Dynamic contour tonometry versus Goldmann applanation tonometry: challenging the gold standard

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Dynamic Contour Tonometry versus Goldmann Applanation Tonometry: Is the Gold Standard for IOP Measurement Changing?

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Abstract

The accurate measurement of intraocular pressure (IOP) is fundamental to almost any ophthalmic examination. Five years ago, dynamic contour tonometry (DCT) was introduced as an entirely novel contact tonometry principle designed to measure IOP largely independent of corneal properties. Since then, many studies have compared the performance of this tonometer to the Goldmann applanation tonometer (GAT) and other tonometers in healthy eyes, as well as eyes with glaucoma or corneal diseases, and after corneal surgery. There is now strong evidence that DCT measures IOP very accurately, with very low inter- and intra-observer variability. This review summarizes the findings of these studies and analyzes the role of DCT in challenging GAT as the gold standard tonometer for IOP measurements.

Keywords: dynamic contour tonometry, Goldmann applanation tonometry, intraocular pressure, ocular pulse amplitude, gold standard

Introduction

In medicine, the term "gold standard" refers to a measure established by general consent to be used as a point of reference, against which everything else will be measured [1]. When applied to a test, the gold standard is an accepted test that most accurately reflects a given condition. The most accurate measuring modality for the determination of intraocular pressure (IOP) is intracameral manometry, the direct use of a pressure sensor to measure pressure in a cannulated eye. Although such an invasive test is not suitable in a routine clinical setting, manometric pressure readings define the truth against which non-invasive tonometers must be validated. Since its introduction in 1957, the applanation tonometer by Hans Goldmann has been commonly regarded as the clinical gold standard. However, Goldmann's fundamental paper indicates that he was well aware of the fact that the readings obtained by applanation were a fair approximation, but not an exact reproduction of the actual IOP [2]. In 2003, the first report on Dynamic Contour Tonometry (DCT) appeared[3]. This novel tonometry principle was based on contour matching rather than applanation, and it was designed to overcome some of the shortcomings of Goldmann Applanation tonometry (GAT) [4]. It is the purpose of the following review to discuss to what extent DCT might challenge the role of GAT as a clinical gold standard for IOP measurement. We propose that the following four groups of criteria are to be used for the comparison of the two tonometric principles: a) the measurements must be accurate; b) the measuring technique must have low inter- and intra-observer variability, so that it can be delegated to technical personnel if needed; c) the device must be robust, commonly available, and easy to maintain, with low costs for consumables; and d) the device must have been used in landmark

studies in which its readings were proven to be a decisive indicator for long-term outcome.

Goldmann applanation tonometry

Based on the applanation formula by Imbert and Fick, Goldmann assumed that the elastic and capillary forces on the tonometer tip balanced each other when the diameter of the applanated area was between 3.0 and 3.5 mm. Under these conditions, a linear relationship exists between IOP and the force required to produce the applanation[2]. When introduced in the middle of the twentieth century, GAT represented a giant step forward in terms of the reproducibility of IOP measurements. Inter- and intra-observer variability were much lower than what could be achieved with alternative tonometers at the time, such as the Schiötz tonometer. The use of GAT is exceptionally easy to learn and for the last 40 years virtually every ophthalmology resident grew up with GAT since his/her first day in training. The Goldman- type tonometer is highly robust, with minimal maintenance needs[5]. The costs for consumables such as fluorescein paper strips are negligible and the life expectancy of a Goldmann-type applanation tonometer is usually regarded to be equal to the professional life of an ophthalmologist. Because of its outstanding performance, GAT was rapidly adopted in all large glaucoma studies, where it demonstrated the ability to improve patients' outcomes. Most slit lamps in ophthalmic practices are now fitted with a Goldmann-type applanation tonometer. Therefore, GAT fulfills all the criteria outlined above for a gold standard device, except for accuracy. Goldmann realized that physiological variations in the corneal resistance to applanation due to differing thickness, curvature, and structure of the cornea

influenced pressure measurements and could cause significant measurement errors of several mmHg[2]. To date, no consistent relation between these parameters and GAT pressure readings has been defined and no correction algorithm has gained general acceptance[6]. Furthermore, the assumptions supporting traditional applanation tonometry are challenged not only by physiological variations but also by corneal surgery. Over the past two decades, a number of new techniques have evolved (such as refractive surgery, collagen crosslinking, and keratoplasty techniques) that fundamentally alter both the architecture and the biomechanical properties of the cornea. In clinical epidemiology, the term "no gold standard situation" is used to describe situations in which the reference standard is imperfect. In such situations, the next logical step is to search for an alternative standard to achieve the highest possible diagnostic accuracy[7].

Dynamic contour tonometry

DCT was introduced as an entirely novel contact tonometry principle designed to measure IOP largely independent of corneal properties. The tonometer tip creates a tight-fitting shell on the corneal surface without applanating the tissue[4]. The tip forces the cornea to assume the contour that most normal corneas adopt when the pressures on the epithelial and endothelial sides of the cornea are equal. In this simulated balance of forces exerted on the cornea, the tissue is thought to be free of internal tensions, allowing for direct transmural measurement of intraocular pressure (Figure 1).

IOP is determined by an integrated pressure sensor inside the contacting surface. As

an additional feature, the detection rate of 100 individual IOP readings per second allows the observer to record the pulsatile fluctuations of intraocular pressure and calculate the ocular pulse amplitude (OPA, Figure 2). So far, the slit-lamp-mounted Pascal® tonometer (Ziemer, Port, Switzerland) is the only commercially available tonometer that is based on the principle of DCT. Further developments based on DCT include handheld prototypes[8-10] and a pressure-sensitive contact lens[11].

Five years after the introduction of DCT, the current review assesses the published literature on DCT with regard to its potential to replace GAT as the gold standard for IOP measurement.

Accuracy of IOP readings

In the initial publication comparing DCT with GAT in a large group of healthy subjects it was shown that DCT readings were not influenced by central corneal thickness (CCT), corneal curvature, or anterior chamber depth[12]. IOP readings obtained by DCT were 1.7 mmHg higher, on average, than the IOP readings obtained by GAT. The difference between the two readings is thought to be due to different calibration techniques, as the Pascal® dynamic contour tonometer is calibrated against a true manometric pressure while the Goldmann-type applanation tonometer was calibrated based on theoretical calculations converting applanation forces into a pressure value. Numerous studies in normal and glaucomatous subjects supported these initial findings[13]. There is now a large body of evidence that IOP readings by DCT are not affected by corneal thickness or curvature, two parameters that have been well documented to influence GAT[13-24].

A surgical reduction in corneal thickness or curvature, as is achieved by refractive surgery, does influence GAT but not DCT readings[3,25,26]. Similarly, it has been shown that increasing the corneal thickness by lamellar endothelial keratoplasty influences DCT readings to a lesser extent, if at all[27]. Even increasing corneal stiffness, as is achieved by collagen crosslinking, has only a minor effect on DCT readings, while it can significantly affect GAT and applanation tonometer readings[28,29]. Recently, an increasing number of studies have proven the robustness of IOP readings by DCT after surgical interventions to the cornea, such as perforation or lamellar keratoplasties[30-32]. Similarly, there is an increasing number of reports indicating that IOP readings by DCT may be less affected than GAT by corneal disease, such as keratoconus, in the absence of surgery[29,33,34].

The validation of any tonometer should be based on manometry. Therefore, the most important study on the accuracy of DCT compared IOP measurements that were taken simultaneously by DCT and by a manometric reference sensor in a large series of cannulated human eyes during cataract surgery[35]. The mean differences between true IOP and DCT readings were 0.02 mmHg (± 1.32 mmHg) at a reference IOP of 15mmHg and 0.84 mmHg (± 1.9mmHg) at a true intraocular pressure of 35 mmHg. Together with an earlier study that revealed the true manometric IOP in cannulated eyes to be an average of 1.2 mmHg higher than indicated by GAT, it can be concluded that DCT readings accurately reflect the true IOP while GAT tends to underestimate IOP.

Modern non-contact tonometers such as the Ocular Response Analyzer try to reduce or eliminate the influence of biomechanical properties of the cornea on the IOP measurement. Therefore, parameters such as corneal hysteresis are used to

calculate a corneal compensated IOP [36]. Compared to GAT and the Ocular Response Analyzer, DCT has demonstrated good measurement precision and the best repeatability and reproducibility. However, the IOP measurements with each device were not interchangeable [37].

In conclusion, the studies mentioned above have shown that DCT measures true IOP very accurately. In contrast to GAT and other tonometers, DCT is not affected by physiological or surgical variations in corneal thickness or curvature. Taken together, DCT fulfills the requirement for accuracy outlined above to establish itself as a clinical gold standard for routine IOP readings.

Inter- and intra-observer variability of repeated IOP readings

It is generally difficult to obtain published data on the learning curve and the reliability of diagnostic reading when delegated to technical personnel. Probably the most reliable parameters for the reliability are the inter-observer (repeated measurements by different observers) and the intra-observer (repeated measurements by the same observer) variability of a diagnostic technique. Already Goldmann realized that the accuracy of GAT lies within +/- 1-2mmHg. Hence the index marks for IOP readings on the Goldmann-type tonometers are set at incremental steps of 2 mmHg. Clinical studies have shown that in routine use GAT can achieve an inter-observer variability of 0.4 to 0.8 mmHg and an intra-observer variability of 0.6 to 2.2 mmHg[37,38].

Several recent studies have compared inter- and intra-observer variability of GAT with DCT and other tonometers. In an initial small study on the accuracy of repeated measurements, four ophthalmic consultants well experienced in GAT achieved a

lower inter- and intra-observer variability with DCT than with GAT despite being instructed only 15 minutes before their first ever measurements on the use of DCT[12]. In subsequent larger and multicenter studies comparing the variability of repeated IOP measurements, DCT has consistently achieved a similar or lower inter- and intra-observer variability than GAT[37]. Interclass correlation coefficency of repeated DCT measurements reached a value of 0.9, which reflects an almost perfect reproducibility of IOP measurements by DCT[39].

The excellent measurement precision obtained in studies might be the result of a special feature of the Pascal® tonometer. In addition to the IOP and the OPA, the instrument provides a Q score which reflects the quality of the measurement. The Q score ranges from 1 (best quality) to 5 (poorest quality). The manufacturer's guidelines recommend to discard results with a Q score of 4 or 5. In most studies however, only good-quality data with a Q score of 1 or 2 were used for analysis.

A potential disadvantage of DCT is the prolonged patient cooperation that is required during IOP measurements, which makes the procedure impossible in some patient subgroups. For patients who are unable to cooperate, an alternative tonometry principle based on a shorter examination time must be available as an alternative solution. While experienced examiners require only one to two seconds to achieve a reliable IOP measurement using GAT, DCT readings require 5 to 8 seconds of constant patient cooperation. Especially in children and handicapped patients, it may be difficult to obtain high-quality DCT readings[40,41].

In summary, DCT readings demonstrate a high level of repeatability and reproducibility. Therefore, assigning the task to suitably trained technical personnel seems feasible. However, DCT requires more patient cooperation than GAT,

especially for recording reliable high-quality data. The second requisite for a gold standard diagnostic technique as outlined above is therefore only partially met.

Maintenance and consumables

Goldmann-type applanation tonometers have become famous for their exceedingly low maintenance requirements. The large majority of Goldmann tonometers delivered over the last 40 years are still in use. Sophisticated electronic devices such as the Pascal dynamic contour tonometer, the Tonopen, or non-contact air puff tonometers will never be able to match the low maintenance needs of a simple mechanical device such as the Goldmann tonometer.

There is also an obvious difference between GAT and modern contact tonometers (such as DCT) regarding the need for consumables and the costs associated with it. Costs associated with the fluorescein-stained paper strips and cleaning solutions for the tonometer tip are negligible for GAT, while single-use tonometer caps for DCT cost approximately 40 cents per patient. These running costs may retard the widespread use of DCT. In high-income areas, the difference between the apparent expenses per IOP reading may become smaller when the true expenses for the time of proper cleaning of a GAT tip are correctly accounted for. While negligence of cleaning has hardly any influence on the accuracy of GAT readings, it may cause severe damage to any modern electronic device such as the DCT. The single-use tonometer cap for DCT eliminates the risk of spreading infectious disease and renders corneal injury caused by damaged tonometer prisms impossible. In the

context of GAT, a comparable safety level can only be achieved with a strong effort for maintenance or the use of disposable GAT tips.

In summary, the virtual lack of maintenance other than occasional calibration and the negligibly low costs associated with consumables are an important factor for the continuous support of GAT as a gold standard in tonometry.

Additional diagnostic value

An important feature of DCT is the recording of continuous IOP fluctuations over a period of 5 to 8 seconds, which are then used to calculate the OPA[42]. Some early data indicate that OPA may have an additional diagnostic or prognostic value when assessing glaucoma patients or the outcome after trabeculectomy[43-46]. There are currently several ongoing studies on the interaction between OPA, ocular biomechanics, and the susceptibility of the eye to glaucomatous damage.

In the event that larger studies in the future show a clear predictive value of OPA in the management of patients, this might become a strong argument in favor of DCT as a routine diagnostic tool. The importance of OPA as an additional factor in favor of DCT is further highlighted by the fact that in countries where recording of a continuous IOP is reimbursed in addition, such as in the United States or Germany, the use of the DCT has substantially increased.

Use in landmark studies

An important prerequisite for a diagnostic technique as a gold standard candidate is its use in important outcome studies such as the Advanced Glaucoma Intervention Study or the Ocular Hypertension Treatment Study. All large glaucoma trials reported so far have used GAT as a reference device for IOP measurements. GAT readings, even if their absolute value differs slightly from true manometric IOP, are used to define target IOPs for a desired outcome in patient care.

Future clinical outcome studies will need to measure the IOP independently of CCT and the biomechanical properties of the cornea. The apparent association between low central corneal thickness and higher morbidity of glaucoma in landmark studies such as the Ocular Hypertension Treatment Study [47]may be due to the influence of CCT on false low IOP readings obtained by GAT, resulting in delayed diagnosis, insufficient treatment, and a skewed study population.

Expert commentary

GAT has been the gold standard of tonometry for more than 50 years. Its use in landmark studies supports this position. The usefulness of new tonometric principles is determined by their advantages and disadvantages relative to GAT.

GAT does not measure the IOP directly. It estimates the force that is necessary to applanate the cornea to a defined level. Therefore, IOP measurement is influenced to a certain point by the shape, thickness, and biomechanical properties of the cornea. An increasing number of patients have undergone procedures, such as refractive surgery, corneal grafting, or corneal crosslinking, that may affect these corneal properties. It is supposed that these eyes carry a risk of over- or underestimation of

IOP when measured by GAT. Correction tables (for aberrant corneal thickness, for example) have been suggested to address this well known issue, but have turned out to be of limited use. Therefore, a device that measures IOP independently of corneal properties might be more reliable.

A review of the literature indicates that DCT has exactly these characteristics, providing precise pressure measurement independent of corneal shape and tissue properties. A large number of studies have shown that DCT is unaffected (or affected to a much smaller extent) by alterations of the corneal tissue after surgical intervention.

DCT is the only device in which pressure readings were compared directly to intracameral manometric measurements in normal eyes, which resulted in IOP readings very close to the true intracameral pressure. Therefore, the precision of DCT clearly outperforms that of GAT and other tonometers.

In fact, validation of any tonometer should be based on manometry and IOP readings can be regarded as precise only if a tonometer has proven its diagnostic accuracy in the context of a special corneal disease or condition. So far, there are no manometric studies available that address measurement accuracy in patient subgroups such as keratoconus or after refractive surgery. In summary, the advantages of DCT clearly outweigh the disadvantages, which are primarily founded on handling and financial aspects.

The high cost of the tonometer head tip covers associated with DCT is put into perspective when compared to the cleaning costs of GAT tonometer heads and the cost of the GAT tonometer head itself, which has a limited lifetime of two years

(personal communication by Haag Streit). The main disadvantage is that the DCT device needs to detect several cycles of ocular pulse amplitude, which takes several seconds. DCT may not be feasible in disabled patients, children, and patients with nystagmus, while a skilled observer using GAT still manages to estimate IOP in such difficult conditions.

The unsuitability of DCT for some subsets of patients, the additional costs of maintenance and consumables associated with DCT, and the fact that until now no large outcome study has used DCT as a device for IOP measurement have prevented DCT from successfully challenging GAT's role as the present gold standard for IOP measurement.

Five-year view

GAT takes static IOP measurements that are affected by the biomechanical properties of the cornea examined. DCT contributes to the optimization of tonometry in terms of reducing its dependency from these well-known sources of measurement error. There is increasing evidence that DCT measures IOP more accurately than any other tonometer. However, accuracy studies may not be sufficient to evaluate the clinical value of a test. This value will ultimately depend on whether it is able to improve patient outcome[7]. We expect to see these improvements in the patients after corneal surgery. Over the past two decades, a number of new techniques have evolved that fundamentally alter both architecture and biomechanical properties of the cornea. In refractive surgery such as laser in situ keratomileusis (LASIK), the peripheral cut in Bowman's layer, the thinning of stroma, and the altered surface contour change the applanation properties of the residual cornea, resulting in an underestimation of intraocular pressure. This may delay diagnosis and treatment of glaucoma especially in the myopic population that is more likely to undergo refractive surgery and in which glaucoma is more common. It was found in several studies that GAT decreased after LASIK whereas measurements by DCT were not affected by the reduction of corneal thickness. Corneal collagen crosslinking represents another example where DCT might improve patient's outcome. UV-radiation in combination with a photosensitizer leads to an up to trifold increase in corneal stiffness, possibly causing false-high pressure measurements. Furthermore, we speculate that the clinical value of the OPA is likely to become more evident within the next five years. Possible applications of this parameter include conditions such as glaucoma or giant cell arteritis. In the future, it is unlikely that any single instrument for measuring IOP

will be able to meet the requirements of different ophthalmological applications. However, because of its favorable characteristics, DCT has the potential to establish itself as an alternative clinical gold standard for IOP measurement.

Key issues

- Goldmann applanation tonometry (GAT) is the established clinical gold standard for intraocular pressure (IOP) measurements. However, it is an imperfect standard in terms of accuracy. Variations in the corneal resistance to applanation due to differing thickness, curvature, and structure of the cornea influence the IOP measurements and can cause significant errors.

- Dynamic Contour Tonometry (DCT) is a contact tonometry principle designed to measure IOP largely independent of corneal properties. Calibrated against the manometric IOP, validation studies confirm that DCT represents an appropriate tonometry principle for routine clinical use.

- DCT compares favourably with GAT with regard to accuracy and repeatability. However, maintenance requirements and the lack of use in landmark studies prevent DCT from successfully challenging GAT as a clinical gold standard for the time being.

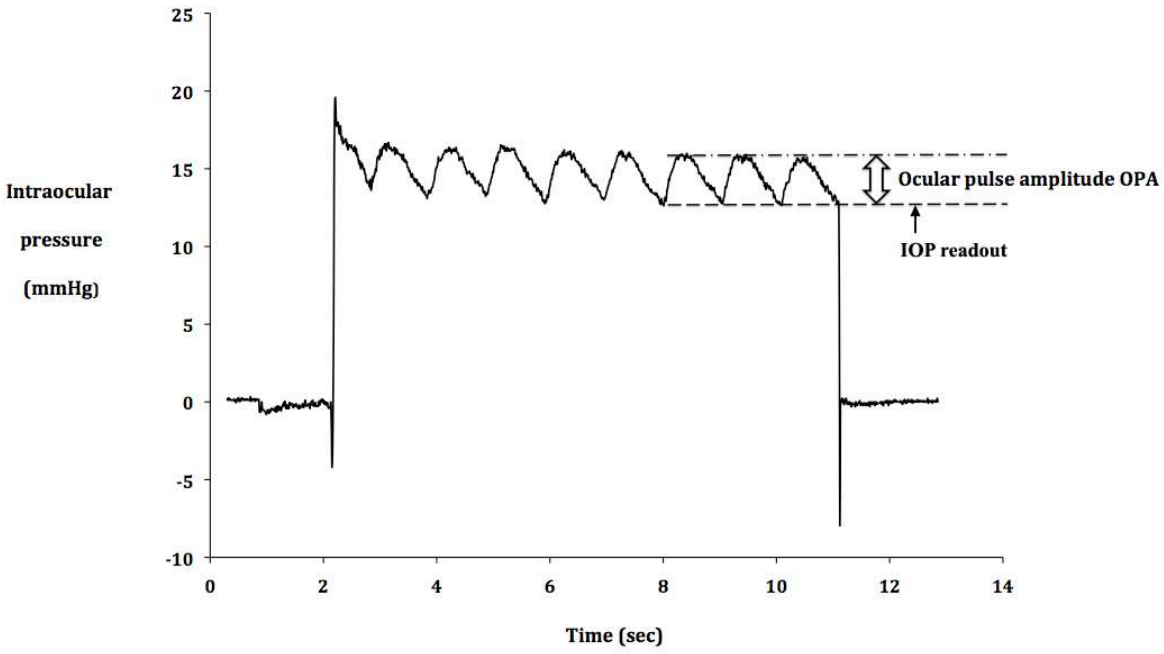
- The second parameter provided by DCT, the ocular pulse amplitude, represents a field of research that connects cerebral and ocular hemodynamics with the elastic properties of the globe. The clinical value of this parameter has not yet been defined and will ultimately depend on whether it is able to improve patient outcome.

Figure 1

Contoured tonometer tip of the Pascal tonometer with an electronic senor. The tip is covered with a thin, disposable cap.

Figure 2

Ocular pulse waves as measured with dynamic contour tonometry. The ocular pulse amplitude (OPA) is the numerical representation of the difference between the minimum (broken line) and maximum (broken and dotted line) of the pulse wave contour. With dynamic contour tonometry, the level of the mean minimum values (broken line) is displayed as intraocular pressure (IOP).



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