True IOP – No Doubt

Facts and Figures

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“THERE IS INCREASING EVIDENCE THAT DCT MEASURES IOP MORE ACCURATELY THAN ANY OTHER TONOMETER.”

F. BOCHMANN ET AL, EXPERT REVIEW OPHTHALMOLOGY 2010
The Early Manifest Glaucoma Trial showed that every millimeter of IOP reduction lowers the risk of glaucoma progression by 10 %.1

“However, the Goldmann applanation tonometer, which is current gold standard, is not precise enough to measure the true IOP within an error of 1 mmHg.” 2

A recent in-vivo study including cannulation and IOP measurement in the anterior chamber has shown that PASCAL measurements are closest to the actual pressure in the chamber and that its accuracy is clearly superior to traditional Goldmann Tonometry (GAT).4

This new method of corneal-independent tonometry allows the detection of more true ocular hypertensives and therefore more of the true glaucoma patients.3 This reduces the risk for blindness due to late or missed diagnosis and treatment.

* At 20 mmHg
“The ideal tonometer is expected to be accurate, repeatable, reproducible, and minimally influenced by factors such as corneal properties and different examiners.”

A. Wang, L. Alencar, R. Weinreb et al., J Glaucoma 2011
PASCAL’s clinical benefits

• **True IOP**
  No corneal influence

• **Superior Precision**
  Highest repeatability and reproducability

• **Ocular Pulse Amplitude**
  A measure for the short term pressure fluctuations

• **Detect the real glaucoma suspects**
  Less false negatives than applanation tonometry
Cannulation study by A. Böhm; 2009: “DCT measurements come close to the true IOP”

Correlation of in-vivo direct manometric measurements (black curve) with simultaneous PASCAL DCT measurements (red curve) performed during cataract surgery in the study of A. Böhm 2009.
Accuracy – True IOP!

The accuracy of tonometric readings is defined by how close they come to the true IOP as measured intra-camerally. This accuracy is an important criterion for tonometry as IOP measurements are critical elements in making sound treatment decisions.

The PASCAL was validated by comparing its measurements with manometric readings in a large series of cannulated eyes with patients undergoing cataract surgery.

A mean difference of DCT to true IOP of only -0.2 mmHg was found, at the level of 20 mmHg.

Results of the original study from A. Böhm et al. 2009⁴

“The concordance between true IOP and [DCT] measured IOP seems to be higher compared with the GAT measurements, as CCT and other parameters had no clinically relevant effect, and therefore no correction of the IOP measurements [on DCT] was necessary.

According to our data, the DCT measurements came close to the true IOP.”
“CORRECTION NOMOGRAMS THAT ADJUST GAT IOP BASED SOLELY ON CCT ARE NEITHER VALID NOR USEFUL IN INDIVIDUAL PATIENTS.”

R. WEINREB, J. BRANDT, D. GARWAY HEATH, F. MEDEIROS 2006, WORLD GLAUCOMA CONSENSUS ON IOP
Influence of corneal properties on GAT

4th World Glaucoma Consensus on IOP
Consensus Points:

“Measurement of Intraocular Pressure:

1. On average, greater central corneal thickness (CCT) results in overestimation of intraocular pressure (IOP) as measured by Goldmann applanation tonometry (GAT). […]

2. Compared to GAT, CCT has a lesser effect on IOP measured by DCT and the OcularResponse Analyser (ORA), CCT has a greater effect on IOP measured by NCT and Rebound Tonometry. […]

6. A thick cornea gives rise to a greater probability of an IOP being over-estimated (and a thin cornea of an IOP being under-estimated), but the extent of measurement error in individual patients cannot be ascertained from the CCT alone. […]

8. The corneal modulus of elasticity likely has a greater effect on GAT IOP measurement error than CCT.”

R. Weinreb, J. Brandt, D. Garway Heath, F. Medeiros 2006
“Correcting GAT-IOP for CCT, 31% of patients with NTG could be reclassified as having POAG and 56% with OHT as normal.”

Copt et al, Arch Ophthalmol. 1999
Correcting applanation IOP for Corneal Thickness (CCT) does not work as it can be seen in the heavy scatter of GAT values. In many cases corrections would work in the wrong direction and even magnify the error. Other factors like corneal rigidity influence the applanation measurement to probably even a bigger extent.

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<th>IOP [mmHg]</th>
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Distribution of IOP relative to CCT
DCT, in contrast to GAT, is nearly independent of CCT. Correction of a single IOP value for CCT is not possible due to the heavy scatter.
“DCT-IOP IS MORE CLOSELY RELATED TO EXTENT OF GLAUCOMA DAMAGE THAN IS GOLDMANN IOP.”

M. SULLIVAN MEE ET AL, J. GLAUCOMA 2007
Detecting the real glaucomas

Correlating IOP with glaucomatous damage: Conclusion of a study from M. Sullivan Mee 2007

“These findings suggest that DCT-IOP is correlated with glaucomatous damage, and moreover, DCT-IOP is more closely related to extent of glaucoma damage than is Goldmann IOP (GAT-IOP). The most likely explanation for these results is that GAT-IOP systematically underestimates IOP compared with DCT-IOP. Our findings also support the hypothesis that corneal biomechanical factors other than CCT are major confounders of applanation tonometry measurements.”

Frequency Distribution of GAT-IOP and DCT-IOP

2157 eyes of primarily Mexican ancestry showed a mean ΔIOP between DCT and GAT of 1.7 mmHg. DCT is calibrated to true IOP while GAT was calibrated to cadaver eyes in the 1950s.
Repeat measurements by the same observer would be within these limits in 95% of the measurements.\(^5\) Variability of non contact tonometers (NCT) was found to be twice as high compared to contact techniques. As NCT measure only over a period of milliseconds, they are influenced by the ocular pulse.

Repeat measurements by different observers would be within these limits in 95% of the measurements.\(^5\) PASCAL shows less variability than the traditional Gold Standard GAT and ORA, because its semiautomatic recording is highly independent from user and environmental influences.
Repeatability and Reproducibility

The precision of a device is defined by its repeatability and reproducibility and is a measure of independency from any user interaction.

High precision allows for the detection of a gradual IOP increase earlier in a highly refined IOP progression analysis. Precision is even more important to monitor IOP when several users are involved.

Conclusion of the original study from A. Wang et al. 2011

“The results of this study suggest that the DCT demonstrates a reproducibility that is better than the GAT or the ORA. The better reproducibility of the DCT may result in more precise measurements for monitoring IOP changes over time compared to GAT and ORA.”

Conclusion of the original study from A. Kotecha et al. 2009

“The PASCAL DCT shows excellent measurement precision, displaying the best repeatability and reproducibility of the 3 tonometers [...]” (GAT, ORA, DCT)
IOP after LASIK
Surgery changes corneal biomechanics, not IOP. GAT and conventional Airpuffs give a false impression by underestimating IOP post-surgery – while PASCAL stays unaffected.

Δ IOP in different treatment groups
After trabeculectomy or with prostaglandin use, higher than normal Δ IOP = DCT – GAT was found. This finding may reflect structural changes in the ocular rigidity or hemodynamics which compromise the accuracy of GAT in a magnitude similar to LASIK.
Accuracy and Precision with unusual corneas

Many surgeries and treatments affect the biomechanical properties of the cornea and lead to an underestimation of IOP by applanation tonometry. PASCAL eliminates most false negative readings because its measurements are independent of corneal biomechanics.

PASCAL is accurate and precise with

• LASIK or PRK\textsuperscript{11}
• Lamellar and penetrating keratoplasty\textsuperscript{12}
• Trabeculectomy\textsuperscript{13}
• Prostaglandin therapy\textsuperscript{14}
• Keratoconus\textsuperscript{15}
• Corneal crosslinking therapy\textsuperscript{16}
**IOP and OPA**

The Ocular Pulse Amplitude OPA is the difference between systolic and diastolic IOP stemming from vascular influences.

**OPA in different glaucoma groups**

Ocular Pulse amplitude is reduced in patients with NTG or POAG as compared to healthy individuals and OHT.
**OPA – An other Glaucoma Parameter**

PASCAL measures IOP 100 times per second, recording the dynamics of the heart rate and the ocular pulse curve. This is displayed as the Ocular Pulse Amplitude (OPA) and the full cycles can be transmitted to a PC.

**OPA and glaucoma: Conclusion of the study by M. Kynigopoulos 2012**

“Decreased OPA seems to be correlated with increased glaucomatous functional and structural damage in OAG. Assessment of OPA by DCT could therefore serve as an important additional parameter in the evaluation of glaucoma patients.”

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**6th World Glaucoma Consensus on Ocular blood flow**

“Dynamic Contour Tonometer and OPA – Clinical Utility

- OPA is reduced in patients with NTG or POAG as compared to healthy individuals and OHT.
- In patients with glaucoma higher OPA seems to correlate with less severe glaucoma.
- Conversely, a small OPA is correlated with moderate to severe glaucomatous visual field loss and might be a risk factor for the development of glaucomatous visual field defects.
- OPA has been correlated with the resistive index in the retrobulbar vessels.”

I. Stalmans, R. Weinreb, A. Harris 2009
DTC Principle

Prof. Goldmann stated, for a correct measurement of the IOP the corneal tissue must be tension free.20

1. IOP induces tensions in the cornea as it pushes against the cornea, but the non-stretchable collagen matrix holds the corneal shape.

2. The cornea is tension free when the pressure is equal on both sides. (Pascal’s Law)

3. When the pressure is made equal just in a small part around the center of the cornea, the center becomes radial tension free and flattens. The flattening comes from surrounding tensions pulling on the relaxed middle section. This new shape is called the DCT-shape and the DCT tonometer tip is formed accordingly.

4. During a measurement a tonometer tip with the DCT shape is brought in contact with the eye. The adhesion of the tear film causes the cornea to conform to the DCT shape of the tip and frees the cornea again from its radial tensions. This allows direct measurement of the IOP as if there were no cornea.
How it works

The PASCAL is a slit lamp mounted tonometer. Its measurement technique, which is similar to Goldmann and pneumotonometry, is relatively user independent and provides an acoustical feedback during measurement.

Unlike Goldmann tonometry, the PASCAL dynamic contour tonometer (DCT) sensor tip does not applanate the cornea. Its concave shape causes a relaxation of the cornea, which helps minimize any influence on measurements that are attributed to various corneal properties.

The pressure itself is acquired by a piezoresistive sensor embedded into the tonometer tip and is digitally sampled 100 times per second. An internal microprocessor analyses this direct proportional signal and extracts IOP and the ocular pulse amplitude (OPA) together with a measurement quality index (Q). These values are then displayed digitally on the PASCAL LCD screen.

A measurement with good quality takes approximately six seconds. Additionally, a quick mode can be selected, to enable measurements in even a shorter period of time.

The DCT principle combined with the LCD display provides IOP measurements which are relatively unaffected by various corneal properties or user bias.
“THE PASCAL DCT IS CERTAINLY AN IMPROVEMENT AND GREAT STEP FORWARD WITHIN GLAUCOMA DIAGNOSTICS. HANDLING IS AMAZINGLY SIMPLE.”

DR. H. BUCHHOLZ, BREMEN
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Article No. 311.941.002
“THE PASCAL-DCT IS THE FIRST TOTALLY NEW CONCEPT IN TONOMETRY IN OVER 100 YEARS.”

R. STAMPER, OPTOM VIS SCI. 2011

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