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Repeatability and reproducibility of Galilei measurements in normal keratoconic and postrefractive corneas

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ABSTRACT

Objective: To assess the repeatability and reproducibility of the anterior segment measurements performed with a dual Scheimpflug analyzer (Galilei) in normal, keratoconic and post-refractive surgery corneas.

Methods: To evaluate the repeatability, two additional measurements were performed by the first examiner. To assess reproducibility, this was later followed by a single reading by the second examiner. The following parameters were recorded and evaluated in this study; central corneal thickness (CCT), thinnest corneal thickness (TCT), mean total corneal power (TCP) in central (0–4 mm), mean posterior corneal power (PCP) in central (0.5–2 mm), anterior and posterior elevation (best fit sphere [BFS]) in central 8 mm anterior and posterior eccentricity (ε^2) in central 8 mm. Repeatability and reproducibility for each corneal parameter was assessed using the Bland–Altman analysis.

Results: Each of the three groups was consisted of 20 subjects (totally 60 patients, 30 men and 30 women). The 95% LoA for repeatability was very small, indicating small discrepancies between measurements related to CCT. Acceptable repeatability was also achieved for the other parameters in each group. However, the 95% LoA for value TCP was larger in keratoconic eyes. The 95% LoA for reproducibility was also very small, and acceptable for all measured parameters in each group. In addition, the 95% LoA was larger for the measurement of CCT and TCT for postrefractive corneas.

Conclusions: The anterior segment measurements provided by Galilei showed good repeatability and reproducibility for normal, keratoconic and postrefractive corneas.

1. Introduction

In the past decade, Scheimpflug video photographic devices have become popular for objective evaluation of cornea [1]. The Pentacam (Oculus, Germany) was the first Scheimpflug analysis system which uses a single Scheimpflug camera to perform multiple photographs of the anterior segment of the eye [2].

In 2007, a new topographer, Galilei (Ziemer Ophthalmology Co.) was marketed. This device uses a double Scheimpflug system combined with a Placido disk. While the Pentacam derives keratometry data of the surface from the Scheimpflug images only; the Galilei system uses the Placido disk to analyze the anterior curvature. Additionally, this dual system provides accurate pachymetry not only of the central cornea but also the peripheral cornea, even in cases of micromovements [3].

Low intraobserver and interobserver alteration is required to perform correct individual measurements in the diagnosis and long-term follow up of corneal diseases [4–6]. Few studies have evaluated the repeatability of the Galilei [1,3,7], and none of them included eyes that had keratoconus.

This study evaluates the repeatability and reproducibility of the anterior segment parameters measured with Galilei dual-Scheimpflug analyzer in normal, keratoconic, and postrefractive corneas.

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2. Materials and methods

In this prospective study, three groups of subjects were assessed: Subjects who had previous myopic photorefractive keratectomy (PRK) or LASIK (at least 3 months elapsed after surgery), subjects with a diagnosis of keratoconus, and subjects with normal corneas. The initial diagnosis of keratoconus was based on clinical slit-lamp findings and associated characteristic Placido-based topographic patterns [8]. The mean simulated keratometric values obtained with Placido-based topography ranged from 45.65 to 59.00 diopters (D). Keratoconic corneas with previous acute corneal hydrops or a history of corneal surgery were excluded from the study. Normal corneas met the following criteria's; no history of ocular surgery, trauma, contact lens usage, or disease except for myopia, hyperopia, and/or astigmatic ametropia. All subjects had best corrected visual acuity (with glasses and rigid contact lenses) of at least 20/40. One eye was randomly selected in each subject. The study was conducted in accordance with the ethical standards stated in the 1964 Declaration of Helsinki. Informed and written consent was obtained from all subjects. The study was approved by the Local Ethics Committee of Turgut Özal University.

Measurements were performed using the Galilei system, which performs anterior corneal measurements by using the Placido and Scheimpflug data. However, Galilei measures the posterior corneal surface by the Scheimpflug data. The device's software (version 5.2.1) was used to perform measurements. Measurements with the dual Scheimpflug analyzer were performed according to the manufacturer's guidelines. The device was brought into focus and the subject's eye was aligned along the visual axis by a central fixation light. The subjects were asked to sit back after each measurement, and the device was realigned before each measurement. Subjects were asked to sit back after each measurement, and to blink completely just before each measurement.

All measurements were taken between 10 AM and 3 PM with non-dilated pupil in identical lighting conditions. All subjects had two repeated readings taken by the examiner 1 (repeatability). This was later followed by a single reading by the examiner 2 who was blind to the results of examiner 1 (reproducibility). The following parameters were recorded and evaluated in this study;

1) *Average and thinnest central corneal thickness (CCT)*: The dual Scheimpflug analyzer used in this study provides corneal thickness measurements for the central 9.0 mm. Data are automatically reported in concentric circles (with a diameter of 1.0 mm, 3.0 mm, and 4.0 mm), although corneal thickness can be measured at any point by manually placing the cursor at that point.
2) *Mean total corneal power*: This is a specific feature of the dual Scheimpflug analyzer used in this study. Measurements of the power of the anterior and posterior corneal surfaces are obtained through ray tracing rather than the Gaussian optics formula, as in the case of the true net power provided by the Pentacam device. For each point on the map, the angle of incidence is calculated relative to the anterior surface normal for incoming parallel rays. The angle of refraction is calculated using the Snell law with air refractive index (Z) 1.0 and cornea Z 1.376. This angle of refraction is used to determine the nonparallel direction of incoming rays relative to the posterior surface normal and is used to calculate the angle of incidence for the posterior surface. A new angle of refraction is calculated for the posterior surface using the Snell law with cornea Z 1.376 and aqueous Z 1.336. This final angle of refraction is used to calculate the intersection of the ray along the (0.0) axis and the resultant focal length that is used to determine total power for that point on the map.
3) *Mean posterior corneal power*: This value (derived from the posterior axial curvature map) is the arithmetic mean of the pair of meridians 90° apart with the greatest difference in average power, from a 0.5 to 2.0 mm distance from the center. The power of the steep and flat meridian is calculated using the cornea (1.376) and aqueous humor (1.336) refractive indexes.
4) *Anterior and posterior elevation (best-fit sphere [BFS]) maps*: These are calculated for an analysis area of 8.0 mm. The corresponding radius of curvature was evaluated in the present study.
5) *Eccentricity (ε^2)*: Eccentricity ε is reported as its square ε^2. This term is one of four parameters by which the shape of a conic section can be described: Q (asphericity), p value and E (corneal shape factor) are the others. Galilei calculates the eccentricity ε^2 of the surface within a central diameter of 8 mm averaged over all meridians. This is done for the anterior and posterior surface.

2.1. Statistical analysis

The definitions of coefficient of repeatability and reproducibility were based on those adopted by the International Organization for Standardization and a previous report [8,9] the coefficient of repeatability was defined as 2 SDs of the differences between the measurements obtained for the same subject at the different sessions by the same observer. The coefficient of reproducibility was defined as 2 SDs of the differences between the measurements obtained for the same participant at the same visit by different observers.

Because the distribution of all the data obtained was not significantly different from normal (Kolmogorov–Smirnov tests, $p > 0.05$), parametric tests were used for analysis of differences. Repeatability/reproducibility of the data obtained was determined only when there was no statistically significant difference between measurements. Plots of the within-examiner (repeatability) or between-examiner (reproducibility) differences against their means and the 95% limits of agreement (LoA) (mean difference ± 1.96 SD) were determined as suggested by Bland and Altman [10] where appropriate. Statistical analysis was performed using the SPSS for Windows Version 11.0 (SPPS Inc., Chicago, IL, USA). p values less than 0.05 were considered statistically significant.

3. Results

Each of the three groups was consisted of 20 subjects (totally 60 subjects, 30 men and 30 women). The mean age of the postrefractive, keratoconic and normal subjects were 36.0 ± 11.8, 25.0 ± 12.5, and 23.0 ± 11.5 years, respectively.

3.1. Repeatability

Table 1 shows the repeatability assessment of examiner 1 for each measured parameters by groups. There were no significant within-examiner differences for any of the parameters tested ($p > 0.05$).

In all groups, measurements related to CCT showed excellent repeatability. The 95% LoA for CCT was very small, indicating small discrepancies between measurements. For the repeatability of CCT, the Galilei gave the 95% LoA values from +5.72 to −9.22 μm for normal corneas, +9.82 to −9.02 μm for keratoconic corneas, and +12.45 to −9.45 μm for postrefractive corneas. Fig. 1 shows the plots of within-examiner differences in CCT for all groups.

Based on the 95% LoA, good repeatability was also achieved for the other parameters in each group. The 95% LoA for TCP was larger in keratoconic eyes. For repeatability of TCP, the 95% LoA values ranged from +1.61 to −1.34 D for normal corneas, +1.98 to −2.09 D for keratoconic corneas, and +0.44 to −0.49 D for postrefractive corneas. Fig. 2 shows the plots of within-examiner differences of TCP for all groups.