Open Journal of Ophthalmology, **2012, 2, 78-82**
http://dx.doi.org/10.4236/ojoph.2012.23016 Published Online August 2012 (http://www.SciRP.org/journal/ojoph)

History and Clinical Validation of the PASCAL® Dynamic Contour Tonometer

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Received April 16th, 2012; revised May 28th, 2012; accepted June 15, 2012

ABSTRACT

Will Goldmann applanation tonometry, the age old "gold standard" of intraocular pressure (IOP) measurement, be replaced with newer methods? One of the newer methods of IOP measurement is PASCAL® dynamic contour tonometry (DCT). A review of the history, scientific principles, clinical validation and clinical utility of DCT is presented.

Keywords: Cornea; Ocular Surface; External Disease Glaucoma Ophthalmic Pathology

1. Introduction

The technology used to estimate intraocular pressure (IOP) has evolved tremendously since, in the late 1800's, Sir William Bowman emphasized the importance of ocular tension measurements. While, in the context of glaucoma diagnosis, the relative importance of IOP measurement seems to have waxed and waned, few would argue that IOP reduction remains our fundamental tool in glaucoma management [1]. If we could measure IOP more precisely, we could then increase our understanding of the role of IOP in the pathogenesis of glaucoma as well as its diagnosis and management. This notion seems to explain why we have been driven to develop technologies which can most precisely estimate that value.

In Bowman's time, digital palpation tonometry became the clinical standard. Since then, there has been a milieu of devices which aimed to increase precision and clinical utility. Since the 1950's, the Goldmann applanation tonometer (GAT) has clearly been the standard in clinic and research [1].

During the past two decades, knowledge has been gained from studies such as the Ocular Hypertensive Treatment Study (OHTS) regarding meaningful systematic errors in GAT measurement [2]. With this in mind, researchers and clinicians have been prompted to seek out methods of correcting GAT's systematic errors and to develop enhanced practical methods of IOP measurement [3-8].

PASCAL® Dynamic Contour Tonometer (DCT)

The PASCAL® Dynamic Contour Tonometer (DCT) is a novel measuring technique, using the principle of contour matching instead of applanation. Approved for distribution in the United States in 2003, the PASCAL® was designed to eliminate or significantly reduce the systematic errors inherent in all previous tonometers, such as the influence of corneal thickness, rigidity, curvature or elastic properties. Initial *in vitro* studies with cadaver eyes and later *in vivo* cannulation studies on live patients have demonstrated a nearly linear relationship of DCT to true manometric IOP. Additionally, DCT values have been shown to remain unchanged in individuals, before and after LASIK surgery. The absence of change in measured IOP after LASIK is compelling repeatable evidence that relative corneal properties seem not to have any effect on its ability to measure IOP.

While this device is similar in appearance to GAT, the DCT it is unlike Goldmann applanation in that it is not a variable force tonometer. DCT implements a miniature piezo-resistive pressure sensor, which is imbedded within a contour-matched tonometer tip. When an electric current passes through it, the sensor vibrates at a predictable rate. When the sensor is subjected to a change in pressure, the vibration rate and resistance are altered and the PASCAL's computer calculates a change in pressure in concordance with the change. The tonometer tip rests on the cornea with a constant appositional force of one gram. This is an important distinction from all forms of applanation tonometry, wherein the probe force is variable.

The contour matched tip has a concave surface of radius 10.5 m. This curvature approximates the cornea's shape when the pressures on both sides of it are equal. This is the key to the PASCAL's ability to neutralize the effect of inta-individual variation in corneal properties, which have significant influence on applanation meas-

urements.

Once a portion of the central cornea has taken up the shape of the tip, the integrated pressure sensor begins to acquire its value, measuring IOP 100 times per second. Complete measurements require about 8 seconds of contact time. During the measurement, an audio feedback is generated, which helps the clinician insure proper contact [8-20].

2. Clinical Validation—Initial Challenges

Beyond the premarket studies, showing the scientific basis for the function of the DCT along with demonstrating reasonable concordance to GAT, the challenge of the research community has been to scientifically establish superior precision of DCT, compared with the GAT standard and, ultimately, to weigh the relative clinical value of such (more precise) data. Early investigators such as Lachkar *et al.* in 2005 [21], attempted, with no success, to compare DCT and GAT measurements in the context of widely accepted central corneal thickness correction algorithms (Ehlers *et al.*) [3]. These types of investigations seemed only to validate the idea that there was no reliable mathematical link between the two IOP values. It soon became clear that the differences in measured IOP values between traditional GAT and DCT could not be explained in terms of individual variability of central corneal thickness (CCT) measurements and other corneal properties must play a significant role [6, 22].

2.1. *In Vitro* Comparison between the PASCAL® DCT and GAT

In 2004, Robert Stamper, MD at University of California, San Francisco performed *in vitro* comparisons intracameral (manometric) between the PASCAL®, DCT and GAT in sixteen freshly enucleated human cadaver eyes. The study revealed a close adherence of DCT to actual manometric values, which seemed to remain relatively unchanged even where the corneal properties were significantly altered during the experiment [13].

2.2. Corneal Properties

Physical models proposed by Roberts *et al.*, in 2005, showed that non CCT corneal properties appeared to account for the majority of factors that accounted for these differences. Roberts showed that, while CCT variability may account for little more than 2 mm Hg error in GAT, variability in corneal properties in total may account of over 10 mm Hg. [6]

2.3. LASIK and DCT

One of the most perplexing challenges of managing the diagnosis and care of glaucoma patients in the context of kerato refractive surgery was the apparent downward shift in GAT in virtually all subjects post operatively. Initially, it was assumed that the mere reduction in CCT caused by LASIK or PRK justified the decrease. Pepose showed that similar GAT decreases occurred in subjects where LASIK flaps were made with no ablation. In these subjects, the CCT decrease from the LASIK microkeratome was between 10-15 microns, compared with CCT decreases of over 100 microns typically seen in LASIK with ablation. Without significant CCT decrease, the only thing that could explain the IOP decrease that Pepose observed in these non-LASIK subjects would be the apparent alteration in corneal properties caused by the creation of the LASIK flap. In simpler terms, while not significantly decreasing CCT, the creation of the LASIK flap alone made the cornea significantly less rigid [17].

In 2003, Kaufmann *et al*. observed 62 patients pre and post LASIK. GAT measurements decreased 3.0 +/– 1.9 mm Hg ($p = 0.001$). In contrast, no significant change in IOP readings was recorded by DCT (0.2 mm Hg +/– 1.5 mm Hg, $p = 0.30$). There was no change in IOP in the untreated control eyes as measured by GAT [10].

Kaufmann's observations were particularly meaningful because he demonstrated that, in the context of significant changes in corneal CCT and properties caused by LASIK, DCT measurements were not significantly affected [10].

2.4. DCT Population Study

In 2004, Kaufmann *et al*. performed a detailed comparison of the PASCAL® Dynamic Contour Tonometer (DCT) with Goldmann applanation tonometry (GAT). The study analyzes IOP measurements and biometric measurements which were taken from a large population of healthy volunteers, and features a careful statistical analysis to determine any influence of corneal thickness, axial length, corneal curvature, and anterior chamber depth on either of the two types of tonometers. Unlike many other comparisons, these authors acquired pressure readings three times per device per patient to analyze intra- and inter-observer variability.

Kaufmann's results showed that DCT readings have a high concordance with GAT readings and that DCT were not significantly influenced by corneal thickness or curvature, axial length, or anterior chamber depth or variations in central corneal thickness. Additionally, they observed that DCT readings are on average 1.7 mmHg higher than GAT readings and that intra-observer variability (reading error made by same observer) in repeated measurements is higher (approximately 2 times higher) with GAT than with DCT [9].

2.5. *In Vivo* Manometric Comparison

Traditionally, the ultimate method for verifying the va-

lidity of a clinical tonometer is *in vivo* comparison to a manometric standard. Manometry (measurement of IOP within the anterior chamber) requires that an IOP measuring device has a direct connection, via intracameral cannulation, to the anterior chamber. Boehm *et al.* published the results of their *in vivo* DCT manometric comparison in 2006.

While difficult to perform, *in vivo* intracameral measurement and comparison between IOP measuring devises is the ultimate validation of tonometric accuracy. During the initial phase of cataract surgery, a cannula is inserted in the anterior chamber. With the cannula in place, true manometric IOP can be monitored and anterior chamber pressure and be altered to desired levels. This technique gives the investigator the opportunity to compare the measurements of the Goldmann and the PASCAL to actual manometric IOP. These tests are performed at different pressure levels and on different subjects with different corneal thicknesses and properties. It is encouraging that the results of these challenging experiments seem to be consistent with previous studies performed on cadaveric eyes, showing that DCT measurements are highly concordant to actual anterior chamber measurements [23].

2.6. Tonometry Practicality and Precision

Schneider *et al.*, in 2006 compared DCT and GAT mathematically and in terms of clinical practicality, showing that DCT seems to be a reliable method for intraocular pressure measurement which, unlike Goldmann applanation tonometry, is not influenced by central corneal thickness. In clinical practice, advantages from DCT can be expected for cooperative patients, outpatients, and patients with sufficient bilateral ocular fixation, whereas Goldmann applanation tonometry measurements are more reliable in case of patients with inadequate cooperation, poor vision, or nystagmus [24].

In 2010, Kotecha *et al*. compared the repeatability and reproducibility of the GAT, DCT, and Reichert Ocular Response Analyzer (ORA) and agreement between tonometers.

Their results showed that the DCT shows excellent measurement precision, displaying the best repeatability and reproducibility of the 3 tonometers. On average, GAT under-read both DCT and ORA IOP measurements by approximately 2 mm Hg. Corneal stiffness, as defined using corneal response factor CRF, was associated significantly with agreement between devices. The IOP measurements with each device are not interchangeable [15].

3. PASCAL® in Clinical Practice

As our understanding of the function of the DCT became more clear along with a more robust knowledge of the more complex range of influences that might influence GAT readings, researchers began to take a closer look at the real clinical value of this new, and presumably more precise, clinical data.

3.1. Comparing GAT and DCT in Patients with Glaucoma

In a novel 2007 study comparing the relationships between glaucomatous visual field loss and IOP as measured by both PASCAL® DCT and GAT, Sullivan-Mee *et al*. suggest that DCT-IOP is correlated with glaucomatous damage, and moreover, DCT-IOP is more closely related to extent of glaucoma damage than is GAT-IOP. The most likely explanation for these results is that GAT-IOP systematically underestimates IOP compared with DCT- IOP. Their findings also support the hypothesis that corneal biomechanical factors other than CCT are major confounders of applanation tonometry measurements [18].

3.2. A Comparison with African Americans

In 2007, Madeiros *et al*. evaluated the relationship between IOP measurements obtained by DCT and GAT in African Americans and assessed whether these measures were influenced by ocular parameters including corneal thickness, corneal curvature, and axial length. Their findings indicate that DCT measurements in African Americans seem to provide an estimate of IOP that is less influenced by corneal properties than those provided by GAT. [16]

3.3. An Insight on DCT's Clinical Value

A review of the abundant literature that now exists seems to point to the conclusion that DCT measurements average slightly less than 2 mm HG above GAT and are relatively uninfluenced by the variations in corneal properties that appear to cause GAT to under read IOP in certain patients. The anecdotal conclusion that one might reach is that one measuring with DCT is less apt to overlook a significant number of patients with increased IOP or early glaucoma. As shown in post LASIK patients, the systematic errors in GAT cause it to read low in a clearly unpredictable manner. Therefore, some patients found to have increased IOP with DCT may be underdiagnosed or diagnosed late when measured with GAT [1,4,9,16].

4. Discussion

As time and technologies progress, doctors are charged with the task of seeking various testing modalities that have demonstrated increased precision and specificity. The apparent goal in this quest is to seek out earlier and

more precise diagnosis. In the case of glaucoma, eye doctors seem to have embraced the dramatic evolution of imaging, where, in the 1950's the standard of care was manual disc drawing, to current automated OCT devices which have retinal and optic nerve resolution of only a few microns. In the case of visual field measurement, the 1950's standards were the Tangent Screen and Goldmann Arc Perimeters. Today, automated devices such as the Octopus (Haag-Streit) and Humphrey (Carl Zeiss) analyzers have understandably become clinical standards.

One must ask why, in this world where we have evolved from the slide rule to sophisticated microprocessors which are expected to soon outpace the human mind, we adhere to the Goldmann "gold standard" in IOP measurement. Consider that the Goldmann tonometer was developed in the 1950's and has well documented clinically significant systematic errors. While a more precise technology seems to exist, why has its acceptance been slow? The answer is probably more economic and practical then it is scientific. Goldmann tonometers are relatively inexpensive and tend to be very durable. Additionally, tonometry as a procedure lacks specific financial reimbursement in the American insurance system. While the financial incentive for newer imaging, visual field tests has helped propel the acceptance of these new technologies, the financial incentive is lacking in the case of tonometry. It has also been apparent that Ziemer Group, AG, Switzerland, the manufacturer of the PASCAL®, is a relatively small and unknown to the ophthalmic community. This reality has seemed to heighten the strategic challenges that one would expect in replacing an age old "gold standard" such as Goldmann applanation tonometry. Given this history, one would hope that a more precise and reliable technology like the PASCAL®, with better precision and reliability, will soon become the new clinical standard in IOP measurement.

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