Contact Lens and Anterior Eye xxx (xxxx) xxx–xxx

Contents lists available at ScienceDirect

Contact Lens and Anterior Eye

journal homepage: www.elsevier.com/locate/clae

Visual quality with corneo-scleral contact lenses for keratoconus management

Juan Carlos Montalt[a], Esteban Porcar[a,*], Enrique España-Gregori[b], Cristina Peris-Martínez[c]

[a] Department of Optics, Optometry and Vision Sciences, Physics College, University of Valencia, Burjassot, Valencia, 46100, Spain
[b] Department of Surgery, Ophthalmology unit, la Fe University and Polytechnic Hospital, Faculty of Medicine and Odontology, University of Valencia, Hospital la Fe, Valencia, 46026, Spain
[c] FISABIO Oftalmología Médica (FOM), Cornea Unit and Anterior Segment Diseases, Catholic University of Valencia, Valencia, 46015, Spain

ARTICLE INFO

Keywords:
Corneal ectasia
Keratoconus
Corneoscleral contact lens

ABSTRACT

Purpose: To assess the visual quality achieved by fitting corneo-scleral contact lenses (CScL) for keratoconus management.

Methods: Thirty patients with keratoconus presented to have CScL fitted because of the unsatisfactory visual quality they experienced with their contact lenses or spectacles. The eye examination included visual acuity assessment, anterior eye biomicroscopy, ocular fundus examination, corneal topographic analysis, endothelial-cell count, contrast sensitivity and aberrometry. The fitting process was performed using a diagnostic trial set. Subjective visual quality and comfort, and contact lens wear time were also reported. Patients were monitored for one year.

Results: Three patients discontinued CScL wear before one year. Therefore, 27 eyes of 27 patients (19 male and 8 female) participated in this study. The mean age was 36.1 ± 13.1 (mean ± SD) years. Statistically significant differences were found in logMAR visual acuity between the best spectacle-corrected vision and after CScL fitting (mean ± SD, 0.23 ± 0.30 and 0.00 ± 0.14, respectively; $p < 0.001$). The total high-order aberrations decreased significantly (55%), and the spatial frequencies of contrast sensitivity all improved to normal range values of the population. Furthermore, high subjective visual quality and comfort ratings, and prolonged usage times (mean ± SD, 13.44 ± 2.38 h a day) were reported. No adverse ocular effects or clinically relevant changes in corneal parameters, visual quality, comfort or usage time were found one year after wearing CScL.

Conclusion: This CScL seems to be safe and healthy, providing optimal visual quality, comfort and prolonged usage times in patients with keratoconus.

1. Introduction

Keratoconus is typically a progressive, bilateral (usually asymmetrical) corneal disorder characterised by corneal paracentral steepening with apical thinning at the same place [1,2]. The main adverse optical effects induced by keratoconus are the presence of irregular astigmatism and the increase in high order aberrations (HOAs), which can have a devastating effect on the quality of vision [1–3]. Keratoconus causes a significant coma aberration, because the cone is usually displaced from the centre of the cornea which is the most important refractive element of the eye [3–6]. Then ocular symptoms, such as halos, glare, starburst and ghost images, along with decreased contrast sensitivity occur depending on the severity of the disease [1,7,8]

Traditional sphero-cylindrical spectacles do not compensate HOAs [3]. Consequently, when a high number of HOAs appear in keratoconus patients, rigid gas-permeable (RGP; corneal, corneo-scleral and scleral) contact lenses are suggested as the best solution for management. These contact lenses provide a regular refractive surface; moreover, with the tear layer between the posterior lens surface and anterior corneal surface, they can mask corneal surface irregularities [9,10]

Corneal RGP lenses may be a successful option in the management of mainly mild-to-moderate keratoconus cases. However, when comfort decreases or corneal damage appears due to the increase of the corneal irregularity, these contact lenses are no longer well tolerated (excessive movement and/or decentred lens) [11]. In these cases, although other types of contact lenses, such as hybrid lenses or a piggyback contact lens system can be tried, corneo-scleral contact lenses (CScL), which rest partly on the cornea and partly on the sclera, or full scleral contact lenses seem to be a suitable option. In relation to corneal RGP lenses, CScL and full scleral lenses provide excellent comfort, centration and

* Correspondence author at: Department of Optics, Optometry and Vision Sciences, Dr. Moliner 50, Burjassot (Valencia) 46100, Spain.
E-mail address: esteban.porcar@uv.es (E. Porcar).

https://doi.org/10.1016/j.clae.2018.01.002
Received 10 August 2017; Received in revised form 10 January 2018; Accepted 12 January 2018

stability (due to their large diameter) [12]. These advantages may provide a greater decrease in HOAs and therefore an improvement in visual quality, since factors like lens movement and decentration bring about increasing HOAs [10].

Studies on fitting corneo-scleral contact lenses in patients suffering from keratoconus are not commonly reported in the scientific literature, especially in the case of small diameters (around 13 mm). To the best of our knowledge, only a few cases of fitting CScL have been reported in previous studies, and these had diameters greater than 14 mm. [11,13] However, fitting CScL with small diameters (12.60 mm to 13.50 mm) has significant advantages in relation to other CScL with a greater diameter or full scleral lenses, as they are easier to handle and commonly do not need fluid upon lens placement nor a plunger for removal. They may avoid problems due to scleral toricity on the surface of the eye [14] and, since the clearance is small (30 to 50 μm or less), the quality of vision is typically better, avoiding problems resulting from a greater tear layer behind the lens, such as turbidity [15].

There is little knowledge about the extent to which fitting CScL can provide an improvement in visual quality. It should be noted that despite the apparently normal visual acuity that may be achieved with RGP lenses, patients with keratoconus could still experience a reduction in contrast sensitivity [7,8]. The residual HOAs may remain elevated, which could affect contrast sensitivity, and the quality of vision may decrease [7]. With a view to dealing with this deficiency, the present study describes our experience in fitting a corneo-scleral contact lens with a multi-aspherical geometry design for the management of keratoconus in terms of visual quality.

2. Patients and methods

2.1. Patients

A total of 30 patients participated in this study. Such patients presented irregular corneas due to keratoconus and they were referred from other ophthalmological centres because of the unsatisfactory visual quality they experienced with the contact lenses or spectacles they were using at that time. They were willing to be fitted with a new corneo-scleral contact lens with a multi-aspherical geometry design to improve their visual quality. None of them presented any ocular-surface disease or associated iatrogenic corneal ectasia. This study complies with the ethical standards required by the University of Valencia which concur with the tenets of the Declaration of Helsinki.

2.2. Data collection and contact lenses used

Prior to contact lens fitting, the patients who wore contact lenses discontinued their use for at least 15 days. All patients underwent a comprehensive eye examination at the FISABIO Oftalmología Médica Clinic, which included the best spectacle-corrected visual acuity assessment, anterior eye biomicroscopy, ocular fundus examination, endothelial-cell count with a specular microscope (SP-3000P, Topcon Medical Systems Inc., Japan), and a corneal topographic analysis using the Pentacam HR Eye Scanner (Oculus Inc., Wetzlar, Germany) which also shows central corneal thickness. Data from the corneal topographic patterns and slit-lamp biomicroscopy findings confirmed the diagnosis of keratoconus (the Amsler-Krumeich classification was used to grade keratoconus).

Visual quality was determined with the Vision Contrast Test System (VCTS 6000, Vistech Consultants Inc., Dayton, OH, USA). This is a subjective test that was performed following the guidelines of the manufacturer with the monocular full correction of patients in place, under photopic conditions of 85 cd/m^2 and a testing distance of 3 m. Furthermore, an aberrometer was also used for evaluating visual quality, the Alcon LADARWave (Custom Cornea Wavefront System, Alcon Laboratories Inc, Ft Worth, Texas, USA). This is an objective ocular aberrometry test, which was performed in a dark room under monocular conditions in accordance with the guidelines of the manufacturer. To calculate ocular aberrations, the pupil size chosen was 6 mm, since ocular aberrations are mainly manifested under mesopic conditions (e.g. driving at night). To reach a pupil size of almost 6 mm, pharmacological intervention for mydriasis (1% tropicamide eye drops; one drop initially and another drop after 5 min) was used. When full dilatation was reached, aberrometry measurements were performed, including the root mean square in terms of micrometres of deviation (μm) of defocus, astigmatism, coma aberration, spherical aberration and other HOAs.

Once an eye examination was performed, patients were fitted with a corneo-scleral contact lens (Scleracon, Lenticon, Madrid, Spain) based on a multi-aspherical geometry design (spherical in the front surface, and spherical optic zone with aspherical peripheral curves in the posterior surface) with three curves: the base curve, the intermediate or small transition curve and the peripheral or scleral curve. The material used to manufacture these lenses is a highly gas-permeable fluoro-silicone acrylate, (Optimum extreme, Contamac Ltd, Saffron Walden, UK): its oxygen permeability (ISO) is 125×10^{-11} (cm^2/s) (mlO2)/(ml x mmHg). The average central thickness of the lenses is approximately 0.29 mm (for −3 D) and the fitting parameters are as follows: base curves range from 5.80 to 9.20 mm (in 0.5 mm steps), peripheral or scleral curves range from 5.60 to 11.4 mm (in 0.10 mm steps), diameter ranges from 12.60 to 13.50 mm, and power from +20.00 to − 25.00 D (in 0.25 D steps). Plasma treatment is suggested for these contact lenses.

2.3. Fitting procedure

The trial-lens method was used to fit the CScL. This trial-lens set consisted of 35 lenses with a specific back optic zone radius (BOZR) and peripheral curve, and a total diameter of 12.60 mm. According to the suggestions described by the manufacturer, two steps are needed to determine the appropriate lens (first the BOZR and then the peripheral curve).

To determine the BOZR, the first trial lens was commonly selected 0.20 mm steeper than the average central keratometry readings, in accordance with the suggestions of the manufacturer, although other flatter lenses can be chosen depending on the severity of the keratoconus (no guidelines are available). Once the lens had been inserted in the eye for some minutes, a sterile strip impregnated with sodium fluorescein (BioGlo; HUB Pharmaceuticals, Rancho Cucamonga, CA, USA) and moistened with one or two drops of saline solution was used, which was applied touching the superior conjunctiva of the eye. Then the patient was instructed to blink several times to assess the fluorescein pattern between the central cornea and the contact lens (Fig. 1). If this trial lens did not fit correctly, it was replaced by another lens with a steeper or flatter BOZR, until it showed a slight alignment to minimal apical corneal clearance. In most cases, a slight “feather touch” on the apex of the cornea is well tolerated since these lenses usually have little movement (0.5 mm) and do not irritate the apex of the cornea [14]. In some cases, although a strong corneal support may appear to be present, this does not necessarily mean that there is actually “touch”, as fluorescein layers may be present with a thin layer of roughly 20 μm, so the human eye is not able to see it [14]. No grade of the corneal apex staining was permitted. Finally, an over-refraction on the selected trial lens was performed.

The second step consisted of verifying the peripheral curve. If the previously selected trial lens did not show an appropriate fluorescein pattern with an adequate tear exchange, other lenses with a steeper or flatter peripheral curve were tried. The lens should show no compression on the limbus (since stem cells are located in this area and are necessary for corneal health) and/or the conjunctival vessels under the contact lens (Fig. 2) [14]. No grade of limbal and/or conjunctival staining was permitted. The overall diameter of the lens was assessed, which should extend beyond the limbus. If changes in the diameter were necessary, it was decided empirically. Finally, the lens should