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Spectral Optical Coherence Tomography vs. fluorescein pattern for rigid gas-permeable lens fit

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Data Collection B
Statistical Analysis C
Data Interpretation D
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Background: This study aimed to evaluate anterior segment spectral optical coherence tomography (AS SOCT) for assessing the lens-to-cornea fit of rigid gas-permeable (RGP) lenses. The results were verified with the fluorescein pattern method, considered the criterion standard for RGP lens alignment evaluations.

Material/Methods: Twenty-six eyes of 14 patients were enrolled in the study. Initial base curve radius (BCR) of each RGP lens was determined on the basis of keratometry readings. The fluorescein pattern and AS SOCT tomograms were evaluated, starting with an alignment fit, and subsequently, with BCR reductions in increments of 0.1 mm, up to 3 consecutive changes. AS SOCT examination was performed with the use of RTVue (Optovue, California, USA).

Results: The average BCR for alignment fits, defined according to the fluorescein pattern, was 7.8 mm (SD=0.26). Repeatability of the measurements was 18.2%. BCR reductions of 0.1, 0.2, and 0.3 mm resulted in average apical clearances detected with AS SOCT of 12.38 (SD=9.91, $p<0.05$), 28.79 (SD=15.39, $p<0.05$), and 33.25 (SD=10.60, $p>0.05$), respectively.

Conclusions: BCR steepening of 0.1 mm or more led to measurable changes in lens-to-cornea fits. Although AS SOCT represents a new method of assessing lens-to-cornea fit, apical clearance detection with current commercial technology showed lower sensitivity than the fluorescein pattern assessment.

Keywords: Spectral Optical Coherence Tomography • Soct • Contact Lens • Lens Fit • Rigid Gas-Permeable • Fluorescein Pattern

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Background

Rigid gas-permeable (RGP) contact lenses are made of durable plastic material that can transmit oxygen due to its silicone content. RGP lenses were designed in the late 1970s for patients who could not obtain successful optical correction with soft contact lenses. They are most often used in eyes with keratoconus, high astigmatism, and presbyopia, and after refractive surgery. RGP lenses often perform better than soft lenses due to their durability, which enables them to retain shape. They are highly resistant to deposits, because their low water content impedes adhesion of tear film proteins and lipids to the surface of the lens [1]. Due to their high endurance, RGP lenses may last for several years. Therefore, it is crucial to achieve a proper initial fit. The back surface of an RGP lens maintains its shape; in contrast, soft lenses conform easily to the anterior cornea. As a result, the complete optical system for the RGP lens consists of a rigid lens, a tear layer, and finally, the eye. Fitting rigid lenses involves assembling this 3-piece structure to maintain functionality, despite repeated displacements caused by blinking or eye movements [2,3].

The final choice of lens must safely fit the patient, cause minimal discomfort, and provide maximal vision correction. Several parameters must be taken into consideration when fitting RGP lenses, including the radius of the back surface, the diameter, the back vertex power, the thickness, and the edge profile. Factors that may impact RGP lens fitting include corneal anatomy, lid geometry and mechanics, and pathological condition, like pterygium or impaired tear secretion [4,5].

The conventional method of fitting RGP lenses is to use a set of trial lenses. This set consists of RGP lenses with the same diameter and back vertex power, but with a range of base curve radii (BCR) that differ by 0.1 mm increments. The initial lenses can be chosen empirically, based on keratometry readings. The criterion standard for evaluating the lens-to-cornea fit has been to examine the fluorescein pattern. However, due to the subjectivity in evaluating the fluorescein pattern and many factors that may alter the image (such as tear secretion insufficiency, allergies, corneal deposits, location and mobility of the lens, local epithelial reaction), there is a need for a new, precise, objective method.

Anterior segment spectral optical coherent tomography (AS SOCT) is a method that has gained increasing clinical importance in anterior segment imaging. AS SOCT is a non-contact, non-invasive method capable of capturing cross-sectional images of contact lenses, tear film, and the cornea [6–8]. AS SOCT also allows video-rate and 3-dimensional cross-sectional imaging of the eye as it is being fitted with a contact lens [9,10].

Although several studies previously described the AS SOCT technique for assessing contact lens fitting, there is little scientific

information on its practical value in this field. Therefore, this study aimed to verify the applicability of currently commercially available AS SOCT technology for evaluating RGP lens alignments and to compare the results with the traditionally used method of examining the fluorescein pattern.

Material and Methods

Twenty-six eyes of 14 patients (10 female, 4 male), with a mean age of 39.6 ± 12.3 years (range: 23–60), were enrolled in the study. Exclusion criteria were any diagnosed corneal pathology (keratoconus, keratopathy, dystrophy, ectasia) or a corneal astigmatism greater than ± 0.5 diopters. RGP lenses were fitted by 1 operator with a trial fitting set (BIAS, Hecht, Germany). The BCR range was 7.3–8.4 mm. The initial BCR of RGP lenses was selected to be 0.1 mm smaller than that indicated by keratometry readings (ARK-530A, Nidek, Japan). After topical anesthesia with proparacaine hydrochloride (Alcaine 0.5%, Alcon Laboratories, Inc.), fluorescein was introduced into the eyes by applying BIOGLO strips impregnated with 1 mg of fluorescein sodium U.S.P. (HUB Pharmaceuticals, LLC, California, USA). The fluorescein pattern and AS SOCT (RTVue 100 FD, Optovue, California, USA) were compared for evaluating the alignment and fit of a set of lenses with decreasing BCRs (in 0.1-mm increments), for up to 3 consecutive changes. The fluorescein pattern was photographed 5 times for each lens with a slit-lamp-mounted Canon EOS 300D digital camera, starting 2–3 seconds after blinking. Five AS SOCT Hi-Res Cornea Cross Line Scan tomograms of 5-micron axial resolution were also acquired for each lens. The time of OCT measurement was also 2–3 sec after blinking, at the moment when the lens was in the center of the cornea (± 1 mm), monitored on the live eye preview image. On each tomogram, the gap between the posterior surface of the lens and the anterior surface of the central cornea (apical clearance) was measured manually, 3 times. Consecutive ANOVA statistical analyses were conducted with Statistica 6.0PL software. The overall significance level was set at 0.05.

This study followed the tenets of the Declaration of Helsinki. Informed consent was obtained from the subjects after explaining the nature and possible consequences of the study. The research was approved by the Ethics Committee of the institution where all authors were affiliated.

Results

The range of apical clearances detected by AS SOCT was 3–62 μm . The mean coefficient of repeatability, defined as the standard deviation divided by the mean result, was 18.2%. The average BCR for an aligned fit, defined according to the fluorescein pattern, was 7.8 ± 0.26 mm. The fluorescein patterns

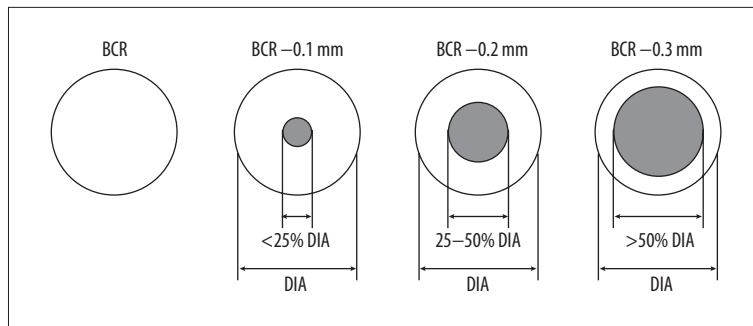


Figure 1. Schematic of apical clearance evaluated with the fluorescein pattern method. Grey region indicates the area of no contact between a rigid gas-permeable contact lens and the cornea. BCR: base curve radius of the trial contact lens.

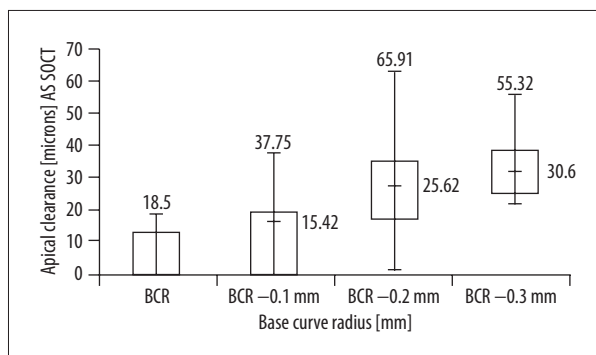


Figure 2. Box plot of apical clearance evaluated with anterior segment spectral optical coherence tomography (AS SOCT) measurements. Values indicate the distance (μm) of no contact between a rigid gas-permeable contact lens and the cornea. BCR: base curve radius of the trial contact lens.

observed in alignment fitting are schematically depicted in Figure 1. BCR reductions of 0.1, 0.2, and 0.3 mm increased the apical clearance detected in the fluorescein pattern (by approximately established percentage diameter value) (Figure 1).

The corresponding mean AS SOCT measurements were 12.38 (SD=9.91), 28.79 (SD=15.39), and 33.25 (SD=10.60) microns, respectively (Figure 2).

The first 2 reductions in BCR (-0.1 and -0.2 mm) caused significant increases in apical clearance ($p < 0.05$ for both), but the

second and third BCR reductions (-0.2 and -0.3 mm) cause similar apical clearances ($p > 0.05$). Figure 3 shows examples of fluorescein pattern images and SOCT imaging measurements for the same eye.

In 5 cases (5.10% of measurements), the apical clearance was visible with the fluorescein pattern, but was not detectable with AS SOCT. Table 1 shows the sensitivity of fluorescein pattern and SOCT methods for apical clearance detection.

Discussion

The fluorescein pattern remains the criterion standard for RGP contact lens fitting [11]. In clinical practice, other aspects are also taken into consideration, including the patient's subjective comfort, lens centration, lens movement, and surface wettability [7]. However, these parameters provide only an approximate assessment of lens fit and alignment. Proper evaluation of lens fitting is subjective and time-consuming. Hence, there is a need for a new, objective, practical tool for contact lens fitting assessments.

Although OCT is the device of choice for retinal imaging, it is also widely used to evaluate the anterior segment, because it enables both structural imaging and morphometric measurements of ocular tissues. It has been proven for efficacy in imaging the tear meniscus and conjunctival folds, in performing

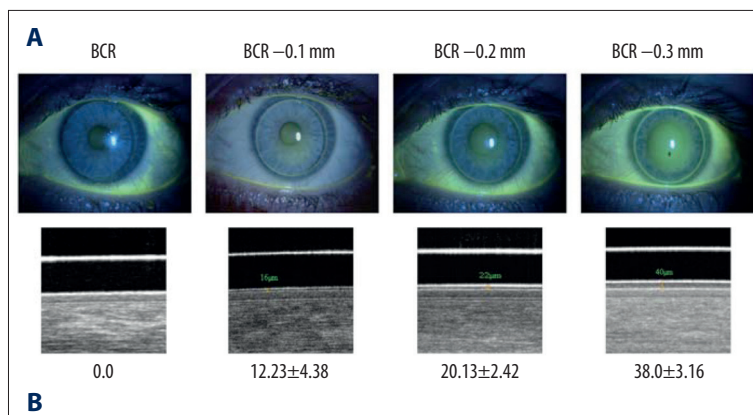


Figure 3. Examples of alignment fitting of trial rigid gas-permeable contact lenses evaluated with fluorescein pattern images and spectral optical coherence tomography (SOCT) measurements. Four trial lenses, each with a different base curve radius (BCR), were evaluated in the same eye with either (A): the fluorescein pattern or (B): SOCT measurements (microns \pm SD).

Table 1. Number of cases with apical clearance detected by fluorescein pattern (FP) and anterior segment spectral coherence optical tomography (AS SOCT).

	BCR -0.1 mm	BCR -0.2 mm	BCR -0.3 mm
Total number of measurements	26	26	20
Apical clearance in FP (sensitivity)	24 (92.31%)	26 (100%)	20 (100%)
Apical clearance in SOCT (sensitivity)	20 (76.92%)	25 (96.15%)	20 (100%)

Sensitivity of these methods is given in brackets. BCR – base curve radius.

pachymetry, and in producing corneal curvature maps [12,13]. The notion that SOCT might be useful for contact lens imaging was previously presented, with emphasis on its potential crucial role in clinical practice [7,10,14].

To the best of our knowledge, no reports have described RGP lens fitting assessments with OCT. However, there are a few reports on soft contact lens fitting evaluations. According to Cui et al., soft contact lens fitting should be based on an objective evaluation, like that provided with OCT measurements. Combining ultrahigh-resolution and ultralong-scan depths, OCT has enabled the dynamic tracking of lens micro-movements, and thus, it represented a new practical method for assessing the fit of soft contact lens [6].

In one of our previous investigations, we studied 3 devices for pachymetry – the RTVue 100 FD (for AS SOCT), the Pentacam, and ultrasound – and we also compared them for efficacy in measuring central corneal thickness. The AS SOCT device showed the highest reproducibility of results, which was consistent with findings from other authors [15–17]. Therefore, we assumed that this method would serve as a good alternative in anterior segment imaging, including for assessments of RGP lens fits. In a study by Prakash et al., corneal epithelial thickness at the vertex was assessed with a Fourier domain AS OCT, and it showed high reproducibility. Thus, it proved to be a reliable tool for quantitative corneal diagnostics [18]. González-Méijome et al. examined *in vivo* physiological reactions with high-resolution SOCT in subjects who wore soft contact lens. They evaluated changes in epithelial, stromal, and contact lens thicknesses. They demonstrated that high resolution SOCT was an advantageous tool for detecting slight hypoxia-induced changes [19].

In the present study, with every BCR change, 15 measurements were taken with the AS SOCT (5 scans, with 3 manual measurements each). In the statistical analysis, we used an average of the positive values obtained; however, in several cases, only some measurements showed apical clearance. This suggests that AS SOCT measurements showed low repeatability. Thus, this method was less sensitive than fluorescein pattern examinations for assessing RGP lens fits. Our manual AS SOCT measurements showed moderate repeatability (18.2%);

these measurements were strongly dependent on the choices of measurement location and time after blinking. We evaluated repeatability according to methods described previously [15]. We took great care to perform the measurements consistently at the same position (in the center of the cornea) and at the same time (shortly after blinking). Nevertheless, the high standard deviation in our results indicated that the measurements lacked precision.

Another important finding was the overlap in results (Figure 2). In practice, the findings reflect a trend towards increasing apical clearance; however, it did not enable an estimation of the exact lens BCR, based on the absolute measurement values.

A standard trial set of RGP lenses for fitting consists of lenses with BCRs that steepen in increments of 0.1 mm. In the present study, a -0.1 mm change from the initial BCR produced a change in apical clearance that was detectable with AS SOCT; however, the sensitivity was only 76.92%, compared to 92.31% for the fluorescein pattern method. This implies that AS SOCT could successfully detect the apical clearance only for lenses with BCRs that differed from the initial trial lens by 0.2 mm or more.

We assume that AS SOCT did not perform well in RGP fit assessments, because it is a dynamic process; both lens position and the placement of the AS SOCT measurement may change during scanning, and this could affect quantitative results. In the fluorescein pattern method, the influence of the lens movements on fit evaluation might be diminished by experience of the examiner or by taking a photograph in a specific moment and location of the lens. Thus, the fluorescein method enabled a more accurate qualitative analysis than the AS SOCT method. However, the fluorescein pattern method has the disadvantages inherent in a manual, subjective technique [20]. A potential solution, to be verified in the future, may be to mount the SOCT device on the slit-lamp to be able to acquire a fluorescein pattern image and a SOCT tomogram at the same moment in time and in a precisely defined plane. This type of device could improve the RGP fit assessment technique, because it would be based on the fluorescein pattern, but also would provide objective, quantitative data.

Conclusions

The lens-to-cornea fit was measurable with the AS OCT method for lens sets with BCRs that steepened in increments greater than 0.1mm. The currently available AS SOCT systems may provide a new method for assessing the lens-to-cornea fit. However, in this study, it had lower sensitivity in apical clearance detection than the fluorescein pattern

method. This observation, combined with its relatively low measurement precision, may limit the clinical value of current AS SOCT systems.

Statement

The authors report no conflicts of interest and have no proprietary interest in any of the materials mentioned in this article.

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