Evaluation of the Orssengo-Pye IOP corrective algorithm in LASIK patients with thick corneas

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Background: The objective of this study was to evaluate the Orssengo-Pye central corneal thickness (CCT) Goldmann applanation tonometry (GAT) corrective algorithm by observing changes in GAT and CCT before and after laser in situ keratomileusis (LASIK) surgery in patients with CCT that remains greater than 545 \( \mu \text{m} \) postoperatively.

Methods: Tonometric and pachymetric measurements were made on 14 patients (28 eyes) before and after LASIK surgery. The selected patients were required to have average or above average postoperative central corneal thickness values in both eyes (not less than 545 \( \mu \text{m} \)). Preoperatively, all patients had CCT and GAT measurements taken. Postoperatively patients had CCT, GAT, and dynamic contour tonometric (DCT) measurements taken.

Results: Preoperatively, median CCT values were 589.536 \( \mu \text{m} \). Median GAT values were 16.750 mmHg. Median corrected preoperative GAT values were 14.450 mmHg. After LASIK treatment, median CCT values were 559.417 \( \mu \text{m} \). The decrease in median CCT was 30.119 \( \mu \text{m} \). Median postoperative GAT values were 11.500 mmHg (decrease, 5.250 mmHg). Median corrected postoperative GAT values were 10.775 mmHg (decrease, 3.675 mmHg). Median postoperative DCT values were 17.858 mmHg.

Conclusions: LASIK treatment causes a significant reduction in measured GAT intraocular pressure (IOP) values. The Orssengo-Pye formula, which attempts to correct for GAT error associated with individual variation in CCT, appears to yield misleading results in these circumstances. An unexpected 3.675-mmHg decrease in “corrected IOP” by the Orssengo-Pye method seen in this study may be attributed to some limitation or error in the formula. After adjusting for the approximate 1.7-mmHg difference, which has been demonstrated between DCT and GAT, postoperative DCT values were similar to preoperative measured GAT values.

Key Words: Central corneal thickness, laser in situ keratomileusis, corrected intraocular pressure, intraocular pressure (IOP), dynamic contour tonometry, Orssengo-Pye

There are several formulae that attempt to compensate for errors in Goldmann applanation tonometry (GAT) resulting from variations in central corneal thickness (CCT). Some rely exclusively on variations in CCT, whereas others include other variables such as corneal radius. Although the authors of these algorithms contend that they provide clinicians with a reasonable tool to correct for individual variations in GAT, there may be circumstances in which the algorithms are misleading.1–12

When implementing corrective intraocular pressure (IOP) CCT algorithms for those with corneas that, even after laser in situ keratomileusis (LASIK) surgery, are thicker than average \( \geq 545 \mu \text{m} \), instructions are to subtract some calculated amount from the measured Goldmann IOP value. Conversely, with thinner than average corneas, the algorithms are designed to add an amount to the measured GAT IOP. One could conclude, therefore, that with all corneas that are thinner than average, GAT inherently underestimates IOP. Conversely, with those that are thicker than average, the Goldmann value overestimates, and the amount of that compensation increases as corneas deviate further from the 545 \( \mu \text{m} \). Given the aforementioned assumptions, one would expect that a thicker than average cornea \( \geq 545 \mu \text{m} \), even subsequent to LASIK, would still yield overstated Goldmann IOP values.1–11,13

The objective of this study was to observe changes in GAT resulting from LASIK in a specific type of patient (postoperative CCT \( >545 \mu \text{m} \)) and to observe and evaluate the Orssengo-Pye CCT–corrected IOP values on these subjects. Additionally, differences postoperatively between
dynamic contour tonometry (DCT) and GAT were observed, and then postoperative DCT values were compared with preoperative measured GAT values.

**Background**

**Influence of change in CCT on IOP**

Little is known of the variation in corneal properties between individuals. There is a substantial population variation in CCT, and it has long been recognized that CCT may influence GAT IOP readings. Additionally, the conclusions of the Ocular Hypertensive Treatment Study emphasized the significance that CCT has as an independent risk factor in the diagnosis of glaucoma.

Despite the statistically significant effect of CCT on IOP determination, CCT accounts for only a portion of the GAT IOP error in individuals. It is likely that corneal properties other than thickness, such as hydration, surgical alteration, hydration patterns, corneal disease, and ultimately the variability in elasticity have an influence on its response to the forces of applanation. Hans Goldmann clearly discussed the likelihood of tonometric measurement error in the event of less than ideal corneal parameters. More specifically, it is likely that the alteration of corneal structural dynamics and subsequent decrease in elasticity resulting from LASIK surgery have significant influence on postoperative GAT measurements beyond the amount that would be accounted for by the mere reduction in CCT. (Elasticity is defined as the propensity to return to an initial form or state after deformation.) Highly elastic corneas will resist the flattening force of the GAT, whereas inelastic corneas will succumb easily.

Those patients with thicker than average corneas (>545 μm) preoperatively who then undergo hyperopic LASIK or myopic LASIK, with low refractive error and relatively small amounts of stromal ablation, could be expected to have a nominal decrease in CCT from LASIK. Because LASIK treatment always includes the ablation of some corneal tissue, most post-LASIK corneas are thinner than average ([545 μm]). Understandably, there are a few corneas that remain thicker than 545 μm postoperatively. An example would be an individual undergoing hyperopic LASIK with preoperative pachymetric values of 600 μm. Postoperative thickness could be expected to be as high as 580 μm. Thicker than average postoperative LASIK corneas were of particular interest because they would, in aggregate, be expected to have average or above average measured GAT values, as is the case in non-LASIK eyes.

**Methods**

In a single-center study, CCT and IOP were measured in patients who had undergone LASIK, in whom the postoperative CCT was greater than 545 μm. CCT and IOP were measured after surgery using ultrasound pachymetry, GAT, and DCT. Although all patients in our clinic who have undergone LASIK surgery have their IOP and CCT determined during routine follow up, those patients with postoperative CCT less than 545 μm were not asked to be included in the study.

The order of testing was (preoperatively) pachymetry (performed by an ophthalmic technician) then GAT (performed by 1 of the 2 practice optometrists). Postoperatively, the order was pachymetry, GAT, and then DCT. (With a digital display of results, the DCT is less prone to user bias.) The optometrists and technician were aware that the subjects were participating in the study but were unaware of data recorded in other testing stations.

GAT values were measured randomly using 1 of 2 slit lamp mounted Goldmann™ applanation tonometers, Model R-900™ (Haag-Streit AG, Koeniz, Switzerland). Both instruments were calibrated and used as instructed in the manufacturer’s manual. Before each reading, the measuring drum was reset to approximately 2 mmHg.

DCT values were measured randomly by 1 of 2 PASCAL®, slit lamp mounted, dynamic contour tonometers (SMT Swiss Microtechnology AG, Port, Switzerland). The manufacturer calibrated both instruments. Tests were performed as instructed in the manufacturer’s manual.

Subjects were all patients at Harper’s Point Eye Associates, Cincinnati, OH. The tests performed on all potential subjects were part of the established protocol for all pre- and postoperative LASIK patients in the practice. Postoperative data were collected between April 5 and Septem-
ber 27, 2004. All 14 subjects volunteered to have their data included in this research, and each signed informed consent documents and were assured that their data would only be reported in an aggregate manner, which would be unidentifiable to them individually. Of the 14 subjects, 5 were men and 9 were women. All were between the ages of 28 and 55. None of the women reported that they were pregnant. All subjects had no known corneal disease and reported taking no prescription medication for any eye disease. Postoperatively, none had taken any prescription eye medicines beyond 10 days postoperatively. Seven of the 14 subjects reported that they regularly (as much as 4 times per day) instilled some variety of artificial tears.

Preoperative refractive errors in all subjects varied between +3.50 and −3.50 diopters sphere and less than −2.50 diopters cylinder in each eye. In the postoperative testing phase of the study, patients were tested at times ranging between 44 days and 18 months after their LASIK surgery. All aspects of testing conformed to the Declaration of Helsinki regarding the use of humans in research.

Before testing, each patient was given one drop of Flurox™ (Ocusoft, Inc. Richmond, TX) Fluorescein Sodium, 0.25%; Benoxinate HCl, 0.4%; and ophthalmic solution, United States Pharmacopeia, in each eye. Testing began no less than 1 minute after drop instillation. All data in each session were then collected within a 5-minute testing window, beginning 1 minute after the drop.

Data were gathered by 1 of 2 optometrists and 1 ophthalmic technician working in our group practice at the same clinic location. With each subject, GAT, DCT, and pachymetry were each performed by separate clinicians who were unaware of the results of other tests performed on the same individual.

In an attempt to minimize the effects of diurnal variation, pre- and postoperative measurements were taken within the same hour of the day [no more than 59 minutes difference].

A statistical analysis was performed. The Wilcoxon Sign Rank test for one group was used. The differences were calculated between the measurement methods for pre- and postoperative measurements. All tests are significant on a 0.05 alpha error probability [see Figure 1]. Because of the study selection criteria, all 14 patients had thicker central corneas than the mean population, even subsequent to LASIK surgery. All patients had measurements taken in each eye and then underwent bilateral LASIK surgery. Because of the strong correlation between the 2
eyes of each patient, mean values of the 2 preoperative measurements were taken as a preoperative characteristic for each patient [CCT as well as IOP measurements]. Similar practice was done for postoperative measurements. The 3 measurements (CCT and IOP) taken on each eye resulted in 6 measurement values for each patient. These six values were calculated to a mean postoperative characteristic [applied on CCT, GAT, DCT]. The influence of the different manufacturers of the measurement devices was not included in the analysis.

Pachymetry

Pachymetry values were measured by a Paradigm-Dicon, Salt Lake City, UT, Ultrasonic Pachymeter (Model 55). The instrument was calibrated and tests were performed as instructed in the manufacturer’s manual. The measurement of CCT by means of ultrasonic pachymetry has been shown to be highly reproducible. 28

Goldmann applanation tonometry

The Goldmann applanation tonometer is a variable force tonometer, which makes a static measurement of the force required to flatten a fixed area of cornea. When Hans Goldmann designed the tonometer, he recognized that corneal effects [resistance to deformation] would influence pressure measurements. 19,20 He, therefore, based his calculations on the resistance to deformation of an average cornea and estimated that the resistance to deformation would be cancelled by the surface tension generated by the precorneal tear film when the area applanated had a diameter of 3.06 mm. Because the measurement of the force required to applanate the cornea is static, and only a single measurement is made, it is not possible to account for inter- and intraindividual variations in corneal resistance or elasticity, and the effects of true IOP and corneal resistance cannot be distinguished.

PASCAL® (dynamic contour tonometry)

Dynamic contour tonometry is a novel measuring technique that was designed to more accurately measure IOP largely independent of the cornea’s thickness, curvature, or elastic properties. In vitro studies with cadaver eyes have found a nearly linear relationship of DCT to manometric IOP independent of corneal thickness or curvature. Additionally, DCT values have been shown to remain unchanged in individuals before and after LASIK surgery. 15-17 Although this device is similar in appearance to GAT, the PASCAL® is not a variable force tonometer. PASCAL® implements a miniature piezoelectric pressure sensor that is imbedded within a contour-matched tonometer tip. The tonometer tip rests on the cornea with a constant appositional force of 1 g. The contour-matched tip has a concave surface of radius 10.5 mm. This curvature approximates the cornea’s shape when the pressure on both sides is equal. Once a portion of the central cornea has taken up the shape of the tip, the integrated pressure sensor begins to acquire its value. 15-17 Assumptions are that the contour matching is independent of corneal curvature, corneal biomechanical properties, contact diameter, and appositional force. Additionally, DCT measurements have been shown to be approximately 1.7 mmHg higher than GAT values in an average population. 17

DCT measurements were taken only postoperatively. Preoperative GAT and CCT data were obtained retrospectively from patient histories. Most preoperative measurements were taken before November 2003, when the DCT became commercially available in the United States; therefore, DCT preoperative values could not be included in this study. Postoperative values were measured at a single visit, which ranged in time between 44 days and 18 months after LASIK surgery. Without taking measurements after a fixed, standardized time after surgery, there can be no assurance whether time-dependent biometric changes after surgery had any influence on our data.

Correcting GAT for changes in CCT

The corrective algorithm used in this study was developed by Orssengo & Pye and was based on whether a patient’s CCT was found to be thinner or thicker than normal [normal defined in the study as 545 μm]. The linear scale added or subtracted 2.5 mmHg to the IOP for every 50-μm difference in CCT from 545 μm (.5 mm Hg for every 10 μm):

Corrected IOP = Measured IOP

\[- \frac{(CCT - 545) \times 2.5mmHg}{50^{15}}\]

For corneas that are thicker than 545 μm, the correction value according to the formula is negative. For those that are thinner than 545 μm, the correction value is positive.
The Ossengo-Pye formula was designed to correct GAT for individual variations in CCT. It was selected for use in this study because it has so frequently been adopted for use in clinical practice for correcting GAT with all types of CCT variations, including post-LASIK. Although it was not specifically designed to correct for CCT changes in individuals who have undergone LASIK surgery, the formula seems to have wide acceptance in clinical eye care, being applied to LASIK as well as non-LASIK patients.

Results
Preoperatively, median CCT values were 589.536 μm. Median GAT values were 16.750 mmHg. Median corrected preoperative GAT values were 14.450 mmHg. After LASIK treatment, median CCT values were 559.417 μm. The decrease in median CCT was 30.119 μm. Median postoperative GAT values were 11.500 mmHg (decrease, 5.250 mmHg) Median corrected postoperative GAT values were 10.775 mmHg (decrease, 3.675 mmHg). Postoperative median DCT values were 17.858 mmHg. Postoperative refractive +1.00 sphere to −0.75 sphere and less than -0.75 diopters cylinder (see Tables 1 and 2).

Conclusions
LASIK treatment causes a significant reduction in measured GAT IOP values on patients with thicker than average corneas. The Ossengo-Pye formula, which attempts to correct for GAT errors related to individual variations in CCT, can possibly yield significantly misleading results when applied to patients who happen to have unusually thick corneas, even after LASIK surgery. A significant reduction in corrected and noncorrected [measured] Goldmann IOP was observed in all 28 eyes. Unless LASIK surgery in all 14 patients [28 eyes] had caused a true decrease in actual manometric IOP, the unexpected 3.675-mmHg decrease in “corrected Goldmann IOP” seen in this study may be attributed to non-CCT corneal variables, which are not considered in the often-used Orssengo-Pye formula. In the absence of a true shift in manometric IOP, corrected GAT IOPs should not have been significantly different pre- and postoperatively.

DCT measurements have been shown to be approximately 1.7 mmHg higher than GAT measurements, given an average CCT of 545 μm in

| Table 1. Descriptive values for pre- and postoperative IOP measurements done with GAT and only postoperative values for DCT |
|-----------------|----------------|-----------------|----------------|----------------|
|                 | Preoperative GAT | Preoperative GAT “corrected” | Postoperative GAT | Postoperative GAT “corrected” | Postoperative DCT |
| Mean            | 16.535714       | 14.258929       | 11.404762       | 10.693452       | 17.517857       |
| Median          | 16.750000       | 14.450000       | 11.500000       | 10.775000       | 17.858333       |
| 3rd QU          | 17.000000       | 15.093750       | 12.708333       | 11.641667       | 19.000000       |
| Max             | 19.500000       | 17.175000       | 13.333333       | 12.700000       | 20.983333       |
| NAs             | 0.000000        | 0.000000        | 0.000000        | 0.000000        | 0.000000        |
| Std Dev         | 1.562349        | 1.744293        | 1.433295        | 1.455447        | 2.004359        |

| Table 2. Descriptive values for pre- and postoperative CCT |
|----------------|----------------|
|                 | Preoperative | Postoperative |
| Min             | 572.000000   | 547.66667     |
| 1st QU          | 583.125000   | 547.66667     |
| Mean            | 590.535714   | 559.22619     |
| Median          | 589.000000   | 559.41667     |
| 3rd QU          | 601.125000   | 562.70833     |
| Max             | 609.000000   | 576.16667     |
| Total N         | 14.000000    | 14.000000     |
| NAs             | 0.000000     | 0.000000      |
| Std Dev         | 12.36537     | 8.43948       |
the study referenced. After adjusting for the approximate 1.7 mmHg difference, mean postoperative DCT values were similar to uncorrected mean preoperative GAT values.17

Discussion
The subjects studied had undergone LASIK treatment and postoperative CCT of at least 545 μm. In an attempt to compensate for significant reduction in GAT IOP values subsequent to LASIK, which have been attributed to CCT reduction, several investigators have provided formulae for calculating "corrected IOP" values, using change in the CCT as the only variable.2,3,7,8,25,29,30 In another approach, one investigator suggested that after monocular LASIK procedures one could determine the IOP differential between the operated and unoperated eyes and continue to use that value as the ongoing fixed compensating factor for that individual.12 Both the unpopularity of monocular LASIK and lack of scientific validation of this technique for pressure calculation have rendered it of nominal clinical value.

In all study subjects, the corrective formula used yielded net values that seemed to be counterintuitive. The seemingly average preoperative measured GAT values (16.750 mmHg) decreased to unusually low postoperative measured values (11.5 mmHg), and the Orssengo-Pye formula adjusted those values to an even lower point (10.775 mmHg). For example, the Orssengo-Pye algorithm (10 μm per .5 mmHg) yields net "corrected GAT IOPs" in the study group that range between 7.65 and 13.23 mmHg. These appear to be extraordinarily low and unrealistic values given a group of normal healthy subjects. A commonly accepted range of normal subjects for GAT is between 12 and 21 mmHg.33 The decrease in median "corrected IOP" of the group was 3.675 mmHg with a decrease in median CCT of 30.118 μm. The Orssengo-Pye "correction" factor for this thickness change accounts for only 1.560 mmHg.33 The decrease in median "corrected IOP" of the group was 3.675 mmHg with a decrease in median CCT of 30.118 μm. The Orssengo-Pye "correction" factor for this thickness change accounts for only 1.560 mmHg. The decrease in median "corrected IOP" of the group was 3.675 mmHg.33 The significant and unaccounted for change in "corrected" Goldmann IOP values (-3.675 mmHg) seen in these subjects helps validate the notion that there seem to be other significant variables (beyond CCT) that contribute to the downward shift in GAT values subsequent to LASIK surgery. Although it is plausible that various corrective algorithms can be reliable with many types of patients, there seem to be circumstances in which the formulae might reasonably compensate for unusual corneal characteristics.

The postoperative measurements taken on the dynamic contour tonometer (DCT range 13.8 and 21.9 mmHg) were consistent with what one expects to see in terms of a normal distribution of IOPs in young, healthy subjects.17,31–33 Interestingly, the adjusted (1.7 mmHg) postoperative DCT values were consistent with preoperative GAT values. Given that Kaufmann et al.15 demonstrated that DCT IOP values are unaffected by LASIK surgery, it seems interesting that postoperative DCT values are similar to preoperative GAT values, whereas postoperative GAT values are significantly lower than preoperative GAT values. Hopefully, other investigators will include a more complete comparison of GAT and DCT pre- and postoperatively with a larger sample of these unusual, thicker than average, post-LASIK corneas, as well as investigate other important circumstances in which corrective algorithms may be less than reliable. Although it is plausible that various corrective algorithms can be reliable with many types of patients, there seem to be circumstances in which the formulae might reasonably compensate for unusual corneal characteristics.

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Ongoing scientific investigation of the changes in corneal structural dynamics induced by LASIK
will hopefully reveal the true source and relative value of these findings as well as similar findings by other investigators.\textsuperscript{1,3–5,6,7,11,15,30}

DCT measurements have been shown to be unaffected by LASIK surgery and have been reported to require no CCT or elasticity correction factor.\textsuperscript{15,17} Because of the absence of preoperative DCT data owing to the unavailability of the instrument, the dynamic contour tonometric information gathered is inconclusive and is somewhat peripheral to the central aim of this study. DCT data have been included to encourage further investigation of DCT as a means of mitigating post-LASIK GAT error and hopefully providing more reliable postoperative LASIK IOP measurements.

Observation of a larger sample of thicker than average postoperative LASIK patients, including pre- and postoperative DCT values, would help further validate the usefulness of DCT for LASIK patients and, perhaps, help discourage the common reliance on the Orsengo-Pye IOP CCT algorithm as well as those that are similar. Ongoing in vivo cannulation studies as well as various noninvasive comparative studies will give us a better understanding of the relative accuracy and value of DCT compared with GAT and true manometric intraocular pressure.

Although this evidence may undermine support and discourage the implementation of the Orsengo-Pye corrective algorithm on LASIK patients, an argument remains supporting additional investigation and understanding of the function, clinical application, and usefulness of dynamic contour tonometry. Additionally, until these concerns have been addressed, eye care practitioners making glaucoma management decisions on their LASIK patients should be encouraged to rely more heavily on non-GAT IOP data, such as 3-dimensional examination of the optic nerve, optic nerve imaging visual fields, and other glaucoma risk factors because their corrected GAT IOP values may be less reliable than previously thought.

**Authors’ Statement**

There is no known redundant publication of the same or very similar work Elliot M. Kirstein, O.D., is a paid consultant and research coordinator for Ziemer Ophthalmic Systems AG, Port, Switzerland, who markets and sells the PASCAL\textsuperscript{®} Dynamic Contour Tonometer. In addition to his work in his private optometric practice, he has been affiliated with Ziemer Ophthalmics from September 2003 through the duration of this study. The PASCAL\textsuperscript{®} tonometers used in the study and the consumable products required for their use [sterile cover tips and instrument batteries], were furnished by the Ziemer Ophthalmics at no cost. The other optometrist, Todd A. Zelczak, O.D., as well as the ophthalmic technician, Kimberly Bryant, are employees of Dr. Elliot M. Kirstein & Associates, Inc. Dr. Elliot M. Kirstein & Associates, Inc underwrote the costs for their work. André Huesler, who performed the statistical analysis for this study, is employed by ISS Integrated Scientific Services AG (a Ziemer Ophthalmic Systems Group Company) CH-2562 Port, Switzerland.

The manuscript has been read and approved by all the authors, the requirements for authorship have been met, and each author believes that the manuscript represents honest work.

**References**


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