Retinal Thickness in Eyes With Mild Nonproliferative Retinopathy in Patients With Type 2 Diabetes Mellitus

Comparison of Measurements Obtained by Retinal Thickness Analysis and Optical Coherence Tomography

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Objective: To compare measurements of retinal thickness in eyes with mild nonproliferative retinopathy in patients with type 2 diabetes mellitus using 2 different techniques: the retinal thickness analyzer (RTA) and optical coherence tomography (OCT).

Methods: Twenty-eight eyes from 28 patients with type 2 diabetes mellitus and mild nonproliferative retinopathy were classified according to the Wisconsin grading system by 7-field stereoscopic fundus photography. Ten eyes were classified as level 10 (absence of visible lesions) and 18 as level 20 or 35 (minimal retinopathy). All eyes were examined by the RTA and OCT. Healthy populations were used to establish reference maps for the RTA (n=14; mean age, 48 years; age range, 42-55 years) and OCT (n=10; mean age, 56 years; age range, 43-68 years). Reference maps were computed using the means+2 SDs of the values obtained for each location. Increases in thickness were computed as a percentage of increase over these reference maps.

Results: The RTA detected increases in thickness in 1 or more locations in 24 of the 28 diabetic eyes examined, whereas OCT detected increases in only 3 eyes. The percentages of increase detected by the RTA ranged from 0.3% to 73.5%, whereas OCT detected percentages of increase of 0.3% to 4.8%.

Conclusion: Optical coherence tomography is less sensitive than the RTA in detecting localized increases in retinal thickness in the initial stages of diabetic retinal disease.

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We used the RTA and OCT to measure retinal thickness in the eyes of healthy volunteers and diabetic patients with minimal nonproliferative DR to compare both methods.

METHODS

PATIENTS

Twenty-eight patients (10 men and 18 women), aged 50 to 69 years (mean ± SD age, 59.2 ± 5.4 years), with an established diagnosis of type 2 diabetes mellitus were recruited to participate in this study. Duration of diabetes mellitus ranged from 1 to 20 years (mean ± SD, 7.9 ± 4.8 years), and glycosylated hemoglobin values ranged from 5.3% to 11.7% (mean ± SD, 7.3% ± 1.9%). Blood pressure levels were 135/85 mm Hg or less.

All patients underwent a complete ophthalmologic examination, including the following assessments: corneal refractive power, refractive error and best-corrected visual acuity, intraocular pressure, SFP, and retinal thickness measurements obtained using both of the quantitative methods (the RTA and OCT). All eyes had a best-corrected visual acuity of 20/20, clear media, no neovascularization, and no CSME or previous laser treatment.

Fundus examination was performed by SLB using a +90-diopter (D) lens and a Goldmann contact lens and 7-field SFP examination, including the following assessments: corneal refractive power, SFP, and retinal thickness measurements obtained using both of the quantitative methods (the RTA and OCT). All eyes had a best-corrected visual acuity of 20/20, clear media, no neovascularization, and no CSME or previous laser treatment.

Retinal thickness was assessed after the clinical examination by using the RTA and OCT in a single session through a dilated pupil (minimum of 5-6 mm), with drops of 2.5% phenylephrine hydrochloride and 1% tropicamide, by an experienced examiner (M.A.S.) who was aware of the clinical findings. A single examination was performed using each method. Before the study, a full explanation of the procedure was given to all participants, and informed consent was obtained in all cases. Tenets of the Declaration of Helsinki were followed.

Two healthy populations volunteered to participate as age-matched control groups for the RTA (n=14; mean age, 48 years; age range, 24-55 years) and OCT (n=10; mean age, 56 years; age range, 43-68 years). All of the individuals in these 2 control groups underwent a complete ophthalmologic examination and had a best-corrected visual acuity of 20/20 OU (refraction was within 2 D of emmetropia), clear media, normal visual fields, and absence of optic disc or retinal abnormalities on fundus examination (performed by SLB using a Goldmann contact lens). Retinal thickness was measured in both eyes using the RTA and OCT by the same examiner through a dilated pupil. Only 1 eye from each volunteer was randomly selected to compute RTA and OCT reference maps, using the means ± 2 SDs. The following mean ± SD results were obtained: for the RTA — central foveal thickness, 141 ± 18 µm; papillomacular area, 179 ± 7 µm; superior area, 180 ± 15 µm; temporal area, 176 ± 17 µm; and inferior area, 169 ± 17 µm; for OCT — central foveal thickness, 187 ± 16 µm; papillomacular area, 264 ± 20 µm; superior area, 263 ± 19 µm; temporal area, 247 ± 22 µm; and inferior area, 260 ± 18 µm (Figure 1).

Figure 1. Retinal thickness analyzer (A) and optical coherence tomography (B) reference maps from controls showing the mean ± SD thickness values for each of the 5 areas of interest. Values are given in micrometers for a right eye. The 5 locations—the fovea (1000 µm) and the papillomacular, superior, temporal, and inferior quadrants of the retina—were automatically measured and averaged.

Figure 2. A. Best fit between retinal thickness analyzer (RTA) and optical coherence tomography (OCT) measurements for the 5 locations of interest. Each square represents an area measuring 200 × 200 µm (RTA). Also shown are 2 concentric circles with 1000- and 3000-µm radii, establishing the limits used by OCT. B. Locations of general RTA measurements vs OCT measurement lines.

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Acquisition time is 1 second for each of the 6 radial lines needed for a complete topographic macular examination. Patient discomfort, however, is minimal.

The software version used was A6.2 (Zeiss Humphrey Systems).

LOCATIONS FOR RETINAL THICKNESS MEASUREMENTS

The OCT scans were performed in the control and diabetic eyes using the 6-radial-lines pattern, each 3.45 mm long, passing through the center of fixation. The scanning protocol for retinal mapping was first proposed by Hee et al. Each of the 6 tomograms (B-scans) was oriented along a line intersecting the central fovea and containing 100 equally spaced axial profiles (A-scans) of optical reflectivity.

For this study, 5 measurements of retinal thickness were considered. These 5 values were automatically obtained in 5 retinal locations within a circle: a central disc area of 1 mm in diameter, centered on the patient's fixation, which was assumed to correspond to the central fovea, and in a peripheral ring area, 3 mm in diameter, in 4 retinal quadrants—papillomacular, superior, temporal, and inferior (Figure 2).

The RTA scans were obtained from the same diabetic eyes by the same examiner (M.A.S.). Retinal thickness measurements made by the RTA, as previously stated, produce an output map in which each value covers an area of 200×200 µm. To compare the measurements made by the 2 instruments, a best-fit overlapping area of both measures was found (Figure 2). Figure 2 shows 2 concentric circles of 1000- and 3000-µm radii. The shaded squares represent locations of RTA measurements to be considered for each of the 5 locations of the OCT measurements (Figure 2A) and the locations of general RTA measurements vs OCT line measurements (Figure 2B).

As a result, the central site of the OCT measures an area of 0.79 mm², and the RTA squares cover an area of 0.84 mm², which is the closest area possible, representing an increase of 6% in total area for this location. For the remaining locations (superior, inferior, papillomacular, and temporal), the process repeats, with the OCT covering an area of 1.57 mm² and the RTA covering an area of 1.40 mm² (12% more area covered by the OCT).

Although in the central area (1 mm in diameter) the information provided by each method can be assumed to be equally detailed in both methods, as we get away from the central fovea, the information provided by the RSA is more detailed than that given by OCT. Optical coherence tomography keeps its formation provided by each method can be assumed to be equally detailed in both methods, as we get away from the central fovea, the information provided by the RSA is more detailed than that given by OCT.

Data Analysis

Retinal thickness maps of the eyes from diabetic patients under study were obtained using the RTA and OCT. Moreover, maps of increased thickness were computed by comparing the thickness values of the eyes under study with both reference maps (means ± 2 SDs) established for the RTA and OCT using a reference population. Reproducibility data for the RTA and OCT can be found elsewhere.

RESULTS

The results are summarized in the Table. The RTA detected thickness increases in 24 of 28 patients, with values ranging from 0.3% to 73.5%. The OCT increased values were noted in at least 1 location in all level 10 patients, in 8 of 11 level 20 patients, and in 6 of 7 level 35 patients. Furthermore, increased thickness was detected in more than 1 location simultaneously in 18 patients, and 9 patients had increased thickness in all 5 locations examined. These 9 patients—3 graded as level 10 (patients 1, 3, and 7), 4 as level 20 (patients 11, 12, 15, and 19), and 2 as level 35 (patients 26 and 27)—seem to have a more diffuse type of macular thickening that may occur independently of the retinopathy photographic level. Four patients—3 graded as level 20 (patients 11, 15, and 19) and 1 as level 35 (patient 27)—had marked central foveal thickness (increases 20% higher than the reference values). No eye graded level 10 showed increases in retinal thickness higher than 20%. The Table shows that these large increases are accompanied by similar large increases in the 4 remaining areas.

Optical coherence tomography detected retinal thickness increases in 2 level 10 eyes (patients 3 and 7) and in 1 level 35 eye (patient 23) ranging from 0% to 4.8%, always located on the foveal area.

The RTA and OCT retinal thickness increases were the same in patients 3 and 7 in the central fovea. However, patient 19 showed a large increase in thickness as measured by the RTA in the foveal area (73.5%), whereas OCT detected no change. On the other hand, OCT detected an increase in central foveal thickness of 0.8% in patient 23, but the RTA did not show any increase.

Patients in this study showed acceptable glycated hemoglobin levels, with a mean value of 7.3%, indicating a general situation of relatively good metabolic control, with duration of diabetes mellitus ranging from 1 to 20 years (mean, 7.9 years). No direct correlation could be established between increases in retinal thickness and duration of disease or short-term status of metabolic control.

COMMENT

Results of the present study show that localized areas of retinal edema, that is, areas of abnormal increase in retinal thickness, are occurring in the macula in the early stages of diabetic retinal disease. Localized areas of increased retinal thickness were identified by the RTA in 24 of the 28 eyes examined but by OCT in only 3 of the 28 eyes.

All 10 eyes with no visible retinopathy showed localized areas of abnormal increase with the RTA. Although the increases were minimal in 4 eyes, they were greater than the values of a reference population (means ± 2 SDs). Optical coherence tomography detected increases in retinal thickness in only 2 of these eyes.

Of 18 eyes with mild nonproliferative retinopathy of level 20 or 33 using the Wisconsin grading, based on SFP, 14 showed localized areas of increased retinal thickness when using the RTA, whereas only 1 showed increased retinal thickness in the fovea using OCT. In this study, the RTA detects abnormal increases in retinal thickness in the diabetic retina before OCT. The results obtained using the RTA demonstrate that localized retinal edema is one of the earliest alterations occurring in the
The localized areas of retinal edema detected in the fovea by the RTA showed increases in retinal thickness that varied from 0.3% to 73.5% higher than the reference values for the respective area under evaluation. The highest increase in eyes with Wisconsin grading level 10 was 19.2%, whereas larger increases reaching 56.5% were detected in eyes graded as level 20 or 35. None of the eyes included in this study had the characteristics of CSME, as described in the ETDRS, and all the diabetic patients had 20/20 visual acuity. No clear correlation was found in this study among duration of disease, level of metabolic control, and the presence of localized areas of retinal edema.

Evidence from previous studies by Lobo et al., using integrated data obtained with the retinal leakage analyzer and the RTA, indicates that 2 types of retinal edema may occur simultaneously in the earliest stages of diabetic retinal disease: retinal edema of the cytotoxic type, occurring independently of an associated breakdown of the blood-retinal barrier, and a vasogenic type of edema directly due to alteration of the blood-retinal barrier.

In a subsequent 1-year follow-up study, of eyes with minimal nonproliferative retinopathy in patients with type 2 diabetes mellitus, retinal edema was shown to be predominantly of the vasogenic type, that is, due to an alteration of the blood-retinal barrier. In that same study, the extent and height of the retinal edema did not correlate with the levels of metabolic control. The reference values and SDs obtained by the RTA and OCT in the present study were similar to those reported in the literature. The central macular thickness in a similarly aged group examined by the RTA and OCT showed mean±SD values of 141±18 µm and 187±16 µm, respectively. None of the eyes included in this study had the characteristics of CSME, as described in the ETDRS, and all the diabetic patients had 20/20 visual acuity. The absolute values of macular thickness quantified by the RTA and OCT are still uncertain because

### Table: Retinal Thickness Increases Detected by OCT and the RTA in Patients With Diabetic Retinopathy

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<th>Patient No./Age, y</th>
<th>Duration of DM, y</th>
<th>Glycosylated Hemoglobin, %</th>
<th>Wisconsin Grading Level</th>
<th>Retinal Thickness Increase, %</th>
<th>Foveal Area</th>
<th>Papillomacular Area</th>
<th>Superior Area</th>
<th>Temporal Area</th>
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*OCT indicates optical coherence tomography; RTA, retinal thickness analyzer; DM, diabetes mellitus; L, left; and R, right.**
comparison between the in vivo retinal thickness measurements and histologic analysis has not been conducted owing to the associated problems. In vitro retinal thickness measurements reported in the literature establishment a range of 100 to 130 µm for the central foveal thickness.

Several authors have published different measures for foveal thickness using the RTA. Zeimer stated a reference retinal thickness of 167 µm in the fovea, with mean local variation of 23 µm. Landau et al minimize retinal thickness to 178 µm. These authors used a previous software version in which the thickness was considered the distance between the sites of maximal steepness of the slit profile. Currently, the thickness is considered the distance between the peaks of 2 lorentzian curves fitted to the slit profile. Particular attention should be given to this fact when comparing different reference values, as not all authors make reference to the software versions used or the area covered in the “foveal area.” Konno et al used only the minimum value in field 5 of the thickness map and found a mean±SD retinal thickness of 107±18.6 µm using software version 2.13 with analysis version 6.30. Neubauer et al, using RTA software version 3 with analysis version 7.06, found a mean±SD value of 181±17 µm. They also found a median of 150 µm, which means that there is equal probability of finding higher and lower values from this mark.

For OCT, Hee et al found a mean±SD retinal thickness of 174±18 µm for the central 500 µm. Konno et al found a mean±SD value of 155±15 µm using software version A4.01 and looking for “...the minimum value located near the center of the image.” Massin et al found a mean±SD value for a central area 1 mm in diameter centered on the fovea of 178±17 µm using software version A5, which differs 9 µm from our results. Finally, Neubauer et al found a mean±SD value of 153±16 µm using software version A4.1. Again, they found a median value of 150 µm, the same median as they found for the RTA.

We established both reference populations in our site. If there is any difference in age-matched populations for the RTA and OCT, it would mean a disadvantage for the RTA because the RTA population is younger. Zeimer states that there is a decrease of 5% per year in macular thickness.

Shahi and associates, using the RTA, reported that clinical examination with SLB permits detection of retinal thickness only when it is more than 60% greater than reference retinal thickness measurements. This is in agreement with our findings. In our study, involving patients who did not have CSME when examined by SLB and SPF disclosed values in this borderline range in the central foveal area in only 2 of the 28 eyes.

There are obvious differences in the technique producing the measurements and the thickness maps between the RTA and OCT. Whereas in the central foveal area the information provided by each method can be assumed to be equally detailed, as we get away from the central fovea, the information provided by the RTA is clearly more detailed than that given by OCT. Optical coherence tomography makes its measurements along lines, not evaluating the thickness in the areas between the lines. This is shown in Figure 2.

In our clinical experience with these methods, another advantage of the RTA is its short acquisition time. The 200 milliseconds required for the scanning procedure are associated with less discomfort to the patient because of less prolonged light exposures. Also, with the RTA, it is easier for patients to maintain steady ocular fixation, and there are fewer problems associated with blinking. On the other hand, in more advanced stages of retinopathy, RTA results may be affected by irregular reflections from hard exudates accumulated in the retina and by the interference of media opacities such as severe cataract or vitreous opacities.

Comparing the 2 techniques to measure retinal thickness, the RTA seems to be particularly appropriate for measuring changes in retinal thickness when these changes are minimal, particularly in the initial stages of diabetic retinal disease and in eyes without media opacities and in the absence of morphologic retinal alterations, such as hard exudates. We consider the RTA to be a promising tool to evaluate quantitatively the changes in retinal thickness before the development of CSME, when an early therapeutic intervention may be more effective. In our experience, OCT is particularly informative when there are changes in the retinal architecture through the formation of cysts or localized fluid detachments. None of these situations were found in the eyes included in this study. Studies in progress performed by our group examining the presence of macular edema after cataract surgery indicate that OCT detects only abnormal retinal thickness values where there is some degree of visible fluid accumulation and cystlike formations are found in OCT cross sections.

In conclusion, localized areas of increased retinal thickness (ie, edema) occur in the retina in type 2 diabetes mellitus in the initial stages of retinopathy. These areas of localized retinal edema may be identified and quantified by the RTA, offering a unique opportunity to study the effects of early intervention in the evolution of diabetic retinal edema to prevent its progression to CSME.

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REFERENCES


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**ARCHIVES Web Quiz Winner**

Congratulations to the winner of our February quiz, Luigi Capasso, MD, II Universita` degli Studi di Napoli, Naples, Italy. The correct answer to our February challenge was calcium deposition. For a complete discussion of this case, see the Clinicopathologic Reports, Case Reports, and Small Case Series section in the March ARCHIVES (Pandey SK, Werner L, Apple DJ, Gravel J-P. Calcium precipitation on the optical surface of a foldable intraocular lens: a clinicopathological correlations. *Arch Ophthalmol*. 2002;120:391-393).

Be sure to visit the *Archives of Ophthalmology* World Wide Web site (http://www.archophthalmol.com) and try your hand at our Clinical Challenge Interactive Quiz. We invite visitors to make a diagnosis based on selected information from a case report or other feature scheduled to be published in the following month’s print edition of the Archives. The first visitor to e-mail our Web editors with the correct answer will be recognized in the print journal and on our Web site and will also receive a free copy of the book *One Hundred Years of JAMA Landmark Articles*.

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**Figure 2.** Photomicrograph of the explanted opacified Hydroview intraocular lens (Bausch & Lomb, Rochester, NV) showing the confluent deposits on the anterior optical surface. The polymethyl-methacrylate haptics are free of any deposits (original magnification ×100).