Hydro cone lens visual performance and impact on quality of life in irregular corneas

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A R T I C L E   I N F O

Article history:
Received 12 February 2016
Received in revised form 11 April 2016
Accepted 17 April 2016

A B S T R A C T

The aim of this study is to evaluate the visual performance (efficiency) of HydroCone (Toris K) soft silicon hydrogel lenses in patients with irregular corneas.
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1. Introduction

Corneal Ectasia is irregular protrusion of cornea as a result of changes in stromal collagen matrix. Primary forms of corneal ectasia are keratoconus, pellucid marginal degeneration and keratoglobus, secondary form is ectasia after refractive surgery [2].

Depending on the activity and stage of keratoconus, eye glasses, contact lenses, intrastromal corneal ring segments, phakic intraocular lenses, photorefractive keratectomy and corneal transplantation at latest stage are utilized in order to improve visual acuity.

At the early stages of the disease, eye glasses can provide visual rehabilitation. As the disease progresses, contact lenses may improve irregular astigmatism with %90 treatment success. Soft contact lenses, rigid contact lenses, hybrid contact lenses, piggyback contact lenses and scleral lenses are also other treatment options. HydroCone (Toris K) lenses are one of the new custom soft silicone-hydrogel CLs (SHCLs), with front toric surface and spherical back optic zone with aspheric flattening. These lenses provide stabilization with nasal and temporal bumps.

The increased attention for quality of life (QoL) as an outcome measure has led to numerous questionnaires to assess this construct in the field of contact lens. Widely used National Eye Institute Visual Functioning Questionnaire (NEI-VFQ 25) questionnaire covers a wide age demographics and all chronic eye diseases. The NEI-VFQ 25 consists of 25 questions which ask patients' complains and performance related to vision in this areas: general health, general vision, ocular pain, near activities, distance activities, social functioning, mental health and role difficulties, dependency, driving, color vision and peripheral vision.

2. Material and method

This study was approved by the local Ethics Committee of Ankara Numune Research and Training Hospital and adhered to the tenets of the Declaration of Helsinki.

This study includes 49 eyes of 30 patients who were treated with HydroCone lens due to keratoconus and traumatic corneal scar in our clinic between 2014 and 2015. According to biomicroscopic examination findings and corneal topography measurements, 47 eyes of 28 patients were diagnosed as keratoconus and 2 eyes of 2 patients were diagnosed as irregular astigmatism due corneal perforation scar. Treatment and routine follow up, medical history review, uncorrected and best corrected distance visual acuity (CDVA), letter contrast sensitivity test (CS), NEI VFQ25 questionnaire, slit-lamp examination, fundus examination and Kmax, total corneal astigmatism values from corneal topographic analysis were recorded.

Exclusion criteria were the presence of any condition that prevents contact lens treatment such as active keratitis and severe dry eye and history of previous ocular surgery including penetrating keratoplasty.

Visual acuity was measured with the logMAR (logarithm of the minimum angle of resolution, Smart System 2 2020 Visual Acuity System: M&S Technologies). Contrast sensitivity was evaluated with a Hamilton- Veale chart with uncorrected and with contact

http://dx.doi.org/10.1016/j.clae.2016.04.003
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lens. This test is modeled on the Pelli-Robson contrast sensitivity and uses a card with 16 pairs of letters over 8 lines. The patient was asked to read the letters and the value was recorded as log contrast sensitivity [log (l/c)]. The contrast range was from 0 to 2.25 log units.

Interviews for Turkish version of NEI-VFQ 25 were performed by the same doctor for all patients and results were recorded. Higher score indicates better QoL [1].

3. Contact lens application

The initial HydroCon lens was chosen for keratoconus K12 in Keratometry >6.8: grade 1 or 2, K34 keratometry <6.8: grade 3 or 4. Add 0.8 diopters to the average K value, then select a trial lens. Lens was chosen for traumatic corneal scar patients add 0.8 diopters to the average K value, then select a trial lens. The first lens helps to validate base curve and total diameter. Patient waited for 30 min. Stabilization marks were evaluated to measure the stabilization axis. Successful fitting of the Toris K lens was assessed by observing the characteristics of the lens behavior on eye movement, rotation, centration and comfort, all of which when optimal, give the best visual acuity. Optimal lens fit characteristics are up to 1–2 mm post blink lens movement on straight-ahead gaze, the vertical lens mark, the central and comfortable lens and the steady vision. Once it is achieved, the over-refraction was performed.

The data were analyzed using SPSS 20.0 for Mac (SPSS, Inc, Chicago, IL). A paired sample T test was performed to compare the visual acuity and NEI VFQ 25 questionnaire, Wilcoxon test was performed to compare the visual acuity contrast sensitivity before and after fitting the lens. A P value of <0.05 was considered statistically significant.

4. Results

This study includes 49 eyes of 30 patients: 47 eyes of 28 patients were keratoconus, 2 eyes of 2 patients were irregular astigmatism due to corneal perforation scar. Mean age of patients (15 female and 15 male) was 30.87 (range 18–46). Mean follow up period was 13.6 months (3–17). Demographic and clinical presentation of patients are as follows (Table 1):

<table>
<thead>
<tr>
<th>Demographic and clinical presentation of patients (Table 1)</th>
<th>N = 49</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (N= 30)</td>
<td>18–46</td>
</tr>
<tr>
<td>Kmax</td>
<td>44.20</td>
</tr>
<tr>
<td>Astigmatism</td>
<td>0.20–1.15</td>
</tr>
</tbody>
</table>

Mean LogMar visual acuity was 1.08 (0.22–2.10) for uncorrected, 0.57 (0.10–0.57) with spectacles and 0.16 (0.00–1.00) with contact lens. Significantly higher visual acuity were observed with contact lens treatment, compared to uncorrected and spectacle correction (p = 0.00, p = 0.00). (Graphic 1)

Mean LogMar contract sensitivity was 0.76 (0.00–1.15) for uncorrected and 1.43 (0.75–1.95) with contact lens. Significantly higher contract sensitivity levels were recorded for contact lenses compared to uncorrected (Graphic 2)

All patients were asked to answer NEI VFQ 25 questionnaire by the same doctor during routine follow up. Overall score patients with contact lens treatment were observed significantly higher compared to uncorrected (p = 0.00). Significantly higher general health, general vision, ocular pain, distance activities, vision specific social functioning, vision specific role difficulties score were recorded for contact lenses compared to uncorrected (Table 2) When 47 Keratoconus eyes were categorized according to their grades; it was seen that nine eyes were Grade 1, twenty five eyes were Grade 2, eleven eyes were Grade 3 and two eyes were Grade 4. No significant difference was observed on visual acuity, contrast sensitivity increase and NEI VFQ questionnaire results (p = 0.12, p = 0.31, p = 0.23)

Two Toris K patients patient stopped wearing lens, after one and two months respectively, because of conjunctivitis. After two weeks of topical antibiotic treatment, both patients started to use their lens once again. During follow up period, any patient did not disuse Toris K lenses.

5. Discussion

Keratoconus is a disease which may have a negative impact on the quality of life because it affects young adults in their active years. Many studies on keratoconus epidemiology from different countries reported an incidence of 1.3–22.3 per 100,000 and a prevalence of 0.4–86 cases per 100,000 [2].

A conservative approach in the management of keratocctasia initially involves spectacles and subsequently, contact lenses. The standard correction of choice has been rigid gas permeable (RGP) contact lenses [3]. Other contact lens options have also been introduced, such as soft spherical and soft toric lenses [4] hybrid lenses [5] scleral lenses, and piggyback lenses [3] in order to provide options for patients with RGP intolerance.

RGP contact lenses mask anterior corneal irregularity. It has been successfully used to increase visual acuity on keratoconus patients for decades [6,7]. However it has been observed that some patients grow intolerance to RGP lenses for some reason, such as accumulating dust and debris between lens and eye, decentralization, excessive movement. Ocular discomfort in these patients prevent them to wear RGP lenses for long periods. For such
patients, unable to use RGP lenses effectively, recently introduced soft silicon hydrogel lenses provides an alternative.

HydroCone (Toris K) lenses are one of the new custom soft silicone-hydrogel CLs (SHCLs), with front toric surface and spherical back optic zone with aspheric flattening. These lenses provide stabilization with nasal and temporal bumps. There has been no significant difference observed between RGP and SHCL in terms of visual acuity increase [8]. Increased visual acuity was observed with SHCL on keratoconus patients [9,10]. In our study we measured mean LogMar VA 1.08 (0.22–2.10) for uncorrected, 0.57 (0.10–0.57) with spectacles and 0.16 (0.00–1.00) with Toris K. Best spectacle corrected visual acuity was observed significantly higher with Toris K CL compared to uncorrected and spectacles (p = 0.00, p = 0.00).

There are studies which observe increased contract sensitivity with RGP lenses [11,12]. In our study, we also found increased contract sensitivity with Toris K compared to uncorrected.

Quality of life (QoL) has been receiving increased attention for assessment of successful treatment in ophthalmology. As a result, numerous questionnaires were developed to measure patients’ QoL. NEI VFQ is one of these questionnaires, developed by Mangione et al. in 1998 for adult patients with chronic ocular diseases. NEI VFQ is a widely used questionnaire to assess QoL since it does not only evaluates vision-related health status but also attempts to assess how the ocular disease affects the patients’ social functions, emotional well-being and daily regular activities.

Kurna et al. found overall score of NEI-VFQ-25 were lower in the keratoconus patients. The difference was more evident in the subscales of general vision, ocular pain, near vision, vision-specific mental health, vision-specific role difficulties, and peripheral vision (P < 0.05). Vision related QoL was worse in keratoconus patients. Success in the contact lens usage and maintaining higher visual acuity may improve vision related QoL [13].

It has been measured significantly higher NEI VFQ 25 scores for RGP fitted patients compared to uncorrected [14,15]. No significant difference was found on QoL of patients when RGP group was compared with SHCL group by using Contact Lens Impact on Quality Life (CLIQ) questionnaire was used [16]. In our study, we observed significantly higher (p = 0.00) overall NEI VFQ score with Toris K (78.64) compared to uncorrected 62.33.

Toris K lens is applied successfully in irregular corneas. Toris K was found to be an effective and well-tolerated contact lens. Although the lens of first choice is RGP, if the patient develops discomfort or intolerance to this type, Toris K offers an alternative for treatment.

**Conflict of interest**

The authors have no proprietary interest in any material or method described in this study.

**Financial support**

None.

**References**