Adjustable Intracorneal Ring in a Lamellar Pocket for Keratoconus

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ABSTRACT

PURPOSE: No theory or method currently exists to preoperatively predict the optimal position of an intracorneal implant for the treatment of keratoconus, or a surgical system or technique to adjust and optimize the position of the implant after its implantation. A surgical technique for adjusting the position of the implant inside the cornea is presented, and by adjusting the position of the implant after its insertion into a corneal pocket, the surgical results in keratoconus treatment may be improved.

METHODS: After the formation of a closed pocket of 9 mm in diameter and 300 μm in depth within the corneal stroma, a flexible full-ring implant is inserted into the corneal pocket via a narrow incision tunnel. After insertion and evaluation of the clinical data, the implant position can be adjusted inside the pocket to achieve an optimal treatment result.

RESULTS: The procedure is quick and easy to perform. An adjustment of the implant position of only 0.5 mm towards the apex of the cone may dramatically improve the surgical result.

CONCLUSIONS: The presented technique enables the surgeon to access all three degrees of freedom possible in theory, which are associated with intracorneal implants in a corneal stroma, including implant diameter, implant thickness, and implant position. This is of particular importance for the treatment of irregularly shaped corneas such as in keratoconus. [*J Refract Surg*. 2010;26:217-221.]

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Keratoconus is a noninflammatory corneal disease characterized by progressive thinning of the cornea and accompanied by ectasia.[1] Abnormalities in the arrangement of collagen fibril layers may be considered an ultrastructural basis for the lack of biomechanical stability.[2] The prevalence of keratoconus in the Western population is approximately 0.1%,[3] but may be much higher in other areas. Adding volume to the peripheral cornea by implanting ring segments into circular corneal tunnels may improve visual acuity and reduce central corneal steepening in keratoconus.[4-8] Such treatment may delay or eliminate the need for corneal grafting and improve the quality of life of affected patients. Because the shape of the cornea is highly irregular in advanced keratoconus, there is no existing theory or method to predict the optimal implant position in a given case prior to surgery. Therefore, it appears necessary to consider an adjustment of the position of an implant after its insertion to achieve optimal results. The presented technique allows the position of the implant to be adjusted inside the cornea. This is the first report that demonstrates the effect of the positioning of a corneal implant on the refractive result.

SURGICAL PROCEDURE

The surgical technique is characterized by a three-step procedure, of which steps 1 and 2 have been described elsewhere[9] for the treatment of high myopia.

STEP 1: CREATION OF A CORNEAL POCKET

Creation of an almost entirely closed intracorneal pocket of 9 mm in diameter and 300 μm in depth via a small

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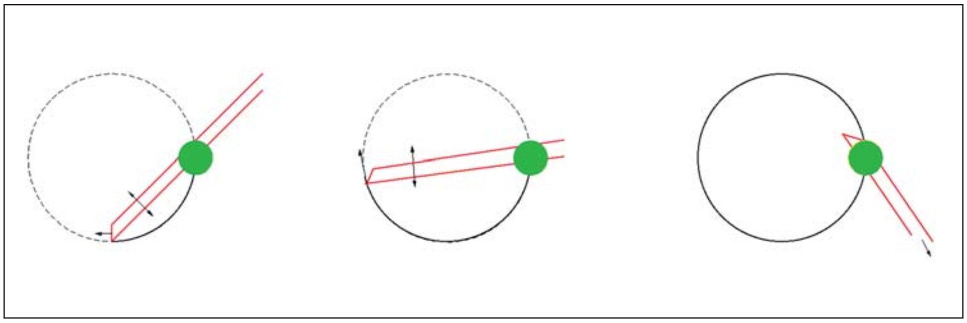

Figure 1. Schematic drawing of the process of creating a corneal pocket using the PocketMaker microkeratome (DIOPTEX GmbH) (from left to right). A micro-vibrating diamond blade (red) is inserted into the applanated corneal stroma via a narrow incision tunnel. The incision tunnel also serves as a pivot (green) for the blade. The tip of the blade is guided along a curved path (interrupted line) to cut a closed pocket (full line). The only opening of the pocket is in the area of the incision tunnel (green).

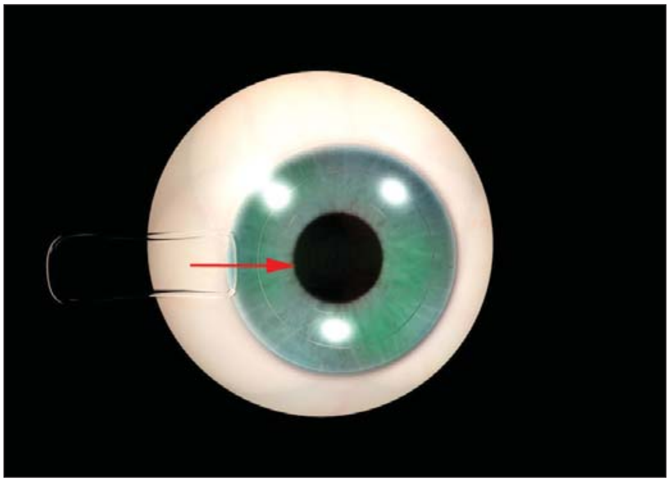

Figure 2. Schematic drawing of the insertion of the flexible MyoRing intracorneal implant (DIOPTEX GmbH) into the corneal pocket via the narrow incision tunnel.

incision of approximately 3 mm is made by means of the PocketMaker microkeratome (DIOPTEX GmbH, Linz, Austria). The device consists of a suction ring; a transparent disposable applanator, which defines the cutting depth; and a micro-vibrating diamond blade with its tip following a circular curve of 9 mm in diameter without penetrating the cornea along this path (Fig 1).

Step 2: Corneal Implantation

The MyoRing intracorneal implant (DIOPTEX GmbH), a flexible full-ring implant of 5 mm in diameter and 270 µm in thickness, was inserted into the corneal pocket via the small incision tunnel (Fig 2). The nomogram was derived from theoretical calculations based on a biomechanical corneal model, which was developed by the author on the basis of experimental data.[2,10,11] This nomogram takes account of the corneal thickness at its thinnest point and the mean central keratometry (K) -reading. In the first placement, the MyoRing usually is centered on the corneal reflex. The procedure is self-sealing and no suturing is required. The smaller the diameter and the bigger the thickness, the higher the corrective effect that can be achieved. A limiting factor may be the pupil size, but is of less importance than in the treatment of high myopia.

Step 3: Enhancement Procedure by Adjustment of the Implant Position

After a minimum of 1 week, refractive data and topography as well as cross-sectional Scheimpflug images using the Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany) were obtained. The data reveal that an enhancement was achieved by adjusting the position of the implant. To achieve such an enhancement, the pocket was reopened using a spatula and the implant was shifted 0.5 mm toward the apex by means of a forceps (Fig 3). The 0.5-mm movement step corresponds to the width of the MyoRing, which makes the intraoperative measure easy. Step 3 can be repeated as long as the best possible refractive result is achieved. The criteria to perform step 3 as an enhancement procedure include

- Uncorrected visual acuity (UCVA) less than 20/40,
- the cone can be further "pushed" out of the center, and
- the degree of patient satisfaction.

Although such results may not be achieved in all cases, they may still serve as a practical guideline. Whether it is advantageous in such cases to implant single ring segments of different thickness in a circular tunnel on their own cannot be answered at the present time.

The procedure (steps 1 to 3) is quick and easy to perform. Creating the corneal pocket according to step 1 is an accurate and safe procedure. To date, no perforations have occurred, not even in cases of a minimal corneal thickness of 360 µm. Cases in which the corneal thickness is <360 µm have not yet been treated.

CASE REPORT

The effect of the new surgical procedure for the treatment of keratoconus is demonstrated in the right eye of a 37-year-old man suffering from grade 4 keratoconus, who became increasingly intolerant of hard contact lenses.

Figure 3. Schematic drawing showing the position of the full-ring implant **left)** before and **right)** after enhancement. During the enhancement procedure, the implant is shifted 0.5 mm towards the apex of the cone.

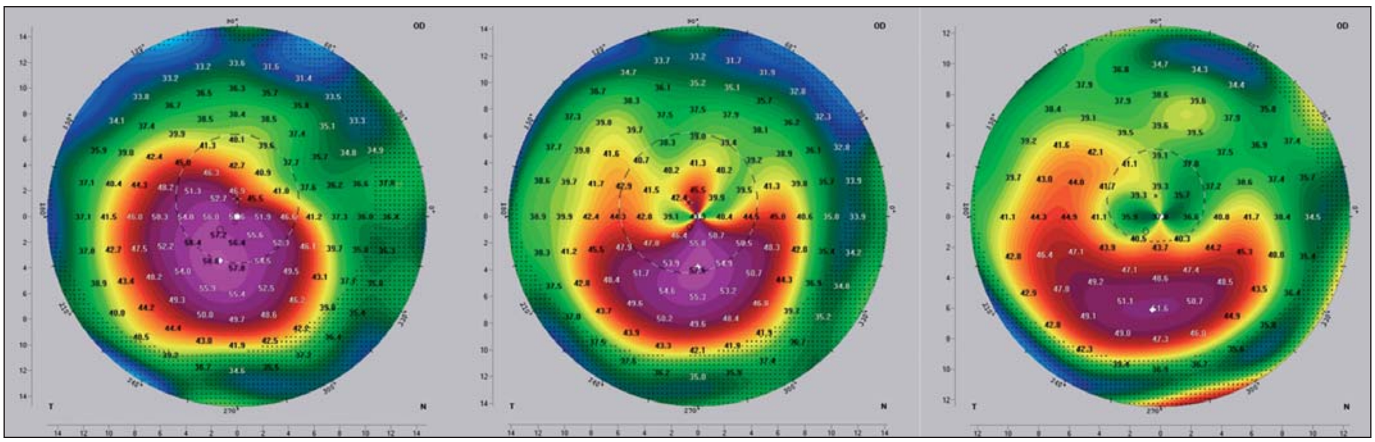

Figure 4. Topography of severe keratoconus **left)** preoperatively, **middle)** after MyoRing implantation centered on the corneal reflex, and **right)** after enhancement by shifting the MyoRing 0.5 mm towards the apex.

Preoperative Data

The severe grade 4 keratoconus was graded according to the grading system implemented in the Pentacam. Best spectacle-corrected visual acuity (BSCVA) was 20/100 with a refraction of +3.00 −2.00 × 80° and UCVA was 20/200. The preoperative topography is shown in Figure 4 (left image). The maximum K-value was 58.80 diopters (D) and the central K-values were 53.60 D at the steepest and 49.60 D at the flattest meridian (mean 51.50 D). Corneal thickness at the thinnest point was 384 µm. The mesopic pupil size was 4 mm.

After Implantation

Three weeks after implantation of the MyoRing (5-mm diameter and 270-µm thickness) centered at the corneal reflex, UCVA was 20/70 and BSCVA was 20/63 with a refraction of +0.25 −0.50 × 65°. The central K-values were 49.10 D and 40.90 D (mean 44.10 D). The topography is shown in Figure 4 (middle image). The subjective refraction did not correspond well with the topographic readings.

Enhancement

After shifting the MyoRing 0.5 mm toward the apex (step 3) inside the corneal pocket, the clinical result showed further improvement. At 2-week follow-up after the enhancement procedure, UCVA was 20/40 and BSCVA was 20/30 with refraction of +1.25 −4.50 × 15°. The K-values were 37.90 D and 42.50 D (mean 40.10 D) (Fig 4, right image). As the patient was highly satisfied with his UCVA, no further enhancement steps were taken into consideration. The situation was the same at 6-month follow-up. The remaining 4.50 D of regular astigmatism may have been eliminated by further enhancement, ie, by replacing the implant for a thicker one.

Although corneal melting or ring extrusion have not yet been observed, it cannot be ruled out entirely that such complications may occur.

In contrast to ring segment surgery in circular tunnels, the present procedure involves the center of the cornea in the treatment due to the formation of a pocket; but the anterior and posterior lamellae perfectly adhere to each other, and there is no gap or hole between them.

As this is also the case when an implant is introduced between the lamellae, it would be more appropriate to speak of a "virtual cleft" rather than a pocket.

DISCUSSION

The presented technique for the treatment of keratoconus by means of intracorneal implants allows the surgeon to add a new degree of freedom to his therapeutic concept: the implant position. As can be seen in Figure 4, changing the implant position by merely 0.5 mm produces a much better result.

From a theoretical perspective, the appropriate implant position may vary depending on the irregularity of the cornea of the individual patient. However, no theory or method exists that would allow for the correct implant position to be predicted for an irregularly shaped cornea, such as in keratoconus, prior to surgery. To make the implant position a new degree of freedom available to surgeons, it is therefore necessary to provide them with the possibility of adjusting the position of the implant after its implantation. In conventional corneal implant surgery, the ring segments are closely associated with the position of the circular corneal tunnel, and so the position of a ring segment may only be changed along the course of the tunnel.[12] The only way to change the position of an implant relative to the center after its insertion is by introducing a flexible full-ring implant into a corneal pocket, as is done in the method presented herein. This method also allows positioning of the implant independent of positioning of the microkeratome.

It cannot presently be discussed whether this technique serves to produce a regular central corneal shape in each specific case or in which cases this technique may be superior to the implantation of a single ring segment in a circular corneal tunnel.[13-15]

As the thinnest area of the cornea is involved in the formation of a pocket (see Fig 1), a cutting depth of 300 μm allows keratoconic corneas with a minimal corneal thickness of 360 μm to be treated.

An important question is whether the formation of a corneal pocket reduces the biomechanical stability of the cornea. From a biomechanical perspective, such an impairment of stability is unlikely to occur. The inner tension of the cornea unfolds more or less parallel to the corneal surface and its magnitude mainly results from the transcorneal pressure difference (intraocular pressure minus air pressure). This is why the "biomechanical framework" represented by the collagen fibrils, which are arranged in approximately 200 successively stacked lamellar layers, is aligned more or less parallel to the surface. These fibrils and lamellae take up the arising forces. Their ability to preserve the corneal stability by taking up such forces and to withstand the transcorneal pressure depends on the cross-section of the biomechanical framework. In the case of the cornea, this framework is the sum of all collagen fibril cross sections of the corneal thickness.[2,9] As long as cutting is performed in the direction in which the tension inside the tissue unfolds, namely parallel to the collagen fibrils, an impairment of the biomechanical stability is not expected. If cutting is performed perpendicular to the tensile forces, such as in LASIK where the collagen fibrils are intersected along the circumference of the flap, the entire flap tissue no longer fulfills its stabilizing function. This is why LASIK leads to a reduction of biomechanical stability, which in turn may result in keratectasia. Such problems should not occur when using the presented method, as the pocket is almost entirely closed along the circumference, and the only existing cut unfolds more or less parallel to the tensile forces (=longitudinal axis of the collagen fibrils); the collagen fibrils are cut through (perpendicular) only in the area of the small incision tunnel. As the pocket is not covered by a flap but is closed almost along the entire circumference, the inserted full-ring implant also produces a smoother corneal surface, which keeps higher order aberrations to a minimum.[9] The underlying theory is based on the principles of topology, a branch of geometry, which is explained in detail elsewhere.[9] Moreover, due to the transcorneal pressure, the implant is "trapped" between the anterior and posterior lamellae, so that a displacement of the implant is unlikely to occur without surgical intervention.

Because keratoconus is a progressive disease, it remains unclear whether the presented technique is able to control the progression of the disease.

Although the presented surgical concept has the potential for improving keratoconus treatment, long-term results for a larger number of patients are currently not available.

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