)	3.36 (± 2.27)	1.55 (± 1.02)	3.41 (± 2.34)	2.96 (± 2.22)
Spherical equivalent (D)	-5.36 (± 4.38)	-1.42 (± 2.71)	-0.97 (± 3.19)	-1.46 (± 2.34)	-0.42 (± 1.74)
Corneal thickness – thinnest part (µm)	431.7 (± 35.4)	427.4 (± 45.8)	425.8 (± 48.3)	422.8 (± 44.5)	412.5 (± 37.6)

Table 3 Statistical significance (P > 0.05) of improvement of uncorrected distance visual acuity between individual observed periods

	preoperatively	1 month	6 months	12 months	24 months
preoperatively		0.00000	0.00000	0.00000	0.00010
1 month			0.09364	0.01426	0.04736
6 months				0.10817	0.48469
12 months					0.75050

Table 4 Statistical significance (P > 0.05) of improvement of best corrected distance visual acuity between individual observed periods

	preoperatively	1 month	6 months	12 months	24 months
preoperatively		0.00331	0.00000	0.00000	0.00011
1 month			0.00404	0.00144	0.02482
6 months				0.11552	0.49996
12 months					0.66922

0.22 (± 0.12) log MAR (3). Tunc describes an improvement of UDVA one year after implementation of UDVA one year after implantation of Keraring segments from 1.36 (± 0.64) to 0.51 (± 0.28) log MAR and CDVA from 0.57 (± 0.29) to 0.23 (± 0.18) log MAR. At the same time he describes SE from -6.42 (± 4.69) to -1.26 (± 1.45) D (18). In his study Haddad compares patients with implantation of Intacts (group 1) and Keraring (group 2), the differences in both groups of patients were not statistically significant. One year after surgery UDVA in group 1 improved by 0.62 (± 0.19) log MAR, in group 2 by 0.67 (± 0.17) log MAR. One year after surgery CDVA improved by 0.12 (± 0.11) log MAR, and by 0.08 (± 0.13) log MAR respectively (16). SE was reduced in group 1 by 2.80 (± 2.87) D, and in group 2 by 2.65 (± 3.0) D (8).

In our study cohort, UDVA improved from 1.03 (± 0.41) log MAR preoperatively to 0.36 (± 0.25) log MAR 12 months after surgery. CDVA improved from 0.48 (± 0.19) log MAR preoperatively to 0.20 (± 0.13) log MAR. SE was reduced from -5.36 (± 4.38) D preoperatively to -1.46 (± 2.34) D one year after surgery, and -0.42 (± 1.75) D 2 years after surgery. Improvement of CDVA is entirely comparable with all the aforementioned studies. Postoperative UDVA in our group is the same (3) or even better (18) in comparison with ICRS implantations. The greater effect of the implantation of a MyoRing could be explained by the greater effect of the full ring on reducing myopia, to which the greater reduction of SE in our cohort corresponds. A similar experience is stated also by other authors who publish the results of implantation of a MyoRing (1, 9, 4).

The results of our cohort are entirely comparable with those of other studies which evaluate the effectiveness of implantation of a MyoRing. Jabbarvand, in a group of 98 eyes, describes an improvement of UDVA one year after implantation of a MyoRing from 1.17 (± 0.36) to 0.62 (± 0.28) log MAR and an improvement of CDVA from 0.85 (± 0.26) to 0.52 (± 0.22) log MAR (9). Daxer, in a group of 21 eyes states an improvement of UDVA one year after implantation of a MyoRing from 0.40 (± 0.17) to 0.12 (± 0.10) log MAR. SE was reduced from -6.27 (± 5.20) to -0.52 (± 3.4) D (10). Alio, in a group of 12 eyes, states an improvement 6 months after implantation of a MyoRing, in the case of UDVA from 1.36 (± 0.33) to 0.61 (± 0.25) D and in the case of CDVA from 0.43 (± 0.24) to 0.32 (± 0.18) log MAR. SE was reduced during the course of these 6 months from -8.19 (± 4.85) to -0.88 (± 2.29) D (1).

When we compared the results for our patients separately in a sub-group of patients in whom only a MyoRing was implanted (8 patients) and a sub-group of patients in whom a combined procedure of implantation of a MyoRing and CXL was performed (24 patients), these differences were not statistically significant. Nevertheless, the evaluated sub-groups were small, and as a result it is necessary to judge this result only referentially. For a comparison of both methods, larger cohorts of patients would be required. Furthermore, the purpose of using CXL in our patients was primarily in order to halt the progression of the disease and not the refractive effect, which is probably in large part covered by the effect of the MyoRing itself.

The method of implantation of a MyoRing and a combination of a procedure of MyoRing + CXL can be considered safe. Daxer describes relative discomfort in 2 out of 15 patients with an implanted MyoRing (4). Jabbarvand describes a case of one explantation of a MyoRing due to patient dissatisfaction in a group of 98 eyes (9). Alio describes one case in a group of 12 eyes in which it was necessary to perform perforating keratoplasty due to an unsatisfactory result in a patient with an advanced stage of keratoconus (1). In our group we did not record any more serious peroperative or postoperative complication which would have necessitated explantation of the MyoRing. Some patients described mild irritation of the operated eye, which nevertheless attenuated in all cases within 14 days of the operation. In isolated cases patients describe the visibility of the ring or a glare effect, especially under worse lighting conditions, in which the size of the pupil probably exceeds the dimensions of the implanted ring.

The main limitation of our study is primarily the small number of patients included in the study cohort, nevertheless, with few exceptions, foreign studies describe results in similarly sized groups of patients. Another certain deficiency

is the shorter observation period, with regard to the chronicity of the disease. At the same time, it was not entirely possible in the evaluation of the results to differentiate the positive effect of performed CXL and implantation of a MyoRing, in particular if both procedures were performed in combination, as was the case for 24 eyes in our group.

CONCLUSION

The one-year and two-year results in our cohort of patients with keratoconus following implantation of a full corneal MyoRing confirm a significant improvement of visual functions. These results are fully comparable with previously published studies, and are also entirely comparable with the results in groups of patients with implanted ICRS. The main advantage of the use of a MyoRing is primarily easy handling, simple implantation, the possibility of combination with intrastromal application of riboflavin and the performance of transepithelial CXL, as well as the theoretical possibility of adjusting the position of the ring in the postoperative period.

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