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Research Article

Are Rigid Gas Permeable Lenses Still the 1st Line of Choice in Corneal Ectatic Diseases?

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Received: January 29, 2020; **Published:** February 26, 2020

Abstract

Purpose: To retrospectively evaluate the long-term results of silicone hydrogel soft contact lens (Toris-K, SwissLens) fitting for the rehabilitation of various corneal ectasias.

Methods: A total of 42 eyes of 27 patients that were fitted with Toris-K lenses and had at least 4-years of follow-up were included into this study. Thirty-six eyes were diagnosed with keratoconus, 3 had pellucid marginal degeneration, 3 had post-LASIK iatrogenic ectasia. Patients were analyzed in terms of visual gain, complications, tolerability and satisfaction with the prescribed lenses.

Results: Pre-lens uncorrected visual acuity (UCVA) was 0.17 ± 0.16 (range: 0.01 to 0.6) and best spectacle corrected visual acuity (BSCVA) was 0.54 ± 0.26 (range: 0.1 to 1.0) in Snellen lines with a mean spherical equivalent of -4.93 ± 4.15 D (range: -1.00 to -16.25). Twenty eyes were fitted with TorisK-K12, 22 eyes were fitted with TorisK-K34 lenses. Best lens corrected visual acuity (BLCVA) was 0.85 ± 0.21 (range: 0.3 - 1.0) ($p < 0.05$ for both UCVA and BSCVA before Toris-K). BLCVA was ≥ 0.8 in 31 eyes (73.8%). One patient reported halos and glare with Toris-K despite 1.0 BLCVA and the optical zones needed to be enlarged. Two of 3 previous rigid gas permeable (RGP) lens users (i.e. 4 of 5 eyes) reported better visual quality with their RGPs compared with the new fit. All new contact lens users were satisfied with the visual gain after Toris-K fit. During the follow-up, corneal transplantation was required in 1 eye and intracorneal ring segment implantation was recommended in 1 eye, due to unsatisfactory vision with Toris-K and RGP intolerance. Satisfactory visual gain and subjective assessment together with a good fit was still achieved in 36 of 42 eyes (85.71%) at the end of follow-up period.

Conclusion: Toris-K lenses seem to be a good initial fit option for unprogressive corneal ectasias.

Keywords: *Corneal Ectasia; Keratoconus; Toris-K; Soft Contact Lenses*

Introduction

Until recently, RGP lens fitting has been considered as the 1st line of treatment for ectatic corneas, which masks the irregular anterior corneal surface with its smooth spherical surface and aids in providing better vision [1]. However, due to uneasy fit and adaptation, as well as subjective complaints, corneal lesions related to central touch and tarsal conjunctival reactions, possibility of having debris under the lenses, and necessity of frequent visits created a demand for more physiologic lens designs. Other options include intralimbal, piggyback, hybrid lenses, as well as spherical or toric soft contact lenses (SCL) [2].

Toris-K (SwissLens, Switzerland) is a silicone hydrogel (SiH) SCL designed for irregular corneas in patients intolerable to RGPs. Recently, it has been used in keratoconus, traumatic keratopathy and other irregular corneas [3-8].

Aim of the Study

This study aimed to analyze the long-term visual performance of Toris-K SCL in eyes with corneal ectasias, both as an initial fit and after RGP use.

Methods

Patients with various corneal ectasias who were referred for visual rehabilitation underwent full ophthalmological examination including measurement of visual acuity in Snellen lines and refractive spherical equivalent (SE), corneal tomography with a Scheimpflug corneal topographer, followed by the Toris-K lens fitting trial. A dedicated set of lenses was used with different base curves and power. The initial lens fitting trials were performed as detailed below.

The records of the patients with at least 4-years follow-up were reviewed retrospectively, in terms of visual gain, complications, tolerability and satisfaction with the prescribed lenses. The study adhered to Tenets of Declaration of Helsinki. Dokuz Eylul University Hospital Ethical Committee approved the conduct of this study (2019/24-24, date: 30.09.2019).

Toris-K lens material characteristics and geometry

The Toris-K is a SiH SCL that has a toric front surface and a spherical back optic zone with strong aspheric flattening. Dynamic stabilization is achieved by nasal and temporal bumps (Figure 1). It has a thickened center that is tapered to the periphery. It requires at least yearly replacement.

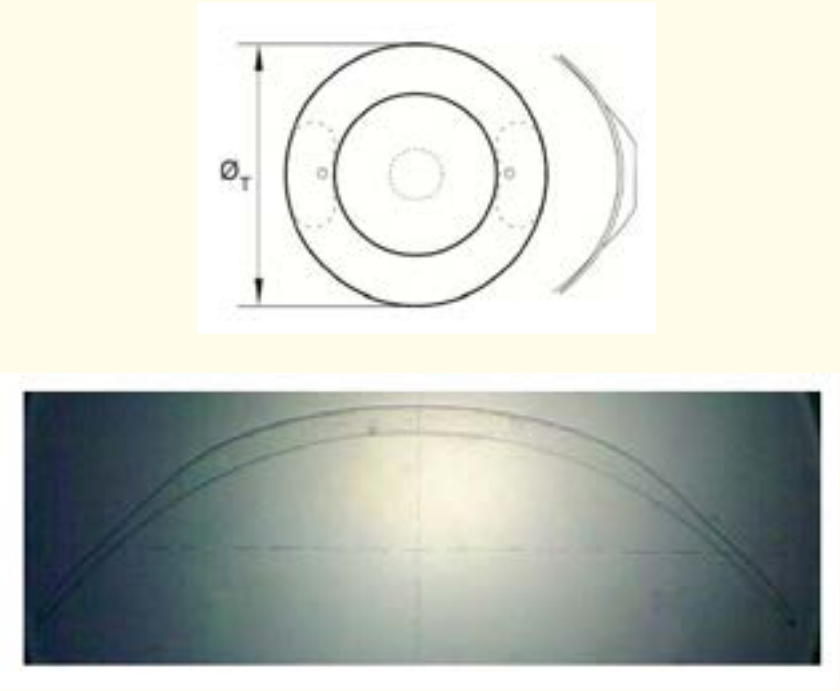

Figure 1: *Geometrical characteristics of Toris-K lenses.*

For manufacturing, the hydrogel Igel 77 (Filcon II3) had been used as the lens material initially. Recently, it has been changed to Definitive 74 SiH material (Filcon V3). The DK Fatt ISO 9913-1 for Definitive 74 is 60/44, whereas that for Igel 77 was 39/29. The water contents of Definitive 74 and Igel 77 are 74% and 77%, respectively. Both materials have UV protection (blue tint) and a refractive index of 1.37. Lens parameter options include spherical power between -40.00 and +40.00 D, cylindrical power between -0.25 and -8.00 D, axis between 0° and 180°, optical zone between 5.00 and 7.50 mm, base curve between 7.20 and 10.80 mm (0.2 mm steps), total lens diameter between 12.00 and 17.00 mm. The central thickness is optimized as 0.45 mm for K12 and 0.52 mm for K34 lenses. The whole lens thickness range between 0.35 and 0.59 mm.

Lens selection and fitting procedure

TorisK-12 was chosen as the initial contact lens trial, for eyes with best spectacle corrected visual acuity (BSCVA) of at least 0.6 Snellen lines from 3 meters in daylight conditions and/or mean keratometry (K) reading of at least 6.8 mm. TorisK-34 with greater central flattening effect was chosen as initial trial for eyes with BSCVA of less than 0.6 Snellen lines and/or mean K reading of less than 6.8 mm. The Amsler-Krumeich classification was used for initial lens selection, which is based on the patient's refractive error, mean K readings on the anterior curvature sagittal map, thickness at the thinnest location and corneal opacities [9]. Ectasia grades 1 - 2 were initially fitted with TorisK-12 and grades 3 - 4 were fitted with TorisK-34 lenses.

For base curve selection, 0.8 D were added to the average K value to select an initial trial lens. Most frequently, base curve of 8.00 mm and diameter of 14.00 mm were chosen for TorisK-12 lenses and base curve of 7.80 mm and diameter of 13.70 mm were chosen for TorisK-34 lenses as the initial trial to validate base curve and total diameter. In all cases, trial lenses with cylindrical power of -0.01 D were used.

Patients were asked to wait for 30 minutes. Stabilization axis of the lens was assessed by the dynamic stabilization marks. Push-up test was performed, where the fitting curve should demonstrate typical fitting of characteristics of a standard soft lens fit. If the fitting curve is too flat, excessive movement and/or edge lift would be seen, necessitating switch to a steeper trial lens. Little or no movement and/or edge impingement would indicate the fitting curve is too steep, necessitating switch to a flatter trial lens. Later, over-refraction was performed. The prescription included both spherical and cylindrical errors with corresponding axis. In case of glare and/or halo perception by the patient, the optical zone was enlarged.

Results

A total of 42 eyes of 27 patients were fitted with TorisK soft keratoconus lenses between 2010 and 2015. Mean age of the patients was 31.67 ± 8.06 years (range: 19 - 49). Thirty-four eyes were diagnosed as keratoconus, 3 eyes as pellucid marginal degeneration (PMD), 3 eyes as post-LASIK iatrogenic corneal ectasia and 2 eyes as forme-fruste keratoconus pattern (Figure 2). Among keratoconus patients, 5 eyes were previously fitted with RGP contact lenses and experienced associated subjective complaints or corneal disturbances, 2 eyes previously underwent corneal cross-linking (CXL) treatment and 1 eye was unsuccessfully fitted with a frequent replacement silicone hydrogel soft contact lens. The average uncorrected visual acuity (UCVA) was 0.17 ± 0.16 (range: 0.01 to 0.6) and BSCVA was 0.54 ± 0.26 (range: 0.1 to 1.0), with a mean SE of -4.93 ± 4.15 D (range: -1.00 to -16.25). The mean simulated K value was 48.08 ± 4.98D (range: 38.25 to 59.48 D) and mean thinnest pachymetry was 474.28 ± 62.61µ on the Scheimpflug corneal tomography.

A total of 20 eyes were fitted with Toris-K12 lenses with a base curve of 8.09 ± 0.2 mm (7.80 to 8.40 mm with 0.2 mm steps with total diameter 14.00 mm); and 22 eyes were fitted with Toris-K34 lenses with a base curve of 7.56 ± 0.19 mm (7.4 mm with total diameter of 13.30 mm to 7.6/7.80 mm with total diameter of 13.70 mm). Mean Toris-K SE was -4.63 ± 3.85 D (range: -0.75 to -18.00 D) Best lens corrected visual acuity (BLCVA) was 0.85 ± 0.21 (range: 0.3 to 1.0) ($p < 0.05$ for both UCVA and BSCVA before Toris-K). In all eyes, BLCVA with Toris-K was equal to or better than both pre-lens UCVA and BSCVA. BCVA increased by a mean of 2.8 ± 1.7 lines in Toris-K12 patients

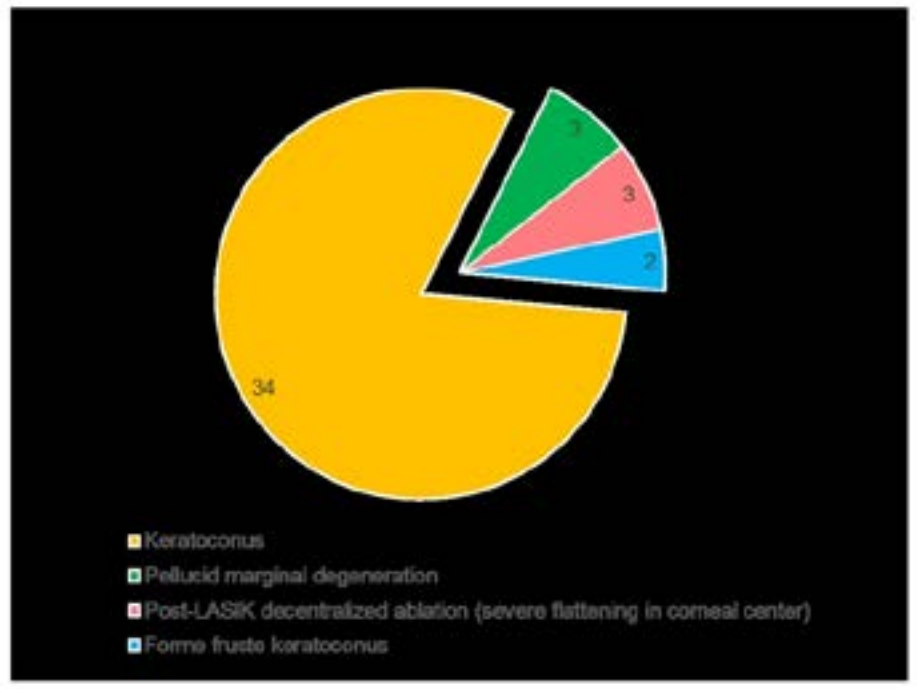

Figure 2: *Distribution of etiology of the eyes with corneal irregularities.*

(range: 0 - 6 lines, median: 2 lines) and a mean of 3.36 ± 1.79 lines in Toris-K34 patients (range: 0-7 lines, median: 3 lines). BLCVA was 0.5 Snellen lines or less in only 3 eyes with Toris-K34 (7.1%), 0.8 Snellen lines or better in 31 eyes (73.8%).

The lens was well-tolerated by the patients. One patient reported halos and glare with Toris-K despite good visual acuity; new Toris-K lenses were ordered with enlarged optical zones. Among previous RGP users, 2 of 3 patients (i.e. 4 of 5 eyes) reported better visual quality with their previous RGP lenses compared with their new fit (Figure 3). All new contact lens users, including those that had undergone CXL, were satisfied with their visual gain after Toris-K. During the follow-up, corneal ectasia did not display significant progression in any of the eye. Corneal transplantation was required in 1 eye and intracorneal ring segment implantation was recommended in 1 eye with keratoconus, due to unsatisfactory visual gain with Toris-K and RGP intolerance. Four eyes required a lens shift to another type due to unsatisfactory vision. Satisfactory visual gain and subjective assessment together with a good fit was still achieved in 36 of 42 eyes (85.71%) at the end of follow-up period.

Discussion and Conclusion

Among all etiologies of corneal irregularities, keratoconus is the most common one. All corneal ectasias present as a result of chronic biomechanical decompensation of the stroma that may include interlamellar and interfibrillar slippage mechanism [10] and are characterized by progressive stromal thinning and steepening. This irregular steepening leads to an increase corneal irregularity and myopic astigmatism [11]. In most cases, optical correction is a challenging problem to ophthalmologists [12,13], where contact lenses are necessary beyond early mild stages [14]. A comfortable contact lens with a significant improvement in visual acuity, reduces the need for surgical intervention. It has been shown that approximately 70% of patients who present for consideration of corneal graft surgery for

Figure 3: *Anterior segment images of a previous RGP user patient who was not satisfied with the visual gain with the Toris-K. Arrows indicate apical scarring due to RGP use for years.*

keratoconus can be maintained successfully on contact lenses [15]. This is particularly important for young patients, who carry greater risk for graft rejection and facing life-long complications including postoperative glaucoma, cataracts, traumatic dehiscence of the graft-host junction, recurrence of the ectatic disease and the need for subsequent transplantations due to graft decompensation [16]. It is also important to point out that allograft surgery in PMD is much less successful than that in keratoconus, since the inferior pathologically thin stromal tissue is peripheral to the usual corneal button size [17].

RGP contact lenses have long been considered as the standard treatment for irregular corneal astigmatism. An RGP aims to neutralize the irregular anterior surface of an ectatic cornea by providing a regular, spherical optical surface before the eye [18] and at the same time provide good tear exchange. However, lens instability is a main concern. Decentration or dislocation on particularly very steep and irregular corneas are not uncommon [19-21]. Despite good visual acuity provided by the RGPs, uneasy adaptation, intolerance and poor corneal physiologic response may cause discontinuation by patients. Mechanical interaction with the ocular surface leads to chronic trauma and inflammation [22-24].

Scleral lenses provide good centration and stability in terms of visual acuity, as well as being free of corneal touch. However, worse tear exchange and a steep learning curve to handle are major inconveniences [2]. Main disadvantages of hybrid and piggyback lens systems include issues related to lens handling [25-27].

There has been a trend towards SCL and toric SCL in cases with early corneal ectasias and RGP intolerance. They enjoy advantages of ocular surface protection [28], improved comfort, good physiologic response and low cost but lack the superior optics of RGP lens materials [29]. The Soft K-lenses (Soflex Contact Lens Industries Ltd.; Israel) were initially manufactured from a hydrophilic hydrogel material; but due to their material and thickness disadvantages, they recently begun to be manufactured using SiH material [28,30]. The KeraSoft (UltraVision; United Kingdom) and Toris-K lenses were manufactured from SiH material. The KeraSoft IC (Bausch&Lomb, USA) with a Filcon II-based material, has a prism-ballasted toric front surface design and a spherical back surface. The periphery of KeraSoft IC can be manipulated independently of the base curve, making it able to conform to the shape of any cornea [31]. The Soft-K and KeraSoft lenses were once deemed inadequate in masking high levels of irregular astigmatism. However recent studies have shown that Toris-K lenses correct both total and higher-order root-mean-square errors significantly; particularly total coma and trefoil aberrations [3]. Even though

RGP lenses were known to provide superior visual performance and greater reduction of 3rd order aberrations [32-34], Jinabhai., *et al*. reported that no significant difference was found in high-contrast acuity between toric SCL (KeraSoft IC) or RGP in keratoconus patients, and the toric SCL significantly reduced 7 out of the 8 higher-order aberration terms evaluated [35]. Similarly, other studies found no significant difference in visual acuity gains between RGP and Kerasoft IC SiH contact lenses [30]. Yıldız., *et al*. also reported similar levels of visual acuity and impact on the quality of life in both RGP-standard design (conflex air 100 UV KE Zeiss-Wöhlk) and SiH contact lenses (KeraSoft IC or Toris-K) [7].

SCLs seem to provide greater comfort and lower cost, but low oxygen permeability is their main disadvantage if not manufactured from a SiH [36]. The lenses designed for ectatic corneas, have increased thickness in optical zone (i.e. between 300 - 700 μm). Furthermore, most designs incorporate toric correction and prismatic or prismodynamic axis stabilization, which makes the lenses thicker in certain areas [2]. This brings the need of materials with high oxygen permeability (i.e. Dk > 80). On the other hand, material modulus has to be the lowest possible (i.e. < 0.60MPa), as an increased volume lens could become more stressing to the ocular tissues [32]. The combination of the above lens characteristics brings the need of more precise fitting parameters.

Toris-K lenses are one of the new custom soft SiH contact lenses, which tend to settle down inferiorly on the ocular surface, owing to its geometry and design. This provides better fitting and visual correction in eyes where the cornea is relatively steep inferiorly as compared to central cornea, such as inferior cones and PMD. Increased visual acuity was reported in patients with keratoconus [3], as well as traumatic keratopathy [4]. Yılmaz., *et al.* reported that Toris-K can improve visual acuity of patients with keratoconus, even in the moderate and advanced form of the disease [8]. Sultan., *et al.* reported improved visual acuity with Toris-K lenses in all grades of keratoconus and even after keratoplasty [6]. Similarly, our results revealed that BCLVA with best Toris-K was equal to or better than BSCVA in all eyes included. Additionally, increased contract sensitivities as well as higher NEI VFQ 25 (National Eye Institute Visual Functioning Questionnaire) scores were reported among Toris -K lens users compared to uncorrected eyes [5].

Other authors have suggested that although the lens of 1st choice is RGP; if the patient develops discomfort or intolerance to this type, Toris-K offers an alternative for treatment [5,6]. Sultan., *et al.* reported that although the most common reason for using Toris-K was inability to of an RGP fit, a significant improvement in BLCVA was seen with Toris-K as compared to UCVA and BSCVA, without any significant difference between BCVA with Toris-K and RGP. Superficial punctate keratitis and giant papillary conjunctivitis were common, but no corneal pannus or neovascularization was observed [6]. We have not encountered any complications related to ocular surface after Toris-K fitting. In our study group, all new contact lens users, including those after CXL, were satisfied with their visual gain and tolerance after Toris-K fit. None of the patients required shifting to another lens type for at least 4 years, even though previous RGP users tend to miss the optical quality. Minimum follow-up of 4 years of this cohort is the main superiority of this study. Nevertheless, a comparative long-term study with groups of patients with similar characteristics but different initial lens preferences would be far superior. Another limitation of this study was not being able to make a statistical comparison between Toris-K12 and Toris-K34 fitted patients, because of small and unequal sample sizes in both groups.

In summary, Toris-K soft contact lenses seem to be a good alternative as an initial contact lens fit to provide increased visual acuity sparing the negative effects of the rigid lenses both on the corneal surface and on tarsal conjunctiva. Cornea and contact lens specialists' algorithm may be reset as to try SiH contact lens fit in patients with corneal ectasias before proceeding to other lens designs, including potentially more complicated and slightly more expensive RGPs, and surgical correction methods.

Disclosure

The authors report no conflicts of interest and have no proprietary interest in any of the materials mentioned in this article.

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