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ORIGINAL ARTICLE

Femto Circular Keratotomy to Halt the Progression of Keratoconus I and II

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ABSTRACT

Aim: To simplify and enhance safety in the generation of a stabilizing intracorneal scar by circular keratotomy (CKT). A femtosecond laser was used to perform individually sized intraparenchymal cuts.

Materials and methods: As equipped, the Ziemer Z6 femtosecond laser cuts a 400-µm-deep incision with a diameter of 7.0 mm around the optical axis. The epithelium, Bowmann's membrane, the internal borders of Descemet's membrane, and the endothelium are not affected.

The 3-, 6-, and 12-month postoperative values were compared with the 1-month postoperative keratometric readings and astigmatism. The preoperative best corrected visual acuity (BCVA) with glasses was compared with the values found at the same time points as noted above.

Results: Statistical evaluation indicated that keratometry within ±1.5D remained in 96.6, 93.1, and 96.6% of cases at the 3-, 6-, and 12-month time points respectively.

Astigmatism was stable at the same time points in 100, 95.8, and 92.3%.

The BCVA improved in 12 cases throughout the first postoperative year (48%, n = 25); however, 11 cases did not change (44%) and 2 cases lost at least one line (8.0%).

Conclusion: Femto CKT halts the progression of keratoconus for at least 1 year in 96.6% of cases. This treatment provides keratometric and refractive stability for over 1 year. This result, in conjunction with the significant improvement in BCVA, demonstrates the potential of this method for patients with stage I and II keratoconus.

Keywords: Circular corneal cut, Circular keratotomy, Keratoconus.

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INTRODUCTION

The methods currently used to attempt to halt the progression of keratoconus include crosslinking, which was introduced by Wollensak et al,[1] and mechanic circular keratotomy (CKT) using the guided trephine system (GTS), which was introduced by Krumeich and Kezirian[2] in 2009 and has been recently discussed in this journal.[3] The femtosecond laser is not currently used in these procedures.

The femtosecond laser can ameliorate grossly warped keratoconus corneae by creating intrastromal channels. Among these are the intrastromal corneal ring segments (Intacs, Addition Technology Inc., Des Plaines, Illinois, USA). These devices for topographic and visual improvement in keratoconus eyes without central scarring were introduced in 2000[4] and have been reported to reduce corneal steepening and astigmatism.

Another keratoconus treatment using the femtosecond laser is the creation of an intracorneal pocket for the insertion of complete rings (MyoRing, DIOPTEX GmbH, Linz, Austria), which has reportedly enabled keratoconus corneal modeling.[5]

Both techniques serve to better the surface of the cornea and improve vision. However, there are no reports of halting cone progression.

Circular keratotomy has been reported as a safe procedure to stop cone progression in at least 86% of cases 5 years after surgery.[2,3] The generation of a circular scar around the optical axis also creates a firm scar that stabilizes the cornea. This method was applied mechanically using the GTS operated with glass plugs of different radii (obturators). These plugs prevented the cornea from bulging into the hollow trephine, thereby avoiding different cutting angles. A corneal thickness in the 7 mm zone of at least 450 µm was a prerequisite for the operation with a 400-µm deep cut. The mechanically created wound had to be sutured, and we used a double running 10 × 0 nylon suture placed at a depth of approximately 350 µm for this purpose. We used the 1-year postoperative data after sutures were taken out as the baseline to evaluate data from the subsequent time points. The sutures required regular postoperative controls and had to be tightened or renewed, with the latter occurring in 3% of cases.

We used the femtosecond laser to create an intrastromal cut to improve the procedure, avoid the uncomfortable

postoperative suture checkups, and increase safety. The Ethical Committee of the University of Muenster Germany agreed to the study design.

MATERIALS AND METHODS

Study Design

Femto CKT procedures were performed in a multicenter prospective controlled study. The operations and follow-up examinations were performed by two surgeons (JHK and DB) at the outpatient clinic Krumeich in Bochum, Germany, and Breyer, Kaymak and Klabe Augenchirurgie in Düsseldorf, Germany.

Out of the study cohort consisting of 66 patients, 56 were operated on by JK in Bochum and 10 patients were operated on by DB in Düsseldorf. We treated stage I or II progressive keratoconus eyes according to the Krumeich clinical classification.[2] Twenty-nine cases with complete follow-up of keratometry measurements for up to 1 year were statistically analyzed and discussed in this paper.

We determined the patient's disease to be progressive if there was an increase in either radius of more than 1.5 diopters within 1 year or if manifest refraction had changed by more than 1 diopter in 1 year. The patient questionnaire included age and sex information, although these data were not included in the evaluation.

All patients were informed of the uncertainty of the outcome regarding stability and the possible need for further treatment, mainly that the placement a double running antitorque suture would be required for stabilization in case of further progression.

The patients were informed of their assignments to a controlled group and that the result of the operation had to be reported to the ethical committee. All patients provided written informed consent.

The corneal analyses included manifest refraction. The corneal radii and topography were evaluated using a Bausch and Lomb manual ophthalmometer (Bausch and Lomb, Rochester, New York, USA), the pachymetry map of the cornea was obtained using an Orbscan scan-slit topograph, and endothelial cell counting was completed with a specular microscope (Tomey EM-3000, Tomey Corporation, Nishi-Ku, Nagoya, Aichi, Japan). Corneal optical coherence tomography (OCT) was measured postoperatively with an RTvue-100 (Optovue, Inc., California, USA).

Femtosecond Laser Settings

The Ziemer Z6 (Ziemer Ophthalmic Systems AG, 2262 Port, Switzerland) laser was used for all operations. The angle of cut was individually calculated for each patient according to the patient's corneal thickness. We began at 60 µm above Descemet's membrane and went up inside the tissue to 100 µm below the epithelium.

The cutting angle was varied from 25° to 45° to attain a cutting length of at least 400 µm. By adjusting the angle of cut, the prerequisite for this operation was a minimum corneal thickness of 450 µm in the 7 mm zone around the optical axis. The Z6 laser beam is operated at low energy (10–20 nJ) and high frequencies (20.8 MHz).

Surgical Procedure

All patients received topical anesthesia and underwent moderate sedation with Tranxilium (Dikalium clorazepat, Sanofi-Aventis Deutschland GmbH, Germany). The operation was carried out under sterile conditions, and the eye was washed with beta-isadonna followed by balanced salt solution.

Because applanation of the laser handpiece could dislocate the center of a steep keratoconus cornea, the mid-pupillary projection was marked with gentian violet prior to applanation. Placement of the laser handpiece was controlled by a microscope to verify the centration and diameter of the applanated area. The center of the circular cut was identical to the optical axis. The cornea was applanated to 9 mm, suction was applied, and the position of the applanation and the gentian violet mark were visible on the screen and could be optimized. The cutting time varied from 20 to 25 seconds depending on the cutting length.

The postoperative prescription was Maxitrol drops 3 times/day for 1 week.

Clinical Outcomes

The stability values of the K-readings and refraction were evaluated to determine whether progression of keratoconus had been halted. In contrast to the evaluation of the mechanical CKT, the 1-month keratometry values were used as the baseline rather than the 1-year values because the sutures, which may change the radii, were not used. The preoperative best corrected visual acuity (BCVA) values were used as baseline to determine changes in visual acuity.

Progression of the cone was defined as follows:

- Keratometry – Steepening of >1.5D in the mean K-readings
- Astigmatism – A change in the eye's astigmatism of >1.5 D
- BCVA – A change of >1 Snellen line.

Corneal optical coherence tomography was measured 1-day postoperatively and at every time point during the follow-up to evaluate the cutting length.

Statistical Analysis

Data were compiled by nonparticipating employees. For the statistical analyses Microsoft Excel 14.0 for Mac

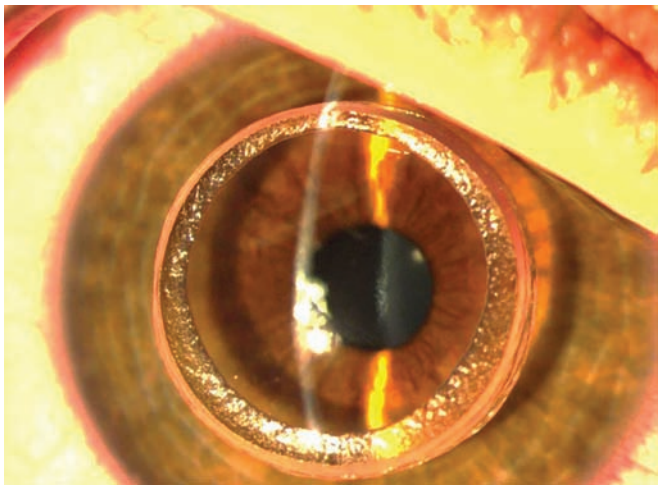


Fig. 1: Femto CKT cut 15 minutes postoperatively

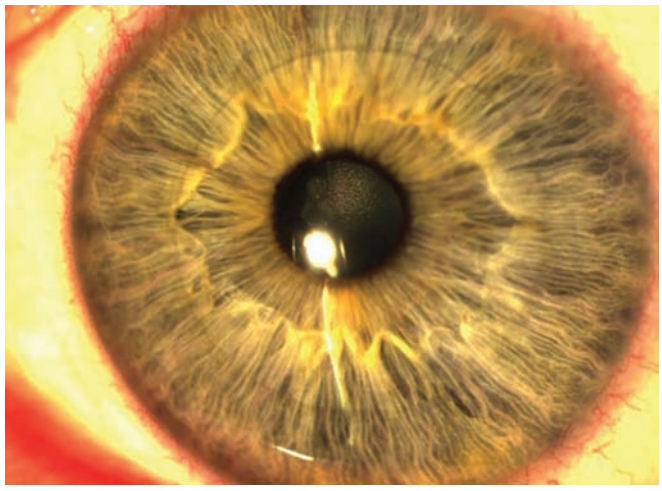


Fig. 2: Femto CKT cut 3 months postoperatively

(Microsoft, Redmond, Washington, USA) with Statplus Mac version 5.8.3.8 plug-in (AnalystSoft, Walnut, California, USA) and an Xlstat 2012 plug-in (Addinsoft, New York, USA) were used.

All data were evaluated according to their distributions using the Kolmogorov-Smirnov test. The data were not normally distributed, and nonparametric testing was performed therefore. Nonmetric data were tested using the chi-square test and the Wilcoxon signed rank test was used for pairwise comparison of metric data. A p-value of <0.05 was considered significant.

Although other indicators like pachymetry, age, and sex were included, we focused solely on two indicators for evidence of statistically significant progression of keratoconus in the treated eyes: first keratometric changes of >1.5D and secondly changes in astigmatism of >1.5 D.

RESULTS

Clinical Outcomes

The patients reported no postoperative restrictions. Many patients reported better vision from the first day after operation and onwards.

The immediate postoperative cut appearance on the 7 mm site resembled a halo (Fig. 1). This halo is a collection of mini blebs that effectuate the tissue separation and cannot escape because they are trapped between the Bowman's and Descemet's membranes. This blown-up circle disappears within hours and does not bother the patient. The epithelium remained intact. On the 1st postoperative day, only subconjunctival petechii coming from the laser suction handpiece were visible. There were no signs of intraocular reactions (Fig. 2).

The cut in the OCT is different to a knife's cut and appears somewhat curved (Fig. 3).

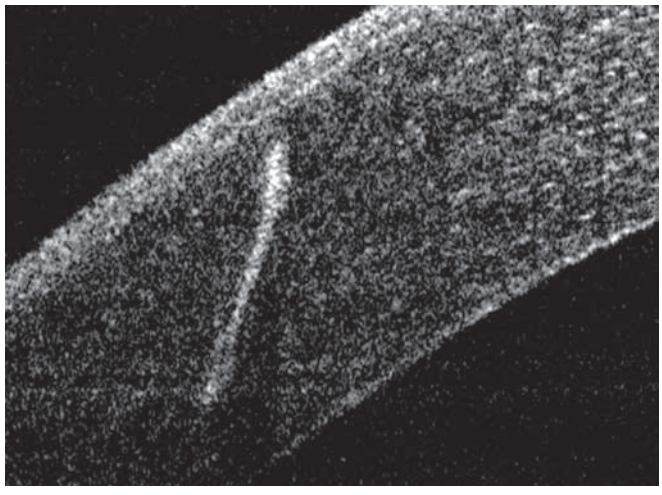


Fig. 3: Corneal OCT 3 months postoperatively

Statistical Outcomes

Keratometry

The radii were stable within 1.5D 1-year postoperatively in 28 cases (96.6%, n = 29). The mean K-values at the 3-, 6-, and 12-month follow-ups were 44.98D (SD 1.37, 41.5–47.98), 45.05D (SD 1.37, 41.2–47.2), and 45.25D (SD 1.48, 43.3–47.95) respectively.

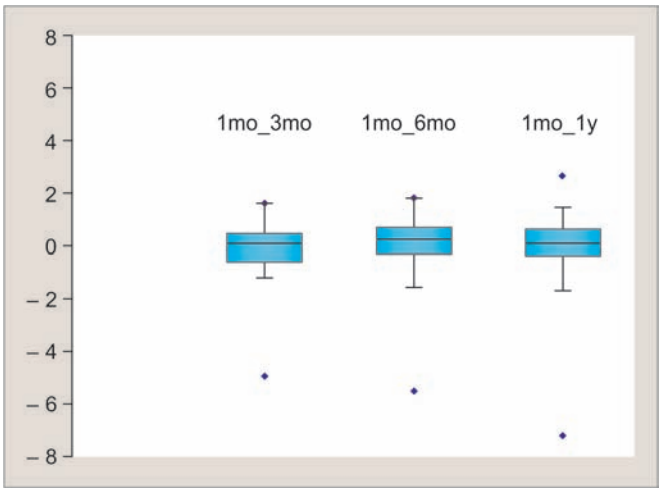
The changes in mean keratometry were 0.31D (SD 0.79, –0.58–3.68, p = 0.955), 0.38D (SD 0.98, –0.60–4.75, p = 0.892), and 0.59D (SD 1.05, –0.45–5.25, p = 0.812) at the 3-, 6-, and 12-month follow-ups respectively.

The changes in keratometric values are presented in Graph 1.

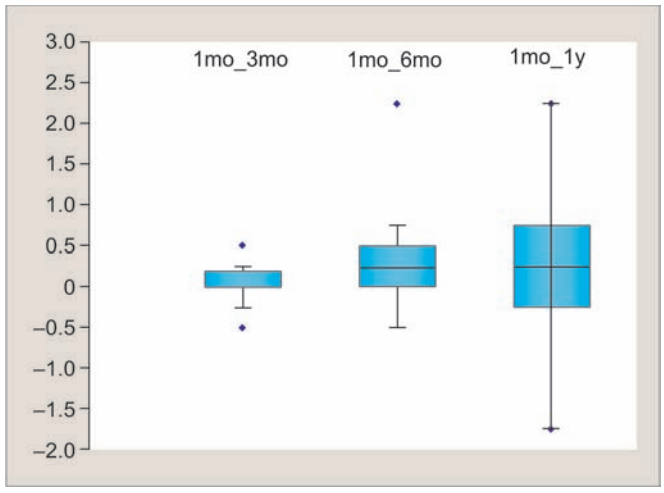
Astigmatism

Astigmatism was stable in 24 cases 1-year postoperatively (92.3%, n = 26).

The mean astigmatism at the 3-, 6-, and 12-month follow-ups was –1.77D (SD 1.22, –5.5–0.0), –2.05 (SD 1.35, –6.0–0.0), and –2.05 (SD 1.6, –6.0–0.0) respectively.



Graph 1: Changes in keratometry, 3-, 6-, and 12-month follow-ups compared to 1-month postoperatively



Graph 2: Changes in astigmatism, 3-, 6-, and 12-month follow-ups compared to 1-month postoperatively

The changes in mean astigmatism was –0.05D (SD 0.26, –0.5–0.5, p = 0.99), –0.33D (SD 0.67, –2.25–0.5, p = 0.12), and –0.33D (SD 0.92, –2.25–1.75, p = 0.44) respectively.

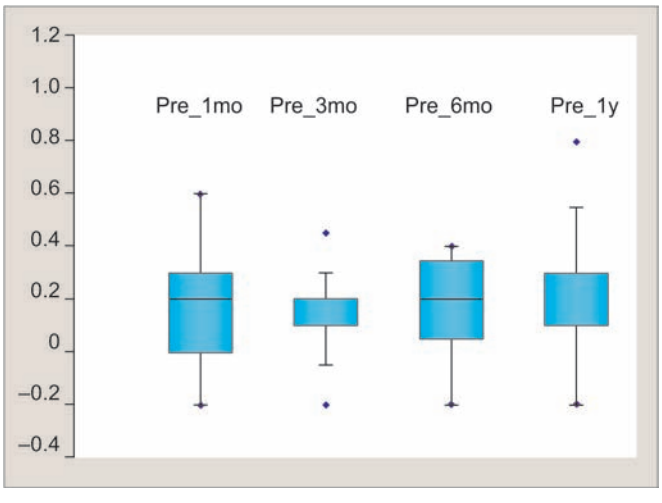
The changes in astigmatism values are presented in Graph 2.

Best corrected visual acuity

The BCVA improved in 12 cases throughout the 1st postoperative year (48%, n = 25), whereas 11 cases did not change (44%) and 2 cases lost at least one line (8.0%).

The mean BCVA at the 1-, 3-, 6-, and 12-month follow-ups compared with the preoperative values were 0.75 (SD 0.2, 0.3–1.2), 0.78 (SD 0.21, 0.25–1.20), 0.80 (SD 0.17, 0.45–1.2), and 0.84 (SD 0.19, 0.50–1.25) respectively.

The mean changes in BCVA at the 1-, 3-, 6-, and 12-month follow-ups were 0.12 (SD 0.17, –0.2–0.45, p = 0.056), 0.15 (SD 0.4, –0.2–0.45, p = 0.01), 0.17 (SD 0.16, –0.2–0.4, p = 0.006), and 0.22 (SD 0.21, –0.2–0.8, p < 0.0001) respectively. The changes in BCVA values are presented in Graph 3.



Graph 3: Changes in BCVA 1-, 3-, 6-, and 12-month follow-ups compared to preoperatively

Complications

Fortunately, we did not have to manage any complications of the operation itself. The procedure did not evoke any intraocular reactions.

DISCUSSION

Keratometric analysis indicated that Femto CKT halts the progression of keratoconus for at least 1 year in 96.6% of cases. The one eye that steepened from 40.0D at 1 month to 45.25 at 1 year was 44.25D before the operation. This eye received a double running antitorque suture after the 1-year time point. Since then, over a period of 4 months, the ophthalmometer values have improved over the 1-year finding and appear stable.

The length and appearance of the cut can be evaluated with a corneal OCT, although this information may mislead the observer directly after the operation. The blow up may be due to a missing reflection of the tissue and appear as a perforation. After a few hours, this image is gone. There was in no case an opening of the AC or of the outer layers. The intraocular pressure measurements remained stable within the normal limits throughout the postoperative course.

Another point of discussion is the laser used. In all of our cases, the laser, i.e., used followed different principles for creating cuts than did other lasers. Whereas the Ziemer laser relies on a high pulse repetition rate of 20.8 MHz and a low pulse energy (10–20 nJ), all competing lasers, including those made by AMO (150 kHz/200–800 nJ pulse energy), Zeiss (500 kHz, 100–260 nJ pulse energy), Bausch and Lomb (40–160 KHz, pulse energy not stated),

and Alcon (200 kHz, 2400 nJ pulse energy),[6] use high intensities and lower frequencies than the instrument we used. In cases where Femto CKT will be practiced routinely, adequate power and frequencies must be identified on an individual basis. New permission from an ethical committee would have to be obtained for such comparisons.

The number of failures for the cases described above was 2 keratometric cases 6 months after the operation but only 1 keratometric case at the 1-year time point.

The most probable explanation is that the scarring necessary to this procedure has not developed in these cases. Likely, no evenly healed or scarred cut may have occurred, which would result in failure to attain the intended goal. This presumption is supported by both slit-lamp examination and corneal OCT, which show uneven scarring for no clear reason. Because there is no apparent difference in the given tissue thickness or transparency, one cannot evaluate this phenomenon clinically. The procedure therefore may be recommended for progressive keratoconus if at stage I and II.

Aside from this occurrence in one case (3.4%), we met with extremely high patient acceptance of the procedure. The advantages of this procedure over mechanical CKT are the screen controlled setup, the painless surgery, the immediate postoperative back-to-work possibility, and the safety of the operation with a high probability of success.

The physician's learning curve is short, few postoperative controls are needed and patient satisfaction is noted as soon as 1 day after the operation.

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