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Evaluation of a Contact Lens-Embedded Sensor for Intraocular Pressure Measurement

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Abstract

Purpose—To evaluate a novel contact lens-embedded pressure sensor for continuous measurement of intraocular pressure (IOP).

Methods—Repeated measurements of IOP and ocular pulse amplitude (OPA) were recorded in 12 eyes of 12 subjects in sitting and supine positions using 3 configurations of the dynamic contour tonometer: slit-lamp mounted (DCT), hand-held (HH), and contact lens-embedded sensor (CL). The IOP and OPA for each condition were compared using repeated measures ANOVA and the 95% limits of agreement were calculated.

Results—The sitting IOP (mean and 95% CI) for each configuration was DCT: 16.3 mm Hg (15.6 to 17.1 mm Hg), HH: 16.6 mm Hg (15.6 to 17.6 mm Hg), and CL: 15.7 mm Hg (15 to 16.3 mm Hg). The sitting OPA for each configuration was DCT: 2.4 mm Hg (2.1 to 2.6 mm Hg), HH: 2.4 mm Hg (2.1 to 2.7 mm Hg), and CL: 2.1 mm Hg (1.8 to 2.3 mm Hg). Supine IOP and OPA measurements with the CL and HH sensors were both greater than their corresponding sitting measurements, but were significantly less with the CL sensor than the HH sensor. The mean difference and 95% Limits of Agreement were smallest for the DCT and CL sensor comparisons (0.7 ± 3.9 mm Hg) and widest for the CL and HH sensors (-1.9 ± 7.25 mm Hg); these wider limits were attributed to greater HH measurement variability.

Conclusions—The CL sensor was comparable to HH and DCT sensors with sitting subjects and is a viable method for measuring IOP and OPA. Supine measurements of IOP and OPA were greater than sitting conditions and were comparatively lower with the CL sensor. HH measurements were more variable than CL measurements and this influenced the Limits of Agreement for both sitting and supine conditions.

Intraocular Pressure (IOP) is typically monitored by clinicians making discrete measurements at a single point in time. Serial tonometry may provide a more complete picture of diurnal variations in pressure for a patient, but the procedure is expensive, inconvenient, and may not sample intraocular pressure at critical points in time. Comparatively little is known about the dynamics of IOP in humans with regard to changes

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over the diurnal cycle,^{1,2} the effects of physical activity, correlation with vascular and cerebral spinal fluid pressure change, and the influence of medications intended to reduce IOP.^{3,4}

The ability to monitor IOP continuously and for prolonged periods of time could greatly improve our understanding of the dynamic nature of IOP in normal and diseased patients.⁵ Telemetric IOP sensors have been successfully implanted in laboratory animals and development for their use in humans is an active area of research.^{6–8} Nevertheless, there is currently no acceptable way to provide this same capability for monitoring IOP in humans. In this study, we evaluate an important step toward this goal using a contact lens-embedded pressure sensor (CL) connected by wire to a central processing unit capable of variable sampling rates and duration.

The dynamic contour tonometer (DCT) is a device designed to measure IOP that differs from traditional Goldmann tonometry in several ways. First, unlike the traditional flat-tipped probe of the Goldmann tonometer, the DCT probe is contoured to minimize the effects of corneal thickness, biomechanical properties, and curvature on measurement error.^{9,10} Second, the DCT is based upon a piezoresistive sensor embedded in the probe tip. When measurements are made, the sensor provides measurement data at a rate of 100 Hz. This permits measurement of both the IOP and variations in the IOP related to the cardiac cycle, which is defined as the ocular pulse amplitude (OPA). In an intracameral manometry study in human cadaver eyes, comparisons of IOP measurements taken with the DCT were consistently closer to true manometric pressures than Goldmann applanation tonometry or pneumotonometry.^{11,12} Other clinical studies have shown good repeatability and unlike Goldmann tonometry, measurements were less dependent on central corneal thickness.^{12–15}

The purpose of this study was to determine: (1) if IOP measurements using a novel CL were feasible, (2) how these measurements compared with the standard DCT configuration, and (3) the effects of body position on IOP and OPA measurements made with this sensor. Our long-term goal is to determine the suitability of a contact lens-based sensor for the assessment of IOP and OPA as a way to evaluate more fundamental physiologic interactions between CSF pressure and cardiovascular dynamics in subjects who are under general anesthesia or on bed rest. For this reason, we sought to determine the potential influence of a subject's body position on measurements of IOP and OPA.

METHODS

Design and Subjects

The Ohio State University Institutional Review Board approved this prospective clinical laboratory investigation comparing 3 different devices for the measurement of IOP and OPA. A total of 15 healthy volunteers were recruited at The Ohio State University Department of Ophthalmology. Subjects were required to have 2 healthy eyes with no prior ocular surgery or current treatment for ocular disease. One eye of each subject was selected for study by a coin toss.

Procedures

Measurements of IOP and OPA for each subject were acquired under several experimental conditions by 1 of the 2 trained examiners (MDT, RHS). One of the examiners (RHS) is not an eye care specialist, but received specific training on measurement procedures for the purposes of this study. This allowed us to assess the difficulty of carrying out these measurements and their suitability for use by trained assistants.

Before IOP measurements, we measured corneal geometry by videokeratography (Keratron Scout, Optikon 2000 Rome, Italy) and blood pressure, heart rate, and mean arterial pressure. All subjects had their IOP measured in 2 different positions, sitting and supine. To begin the study, we measured IOP in a sitting position with the standard configuration of the DCT. A coin toss was then used to determine the subjects starting position for subsequent measures. All changes in position were followed by a 10 minute wait before further blood pressure, pulse, or ocular measurements.

Measurements of IOP and OPA were taken with each of 3 different configurations of the DCT: (1) the standard configuration, (2) a hand-held (HH) configuration, and (3) a modified sensor embedded in a contact lens. Although the standard DCT was used in the sitting position to begin, the order of the HH and contact lens probes were randomly selected by a coin toss. The minimum duration for each measurement was a minimum of 10 oculocardiac pulsations. The total contact lens sensor wearing time required for 3 repeated measurements in 2 different positions (sitting and supine) was approximately 10 minutes.

Tonometers

The DCT probe surface is curved to minimize the influence of corneal shape and thickness on measurements of intraocular pressure. The concave radius of curvature of the probe tip is 10.5 mm (32 D). The center of the probe contains a flush mounted piezoresistive sensor that normally provides data to the base unit at 100 Hz. The unit used for this study had custom software capabilities to permit wireless connectivity between the base processing unit and a laptop computer for continuous data acquisition. Although the probe sensor was directly connected to the base unit by wire, the custom software allowed us to control the sampling frequency and duration that was only limited by battery life of the base unit.

The HH DCT is an adaptation of the standard DCT contour probe such that it replaces the Goldmann applanation probe tip in a portable HH Goldmann tonometer. This adaptation connects the base processing unit of the DCT to the DCT probe sensor by a cable (length = 1 m), Figure 1. This configuration permits use of the DCT with patients who are supine or unable to achieve the posture required for measurement with conventional slit-lamp mounted instruments.

The contact lens sensor used for this study was provided by the manufacturer (Ziemer Ophthalmic Systems AG; Port, Switzerland), and was comprised of a rigid gas-permeable contact lens and the same piezoresistive pressure sensor embedded in the DCT probe tip. This sensor was geometrically centered within the lens and mounted flush with the posterior contact lens surface, Figure 2. The contact lens carrier was a commercially available orthokeratology lens design with proprietary lens parameters. Only 1 lens geometry was evaluated in this study. The lens material has high oxygen transmissibility suitable for overnight wear. The anterior lens surface and sensor electronics were sealed in an epoxy base. The lens was cleaned between subjects by swabbing it with alcohol and allowing it to air dry. Wire leads extending from the sensor were affixed to the anterior lens surface with a smooth silicone-based adhesive. These sensor leads then attach to the same physical harness and connectors used to extend the HH probe to the DCT base processing unit, Figure 3. This harness was held by the examiner and steadied by placing a hand on the subject's cheek to prevent the weight of the harness from displacing the contact lens sensor. An example of the continuous data stream from the CL is shown in Figure 4. IOP and OPA measurements were provided by the native software routines of the DCT device. In summary, the DCT measures IOP at a rate of 100 Hz and the DCT derived IOP represents the average diastolic IOP over the measurement period. The OPA is the average difference between systolic and diastolic IOP (personal communication, Elliott Kirsten, OD, Zeimer).

Subjects were anesthetized with 1 drop of Proparacaine Hydrochloride (0.5%) before IOP measurements. Three measurements were made with each tonometer and for each subject position. As with standard Goldmann tonometers, it is not possible to use the standard DCT with subjects in a supine position. Measurements with a quality index worse than 3 (4 or 5) as determined by the standard instrument output were recorded and used only to determine the frequency of poor quality measurements. When low-quality measurements occurred, additional measurements were made until a total of 3 measures with a quality index of 3 or better were achieved. A quality index of 3 or better was required for all measurements included in the statistical analysis of measurement reliability.

Outcome Measures

Measurements of IOP and OPA acquired with the HH and contact lens sensors were compared with standard DCT made in the sitting position. Measurements acquired with subjects in the supine position—HH and contact lens sensors—were also compared with each other.

The mean differences between IOP and OPA measurements were compared using a repeated measures analysis of variance model that included subjects, position, sensor, and measurement order as factors. Statistical significance was defined a priori as $P < 0.05$. After evaluating interaction between factors in the ANOVA model, any significant main effect was then tested for significant differences using repeated t tests, and P-values were adjusted post hoc using Tukey method. Assumptions of the repeated measures ANOVA model were evaluated and satisfied. Statistical computations were carried out with Stata for Windows (v. 10, College Station, TX).

The frequency and reasons for measurement failure by measurement method were evaluated. Measurement reliability was assessed using methods described by Bland and Altman.¹⁶ The mean difference between the contact lens and HH sensors were compared with standard DCT carried out in the sitting position. Similar comparisons were made for the contact lens and HH sensors with patients in the supine position. The 95% limits of agreement (mean $\pm$ 1.96 SD) are reported for each of these comparisons.

RESULTS

A total of 15 subjects were enrolled in this study. Three subjects were excluded as we were unable to measure IOP using the contact lens sensor in these subjects. We discuss possible reasons for these failures in the discussion section. Subjects were mostly male, 11/15 enrolled (10/12 evaluated). The median age of these subjects was 25 and the interquartile range of the age distribution was 23 to 35 years. Corneal diameter for successfully measured eyes: 11.3 mm (mean), 11.1 to 11.6 mm (range) was similar to what we observed for unsuccessful subjects who did not complete the study: 11.4 mm (mean), 11.1 to 11.6 mm (range). Corneal curvature in successful eyes tended to be steeper in measurable eyes: 43.72 D (mean), 42.66 to 45.81 D (range) when compared with immeasurable eyes: 40.91 D (mean), 39.57 to 42.01 D (range). Corneal toricity in measurable eyes ranged widely: 1.20 D (mean), 0.47 to 2.59 D (range). Corneal toricity in immeasurable eyes was lower: 0.79 D (mean), 0.66 to 0.89 D (range).

Blood Pressure, Intraocular Pressure and Ocular Pulse Amplitude

The mean arterial pressure was higher for the sitting position: 88 ± 9 mm Hg (mean $\pm$ SD) than for the supine position 82 ± 3 -mm Hg ($P = 0.04$). The heart rate was also less in the supine condition: 71.9 ± 9.7 bpm (sitting), versus 57.8 ± 3.3 bpm (supine); $P < 0.001$. We noted a weak trend (not statistically significant; all Bonferroni corrected $P > 0.05$) toward

greater IOP as a function of mean arterial pressure for the contact lens and DCT sensors that was decreasing in the HH sensor (Fig. 5). The OPA measurements trended lower (not statistically significant; corrected $P>0.05$) as a function of increasing mean arterial pressure for all sensors, and although this effect was greater in the contact lens and DCT configurations, it was also seen with the HH sensor.

Measurement Quality

The frequency of measurements with a quality index of 3 or better are summarized by measurement method in Table 1. Acceptable quality measurements were most frequent with the standard DCT instrument—only 1/37 (3%) of measures were excluded from the analysis. In contrast, 33% (35/107) HH measurements were excluded and 10% (8/80) of the contact lens sensor measures were excluded owing to a low-quality index. We further evaluated measurement quality as a function of examiner experience by comparing the number of low-quality scans for each examiner as a function of the fraction of total poor quality scans and the fraction of total measurements made by each examiner. The experienced examiner (MDT) had 9/12 of the total low-quality measurements and was responsible for a total of 135 measurements. By comparison, the newly trained examiner (RHS) had 3/12 of the total low-quality measurements and was responsible for 45 total measurements.

Intraocular Pressure Measurements

The distribution of IOP measurements by method and patient position are shown in Figure 6. The distribution of these measures is presented as a standard box plot. The box represents the middle 50% (25th to 75th percentile) of the distribution and the line within the box is drawn at the median. The whiskers extend from the box in both directions to include points within 1.5 times the interquartile range. Any point beyond this range is considered an outlier and is plotted as a single point.

The mean sitting IOP measured with standard DCT was 16.3 mm Hg (95% CI = 15.6–17.1 mm Hg). The mean sitting IOP measured with the HH sensor was 16.6 mm Hg (95% CI = 15.6–17.6 mm Hg). The mean IOP measured with the CL was 15.7 mm Hg (95% CI = 15.0–16.3 mm Hg). A repeated measures ANOVA model was used to account for multiple measurements, measurement order, and the interaction between measurement device and measurement order. The observed differences in mean sitting IOP by measurement method were not statistically significant (Box adjusted $P = 0.053$). The statistical test for order effects ($P = 0.050$) did not quite achieve our declared threshold for statistical significance ($P<0.05$) and tests for interaction between measurement device and measurement order were also not significant ($P = 0.10$).

With subjects in the supine position, the IOP could not be measured using the standard DCT. The mean supine IOP measured with the HH instrument was 19.6 mm Hg (95% CI = 18.3–21.0 mm Hg). The mean supine IOP measured with the CL was 17.7 mm Hg (17.0 to 18.4). This mean difference was statistically significant using the same repeated measures ANOVA model (Box adjusted $P = 0.003$). There was no statistically significant interaction between measurement device ($P = 0.80$) and measurement order ($P = 0.88$). Supine measures of IOP were higher than what was measured for sitting subjects with both the HH and the CL. The measured difference in IOP as a function of subject position using the HH sensor was 3.0 mm Hg (95% CI = 1.8–4.3 mm Hg, $P<0.001$). The difference in IOP by subject position using the CL was 2.0 mm Hg (95% CI = 1.2–2.8 mm Hg, $P<0.001$).

Ocular Pulse Amplitude Measurements

The distribution of OPA measurements by method and patient position are shown in Figure 7. The mean difference in sitting OPA by device was significant by repeated measures

ANOVA ($P = 0.003$). There was no significant interaction between measurement order and measurement device ($P = 0.77$) and there was no significant difference related to measurement order ($P = 0.11$). The mean sitting OPA using the standard DCT was 2.4 mm Hg (95% CI = 2.1–2.6 mm Hg).

The mean sitting OPA with the HH sensor was 2.4 mm Hg (95% CI = 2.1–2.7 mm Hg). The mean sitting OPA for the contact lens sensor was 2.1 mm Hg (95% CI = 1.8–2.3 mm Hg). There was no significant difference between the standard DCT and HH instrument configurations ($P = 0.75$). The difference between sitting measurements of OPA using the CL and the standard DCT was significant ($P = 0.01$). Similarly, the CL measured significantly lower OPA when compared with the HH device ($P = 0.002$).

Supine measurements of OPA were greater than sitting measurements regardless of instrument configuration. The difference in sitting and supine OPA measures with the HH device was 0.40 mm Hg (0.13 to 0.66 mm Hg, $P = 0.004$). The difference between sitting and supine measures of OPA as measured with the CL was 0.39 mm Hg (0.22 to 0.55 mm Hg, $P < 0.001$). The mean supine OPA with the contact lens sensor was 2.5 mm Hg (95% CI = 2.2–2.8 mm Hg). The mean supine OPA with the HH sensor was 2.8 mm Hg (95% CI = 2.5–3.1 mm Hg). The difference in OPA by these 2 measurement methods was statistically significant (0.3 mm Hg, 95% CI = 0.08–0.59 mm Hg, $P = 0.01$).

Limits of Agreement

Plots comparing the difference between measurement methods are provided in Figures 8 to 11. These plots show the residual differences between paired measurements as a function of the mean of these 2 measurements. In each plot the mean difference between two measurement methods is represented as a solid horizontal line that indicates the magnitude of the mean bias for the 2 measurement methods. The width of the residual error distribution graphically illustrates the repeatability of the two measurement methods. The upper and lower dashed lines indicate the 95% limits of agreement calculated as the mean residual difference ± 1.96 SD. This differs from estimates of the precision of any single measurement method and is typically wider than the 95% confidence interval used to describe the mean of any one measurement method.

The limits of agreement (mean difference; upper to lower 95% limit) for sitting IOP measurements with the standard DCT and the CL shown in Figure 8 were 0.7 mm Hg (–3.2 to 4.6 mm Hg). The mean difference in sitting IOP measurements for the standard DCT and the HH DCT was –0.3 mm Hg (–5.9 to 5.3 mm Hg), Figure 9. The limits of agreement for comparisons of sitting IOP measurements using the HH and contact lens sensors are shown in Figure 10. The observed difference between these 2 sensors was correlated with the mean IOP measurement ($y = -0.78 \times +11.6$; $R^2 = 0.19$; $P = 0.007$). The mean difference and limits of agreement for sitting IOP measured with the HH and contact lens sensors was –1.0 mm Hg (–7.3 to 5.4 mm Hg).

The limits of agreement for supine IOP measurements using the HH and contact lens-embedded tonometers was –1.9 mm Hg (–9.2 to 5.3 mm Hg). A plot of the supine measurement distribution and limits of agreement are shown in Figure 11. The observed difference between these two sensors was correlated with the mean IOP measurement ($y = -0.86 \times +14.2$; $R = 0.37$; $P < 0.001$).

DISCUSSION

Many clinical comparisons between DCT and Goldmann tonometry have been reported.^{13–15,17–20} Most of these studies have shown that there is good correspondence

between these 2 measurement methods and less dependence on central corneal thickness with DCT. Our results show that IOP measurements using the contact lens-embedded configuration of the DCT sensor are possible and that the IOP measurements obtained for subjects in a sitting posture compare favorably with the standard DCT instrument configuration. Although they appear to differ (with the contact lens sensor measuring lower) the mean sitting IOP measurements were not statistically different for any of the 3 instrument configurations tested. There were differences in the measurement variability by instrument. The CL had the least variability (width of 95% CI = ± 0.7 mm Hg) and the HH sensor was the most variable (width of the 95% CI = ± 1.0 mm Hg).

As it was not possible to carry out IOP measurements using the standard DCT with patients in a supine position, we compared the HH instrument with the CL. As expected, we found that the supine IOP and OPA measurements were significantly higher than sitting measures of IOP and OPA. This is consistent with earlier findings of other investigators.^{1,21–23} As with the sitting measurements, we also found that the CL measurements were lower and less variable than those obtained with the HH sensor. The magnitude of the observed IOP measurement differences for sitting IOP measurements between the DCT, CL, and HH sensors were not statistically significant and unlikely to be clinically meaningful considering that the within-subject standard deviation of IOP measurements for the DCT, CL, and HH sensors used in this study were 1.2, 1.5, and 2.1 mm Hg, respectively. This compares favorably with earlier reports of other comparisons of DCT sensors²⁴ and with reported standard deviations of Goldmann tonometry (± 2 to 3 mm Hg).^{14,25}

We specifically chose not to compare the contact lens or HH DCT sensors with Goldman Tonometry measurements. Comparison of DCT measurements with other methods is a separate question that was not the specific purpose of this research; a question that several investigators have thoroughly addressed before.^{13–15,17–20} Although comparisons with traditional clinical standards such as Goldmann tonometry are useful and interesting, such comparisons potentially introduce additional confounding variables and raise additional questions about the validity of either measurement technique. These comparisons and other experiments are the focus of ongoing research. Our purpose was to determine how modifications of the DCT compared with the standard DCT design, not how they compared with other standards.

The 95% limits of agreement were smallest when comparing the standard DCT tonometer to the CL indicating good agreement between these 2 measurement methods. The width of the 95% limits of agreement for comparisons that included the HH sensor were wider and driven in part by the greater variability of measurements seen with this instrument configuration. This was true regardless of subject position, for example, sitting or supine. The HH sensor was much more difficult to stabilize on the eye than a HH Goldmann tonometer. Very slight differences in axial pressure or lateral position of the device resulted in pressure variations that led to unacceptable quality indices. Another factor that contributed to these wider limits of agreement was a correlation between the measurement difference and the mean IOP level—a correlation that we also observed to a lesser degree in sitting subjects. This correlation in the residual error may be owing to either device configuration and would be best evaluated in additional manometric studies. Given the excellent agreement observed between the sitting contact lens sensor measurements and the standard DCT configuration, we suspect that the residual error correlations we observed between the contact lens and HH sensors is likely owing to the HH configuration. One could also speculate, however, that the contact lens sensor should be more prone to these errors as use of this device does not depend upon application of the sensor with a consistent level of external force as is required with either the slit-lamp or the HH configurations. In these 2 configurations, the sensor is embedded in a Goldmann-style prism and measurements are

taken after a constant force is applied to contour match the central area of the tonometer probe. Nevertheless, if these systematic measurement errors are attributable to the contact lens sensor, it may be possible to account for these errors using simple calibration procedures.

Both sitting and supine OPA measurements made with the contact lens sensor were lower than the corresponding measurements with the HH sensor. The mean difference in OPA between the contact lens and HH sensors in the sitting (2.1 vs. 2.4 mm Hg) and supine (2.5 vs. 2.8 mm Hg) positions were small, but consistently lower with the contact lens sensor. The corresponding clinical significance of these observed differences is not known and this is the topic of future research. The trend for OPA to decrease as a function of increasing mean arterial pressure suggests that these 2 parameters are not directly coupled and that the OPA arterial pulse amplitude is dampened relative to the arterial pulse. These differences may be physiologically meaningful and should be compared with other techniques in future studies to fully understand the implications of these observations in the context of glaucoma and other ocular diseases. Our current contact lens sensor measurements compare favorably with pneumotonometry values reported from other studies and earlier reports of OPA using the standard DCT by other investigators.²⁶

There are several unique advantages of using this sensor to measure intraocular pressure. First, our data indicate that measurements are repeatable and had the lowest variance of any of the 3 instrument configurations tested. Second, it was possible to train a non-eye care specialist to use this device without sacrificing the quality of measurements. There were 2 or fewer low-quality measurements obtained using the CL for either examiner with patients in either position. The skills required to obtain good quality measurements were dependent on the ability to insert a rigid contact lens and maintain a steady hand throughout the measurement period.

Another potential advantage of this contact embedded lens sensor is the capability of prolonged measurements. Although these data are not reported here, it was possible to place and record from the contact lens sensor on the eye over the course of several minutes. Prolonged measurements also allow the user to select the region of best quality for estimation of the IOP and OPA. This permitted us to observe the stability of measurements over time and to observe the interactions between the sensor, tear volume, and blinking. Future studies are needed to address the possibility of sensor drift (mean changes) with prolonged measurements, the influence of blinking and eyelid-lens interactions on measurement accuracy and reliability. Future studies are needed to fully address the limits of physiologic tolerance, and the associated capability of extended data recording.

The IOP and OPA values analyzed in this study were calculated by the native DCT algorithms. The DCT unit derives IOP and OPA values from data over a select region of the total measurement time period. Although the interval is given, the basis for selecting this time segment is not described. We noted that IOP during these measurement periods was not always stable, but was typically more stable than surrounding regions. These selected regions typically include small magnitude linear drifts or low-frequency sinusoidal cycles coinciding with inhalation and exhalation (Fig. 4). In some cases, these measurements also included high-frequency signal variations that may have influenced computation of IOP and OPA values, and thus the quality score, for example blinking. These features are included in DCT calculations of IOP and OPA and will contribute some measurement error to our estimates of repeatability.

There are several limitations to the current contact lens sensor configuration. First, the current contact lens geometry does not work with all eyes. Successful measurements require

a good fit between the posterior contact lens surface and the corneal contour. In several cases (3/15) we were unable to measure IOP using the contact lens sensor. The common characteristic of immeasurable eyes was a flat corneal curvature less than or equal to 42 D in which we observed a loose fitting contact lens with less central corneal touch. A good fitting relationship was observed in corneas with an average to steep curvature (from 42.5 to 46 D) and was seemingly independent of corneal toricity less than 2.6 D and corneal diameter. Additional studies with more than 3 failures are needed to better understand what characteristics are associated with an inability to use this contact lens sensor on some subjects. It may be possible to optimize the posterior lens surface geometry and lens diameter to allow measurements in larger, flatter eyes. It is also important to systematically evaluate the response of this sensor as a function of corneal geometry for successful measurements to determine whether or not reported IOP and OPA depend upon corneal curvature or other corneal characteristics.

Another limitation of this contact lens sensor is that it currently requires a connection by wire to the standard DCT base to permit data capture and recording. This is not optimal in part because it increases the interaction between the sensor and the eyelid producing potential artifacts in the measurements. Blinking produced obvious discontinuities in the measured signal such as an instantaneous drop (sometimes to values <0mm Hg) or rise in measured pressure that was easily identified as an artifact. Although subjects initially received a drop of topical anesthetic, most experimental sessions lasted more than 30 minutes, enough time for most of the anesthetic effects to subside. Although subjects were aware of the sensor and could feel the lens and harness with the lids and lashes upon blinking, none were in distress or reported discomfort in excess of typical rigid contact lens use. Our results show that a sensor embedded in a rigid contact lens design is possible and future design improvements could permit wireless data transmission. This would allow further evaluation of the effects of eyelid and blinking on measurements, the influence of tear volume, and lens geometry on measured IOP and OPA.

Biocompatibility with prolonged use is a concern as well. At this point, it is too early to know how corneal physiology may be affected by prolonged use, for example, overnight lens wear. Although the lens material selected is highly permeable to oxygen, prolonged placement of this sensor in a closed eye could lead to corneal swelling and compromise of the epithelial barrier directly over the sensor.

This unique device is an important first step forward toward the ability to monitor IOP continuously and for prolonged periods in the human eye. To address some of the current limitations, future developments in microelectronics should lead to wireless sensors of smaller size capable of recording and storing data much like current cardiac monitors.

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FIGURE 1. Modified hand-held (HH) Goldmann tonometer that permits use of the standard dynamic contour tonometer (DCT) probe and electronic recording base. This configuration permits measurements of intraocular pressure (IOP) and ocular pulse amplitude (OPA) in a variety of patient positions and instrument orientations.

FIGURE 2.

Close view of the posterior surface of the contact lens embedded intraocular pressure (IOP) sensor. A sealed wire extends from the anterior surface of the lens to the electronic base, which attaches to the standard dynamic contour tonometer (DCT) base or the extension cable pictured in Figures 1 and 2.

FIGURE 3.
Contact lens-embedded sensor (CL) attached to the extension cable and the tonometer base unit.

FIGURE 4.

Intraocular pressure (IOP) as a function of time recorded with the contact lens-embedded sensor (CL). After placing the sensor on the eye (0 s), the intraocular pressure (IOP) is sampled at 100 Hz. High-frequency variations in pressure correspond to the cardiac cycle and show the amplitude of the ocular pulse and its effect on measured intraocular pressure; low-frequency sinusoidal variations correspond to the respiratory cycle. The dynamic contour tonometer (DCT) reported IOP and ocular pulse amplitude (OPA) were derived from the framed portion of the measurement (10 to 16 s).

FIGURE 5.

Plot of intraocular pressure (IOP) and ocular pulse amplitude (OPA) as a function of mean arterial pressure by measurement device: CL indicates contact lens-embedded sensor; dynamic contour tonometer (DCT), standard dynamic contour tonometer; hand-held (HH) DCT configuration. Note that all trends are non-significant.

FIGURE 6.

Box-plot distributions of intraocular pressure (IOP) by device and by subject position. CL indicates contact lens-embedded sensor; dynamic contour tonometer (DCT), standard dynamic contour tonometer; hand-held (HH) DCT configuration.

FIGURE 7. Box-plot distributions of ocular pulse amplitude (OPA) by device and by subject position. CL indicates contact lens-embedded sensor; DCT, standard dynamic contour tonometer; hand-held (HH) dynamic contour tonometer (DCT) configuration.

FIGURE 8.

Difference of intraocular pressure (IOP) as a function of mean measured IOP. Comparison of the hand-held dynamic contour tonometer configuration (HH) and the standard dynamic contour tonometer (DCT) for sitting subjects. The mean difference is indicated by the solid horizontal line. Dashed lines represent the upper and lower 95% limits of agreement.

FIGURE 9.

Difference of intraocular pressure (IOP) as a function of mean measured IOP. Comparison of the contact lens-embedded sensor (CL) and the standard dynamic contour tonometer (DCT) for sitting subjects. The mean difference is indicated by the solid horizontal line. Dashed lines represent the upper and lower 95% limits of agreement.

FIGURE 10.

Difference of intraocular pressure (IOP) as a function of mean measured IOP. Comparison of the hand-held (HH) dynamic contour tonometer (DCT) configuration HH and contact lens-embedded sensor (CL) for sitting subjects. The mean difference is indicated by the solid horizontal line. Dashed lines represent the upper and lower 95% limits of agreement.

FIGURE 11.

Difference of intraocular pressure (IOP) as a function of mean measured IOP. Comparison of the hand-held (HH) dynamic contour tonometer (DCT) HH and contact lens-embedded sensor (CL) for supine subjects. The mean difference is indicated by the solid horizontal line. Dashed lines represent the upper and lower 95% limits of agreement.

Table 1

Summary of Measurement Quality by Method

	Excluded			Included		
	Total	Sit	Supine	Total	Sit	Supine
DCT	1	1	—	36	36	—
HH	35	22	13	72	36	36
CL	8	4	4	72	36	36
Total	44	27	17	180	108	72
Grand total	224	DCT	HH	CL		
% Excluded	20	3	33	10		

CL indicates contact lens-embedded DCT sensor; DCT, dynamic contour tonometry; HH, hand-held DCT tonometry.