Contact Lens & Anterior Eye 38 (2015) 168–172

Contents lists available at ScienceDirect

Contact Lens & Anterior Eye

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

Repeatability of in vitro power profile measurements for multifocal contact lenses☆

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ARTICLE INFO

Article history:
Received 15 November 2014
Received in revised form 19 January 2015
Accepted 26 January 2015

Keywords:
Multifocal contact lens
Contact lens power profile
Repeatability
Schlieren principle

ABSTRACT

Purpose: To evaluate the repeatability of an optical device (NIMO TR1504, Lambda-X, Belgium) for measuring multifocal contact lens power profiles.
Methods: The NIMO TR1504 was used to measure power profiles 30 times for each of 10 different contact lenses from 4 major companies. All contact lenses were labelled as −3 D for distance vision; half were for high addition and half for low addition. The optical zone in all measurements was set to 3-mm radius. For each lens, the median power profile and the residuals of the 30 measurements were calculated. The 95% confidence bands and two indices that summarize measurement errors were calculated: the repeatability limit and an index of repeatability heterogeneity, quantifying heterogeneity of measurement errors over the optical zone.
Results: The repeatability limit was good (from 0.04 D to 0.12 D), for all multifocal contact lenses. Variability of measurement errors of power profiles was quite homogeneous along the optical zone for all lenses, although for some lenses variability was slightly higher in the centre than peripherally.
Conclusions: The repeatability of measured power profiles obtained by the NIMO TR1504 is lower than 0.12 D for the multifocal contact lenses.

1. Introduction

Accurate repeatable measurement of the power profile and of its variability is necessary to assess the quality of a multifocal contact lens and how well the final product meets the design specifications. Objective measurements of the power profiles provide helpful information for prescribing lenses on presbyopic patients [1], give practitioners a better understanding of the behaviour of these contact lenses, and enhance fitting nomograms. For example, it has been reported [2] that modifying the distance nominal power in a multifocal contact lens has double effect: change both the near addition, and the pupil diameter for which the lens provides the distance correction.

There are different techniques that have been used to measure contact lens power profiles objectively: Meier et al. [3] used a series of double aperture stops on a lensometer to measure the power distribution across the Bausch & Lomb bifocal lenses; Bullimore et al. [4] assessed power variation across the surface of a multifocal lens using a video-keratographic method; and Collins et al. [5] measured power variations across the optic zone using a computer-interfaced vectometer. More sophisticated methods are used nowadays to measure in vitro power profiles, such as in Ehrmann et al. [6], where an optical system was developed for power mapping intraocular and contact lenses using a paraxial laser scan. Papas et al. [7] evaluated the refractive power within the optical zone with a contact lens power analyser. Plainis et al. [8], measured the power profile of several multifocal contact lenses with a lens profiler based on ptychographic imaging. And Wagner et al. [1] investigated the power profile of single vision and multifocal contact lenses with a wavefront sensing instrument.

The NIMO TR1504 (Lambda-X, Belgium) is an optical device that measures refractive power and optical aberrations of spherical, toric, and multifocal lenses. It is based on a deflectometry technique and combines the Schlieren principle with a phase-shifting method [9,10]. With a single measurement, this device obtains information

☆ This research was supported in part by the Starting Grant funded by the European Research Council (ERC-2012-StG-309416-SACCO) to Prof. Robert Montés-Micó, and by a "Atracció de talent" research scholarship (*Universidad de Valencia*) awarded to Alberto Domínguez Vicent (UV-INV-PREDOC13-110412).

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http://dx.doi.org/10.1016/j.clae.2015.01.013
1367-0484/

Table 1
Detailed description of the contact lenses.

Multifocal contact lens	Material	Centre	Design	Base curvature (mm)	Lens diameter (mm)	Additions
Acuvue Oasys for Presbyopia	Senofilcon A	Distance	Concentric aspheric zones	8.40	14.30	Low (up to +1.25 D) High (up to +2.50 D)
Air Optix Aqua Multifocal	Lotrafilcon B	Near	Bi-Aspheric	8.60	14.20	Low (up to +1.25 D) High (up to +2.50 D)
PureVision 2	Balafilcon A	Near	Bi-Aspheric	8.60	14.00	Low High
Biofinity Multifocal	Comfilcon A	Distance	Aspheric	8.60	14.00	+1.50 D +2.50 D
Biofinity Multifocal	Comfilcon A	Near	Aspheric	8.60	14.00	+1.50 D +2.50 D

about Zernike coefficients, power profiles, sphere, cylinder and axis. Joannes et al. [11] found a reproducibility standard deviation for monofocal contact lenses with the NIMO device of 0.05 D (Table 5 in their paper [11]); being then more precise than any current ISO referenced method. Although they did not report repeatability data directly, they stated that the repeatability standard deviation for monofocal contact lenses was of the same order of magnitude as the reproducibility one.

Repeatability of NIMO for multifocal contact lenses has not been assessed up to now. Thus, the aim of this study is to evaluate the repeatability of the NIMO for multifocal contact lenses when it comes to measure their power profiles.

2. Methods

2.1. Multifocal contact lens included in the study

For the repeatability analysis of the NIMO TR1504, 10 contact lenses of 4 major companies were used. All lenses had a nominal power of −3 D for distance vision. The lenses included were:

a. Air Optix Aqua Multifocal (Alcon Laboratories, Fort Worth, USA) – low- and high-addition with centre-near design.
b. Acuvue Oasys for Presbyopia (Vistakon, Division of Johnson & Johnson Vision Care, Jacksonville, PL, USA) – low- and high-addition with centre-near design.
c. PureVision 2 multifocal (Bausch & Lomb, Rochester, NY, USA) – low- and high-addition with centre-near design.
d. Biofinity Multifocal (Cooper Vision, Fairport, NY, USA) – +1.50 D and +2.50 D addition lenses. For each addition two lenses were selected with centre-near design (the distance correction is at the lens periphery), and with centre-distance design (the distance correction is at the lens centre).

For a detailed description of these lenses see Table 1. Only one lens of each type was measured, which is enough for the purpose of this study. This setup does not consider the differences between contact lenses of the same company and design that may emerge during the fabrication process.

2.2. Measurements

The NIMO TR1504, which diagram is shown in Fig. 1, is based on a quantitative deflectometry technique [10], and combines the Schlieren principle with a phase-shifting method to measure contact and intraocular lenses. This optical device uses a measuring light source with radiance peaking at 546 nm and obtains light deviations, from which it is possible to calculate the power characteristics of optical lenses. Detailed descriptions of the method used to measure power profiles can be found elsewhere [2,9,11]. The NIMO is able to obtain spherical and cylinder power with its axis, Zernike coefficients, and contact lens power profiles. All contact lenses were immersed in a cuvette, see Fig. 1, to preserve hydration during the measurement procedure.

The measuring protocol was as follows. First, each lens was removed from its blister and immersed for 24 h in the same saline solution that was used during contact lens measurement, as established in the ISO 5725-2 [12] for repeatability studies. Second, after these 24 h, the contact lens was transferred to the cuvette with its back surface oriented to the bottom. Third, one measurement of the contact lens power profile was taken as the radial power averaged on a circle as a function of the distance to the centre. Fourth, the cuvette and contact lens were removed and the NIMO was recalibrated in order to get independent measurements [13]. Finally, steps three and four were repeated 30 times to obtain a total of 30 power profiles.

2.3. Statistical analysis

For the 30 measured power profiles for each contact lens, the median power profile was obtained with the non-parametric additive quantile regression smoothing method [14]. The smoothing parameter necessary to the non-parametric quantile regression was set up manually, since no automatic method for selection is available [14].

Residuals were obtained as the difference between each measurement and the estimated median. The 95% confidence bands with the residuals were calculated with an additive quantile regression smoothing method. If residuals were Gaussian with zero mean with homogeneous variance over the optical zone (homoskedastic), then confidence bands calculated with quantile regression would be the same as those calculated as ±1.96 times the standard deviation of the residuals except for sampling error.

For a particular point in a power profile, e.g., at 0 mm or 1 mm of radial distance, its repeatability limit is defined as the value for which 95% of the differences between two measurements are lower, when these measurements are taken under repeatability conditions [12,13]. The repeatability limit is often obtained from the standard deviation calculated from repeated measurements, or the repeatability standard deviation. If s_r denotes the repeatability standard deviation, then the standard deviation of the difference between any two independent measurements is $\sqrt{2}s_r$. It is typically assumed that differences between any two measurements are Gaussian and, hence the critical value that delimits the 95% limit of agreement is 1.96 the standard deviation of their difference. That is, the repeatability limit is 1.96 $\sqrt{2}s_r$. For the power profile of a multifocal contact lens, repeatability limit may differ with the power measured at each radial distance, from 0 to 3 mm. We summarize repeatability results for each multifocal power profile with two values: the repeatability limit, the mean repeatability