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Feasibility of custom-made hydrogel contact lenses in keratoconus with previous implantation of intracorneal ring segments

Fernando José Fernández-Velázquez*, Maria José Fernández-Fidalgo

Centro Fernández-Velázquez, Madrid, Spain

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ABSTRACT

Purpose: To analyze the feasibility of a custom-made hydrogel silicone contact lens (CL) in keratoconus with intracorneal ring segments (ICRS) and to compare outcomes taking in consideration the geometry of the fitted lens—full periphery (FP) vs. sector management control (SMC).
Method: A retrospective review of cases with previous KeraRings ICRS implantation and subsequently fitted with Kerasoft-IC CL was performed. The main outcome measurements were corrected spectacle distance visual acuity (CDVA), differences between flat and steep simulated keratometries (K-diff) and between steep and flat *P* values (CPV-diff), CL visual acuity (CLVA), wearing time (WT) and complications associated with wear.
Results: Thirty eyes of 22 patients and a follow-up time of 10.3 ± 2.3 months were reviewed. Statistically significant improvement was observed between LogMAR CDVA and CLVA (0.25 ± 0.19 vs. 0.04 ± 0.05; $P < 0.0001$). WT was $11.2\,h \pm 1.2$. Two eyes with mild corneal staining and another two with mild injection were noted. Twenty SMC designs were recorded and associated with lower levels of CDVA (0.36 ± 0.22 vs. 0.18 ± 0.10; $P = 0.006$), CLVA (0.06 ± 0.05 vs. 0.01 ± 0.03; $P = 0.03$), and larger amounts of CPV-diff (2.31 ± 1.86 vs. 1.03 ± 1.11; $P = 0.02$) than those eyes fitted with FP designs. No statistical differences were found in the amount of K-diff and WT between both sub-groups.
Conclusions: Fitting custom-made hydrogel silicone CL in keratoconus with ICRS is a feasible treatment with low rate of complications and adequate visual acuity and WT.

1. Introduction

Intracorneal ring segments (ICRS) are an effective additive surgical procedure for the management of keratoconus with clear corneas, contact lens intolerance and adequate corneal thickness [1–3]. Acting as passive spacing elements that shorten the arc length of the anterior corneal surface, they flatten the central cornea [4]. Patients' quality of vision and life have been reported to increase after ICRS implantation [5], however other studies have demonstrated that inadequate refractive and visual acuity outcomes are one of the most common reasons for explantation or even further surgical procedures such as penetrating keratoplasty [6]. This is particularly important in cases of mild keratoconus in which corrected visual acuity can decrease significantly after ICRS implantation [7].

There are a variety of ICRS used worldwide, including the Bisantis Intrastromal Segmented Perioptic Implant (Opticon 2000 SpA and Soleko SpA, Rome, Italy), the Keraring Intrastromal Corneal Ring Segment (Mediphakos Inc., Belo Horizonte, Brazil), the Ferrara Ring Segment (Mediphakos, Brazil), the MyoRing intracorneal continuous ring (Dioptex GmbH, Linz, Austria), and the Intacs Ring Segment (Addition Technology Inc., Sunnyvale, California). The Keraring implants, with technical specifications that are similar to those of the Ferrara ICRS, are characterized by a triangular cross-section that induces a prismatic effect on the cornea when the flat posterior surface is inserted facing the corneal endothelium [8].

Contact lenses can be considered for vision enhancement after ICRS implantation, as initially reported by Nepomuceno et al. [9]. However, reports regarding the possible impact of this surgery on the ability to wear contact lenses again are contradictory. Some authors have claimed that these implants can have a positive impact [10–12], others, in particular several case reports, have found the opposite, reporting that these corneas often need more complicated lens designs and require a large array of different types of lenses in order to attain a successful fit [13–16]. With regards to CL wear, Moreira et al. [17] reported soft contact lenses are more likely to provide adequate levels of comfort and enable

* Corresponding author. Tel.: +34 915 417419.
E-mail address: info@fernandez-velazquez.com (F.J. Fernández-Velázquez).

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patients to renew contact lens wear after ICRS implantation than are gas-permeable designs.

KeraSoft® IC (Ultravision International Limited, Bedfordshire, UK) is a custom-lathed, front-surface toric soft silicone (Efrofilcon-A) hydrogel contact lens with a modulus of 0.38 MPa intended for the management of irregular corneal astigmatism. The goal of KeraSoft IC is to offer a solution to the clinical dilemma by providing the comfort of soft contact lenses with the visual acuity of gas-permeable lenses [18]. In this design, the periphery can be manipulated independently of the base curve, by as many as four steps flatter or steeper, and it offers two different geometries: full periphery (FP) and sector management control (SMC). The latter is a quadrantic design, in which up to two sectors can be modified independently of each other and customized to the specifications of the practitioner.

The aims of this study were to analyze the difference between the corrected distance visual acuity with spectacles (CDVA) and the visual acuity with the contact lens (CLVA), as well as the overall feasibility of wearing this contact lens in a cohort of keratoconic patients with previous implantation of ICRS because of self-reported RGP intolerance. All of the patients in this cohort were fit with KeraSoft IC contact lenses. Moreover, the authors also intended to evaluate the relationship between the post-surgical peripheral corneal topographical configuration and the outcome of the contact lens fitting process. To the best of our knowledge this is the first report on the role of the exclusive use of soft contact lenses in the management of these post-surgical cases.

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
• Age 18 years or more.
• Minimum of 6 month follow-up with contact lenses.
• Willingness to adhere to the instructions set in the clinical protocol.
• Signature of the informed consent form.
• Previous diagnosis of keratoconus.
• At least 6 months after ICRS insertion to be fitted with contact lenses.
• Manual tunnel creation.
• Reported RGP lens intolerance as the main reason for the surgery.
Exclusion criteria
• Superficial implantation with risk of extrusion.
• Previous history of laser corneal refractive surgery, cataracts, cross-linking, amblyopia, strabismus or the presence of any disease limiting visual acuity that could negatively impact clinical outcome.
• Systemic or ocular allergies, which might have interfered with contact lens wear.
• Systemic disease which might have interfered with contact lens wear.
• Ocular disease which might have interfered with contact lens wear (hypoesthesia, insufficient lacrimal secretion).
• Use of medication which might interfere with contact lens wear.
• Active ocular infection.
• Pregnancy or lactation.

2. Methods

2.1. Patients

A retrospective chart review at a specialized private optometric center (Madrid, Spain) was carried out to identify the clinical records of thirty eyes from 22 consecutive keratoconic patients (13 males/9 females) who had previously undergone Kerarings ICRS implantation and been fitted with KeraSoft IC contact lenses between September 2010 and January 2012. In all cases the surgical procedures had employed a manual technique and optic zone of 5 mm. Eight cases were bilateral implantations and the remaining cases were unilateral. Keratoconus was stage I in 5 eyes (16.6%), stage II in 15 eyes (50%) and stage III in 10 eyes (33%) according to the Amsler–Krumeich classification [19]. All patients completed at least six months of follow-up. The inclusion and exclusion criteria are defined in Table 1. The study protocol adhered to the tenets of the Declaration of Helsinki and Spanish legislation and was approved by the Institutional Review Board of the Centro Fernández-Velázquez, Madrid. Written informed consent was obtained from all patients before the study outset.

2.2. Examination and contact lens fitting protocol

At least six months after surgery (9.2 months ± 2.1, range 6–13 months), all patients underwent an optometric examination at the same center. Refractive evaluations were performed as a first step with the aid of a Retinomax 2 autorefractor (Nikon Corporation, Tokyo, Japan) and refined with a trial lens refraction. Topographical evaluations were performed with the Keratron Scout Version 4.1.0 (Opticon 2000 S.p.a., Rome, Italy), immediately before fitting the contact lens. The same measurement protocol was used in all cases. The patient was asked to blink twice and then look at the fixation device before each measurement. Then the system took the images of the cornea. Up to six measurements were taken by the same experienced observer for each eye. The repeatability check of the device then chose three readings with a very good repeatability. This was considered to be when the deviation of the best fit sphere (BFS) was less than 0.12 diopters. Three consecutive readings were the minimum number of sequential measurements that the software accepted for repeatability analysis. Gobbe et al. [20] showed that this number of measurements is sufficient to obtain a reliable result with this device. For analysis purposes, one measurement was chosen randomly for each measured eye. Evaluations of the anterior segment were performed with an SL-D4 slit lamp (Topcon Corporation, Tokyo, Japan). Distance high contrast visual acuity was measured at 4 m with best spectacle correction (CDVA) and after contact lens fitting (CLVA) using the Acuity Pro version 6.0 (Vision Science Software, Elk City, USA), a computerized eye acuity chart with random letter presentation, and converted into LogMar units for this study.

In all cases, the KeraSoft IC was the first contact lens chosen, and all lenses were ordered from the same manufacturer. The fitting procedure as provided by the manufacturer was followed in all cases. Using a dedicated set of trial lenses with plano power and different base curves and peripheral radii as provided by the manufacturer, the first lens is chosen based on the corneal profile (i.e. central versus decentred keratoconus) and the keratometric severity of the condition (mild, moderate and advanced). When the theoretically best-fitting lens is inserted, it should be allowed to settle for approximately 5 min and then assessed following the acronym MoRoCCo VA, which represents movement, rotation, centration, comfort and visual acuity with the lens on. Correct fit was achieved when the post-blink movement was no more than 3.0 mm on straight-ahead gaze, as long as the patient was comfortable, the laser mark was vertical, the lens was centered and vision was steady with no fluctuation. In cases of irregular cornea, a standard periphery lens did not always provide an optimal fit; one lens could provide the best overall fit in terms of rotation and movement but a different lens, flatter or steeper, might give the best VA. In those cases and during the fitting assessment the trial lens that gave the best fitting characteristics was recorded and then the lens providing the best VA fitting was also recorded. The difference in base curves was then calculated (i.e. the best possible VA was found using an 8.00 mm trial lens but