# Complications of Intrastromal Corneal Ring Implantation (Keraring 355°) using a Femtosecond Laser for Channel Creation

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#### ABSTRACT

**Purpose:** To report complications after the implantation of Keraring 355° intrastromal corneal ring (ICR; Mediphacos, Belo Horizonte, Brazil) in keratoconic eyes using a Ziemer LDV femtosecond laser (Ziemer AG, Switzerland) for channel creation.

**Materials and methods:** Five eyes suffering from keratoconus underwent Keraring 355° insertion using Ziemer LDV for corneal pocket creation. Intraoperative and postoperative complications were recorded.

**Results:** While intraoperatively there were no complication, postoperatively all cases showed severe side effects.

**Conclusion:** In this small case series, intracorneal ring (Keraring 355°) implantation using a femtosecond laser for channel creation was related to a number of significant postoperative problems in all cases. The most common complication was corneal melting (postoperatively).

**Keywords:** Femtosecond laser-intrastromal corneal ring, Keraring 355°, Keratoconus-complication.

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#### INTRODUCTION

Intrastromal corneal ring segments (ICRS) implantation is a minimally invasive surgical procedure that made a prominent evolution to the management of keratoconus. Long-term data on ICRS procedures demonstrated promising results in topographic regularity and in uncorrected visual acuity (UCVA).<sup>1-3</sup> Mechanical dissection and femtosecond

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laser are two main techniques that generally are used for tunnel creation during ICRS implantation.<sup>4</sup> While, according to previous studies,<sup>5-7</sup> manually channel creation using mechanical devices was related with a number of possible complications, Intacs implantation using a femtosecond laser can deliver energy accurately to a precise depth in a programmed way and shown to be a safe and effective procedure for treating keratoconic corneas.<sup>8-14</sup> There are several different types of intracorneal rings, with varying curvature, width and zone of implantation. The Keraring 355° (Mediphacos, Belo Horizonte, Brazil) is a newly developed implantable intrastromal corneal ring segment made of polymethyl methacrylate (PMMA) with UV blocker. It is characterized by a triangular cross-section that induces a prismatic effect on the cornea which is available in a diameter 5.7 mm and thickness range of 200 and 300 µm. To our knowledge, this study is the first clinical trial examining the complications of this type of intracorneal ring segment using the femtosecond laser for channel creation in keratoconic patients.

#### MATERIALS AND METHODS

This prospective single-center study was performed as an interventional case series at Basir Eye Hospital, Tehran, Iran. Institutional review board approval was obtained. All patients gave informed consent prior to their operation, in adherence to institutional guidelines and the tenets of the Declaration of Helsinki. Five eyes (5 patients) with moderate and severe keratoconus underwent intrastromal corneal ring implantation (Keraring 355°) using a Femtosecond laser (Ziemer AG, Switzerland) for channel creation. The mean follow-up was 12 months. The primary inclusion criteria were clear central corneas without scars, contact lens intolerant and corneal thickness at least 360 microns. Patients were excluded if any of the following criteria applied after the preoperative examination: history of intraocular or corneal surgery, history of herpes keratitis, anterior segment pathology, corneal dystrophies, a history of systemic disease or use of systemic medication likely to affect corneal wound healing and systemic connective tissue disease. A complete ophthalmological examination was performed preoperatively, including uncorrected visual acuity (UCVA),

best spectacle-corrected visual acuity (BSCVA), manifest refraction, biomicroscopy and corneal topography.

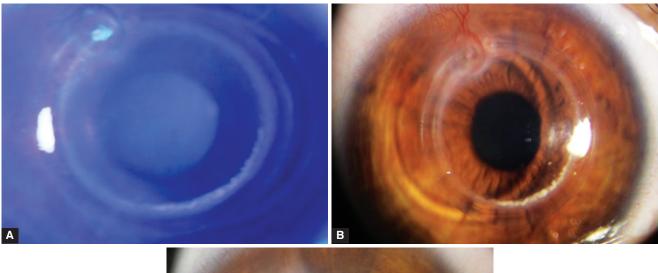
# SURGICAL TECHNIQUE

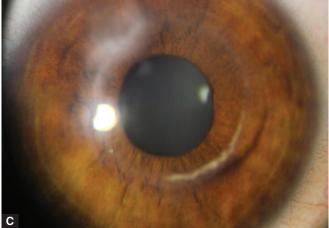
The same surgeon (Khosrow Jadidi) performed all surgical procedures under sterile conditions with topical anaesthetic drops; proparacaine hydrochloride 0.5% (Alcaine, Alcon). The intracorneal tunnel entry was created on the steepest corneal topographic axis using a Ziemer LDV femtosecond laser (Ziemer AG, Switzerland). The tunnel depth was set at 300 micron of the corneal thickness at the incision site. The inner to outer diameter was from 5 to 7 mm. The entry cut vertical incision was made using a radial keratotomy (RK) diamond knife adjusted at thickness of 330 micron (30 micron more than the depth) at steepest meridian. Then, the intrastromal tunnels was easily opened using a dissecting spatula. The intracorneal ring segment (Keraring 355°) were implanted immediately based on authors nomogram (Table 1). Subsequently, a silicone-hydrogel bandage contact lens (Bausch and Lomb) was placed on the cornea. Postoperatively patients were given betamethasone, drops (Sina Darou) 4

times a day, chloramphenicol drops (Sina Darou) 6 times a day, and nonpreserved artificial tears (Artelac) (Baush & Lomb, France) 6 times a day. Chloramphenicol drops was discontinued 5 days postoperatively but betamethasone drops tapered off during 4 weeks. Bandage contact lenses were removed one day postoperation. Patients were scheduled for postoperative clinical examination at 1st day and afterward on the 1st, 3rd, 6th month and yearly. Intraoperative and postoperative complications were recorded.

# RESULTS

In this study, 5 eyes of 5 patients (2 men, 3 women) were evaluated. The mean age of the patients was 25 years (range 20 to 30 years). The characteristics of patients included in the study are summarized in Table 2. The preoperative and postoperative data for the manifest refraction and the visual acuity are shown in Table 3. In this case series, no intraoperative complications occurred. Postoperatively, corneal melting and scar was observed in all cases, yellow-white intrastromal deposits in three cases and corneal neovascularization was found in one case (Figs 1A to C).





**Figs 1A to C:** (A) Corneal slit-lamp photograph of patient 1, a 30-year-old female with corneal fluorescein staining at incision site, (B) corneal neovascularization at incision area and (C) superior paracentral scar and regression of vascularization 1 month after ring removal with restoration of corneal clarity



# DISCUSSION

The traditional mechanical technique for tunnel creation can cause several complication including epithelial defects at the keratotomy site, extension of the incision, anterior and posterior perforations, infectious keratitis, shallow placement of intrastromal corneal ring segments, decentration, asymmetric placement, persistent incisional gaping, corneal stromal edema around the incision and stromal thinning.<sup>5,6</sup> Study of Kanellopoulos et al demonstrated a 35% rate of postoperative complications, such as corneal melting, segment movement and exposure with the mechanical tunnel dissection method. Femtosecond laser believed to reduce these complications due to the rapidity, precision, ease of channel creation and centration with minimal associated stromal edema.<sup>12,15,16</sup>

In this small sample case series, the complications after implantation of Keraring 355° intrastromal corneal ring in keratoconic eyes using a Ziemer LDV femtosecond laser for channel creation were assessed.

Intraoperative complication using femtosecond laser for channel creation rarely was reported. However, postoperative complication was reported by several authors.<sup>8,9,12,14,17</sup> Study by Ertan et al<sup>12</sup> found epithelial plugs and segment migration in 15.2 and 4.5% of cases respectively. Rabinowitz et al<sup>17</sup> reported significant epithelial defects in three patients (15%) and Gram-positive infection in one patient (5%) during the postoperative period in the femtosecond group. Similarly, Carrasquillo et al<sup>8</sup> demonstrated corneal neovascularization (12.5%) and fungal infection  $(6.25\%)^7$  months after surgery. Moreover, during kerarings implantation using femtosecond laser for channel creation, no intraoperative complications was reported in previous studies.9,14 In contrary, segment migration was found in 6% of cases by Coskunseven et al<sup>9</sup> and infectious keratitis and incision opacification was reported in 4.8 and 38% of cases respectively by Shabayek and Alio'14 postoperatively.

Albeit ours was a small case study, no intraoperative complication was found in this study. In contrast to ours' anticipation, we found relatively more complications postoperatively including corneal melting and scar, corneal neovascularization and yellow-white intrastromal deposits. The reason for this happening is not clear yet.

On one hand, ICRS implantation using mechanical or femtosecond tunnel creation was found to be a safe method for managing corneal ectasia, astigmatism, and keratoconus by several authors<sup>9,14,18-21</sup> or even no significant difference between the use of femtosecond laser and mechanical dissection was displayed by others<sup>17,18</sup> but on the other hand, Coskunseven et al<sup>20</sup> and Ferrer et al<sup>24</sup> reported more complications postoperatively in the Intacs group in those cases in which the channels were created by femtosecond.

Therefore, the discrepancy between the complication rates reported in the literature versus our study cases may not be simply/entirely explained by the surgical technique.

In the current study, the most severe and potentially sight-threatening complication was corneal melting that we found in all cases after the procedure. Although, corneal melting is a relatively rare phenomenon, the development of corneal melting after ring implantation can be catastrophic. One assumption is that the new ring design may play a major role. In other words, the differences in segment characteristics may represent a pivotal role. In this study, a new keraring including a 5° notch was implanted at incision site where all corneal melting occurred proximity to that area. If this claim is true, we can conclude that the new ring design may be the reason of late side effects.

Our finding is in accordance to the reports by Kugler<sup>23</sup> from a literature review on corneal melting in 12 eyes out of 1,835 eyes that had undergone implantation related to keratoconus or ectasia. Similarly he found corneal melting after radial keratotomy close to the incision site overlying the implant. Hence, we suppose using a new model of ring structure, such as Keraring 340° to prevent such complication.

We also found other mild complications with this ICRS model such as superficial wound site neovascularization, again agreeing with results in other studies.<sup>22,25</sup> In this case series, corneal neovascularization was demonstrated in one 30-year-old female postoperatively that was regressed 1 month after ring removal (Fig. 1).

Yellow-white intrastromal deposits were revealed in 3 eyes (60%) in our study. Likewise, in a study of Intacs ICRS in myopic eyes, Ruckhofer et al<sup>22</sup> found yellow-white intrastromal deposits in 74% of cases that is in agreement to our study.

Furthermore, in the event of corneal melting, the ring has to be explanted immediately. In the same way, we removed the ring when patients made complaint (Table 3).

This article has several potential limitations: the absence of a comparative mechanical group and the visual and refractive outcomes of the participants after ring removal and reoperation.

In summary, we described several complications of intrastromal corneal ring segment (Kerarings 355°) implantation with femtosecond laser for channel creation. The most common complication was corneal melting (postoperatively) that may be related to the corneal ring design. However, future prospective comparative randomized studies, including more patients, are needed to clarify our finding.

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