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The use of ocular anatomical measurements using a rotating Scheimpflug camera to assist in the Esclera® scleral contact lens fitting process

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ABSTRACT

Purpose: To test for associations between Pentacam® derived topography variables and to evaluate the predictive power of those variables in relation to scleral contact lens (SCL) fit.
Setting: Department of Ophthalmology and Visual Sciences, Federal University of São Paulo, São Paulo-SP, Brazil.
Design: Prospective observational non-randomised, non-comparative study.
Methods: Forty-seven patients (63 eyes) were indicated for the use of Esclera® SCL. All patients underwent Scheimpflug imaging before the initial SCL evaluation. The following parameters were measured by Pentacam: corneal elevations, thickness, density, and anterior chamber depth (ACD). Correlations between the SCL parameters and the Pentacam measurements were analysed with Pearson's correlation coefficients. A simple linear regression model was created for each lens parameter using the most-correlated Pentacam variable.
Results: In the total group, the results show correlations between the SCL parameters and the corneal astigmatism, ACD and pentacam-measured corneal height (Hm), with $p < 0.001$ each. In addition, an inverse correlation between the lens sagittal depth (LSD) and the anterior radii minimum was shown ($p < 0.001$). In the keratoconus group, the results show correlations between the SCL parameters and ACD and Hm ($p < 0.001$, each). An inverse correlation between the LSD and the total thickness corneal density average was also observed ($p = 0.003$).
Conclusion: There was a positive correlation between the LSD and ACD, even as LD and ACD in the keratoconus group. Thus, these results suggest that certain Pentacam measurements can be good predictors of the most appropriate Esclera lens to be fitted in keratoconus patients.

1. Introduction

In 1508, Leonardo da Vinci proposed the idea of optically neutralising the cornea with a lens by enclosing a liquid reservoir over the front corneal surface [1]. Nearly 400 years later, Fick designed the earliest practical scleral contact lens (SCL) [2]. His goal was to neutralise the optical effects of corneal distortion for patients with irregular astigmatism using afocal scleral glass shells.

Modern SCLs are indicated for ocular conditions, such as keratoconus; pellucid marginal degeneration; corneal irregularities after penetrating keratoplasty (PKP); eyes post-refractive surgery; and ocular surface disorders; such as Stevens-Johnson syndrome, exposure keratopathy and dry eye disease [3–6]. Such lenses can usually be fitted successfully; however, fitting is challenging in patients with irregular corneas [7].

The Esclera® lens (Mediphacos, Belo Horizonte, Minas Gerais, Brazil) has a fluid-filled SCL design. This lens is the seventh generation of the Maxim® (Accu Lens, Denver, CO, USA) gas-permeable scleral lens, which vaults the cornea and limbus and rests entirely on the sclera. The space created by the vault of the Esclera is filled with preservative-free saline solution, which is placed in the lens reservoir at the time of insertion.

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Table 1
Manufacturer's fitting guide suggestions for trial Esclera lens fitting.

Moderate cone	Advanced cone	Post surgical/Pellucid (Lasik/RK)	Post surgical (bulging)
4.47 LSD/16.0 LD	4.64 LSD/16.0 LD	4.75 LSD/16.5 LD	4.89 LSD/16.0 LD
5.20 LSD/17.5 LD	5.64 LSD/17.5 LD	5.20 LSD/17.5 LD	5.64 LSD/17.5 LD

LSD, lens sagittal depth; LD, lens diameter.Font: Adapted from http://www.acculens.com/fitting_maxim.htm.

The trial lens depends on the sagittal depth value and not the base curve, in contrast to other rigid corneal contact lenses. Currently, there are no known anatomical parameters for determining which lens will adapt better to a patient's eye, leaving the choice of lens to be based nearly entirely on professional experience.

The Pentacam® (Oculus, Wetzlar, Germany) is a rotating Scheimpflug camera that images the anterior segment of the eye. This device can provide topographic maps of the anterior and posterior corneal surfaces, pachymetry maps, and biometric measurements of the anterior segment of the eye [8–10]. Several studies have evaluated the reproducibility and repeatability of Scheimpflug imaging devices, which have been shown to give reliable corneal measurements for eyes with irregular corneas [11–14].

The purpose of the present study was to test for associations between Pentacam-derived topographic variables and to evaluate the predictive power of those variables in relation to SCL fit.

2. Method

This was a prospective, observational, non-randomised and non-comparative study that comprised eyes for which SCL use was indicated from February to November 2013 at the Federal University of São Paulo. The Esclera contact lens was indicated for 63 eyes of 47 patients. When a patient had an indication for SCL in both eyes, the values for each eye as independent variables, considering that each eye presents independent anatomical and physiological features were analysed. All patients underwent Pentacam examinations before the initial evaluation of the SCLs.

This study included patients with a formal indication for SCL use. The exclusion criteria were as follows: the presence of glaucoma, a disorder affecting sensitivity (e.g., herpetic disease or diabetes mellitus), corneal decompensation, active ocular infection or a persistent epithelial defect, pregnancy and an inability to correctly handle and care for SCLs.

Following the tenets of the Declaration of Helsinki, all subjects gave written informed consent after receiving an explanation of the risks and possible consequences of participating in the study. In addition, institutional ethical board committee approval was obtained.

2.1. Scleral contact lens fitting

The Esclera device is an SCL composed of a fluorocarbon material, with an optical zone measuring from 9 to 10.5 mm and a diameter ranging from 16 to 18.2 mm. This lens incorporates a patented multiple posterior curve system to achieve corneal alignment. The Esclera lens is specifically manufactured from a rigid, gas-permeable material that is transparent and non-fenestrated and has a plasma-treated surface and outstanding oxygen permeability (141 Dk using the ISO/Fatt method), called Boston XO_2.

SCL fitting using the Esclera lens is considered to be ideal if it is based on the following parameters: the size of the lens relative to the eye, with the lens needing to measure at least 2 mm beyond each side of the limbus, and an ideal apical clearance of 100 μm, allowing the distribution of fluorescein between the posterior surface of the lens and the anterior surface of the cornea. In addition, the SCL should not touch the cornea, and the edge of the SCL should not exhibit vascular impingement, conjunctival blanching or scleral indentation.

The initial diagnostic lens was selected based on suggestions in the manufacturer's fitting guide (Table 1) and according to both a patient's corneal topographic diagnosis and a gross visual assessment of the corneal contour from the lateral perspective.

2.2. Scheimpflug assessment

All patients who were subjected to SCL fittings underwent examinations with the Pentacam rotating Scheimpflug imaging system (Oculus, Wetzlar, Germany) before the initial SCL evaluation. During the Pentacam examination, the patient was comfortably positioned at the instrument, with proper placement on the chin rest and forehead strap. The patient was asked to blink a few times and then to open both eyes and stare at the fixation target. After proper alignment was obtained, the automatic release mode started the scan using 25 individual Scheimpflug images captured within 2 s for each eye. Only the patients with images of acceptable quality were included in the study. The Pentacam software was used to automatically extract the data from each examination and to add these data to a Microsoft Excel® (Microsoft, Redmond, WA, USA) spreadsheet.

The variables assessed using the Pentacam included the anterior and posterior corneal elevation values, the corneal thickness at the thinnest point, the corneal volume, the anterior chamber depth (ACD), the anterior chamber angle and the corneal density.

Two objective measures were created to obtain anatomical eye measures proportional to the lens sagittal depth (LSD) and lens diameter (LD), without interference from the thickness of the cornea and the forward displacement of the lens, to reduce confounding factors in the measures. The measured anterior chamber diameter from angle to angle was termed the anterior chamber width (ACW), and the distance from the posterior corneal surface to the intersection point was termed the corneal height (Hm) (Fig. 1).

To obtain the Hm and ACW measurements, the Scheimpflug image of the horizontal meridian was displayed. The software showed the locations of the anterior chamber angles, and the

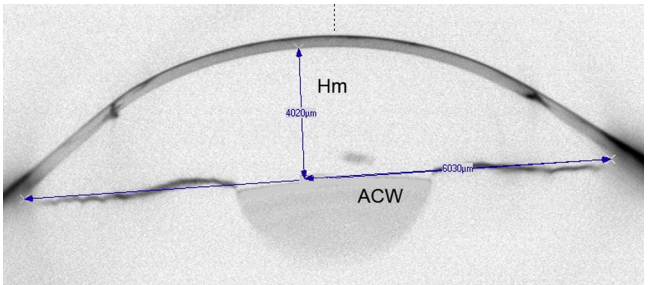

Fig. 1. A Scheimpflug image obtained using the Pentacam. The distance between the 2 anterior chamber angle points was termed the ACW, and the distance from the posterior corneal surface of the vertex to the line connecting the anterior chamber angles was termed the Hm.