Title of the Protocol: Effect of intracorneal ring segments on posterior corneal tomography in eyes with keratoconus

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What is already known on this subject? AND What does this study add?

It is known that eyes with keratoconus have significant values of posterior astigmatism compared to normal eyes. Intracorneal ring segments are an effective method of treatment of keratoconus. It is known that anterior corneal curvature decreases after ring segment implantation. However, only a few studies focused on the effect on the posterior corneal surface. The aim of this study is to determine the effect of intracorneal ring segments on the posterior corneal surface and correlate this effect with the change in the anterior surface and with the visual outcome. To the best of our knowledge, this is the first prospective study on this subject.

1. INTRODUCTION/ REVIEW

Keratoconus is a bilateral progressive ectatic corneal disease that leads to paracentral thinning and protrusion of the cornea, eventually assuming a conical shape. This leads to visual impairment due to progressive myopia and irregular astigmatism. [1] Keratoconus is classified into 4 stages according to Amsler-Krumeich classification, based on astigmatism, myopia, keratometry, corneal transparency, and pachymetry. [2] Changes in the posterior corneal surface are an early indicator of ectatic changes in keratoconus. They often precede changes on the anterior corneal surface, and sometimes they could be the only evidence of early keratoconus. Placido disc based corneal topography only detects changes in the anterior corneal surface. The development of Scheimpflug imaging devices allowed the imaging of the posterior corneal surface and highlighted its significance in diagnosis of keratoconus.[1]

Posterior corneal astigmatism has been long overlooked because of the minimum difference in refractive index between the cornea and the aqueous. [3] However, several studies reveal that the posterior corneal astigmatism has higher magnitude in keratoconus eyes compared to normal eyes and demonstrate a significant influence of posterior astigmatism on the total corneal astigmatism. The magnitude of posterior astigmatism tends to increase with increasing keratoconus severity. This means that the effect of posterior astigmatism on visual performance of patients is not necessarily negligible. It is a factor that should be considered when correcting vision in keratoconus patients by spectacles, rigid contact lenses, or toric intraocular lenses. [4-6]

Intracorneal ring segments (ICRS) is a commonly used method for treatment of keratoconus. They aim to induce peripheral steeping and therefore central flattening of the anterior corneal surface. This helps to regularize the corneal surface. [7] ICRS were shown to be effective in reducing irregular astigmatism and improving both uncorrected and best corrected visual acuity in keratoconus patients. [8] However, there remains some controversy regarding the predictability of the visual outcome after ICRS implantation, with some eyes showing limited improvement and sometimes loss of best corrected visual acuity after surgery. [9]

Although many studies have shown the effect of ICRS on the anterior corneal surface, only a few studies focus on the changes in the posterior surface. There is also some controversy about these changes, with some studies demonstrating a flattening effect of ICRS on the posterior surface [10], while other studies show that the posterior surface becomes steeper after ICRS implantation. [11,12] The disparity between anterior and posterior surface changes may be explained by a different

biomechanical response of the anterior and posterior surfaces to ICRS implantation. The change in posterior surface may explain, at least in some part, why visual acuity may be unpredictable and is sometimes hard to improve with spectacles or rigid contact lenses after ICRS implantation. [11]

The aim of our study is to demonstrate the effect of ICRS on the posterior corneal surface in keratoconus patients and correlate it with the change in the anterior surface and with the visual outcome.

2. AIM/ OBJECTIVES

To evaluate the effect of intracorneal ring segments on the posterior corneal surface and correlate this effect with the visual outcome.

Primary outcome:

Change in the posterior corneal curvature at 6 months.

Secondary outcomes:

Best corrected visual acuity at 6 months in relation to baseline acuity.

3. METHODOLOGY:
Patients and Methods

- **Type of Study:** Prospective, interventional case series.
- **Study Period:** 2 years.
- **Study Population:** Patients diagnosed with keratoconus who are candidates for intracorneal ring segments implantation.
- **Selection criteria for cases**

Inclusion Criteria:

- Age ≥ 18 years.
- Patients with keratoconus grade 1, 2 or 3 according to Amsler-Krumeich classification.
- Corneal thickness ≥ 400 μm at the location of ICRS implantation.
- Clear central cornea.

Exclusion Criteria:

- Central corneal opacity.
- Previous corneal laser refractive surgery.
- Previous corneal collagen cross linking.
- Previous cataract surgery or phakic IOL implantation.
- History of herpetic keratitis.
- History of acute hydrops.
- Ocular comorbidities such as cataract, glaucoma or retinal disease.
- Systemic diseases affecting healing process such as autoimmune or connective tissue disease.

- **Sample Size:** 60 patients.
- **Ethical Considerations:** The study will be conducted in accordance with the ethical standards stated in the Faculty of Medicine Ain Shams University.

- **Study Procedures:**

The following will be done for the patients at initial presentation:

- Unaided and best corrected visual acuity measurement.
- Manifest and cycloplegic refraction.
- Anterior segment examination by slit lamp biomicroscopy.
- Intraocular pressure measurement using Goldmann applanation tonometer.
- Fundus examination.
- Corneal imaging with Scheimpflug imaging device (Sirius; CSO, Firenze, Italy), with recording of the parameters of the anterior and posterior corneal surfaces.

- **Procedure:**

Patients will undergo intracorneal ring segments implantation using femtosecond laser (iFS Advanced Femtosecond Laser; Abbott Medical Optics, Santa Ana, California, USA) to create the tunnel. Ring segments of 5 mm diameter will be implanted at 80% depth of the corneal thickness at site of implantation. Ring segment arc length and thickness will be tailored according to each particular case.

- **Duration of follow up:** Twelve months.

- **Follow up schedule:**

Follow up visits will be at 1, 3, 6 and 12 months intervals. During each subsequent visit the following will be done:

- Manifest and cycloplegic refraction.
- Unaided and best corrected visual acuity.
- Slit lamp examination.
- Corneal imaging with Scheimpflug imaging device, with recording of the parameters of the anterior and posterior corneal surfaces.

4. REFERENCES

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