Method for measuring the intraocular pressure through the eyelid and device for realizing the same have no analogues in the world and are protected by the Patent of Russia № 2123798, United States Patent № US 6,394,954 B1 and Patent of Japan №3593314.

**Certificates:**

Certificate of Conformity of Russian Federation No. РОСС RU. ИМ02.В15882

Registration Certificate ФСР 2008/02643

Health Canada Medical Device Licence

**International Awards:**

26th International Inventions Show, Gold medal and diploma, (Geneva, Switzerland, 1998)

**Tonom GmbH** is the official distributor of Non-Corneal Diaton tonometer for IOP measurement through the eyelid.

**Diaton-tonometry is the unique Non-Corneal methodology of IOP measurement Through Eyelid**

- No contact with the cornea
- No risk of infecting
- No need to take out contact lenses
- No need to adjust with pachymetry
- No anesthesia drops
- No consumables
- No sterilization

IOP measurement with Diaton tonometer can be performed for the patient being in sitting or reclining position.

**Fields of Diaton tonometer application:**

- Ophthalmology (including children’s)
- General medical practice (GPs)
- Optometry
- Neurology

The unique methodology of IOP measuring with Diaton tonometer widens the possibilities in ophthalmotonometry and unquestionable advantages for doctors, optometrists and patients.

- Simplicity, quickness and efficiency for doctors and optometrists.
- Comfort and safety for the patient.
- Possibility of IOP monitoring during medicine adjustment (measuring is possible repeatedly during the day).

**Diaton tonometer is the ideal device for IOP screening.**

The technical ‘know-how” applied in transpalpebral Diaton tonometer makes this device unique in the world. It has no disadvantages compared to corneal tonometers.

Diaton tonometer makes possible to measure IOP in most complicated medical cases and is effective and irreplaceable in various situations:

- Screening examinations of the patients.
- IOP control during selection of adequate medicines
- Ophtalmotone day monitoring
- IOP measuring during contact correction (lenses are not taken out)
- IOP measuring in immobilized patients and in children
- **IOP measuring in patients with cornea pathology and allergy to anesthetics**
- **IOP measuring in patients after corneal surgeries**
### Features

<table>
<thead>
<tr>
<th>Features</th>
<th>diaton</th>
<th>Goldman</th>
<th>Shiotz</th>
<th>Air-jet</th>
<th>TONO-PEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>No direct contact with the cornea</td>
<td>+</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Displays independence from cornea curvature</td>
<td>+</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Portability</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Digital IOP indication</td>
<td>+</td>
<td>+</td>
<td></td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Measurement in sitting position</td>
<td>+</td>
<td>+</td>
<td></td>
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<td>+</td>
</tr>
<tr>
<td>Measurement in reclining position</td>
<td>+</td>
<td>+</td>
<td></td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>(some models)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Short-time measurement</td>
<td>+</td>
<td></td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Anesthesia is not required</td>
<td>+</td>
<td></td>
<td></td>
<td>+</td>
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</tr>
<tr>
<td>Sterilization is not required</td>
<td>+</td>
<td></td>
<td></td>
<td>+</td>
<td>Disposable probes</td>
</tr>
<tr>
<td>Lasik/PRK measurement</td>
<td>+</td>
<td></td>
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### Technical features

<table>
<thead>
<tr>
<th>Feature</th>
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<tr>
<td>Measurement range</td>
<td>5-60 mm Hg</td>
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<tr>
<td>Measurement error</td>
<td>Limit of the admissible measurement error in the range, not more: from 5 to 20 mm Hg - ± 2.0 mm Hg; from 20 to 60 mm Hg ± 10%</td>
</tr>
<tr>
<td>The time of a single measurement, s, not more</td>
<td>3</td>
</tr>
<tr>
<td>Supply voltage, V</td>
<td>3</td>
</tr>
<tr>
<td>Number of measurements using one battery set, not less</td>
<td>1500</td>
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<tr>
<td>Service life, years, not less</td>
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<tr>
<td>Weight, g, not more</td>
<td>89</td>
</tr>
<tr>
<td>Dimensions, mm, not more</td>
<td>174 x 26 x 20</td>
</tr>
</tbody>
</table>
Comparison of IOP measurements between Goldmann Applanation Tonometry and Ballistic Principle Diaton Tonometry in several groups of patients

N. MICHAIlIDOU, A. POLYCHRONAKOS

Ophthalmology Clinic of Thessaloniki, General Hospital” O Agios Dimitrios”
Director Dr. A. Polychronakos

PURPOSE

To compare the intraocular pressure [IOP] between the Goldmann with Applanation Tonometry and the Ballistic Principle Diaton Tonometry above the eyelids in different groups of patients. Diaton tonometer can be used as an alternative device for the screening of population and the diagnosis of glaucoma at its early stage.
METHODS

572 eyes of 287 patients were studied. The selection of patients was random. There were 45.5% of males and 54.5% of females of various ages in the group. The overwhelming majority of the patients were more than 60 years old (Figure 1). The research group contained the patients suffering from glaucoma (22.7%), ARMD (24%), diabetics (21.8%) and healthy patients (43.8%). Obviously, there were a few patients that suffer from glaucoma and simultaneously they were diabetics. The intraocular pressure was measured in both eyes from all the above patients with the exception of 2 to whom it was measured only one eye. The IOP was measured with the Goldmann and the Diaton tonometer and the values were recorded. The measurements with the Goldmann tonometer were carried out by all doctors of the clinic whereas the measurements with the Diaton tonometer were carried out by the same doctor and always with the same method. The patients were in sitting or lying position during the examination with the Diaton tonometer.

RESULTS

There was statistically significant correlation between the measurements of both tonometers (p < 0.001). 83.11% of the research group had absolute difference between the values of the two measurements up to 2 mmHg. There is also significant correlation between the “absolute difference between the
values of the two measurements” and glaucoma (p < 0.05). Moreover, absolute difference between the values of the two measurements seems to be related with age but more measurements are needed to verify this relation statistically. For the so-called “healthy”, divergence between the measurements of the 2 tonometers greater than 5mmHg is observed for less than 5% of the sample, whereas for the patients with glaucoma divergence greater than 5mmHg is measured for the 15% of the sample. There is no correlation between divergence and parameters such as gender, diabetes, ARMD, thyroid ophthalmopathy, refractive abnormalities and cataract (p>0.05).

<table>
<thead>
<tr>
<th>Deviation between measurements</th>
<th>Frequency</th>
<th>Percent %</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>170</td>
<td>31.10</td>
<td>31.10</td>
</tr>
<tr>
<td>1</td>
<td>182</td>
<td>33.28</td>
<td>64.39</td>
</tr>
<tr>
<td>2</td>
<td>102</td>
<td>18.71</td>
<td>83.11</td>
</tr>
<tr>
<td>3</td>
<td>28</td>
<td>5.14</td>
<td>88.25</td>
</tr>
<tr>
<td>4</td>
<td>21</td>
<td>3.36</td>
<td>96.1</td>
</tr>
</tbody>
</table>

**CONCLUSION**

Ballistic Principle Diaton Tonometry can be used as an alternative for the measurement of the intra-ocular pressure above eyelids for patients with recent ocular surgeries, after refractive surgeries, with severe corneal injuries, with corneal apoptosis of epithilium and with large pterygium. Additionally, children can be measured easily with Diaton for IOP and also it can be used in patients with mobility problems.
Clinical use of Diaton tonometer in the research of the influence of the anti-hypertensive drugs on the Intraocular pressure level

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1. Russian State Medical University, Department of Clinical functional diagnostics, Moscow, Russia
2. Central Clinical Hospital of the Administrative Department of the President of Russian Federation, Moscow, Russia

AIM AND BACKGROUND

Analysis the influence of the anti-hypertensive medicines of different pharmacological groups on the intraocular pressure (IOP) level in patients.

MATERIAL & METHODS

15 patients of the control group without ophthalmopathology who were measured IOP with Non-corneal Tonometer (NCT) and with Diaton. 82 patients with arterial hypertension of the 1-st and 2-nd degree with high cardiovascular risk, 10 patients from this group had the Primary open-angle glaucoma (POAG). Anti-hypertensive drugs were prescribed after 3-5 days elimination period in average therapeutic doses. We used diuretics (Hydrochlorothiazide 12,5-25 mg/day), calcium channel-blocking agent (Amlodipine 2,5-5 mg/day), beta-adrenergic blocking agents (Bisoprolol 2,5-5 mg/day), inhibitor of angiotensin converting enzymes (iACE) (Enalaprilum 5-10 mg/day), nitrates (Isosorbide mononitrate 40-50 mg/day and Isosorbide dinitrate (1,25 mg/day). All the patients were measured IOP on both eyes with transpalpebral diaton tonometer before taking the medications, 3 and 24 hours after taking the medications and after 7-14 days. The IOP was measured initially during the use of Isosorbide dinitrate as the spray (ISOKET) 30, 60 and 90 minutes after taking the medicine.

RESULTS

The results of IOP measuring in the control group were reliable (mean IOP NCT 19,4±1,5 mm.Hg., mean IOP Diaton 22,6±2,8 mm.Hg.). The reliable change of IOP wasn’t detected in patients who were taking diuretics, calcium channel inhibitors, iACE and α-adrenergic blocking agent neither during the acute pharmacological testing, nor during the intake of the anti-hypertensive medicines. The reduction of the IOP was found during the intake of the β-adrenergic blocking agents (mean initial IOP 19,2±1,3 mm Hg, IOP 3 hours after the intake 19,1±1,5mm Hg, IOP 24 hours after the intake 18,9±1,1 mm HG, IOP after 7-14 days 16,3±1,4 mmHg). The increase of IOP was observed during the intake of the nitrates (mean initial IOP 18,8±1,2, mean IOP after 3 hours 20,1±1,2, mean IOP after 24 hours 19,1±1,1, mean IOP after 7-14 days 23,8±1,3 mm Hg). These changes were found during the first
days of the treatment and increased during the whole course of medicines intake. According to the results of the acute pharmacological testing the IOP increase was observed 40 min after the intake of one dose (1,25 mg) of Isosorbide dinitrate and remained increased up to 1,5 hours on patients with POAG (mean initial IOP 22,7±1,8mm Hg, IOP after 40 min 26,1±1,9 mmHg, IOP after 90 min 25,8±1,9 mmHg)

CONCLUSIONS

Portable, ergonomic ophthalmotonometer diaton suits perfectly in general medical practice for IOP monitoring to make anti-hypertensive drugs treatment safe and qualified.

Comparison of Accuracy of Diaton Transpalpebral Tonometer Versus Goldmann Applanation Tonometer, Dynamic Contour Tonometer and Ocular Response Analyzer

Henry D. Perry, MD (1), S.E. Avetisov MD (2), V.P. Erichev MD, A.A. Antonov MD, A.R. Illarionova MD(3)

1. Ophthalmic Consultants Of Long Island
2. Eye Diseases Research Institute of Russian Academy of Medical Sciences, Moscow
3. Central Clinical Hospital of the Administrative Department of the President of Russian Federation, Moscow

PURPOSE

To compare intraocular pressure measurements obtained with the diaton transpalpebral tonometer with those from ocular response analyzer (ORA), dynamic contour tonometry (DCT) and Goldmann applanation tonometry (GAT) in patients diagnosed with primary open-angle glaucoma (POAG) and glaucoma suspects, and to determine the effects of central corneal thickness (CCT) and corneal hysteresis (CH) on intraocular pressure (IOP) measurements with these devices.

PATIENTS

40 patients (80 eyes) age 42-83 years with POAG and glaucoma suspects were included in the study.

Research exclusion criteria:
– Patients who came through the eye surgery;
– Patients with cornea, sclera and lid pathology;
– Patients with high-grade myopia or hypermetropia;
– Patients with visual acuity less than 0,1
METHODS

**IOP was estimated using:**

- CCT was estimated using ultrasonic pachymeter that was built-in ORA
- The average of ORA (corneal compensated IOP [IOP-ORAcc] and Goldmann-correlated IOP [IOP-ORAg]), DCT, GAT, and Diaton tonometer levels were compared and the devices were examined with respect to CCT and CH
- Spearman’s correlation tests were used for statistical analysis

RESULTS

- Mean CCT was 561,2±32,4umum and mean CH was 10.6+/-2.0 mmHg
- Mean IOP, measured with the tonometers that were used in the research

<table>
<thead>
<tr>
<th></th>
<th>IOP, mmHg</th>
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<tbody>
<tr>
<td></td>
<td>M±σ</td>
</tr>
<tr>
<td>GAT</td>
<td>18,4±4,1</td>
</tr>
<tr>
<td>ORA IOPg</td>
<td>18,4±3,5</td>
</tr>
<tr>
<td>ORA IOPcc</td>
<td>18,2±3,4</td>
</tr>
<tr>
<td>DCT</td>
<td>18,9±4,1</td>
</tr>
<tr>
<td>Diaton</td>
<td>17,0±3,0</td>
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</tbody>
</table>
Correlated rates relations

<table>
<thead>
<tr>
<th></th>
<th>Diaton</th>
<th>ORA IOPcc</th>
<th>DCT</th>
<th>GAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diaton</td>
<td>0.96</td>
<td>0.96</td>
<td>0.87</td>
<td>0.61</td>
</tr>
<tr>
<td>ORA IOPcc</td>
<td>0.96</td>
<td>0.89</td>
<td>0.56</td>
<td></td>
</tr>
<tr>
<td>DCT</td>
<td>0.87</td>
<td></td>
<td>0.73</td>
<td></td>
</tr>
<tr>
<td>GAT</td>
<td>0.61</td>
<td>0.56</td>
<td>0.73</td>
<td></td>
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</table>

The performed analysis of correlation between IOP meanings shows high conformity of results of Diaton with IOP-ORAcc and DCT.

The differences between the measurements of DCT, ORA and Diaton were statistically significant.

**CONCLUSIONS**

Transpalpebral Tonometry is an accurate method of IOP measurement that is also independent from the biomechanical characteristics of cornea.

It can be recommended for IOP measurements of patients diagnosed with glaucoma including those cases where cornea pathology or cornea characteristics have been altered.

**Poster at AAO 2010**
DIATON TRANSPALPEBRAL TONOMETRY VERSUS
STANDARD GOLDMANN APPLANATION TONOMETRY

Tran Thi Phuong Thu, Phan Thi Anh Thu

BACKGROUND

The new digital Diaton tonometer measures intraocular pressure through the eyelid without corneal contact.

PURPOSE

The purpose of this study was to compare intraocular pressure (IOP) measurements obtained with the Diaton transpalpebral tonometer (DT), and Goldmann applanation tonometer (GAT).

METHOD

This study included 315 eyes selected randomly from the outpatients who attended Eye Hospital Hochiminh City. The intraocular pressure of each eye was measured with DT and GAT within 5 minutes in random order.

RESULTS

The average IOP reading was 18.49 ± 6.49mmHg for DT and 18.50 ± 8.04mmHg for GAT. The mean difference between DT and GAT was -0.02 ± 3.86mmHg (p>0.05). There were very high correlation between IOP readings obtained using DT and GAT (r=0.88; p<0.001). Compared with GAT 72.06% of the IOP readings measured by DT were in an interval of ±3mmHg. A cutoff value of 21mmHg gives a sensitivity of 89.02% and specificity of 91.85%

CONCLUSIONS

The eyelid tonometer DT may be helpful as a screening tool in routine eye exams and especially when GAT is not applicable.

Clinical Use of Transpalpebral Diaton Tonometer in General Medical Practice

U.M. Devyataeva, I.G. Cherkashina, N.A. Golubeva, V.S. Polovinkina

The I.M. Sechenov Moscow Medical Academy, Department of Family Medicine

For the present time it becomes more and more important to determine new ways and new technologies that will allow Family doctors to help solve a problem of Blindness due to Glaucoma, the second most common cause of blindness Worldwide.
It is estimated that 4.5 million people globally are blind due to glaucoma. This number will rise and more than double to 11.2 million by 2020. It is important to note that due to the silent progression of this disease up to 50% of affected people in the developed countries are not even aware of having glaucoma, especially in the early stages. This number is as large as 90% in underdeveloped parts of the world.

How can Family Doctors Help with this ongoing and life-changing problem? Today in the family and general practice - we have quick and easy methods to measure blood pressure and glucose blood level, these important tests allow us to decrease the risk of heavy complications of hypertensive disease and diabetes – As a result save patients’ lives!

This raises a number of questions - Why should a family doctor be involved with pre-screening for glaucoma?

We know that for ophthalmologists, measuring Intraocular Pressure (IOP) is one of the main obligations and every day practice to diagnose eye diseases when seeing patients 40 years and older.

Besides the normal IOP range, there are the following pathological states of the IOP: hypotension and hypertension. Hypotension is a symptom of various difficult eye diseases, such as retinal detachment, penetrating wound of the eye, mesenchymal and mesodermal dystrophy, among others. Elevated IOP can indicate glaucoma, as well as a potential symptom of inflammatory diseases of the eye, intraocular and/or orbital tumor process, or exophthalmos of various different causes. IOP abnormality can be a symptom of different diseases. Therefore, regardless of the reason why the patient decided to consult the family doctor, it is necessary to evaluate IOP in order to perform primary diagnostics of his condition and decide an issue of necessity and urgency of a consultation by an ophthalmologist.

One of the reasons of late detection of glaucoma at its early stage is the absence of clear symptoms that attract patients’ attention - in most cases there is no pain. Once incurred, visual damage is mostly irreversible, and this has led to glaucoma being described as the “silent blinding disease” or the “sneak thief of sight”. It is considered that the rise of intraocular pressure (IOP) is one of the main risk factors of glaucoma development. By following up with patients, having information about possible genetic predispositions and paying close attention to patients in high-risk groups, family doctors have the opportunity to detect glaucoma at its early stage with the ability to measure intraocular pressure with an easy and available way – non-invasive, transpalpebral, over the eyelid tonometry.

The purpose of our research was to determine the necessity of IOP measuring by a general practitioner (family doctor) for intraocular pressure estimation.

Transpalpebral tonometer diaton (GRPZ, Russia) was used for IOP measuring. The device is user-friendly, does not contact directly with the eyeball during the measurement and the test is done through the upper eyelid.

Since the measurement is done over the upper eyelid there is no contact
with the eyeball, there is no risk of infection during the test, making this procedure safe. Transpalpebral tonometry doesn’t require the use of anesthesia drops and staining agents and it is comfortable for the patient and saves time for medical staff. IOP measurement with diaton can be taken with the patient being in sitting position or laying down. Since the measurement is done through the upper eyelid and over the sclera, not the cornea, corneal parameters such as corneal thickness, crookedness or past corneal surgeries do not affect the IOP reading - even contact lenses do not need to be removed for accurate reading.

Intraocular pressure measurements were carried out either by general practitioners (family doctors), nurses or other assisting medical technicians.

• 440 patients were examined, ages 10 – 92.
• 404 patients had normal values of intraocular pressure.
• 24 patients, age 66 – 92, with diagnosed glaucoma, who use constant medication, but didn’t have regular IOP monitoring, had high intraocular pressure which indicates an advance of the illness.

3 patients had high intraocular pressure which was detected for the first time, and resulted in diagnosed glaucoma after consultation with ophthalmologist.

8 patients had low intraocular pressure and they were referred to an ophthalmologist.

5 patients had upper, border line normal IOP. After further consultation by the ophthalmologist the IOP was normal.

Thus, the comparison trial results that were carried out, allowed to make the following conclusions:

1. Tonometer diaton device is the non-invasive, safe method which is comfortable for the patient and handy for the doctor for IOP estimation.

2. You can carry out repetitive daily monitoring of intraocular pressure with diaton without losing quality of the consecutive measurements. The importance of this monitoring is unquestionable for progress monitoring and detecting pathology advancement, and for selecting the optimal choice of treatment tactics during regular medical check-ups. When you are recording the log journal of IOP readings, you help an ophthalmologist to see the clinical presentation, take into account individual features of the patient and choose the unique glaucoma treatment regimen.
3. diaton allows, without damage to the patient, to determine intraocular pressure and to control medications which can lead to possible ocular hypertension, as their secondary effect.

4. Maintenance of the device in the family doctor’s office presents no difficulties.

5. diaton can be used either by a family doctor or by any trained medical staff within the general practice department.

Considering the necessity and availability for general doctors to obtain IOP, without the need for specialized ophthalmologic office setup, we came to the conclusion that the evaluation of intraocular pressure is an integral and especially significant part of the general medical examination. Only joint efforts of the family doctor and ophthalmologist can make a prognosis for ophthalmologic diseases and save vision for many years.

To emphasize the importance of this quick intraocular pressure test by family doctors and its potential benefits on a larger scale, being here in beautiful Mexico with a population of 111 million - in correlation with an outcome of our study we would be able to diagnose and potentially save vision of about 1 million people.

Please note that other country statistics may be lower or higher due to demographics and population base.

And a last statistics that needs to be shared with: There are only 150,000 ophthalmologists for a world of 7 billion people - that comes to 46,000 people per ophthalmologist - the people and the eye doctors surely need your help.

**WONCA WORLD CONFERENCE 2010**

*Cancun, Mexico*

*Oral Presentation*

*Presenter: A.R. Illarionova, M.D., Sechenov Moscow Medical Academy*
Accuracy of Transpalpebral Tonometer Compared to Goldmann Applanation Tonometer in Normal and Glaucomatous Eyes

Authors: M.A. Latina, T.A. Shazly, R. Iospa, E.W. Chynn

Reading Health Center, Reading, MA; Ophthalmology, Massachusetts Eye and Ear Infirmary, Boston, MA; Bicom, Inc., New York, NY; Park Avenue Laser Vision, New York, NY.

BACKGROUND/PURPOSE

To compare intraocular pressure measurements obtained with the Diaton, a new digital transpalpebral indentation tonometer, with those from Goldmann applanation tonometry (GAT) in normal and glaucomatous eyes.

METHODS

Sixty six eyes of 33 consecutive subjects, 46 eyes having glaucoma and 20 eyes without glaucoma, were included in the study. Patients were excluded with clinically significant lid, scleral or motility disorders, a history of recent intraocular surgery or previous trabeculectomy, glaucoma shunt, or scleral buckle.

Goldmann tonometry was performed by one of the authors, while the Diaton measurements were performed by another author in a masked fashion. Applanation measurements were performed in an upright sitting position taking two IOP readings.

Diaton measurements were performed until the device signaled acceptable measurements, with the back of the chair reclined to achieve a horizontal head position.
RESULTS

The age ranges:
- glaucoma group - 46 to 90 years (69.37 + 10.07):
- normal group - 62 to 88 years (76.85 + 9.07)

- Goldman applanation IOPs for the normal group ranged from 11 to 19 mmHg (mean 14.55 and SD, 2.32), while the Diaton measurement for the same group ranged from 12 to 19 mmHg (mean 14.95 and SD, 2.21).
- For the glaucoma group, the Goldman applanation IOP ranged from 6 to 31 mmHg (mean 15.42 and SD, 4.77), while the Diaton measurement for the same group ranged from 9 to 31 mmHg (mean 16.13 and SD, 4.30).
- The Pearson’s correlation coefficient (r) between Goldman applanation pressure and Diaton pressure was 0.725 for the whole group (66 eyes, p < 0.01) and 0.778 for the glaucoma group with p < 0.01.
- In both normal and glaucoma groups, 15.15% of the Diaton measurements exactly the same as the Goldman applanation tonometer, Diaton underestimated the IOP compared to the applanation pressure in 37.87% (1-6 mmHg), and over-estimated the IOP by (1-8 mmHg) in 43.93% of the eyes tested.
- The difference between Diaton and GAT reading was ≤ 1 mmHg in 51.51% of eyes measured, ≤ 2 mmHg in 65.15%, ≤ 3 mmHg in 83.33%, ≤ 4 mmHg in 89.39%, and was 5-8 mmHg in 10.6% of eyes measured.
CONCLUSION

The Diaton, a transpalpebral measurement device, which avoids corneal contact, correlates within 3 mm Hg of Goldmann applanation tonometry in 83.3 % of eyes in this limited study.

Diaton tonometer may be a clinically useful screening device for measuring IOP.

REFERENCES


ARVO 2009
IOP measurements with new transpalpebral tonometer appear as accurate as gold standard device

FORT LAUDERDALE, Fla. — The Diaton tonometer measured IOP within 3 mm Hg of the gold standard applanation tonometer in a majority of glaucomatous and nonglaucomatous cases, a study found.

Mark A. Latina, MD, and colleagues found that the Diaton tonometer (Bi-com) measured within 3 mm Hg in 83.3% of eyes when correlated with measurements by Goldmann applanation tonometry.

In an interview with Ocular Surgery News at the Association for Research in Vision and Ophthalmology meeting, Dr. Latina said IOP measurements with the Diaton tonometer are equivalent to Goldmann applanation tonometry. The Diaton device offers a safe, noncontact method of measuring pressure via the eyelid, he said.

“It works,” Dr. Latina said. “It gives you a reasonable estimation of the pressure without having to anesthetize the cornea through a transpalpebral approach.”

Dr. Latina and colleagues presented results of the study in a poster presentation. The study examined IOP measurements in 66 eyes of 33 consecutive subjects; 46 eyes had glaucoma and 20 did not. Measurements were masked, with one researcher using Goldman tonometry and another using the Diaton.

Posted on the OSN SuperSite May 6, 2009

Handheld tonometer offers simple, reliable way to measure IOP
Pen-like tonometer designed to be patient-friendly
(Abstracts from publications in Ophthalmology and Optometry Times)

By Jennifer A. Webb. Reviewed by John Hope, MD, and Mark Latina, MD

Long Beach, NY—A handheld tonometer that measures intraocular pressure (IOP) through the eyelid and over the sclera is proving helpful for optometrists faced with patients who are apprehensive about seeing an instrument approaching their eyes or who have a corneal abnormalities.

The tonometer (Diaton, BiCOM, Long Beach, NY) is a pen-like instrument that measures IOP within seconds without the need for anesthesia or sterilization. Approved by the FDA in 2006, the instrument has been the subject of numerous clinical trials, where it has been found comparable to the eye doctor’s “gold standard” – the Goldmann applanation tonometer.

The device appeals to optometrists and ophthalmologists who see pediatric patients and those with patients who have corneal edema or erosions, or have keratoprosthesis. Because the device is used on the upper eyelid, out of the patient’s field of vision as they recline and look at a 45-degree angle,
they do not tend to blink or squeeze their eyes shut prior to the reading, which can skew the IOP measurement.

“It is convenient for the doctor and painless for the patient,” the company’s CEO, Roman Iospa said. “There is really no discomfort, especially for the patient who might be slightly anxious.”

H. Arnold Papernick, OD, an optometrist in private practice in Mt. Pleasant, PA, said the device has been helpful when examining pediatric patients or anyone who is averse to objects coming at their eye. Excessive blinking can cause IOP measurements to read abnormally high, he explained.

Mark Latina, MD, and Tarek Shazly, MD, members of the Department of Ophthalmology, Massachusetts Eye & Ear Infirmary, Boston, MA, and Emil William Chynn, MD, an ophthalmologist in private practice at Park Avenue Laser in New York, coordinated a study of Diaton tonometer to compare IOP measurements taken with Diaton with those from the Goldmann applanation tonometer in normal and glaucomatous eyes.

In both the normal and glaucoma groups, 15.15% of the Diaton measurements were exactly the same as those obtained with the Goldmann tonometer. Diaton under-estimated the IOP compared with the Goldmann in 37.87% of eyes, and over-estimated the IOP in 43.93% of eyes.

Meanwhile, John Hope, MD, an ophthalmologist in private practice in Oklahoma City, OK, and a diplomate, American Board of Ophthalmology, said he is impressed with the instrument and prefers it because patients “hate the non-contact tonometry” and applanation tonometry is time-consuming and often requires support staff. He has used the instrument routinely on every patient for at least six months.

Ophthalmology Times, October 15, 2009
Optometry Times, November 2009

Eye Pressure Measurement for Glaucoma Detection and Treatment

Seppo similä LKT company, the head of research, Pedihealth Oy Company, Oulu, Finland

One of the risk factors of glaucoma development is the intraocular pressure increase. To decrease the progression risk of the disease it is necessary to prevent the progression of glaucoma optical neuropathy. It is necessary to learn to use devices for eye pressure measurement correctly. Pressure measurement in the superior eyelid area is safe and does not give patients any troubles. It is easy to learn the operation method of the device after a short familiarization for the medical personnel of the health centers. This article is based on the training program of students Ricca Ervasty and Yenny Nousy-aynen, which was held in autumn 2008.
Glaucoma (from ancient Greek «greenness of sea») is the disease caused by a disturbance of the intraocular pressure regulation, the progressive damage of an optic nerve. Glaucoma symptoms can be unnoticed for a long time. The reasons of disease are not studied entirely. In 2006 in Finland there were 72,223 people with glaucoma, among them 24,049 were men and 48,174 were women. According to research nearly half of them did not feel any symptoms. People over 45 need to examine their eyes once a year, and people over 60 should visit ophthalmologists more often. It is also recommended to reduce intervals between medical examinations for people with myopia as well as for people with a genetic predisposition to the disease. The treatment should correspond to age-related changes, eye pressure measurement results and ophthalmologist’s examinations.

The eye examination of drivers at health centers is limited to visual acuity and visual field check only.

Table 1. Glaucoma detection at an early stage through the eye pressure measurement.
Relates to a risk group.

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Risk volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Before 40 y.o. 0,6%, over 40 y.o. 1,5%</td>
</tr>
<tr>
<td>Eye pressure 22-29 mmHg</td>
<td>10-13 times</td>
</tr>
<tr>
<td>Myopia (short-sightedness) over -3D</td>
<td>2-4 times</td>
</tr>
<tr>
<td>Pseudoexfoliation</td>
<td>5-10 times</td>
</tr>
<tr>
<td>Genetic predisposition</td>
<td>3-9 times</td>
</tr>
<tr>
<td>Hypermetropia (long-sightedness)</td>
<td>Small anterior chamber, visual field limitation</td>
</tr>
<tr>
<td>Diabetes, blood-vessel diseases</td>
<td>Extensive risk</td>
</tr>
</tbody>
</table>
The eye pressure measurement is made exclusively at people with evident symptoms of glaucoma or in connection with the disease detection. The glaucoma treatment in a health center is based on eye pressure measurement results and ophthalmologist’s research. As medical and optical services in our country are unevenly distributed, glaucoma detection and its diagnostics are not carried out in full.

The disturbance of the intraocular pressure regulation is the most important and common factor leading to an optic nerve damage and glaucoma, visual field reduction and finally blindness development. However, the disturbance of the intraocular pressure regulation is not the only reason of all glaucoma cases, since researches have shown that approximately half of patients at the incipience had standard 10-21mmHg pressure and the optic nerve damage at the same time. So every case is individual.

The glaucoma diagnosis is made on the basis of eye pressure measurement results, optic nerve examination, visual field and anterior chamber angle (gonioscopy). Nevertheless, nowadays there is no description of diagnostics criteria for glaucoma and uniform terminology. Actions on the glaucoma diagnostics require joint efforts of health centers, opticians and ophthalmologists. The task of the local health centers is to reveal a risk group through the eye pressure measurement and carry out the further glaucoma treatment.

**INTRAOCULAR PRESSURE MEASUREMENT**

The intraocular pressure measurement or ophthalmotonometry, primary actions on the disease recognition are the important part for the eye state examination. Tonometry is expressed in an intraocular pressure (IOP) value mmHg.

There are different methods of examinations by opticians, therapists and ophthalmologists. Opticians rely on intraocular pressure measurement results and ophthalmologist’s conclusion. An ophthalmologist examines eyes completely. A therapist defines visual acuity, a visual field, carries out eye ground examination and measures intraocular pressure. When measuring pressure, eye elasticity is applied, which allows measuring pressure on the external side.

The technique of intraocular pressure measurement with devices is based on external pressure for visual organ deformation and its interpretation. The more external pressure is required for eye deformation, the more internal pressure.

For the pressure measurement both devices are used, contact an eyeball (CT or contact tonometer) and not-contact (NCT non-contact tonometer). For the pressure measurement with contact devices it is necessary to fix an eyeglobe, these actions are carried out by a doctor or a nurse under the doctor’s supervision. Opticians use a noncontact method that provides speed, accuracy and good results.
EYEGLOBE CONTACT METHOD

Schotz tonometer (indentaa tonometri) is the oldest manual tonometer which is used so far. During procedure the patient lies, his eyeglobe is fixed; the device is set on a cornea. Pressure on the cornea is performed with the device. The more pressure, the less depression on the cornea. The result is shown on a mechanical scale in mmHg value.

For the intraocular pressure measurement Goldmann tonometer (GAT tonometer) has been considered as a "gold standard" for a long time. It is used as a standard for all devices measuring eye pressure. The tonometer usually joins a corneal microscope, and results are obtained under the examination control. For the measurement with this tonometer is necessary to fix an eyeglobe, and the procedure is carried out by a doctor.

ELASTOTONOMETER

Measurement with elastotonometer iCARE does not require fixation on an eyeglobe. During measurement the disposable sensors, which easily and cautiously contact with cornea are used. The activity of this device is grounded on an electromagnetic induction. Advantage of the device is the speed and minor propulsive energy (speed up to 0,3 m/s, weight 26mg). Frequently patient at all does not feel a procedure.

The study of elastotonometer have begun in Finland in the second half 1990. The device was introduced on the market by Tiolat Oy corporation in autumn 2003. At once it has received wide distribution in Finland and strongly has taken the place in medical practice as practically alone device.

NON-CONTACT TONOMETERS

The first contactless tonometer was shown in 1972. In the basis of its activity lies the technique of an air injection on a cornea of an eye (Air-puff) / Results of research - by quantity of uniformly injected air on a cornea of an eye. The further modifications of the device have made it convenient in maintenance. Now different models are used in practice, such as Keeler, Pul-sar and Reichet. During a procedure the patient sits, the optical motions are formed by air weight of a metering tonometer. The device has a small size, it is convenient for transportation.

TONOMETERS METERING PRESSURE IN THE SUPERIOR EYELID OF AN EYE

Technique of measurement with Diaton tonometer, grounded on measurement of elasticity of an eye is conducted by free pressure for the superior eyelid by a rod of the device. The device measures the value automatically, according to eye pressure in mmHg. The device has the small size (17,4x2,6x2,0см), light (89gr), outwardly resembles the pen.
Table 2. Advantages and disadvantages of Diaton tonometer in comparative research with other devices.

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does not cause anxiety to the patient</td>
<td>Dependent on professionalism of staff which is making measurements</td>
</tr>
<tr>
<td>Speed of measurement</td>
<td>Effecting the result of position of an eyeglobe, line of sight fixing</td>
</tr>
<tr>
<td>The simplicity of measurement</td>
<td>A buzzer can trouble the patient</td>
</tr>
<tr>
<td>Reliability of measurement</td>
<td>Slight tingling of eyelid</td>
</tr>
<tr>
<td>Measurement in lying positioning</td>
<td>Inconvenient for patient sitting position</td>
</tr>
<tr>
<td>Self-sufficiency</td>
<td>Hazard of switching-off during a procedure</td>
</tr>
<tr>
<td>The device is of the small size, is convenient for transportation</td>
<td>Requires a special case</td>
</tr>
</tbody>
</table>

The device is designed in Russia at Ryazan State Instrument-making Enterprise. At realization of a procedure the patient is preferentially lies on his back. He is asked to look upwards angularly 45 degrees. The tip of the device is set close to eyelashes edge so that it will be placed in the middle of imaginary vertical to an eyeglobe. For correctness of the installation the device is provided with beep. If the device is established not upright, the buzzer sounds, at the exact installation the buzzer becomes silent. The measurement is made up to 6 times, the average result is injected on the display by pressing the key.

MATERIALS ON TONOMETERS STUDY

By order of the company Pedihealts Oy within the framework of the OAMK program training of the students, developed by Ricca Ervasty and Yenny Nousayynen, the testing was conducted for matching activity of three different devices Keeler Pulsair, Reichert Ophthalmic and Diaton. 120 persons participated in testing, the measurement of pressure was conducted on both eyes. Age groups 20-85 years. Average value by results of measurement of all three tonometers of the right eye 11,7, left eye 11,74 mmHg. In the table 3 the average values and their dispersions (mmHg), obtained at measurement by different devices are shown. The results, obtained by different tonometers, slightly differ, but there is no considerable distinctions for statistics. By materials, only three probationers had pressure more than 20 mmHg.
Table 3. Average values and their dispersion, obtained as a result of measurement by different devices.

<table>
<thead>
<tr>
<th>Tonometer</th>
<th>Total</th>
<th>Right eye</th>
<th>Left eye</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keeler</td>
<td>119</td>
<td>13,13+1,50</td>
<td>12,73 ± 1,79</td>
</tr>
<tr>
<td>Reichert</td>
<td>119</td>
<td>10,41 ± 1,70</td>
<td>10,32 ± 2,11</td>
</tr>
<tr>
<td>Diaton</td>
<td>120</td>
<td>11,53 ±2,60</td>
<td>12,02 ±3,12</td>
</tr>
</tbody>
</table>

The straight regression would be more informative, if the tested group included more patients with ophthalmohypertension. Unfortunately, there is no sufficient material in Finland.

In the USA at Colorado university Theodore H. Curtis, Douglas I Mackenzie, Robert J. Noecker and Malik Y. Kahook have made the comparative analyses of results of measurement of an eye pressure for the patients suffering from glaucoma in hospital by Diaton and Tono-Pen devices. Average pressure on Diaton 16,24mmHg, on Tono-Pen 16,37mmHg. Comparative boundaries of eye pressure - 8-33mmHg and straight regression under the analysis y=0,9955x. By the results of analyses Diaton was recognized the best device for measurement of eye pressure for adults and children.

THE PREVENTIVE MEASURES OF ORGAN VISION DAMAGES

The purpose of detection and treatment of glaucoma is preventing the development of blindness. For today there are not enough researches, dedicated to preventive measures of organ vision damage. The purpose of detection and treatment of glaucoma is preventing the development of blindness. For today there are not enough researches, dedicated to preventive measures of organ vision damage.

The hazard of glaucoma disease is magnified with age. In the age group higher 50 years it is detected on the average for 1,5-2,0 %. Seven times there are more people with suspicion on glaucoma, that equals to the sum of all ill.

For the last five years the reduction of field boundaries of vision for 5% of the patients is marked, for them the eye pressure was considerably increased. For the same period quantity of people suffering from glaucoma from initial stage up to full blindnesses in the age of 30-40 years has increased. In the age group 70-79 years detection and the treatment of a glaucoma is ordered. Nevertheless, in the ordered program the poor notice is given to researches of disease. The development of tonometers considerably simplified intraocular measurements. Now these devices are used in all health centers. Today it is necessary to activate detection of glaucoma.
One product potentially on the ophthalmic wish list is a unique new ocular pressure measuring device that received Food and Drug Administration (FDA) approval this year. The pen-like device, dubbed the transpalpebral Diaton tonometer (BiCom, Long Beach, New York) measures intraocular pressure (IOP) through the eyelid and requires no direct contact with the cornea, as other methods have previously necessitated.

Henry D. Perry, M.D., clinical professor of ophthalmology, Cornell Weill School of Medicine, New York, said the device, which is used with the patient’s eyes closed, is much less anxiety-provoking for people. “Patients often have a fear of anything coming toward their eyes,” he said. “With their eyes closed there is less guarding and fewer false readings as when somebody squeezes their eyelids.”

The transpalpebral tonometer works by pressing it to the closed eye and depressing a plunger that gently hits the lid. “By the amount of pressure exerted on the plunger when striking the eyelid and slightly indenting the globe, it can judge the IOP within 2 to 4 mmHg, when compared with the Goldman applanation tonometer (Haag Streit, Mason, Ohio), which is the standard of care,” Dr. Perry said.

He said he did a study where he evaluated 100 consecutive patients and found a 95% correlation with the Goldman tonometer, proving its accuracy. However, there is a bit of a learning curve for some technicians. Dr. Perry said there was one technician in his practice whose results were always precise, while others had outcomes that varied.

Dr. Perry said the new handheld tonometer, has a good fit for screenings in large clinics, where technicians or optometrists may be in charge. “I think in settings like that it may be easier to use,” Dr. Perry said. It may also be better for children.
Transpalpebral tonometer application during intraocular pressure evaluation in the patients with refraction anomaly before and after keratophotorefractive surgery

Prof. A.P. Nesterov, MD., T.B. Dzhafarli, MD., A.R. Illarionova, MD. Russian State Medical University, Moscow.

Cornea, as the basic optical lens of the eye, is the main element to be influenced during various, and first of all laser, surgeries with refractive, reconstructive, optical and other purposes.

Great success of the modern keratorefractive surgery, especially excimer-laser cornea microsurgery (FRK, LASIK, LASEK, Epi-LASIK) and its wide spread require high attention to the eye morphophysiological rates in pre- and postoperational period. The most important rates are still the characteristics of the cornea, such as thickness and its changes, regenerative response of corneal tissue and its regulation, as well as the data of intraocular pressure (IOP) and their correlation with cornea metrical rates.

According to the data of numerous investigations, underestimation of IOP level during applanation tonometry in patients, which were subject to keratophotorefractive surgeries, is of great importance in glaucoma diagnostic search. Hence, the advantages of scleral tonometry application in this category of patients for ophthalmotone appropriate evaluation and timely ophthalmohypertension detection are clear.

**PURPOSE**

The purpose of the study is to evaluate the clinical use of transpalpebral scleral tonometry, reliability of its application in the patients with refraction anomaly in pre- and postoperational period, dynamics of eye morphometric rates (pachymetry of the central corneal zone, IOP) and their correlative bond before and after photorefractive surgeries.

**METHODS**

We have analyzed the results of prospective comparative case series clinical study in 98 patients (194 eyes) with ametropia of various degrees, among which 59 persons (118 eyes) form the group of patients, who have no keratophotorefractive surgeries in past history, and 39 patients (76 eyes), which were the subject to excimer-laser vision correction (Epi-LASIK, LASIK, FRK) with various length of postoperational period from 7 days to 4 years.

The patients age distribution was from 18 to 53 years, the women make 61%, the men - 39%.

The following factors were exclusion criteria from the study:
- Cornea pathology, influencing prognostically the applanation tonometry results;
- Upper eyelid and sclera pathology, which are the contraindications for
transpalpebral diaton-tonometry.

Before and after the surgery all patients were subject to the complete refractive examination, including keratotopography and wavefront- aberrometry (AMO, USA). In a number of patients for cornea state morphologic evaluation we conducted US-biomicroscopy of the corneal optical zone before and in two months after laser correction (Picture 1).

Before and after surgery we trice measured pachymetry corneal thickness in central (4 points) zone - central corneal thickness (CCT) in each patient. We realized the study using two devices: US-pachymeter UP 1000 by NI- DEK (Japan) and A-scan-pachymeter P55 by Paradigm (USA). IOP was measured with Goldmann applanation tonometer (Rodenstok, Germany), pneumotonometer (NIDEK, Japan) and transpalpebral scleral diaton tonometer (RSIME, Russia, picture 2) using traditional methodology (picture 3), all ophthalmotone measurements were realized the patients being in the sitting position with time interval being 2-3 minutes between two investigators.

The surgeries were carried out using excimer laser VISX Star S4 IR (AMO, USA), microkeratome LSK Evolution II (Moria, France) and epikeratome Centurion SES (Norwood, Australia)

Statistical treatment of the received results was realized using common methods of medical mathematical statistics. Statistic calculations were carried out using “Analysis Tools Pack”. Determination of differences reliability between the groups being compared in the presence of normal distribution in sampling of one-type factors was realized using two-sample t-tests. Correlation analysis by Pearson allowed detecting the character of correlations between showings. Correlation with P<0,05 was considered to be reliable.

RESULTS AND DISCUSSION

In 93,6% cases visual acuity without correction after surgery was 0,6 - 1,0 (Table 1) in the early postoperative period.

Results of the study are shown in Tables 2 and 3.

While analyzing morphometric parameters in the group of patients which were not the subject to photorefractive surgeries the mean PCT value was 554,5±32,4 μm, and the mean value of applanational IOP – 16,1±2,6 mm Hg, the fluctuation being from 10 to 21 mm Hg; mean ophthalmotone level evaluated with diaton tonometer - 14,7±2,5 mmHg, the fluctuation being from 9 to 20 mmHg. At that correlation between values of the applanation tonometer and transpalpebral scleral diaton tonometer was highly reliable (r = 0,73, p≤0,005). To define the advantages of scleral tonometry in comparison with the traditional keratoapplanational method we made calculations of real ophthalmotone in the patients of this group taking into account pachymetry (PCT), ophthalmometry and applanation tonometry data. Mean value of the real IOP after applanation value converting was 15,4±2,4 mmHg. Pearson correlation coefficient between real IOP (modified result, received with applanation tonometry) and the value, determined with diaton tonometer was
In the groups of patients, underwent photorefractive vision correction, mean PCT was 499.8±50.9 μm (fluctuations from 407 to 513 μm), mean applanation value of IOP – 12.4±2.91 mmHg (fluctuations from 7 to 20 mmHg), modified taking into account keratometry IOP rates – 13.9±3.0 mm Hg, mean diaton-tonometry result - 15.1±2.75 mm Hg. At that we notice approximation of diaton-tonometry figures to the modified applanation IOP value taking into consideration keratometric rates - increase of correlation coefficient from 0.51 to 0.81 (table 4).

Correlation analysis of PCT and IOP results in the group of patients, examined both in preoperational period and after photorefractive vision correction showed reliability of this correlation, p<0.005, reduction of IOP for 1 mm Hg is registered PCT being decreased for 29.7 μm. At that difference between pre- and postoperational IOP during applanation tonometry was 3.5 mm Hg, and during diaton-tonometry - 1.8 mm Hg, that is statistically dissimilar (t>2, p<0.005), which shows significant advantage of ophthalmotone evaluation if we omit cornea.

Conclusion. Thus, cornea thickness is the important factor of IOP evaluation and monitoring and requires the necessity of including corneal pachymetry in the program of examination the patients with suspicion of glaucoma and hypertension, especially after various keratorefractive surgeries while using the traditional corneal methods of ophthalmotonometry. At the same time clinical application of transpalpebral scleral diaton tonometer makes it possible to evaluate IOP using only one device, the procedure being efficient, economical, simple in performance and requiring no additional instrumental examination.

Picture 1. Topographic ultrasonic biomicroscopy of the cornea in optical zone of normal myopia eye (A), after PRK (B) and after LASIK (C)
Picture 2. Transpalpebral scleral diaton tonometer

1 - body
2 - tip
3 - STOP button
4 - rod
5 - OPERATION button
6 - display
7 - cap

Picture 3. Methodology of transpalpebral tonometry
Table 1. Visual activity dynamics in patients after keratophotorefractive vision correction

<table>
<thead>
<tr>
<th>Visual activity</th>
<th>Age of the patients with ametropia</th>
<th>before 25</th>
<th>26-35</th>
<th>36-45</th>
<th>46 and older</th>
<th>total</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCVA before surgery</td>
<td>0.096</td>
<td>0.0106</td>
<td>0.097</td>
<td>0.067</td>
<td>0.098</td>
<td></td>
</tr>
<tr>
<td>UCVA after surgery</td>
<td>0.945</td>
<td>0.87</td>
<td>0.836</td>
<td>0.767</td>
<td>0.889</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Morphometric description of the group of patients with refraction anomaly, which were not subject to surgical laser vision correction

<table>
<thead>
<tr>
<th>Morphometric indexes</th>
<th>M±SD</th>
<th>min</th>
<th>max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmotonometr, D</td>
<td>43,8±1,4</td>
<td>36,5</td>
<td>46,75</td>
</tr>
<tr>
<td>Pachymetry central corneal thickness, µm</td>
<td>554±32,4</td>
<td>471</td>
<td>637</td>
</tr>
<tr>
<td>Applanation tonometry, mm Hg</td>
<td>16,1±2,6</td>
<td>10</td>
<td>21</td>
</tr>
<tr>
<td>Transpalpebral diaton tonometry, mmHg</td>
<td>14,7±2,5</td>
<td>9</td>
<td>20</td>
</tr>
</tbody>
</table>

Table 3. Morphometric description of the group of patients after keratophotorefractive ametropia correction

<table>
<thead>
<tr>
<th>Morphometric indexes</th>
<th>M±SD</th>
<th>min</th>
<th>max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmotonometr, D</td>
<td>39,8±2,48</td>
<td>34,5</td>
<td>46,5</td>
</tr>
<tr>
<td>Pachymetry central corneal thickness, µm</td>
<td>499±50,9</td>
<td>399</td>
<td>610</td>
</tr>
<tr>
<td>Applanation tonometry, mm Hg</td>
<td>12,4±2,91</td>
<td>7</td>
<td>20</td>
</tr>
<tr>
<td>Transpalpebral diaton tonometry, mmHg</td>
<td>15,1±2,75</td>
<td>10</td>
<td>21</td>
</tr>
</tbody>
</table>

Table 4. Correlation analysis of ophthalmotonometry rates in patients before and after photorefractive surgeries

<table>
<thead>
<tr>
<th>Ophthalmotonometry results</th>
<th>Correlation coefficient r, p&lt;0,005</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperational period</td>
</tr>
<tr>
<td>Applanation corneal/Transpalpebral scleral tonometry</td>
<td>0,73</td>
</tr>
<tr>
<td>Modified applanation corneal/ Transpalpebral scleral tonometry</td>
<td>0,89</td>
</tr>
</tbody>
</table>


Comparison of the Diaton Transpalpebral Tonometer Versus Goldmann Applanation

R. S. Davidson 1; N. Faberowski 2; R. J. Noecker 3; M. Y. Kahook 1
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2. Ophthalmology, Denver Health Medical Center, Denver, CO, USA.
3. Ophthalmology, UPMC, Pittsburgh, PA, USA.

FINANCIAL DISCLOSURE

The authors have no financial interest in the subject matter being presented.

BACKGROUND

Diaton tonometry is a unique approach to measuring intraocular pressure (IOP) through the Eyelid. It is a non-contact (no contact with cornea), pen-like, hand-held, portable tonometer. It requires no anesthesia or sterilization.

PURPOSE

To investigate the agreement in the measurement of intraocular pressure (IOP) obtained by transpalpebral tonometry using the Diaton tonometer versus Goldmann applanation in adult patients presenting for routine eye exams.

METHODS

Retrospective chart review of consecutive IOP measurements performed on 64 eyes of 32 patients age 34-91 years with both the Diaton tonometer and Goldmann applanation. Results between groups were examined using analysis of variance (ANOVA) where appropriate.
RESULTS

Mean IOP was 15.09 +/- 4.31 mm Hg in the Goldmann group and 15.70 +/- 4.33 mm Hg in the Diaton group (p=0.43).
Mean IOP variation between groups was 1.74 +/- 1.42 mm Hg (range 0-8). 83% of all measurements were within 2 mm Hg of each other.

CONCLUSIONS

The transpalpebral method of measuring IOP with the Diaton tonometer correlates well with Goldmann applanation. Diaton applanation may be a clinically useful device for measuring IOP in routine eye exams.

Comparison of the Diaton Transpalpebral Tonometer Versus Tono-Pen Applanation

Theodore H. Curtis, M.D.1, Douglas L Mackenzie, M.D.1, Robert J. Noecker M.D.2, and Malik Y. Kahook M.D.1

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2. Eye and Ear Institute, University of Pittsburgh Medical Center, Pittsburgh, PA

FINANCIAL DISCLOSURES

None of the authors have financial interests relevant to the subject discussed.

PURPOSE

To compare intraocular pressure (IOP) measurements obtained with Diaton trans-palpebral tonometry versus Tonopen applanation tonometry in children and adults.

INTRODUCTION

Goldmann applanation is the gold standard for IOP measurement. It has been supplanted by TonoPen applanation in many settings because of its ease of use, portability, convenience, and minimal training requirements.
The TonoPen requires contact with the corneal surface, and has the risks of iatrogenic corneal injury, spread of pathogens, and requires topical anesthetics.
The newly-developed Diaton tonometer is a handheld device that measures pressure through the tarsal plate (Figures 1 & 2).
It avoids contact with the cornea and the need for topical anesthesia.

**METHODS**

We looked at 74 eyes of 38 consecutive patients who received both TonoPen and Diaton tonometry. TonoPen measurements were taken in the sitting position following topical anesthesia with proparacaine. Diaton measurements were performed in the sitting position with the patient gazing at a 45° angle, placing the eyelid margin at the superior limbus. If necessary, gentle traction was placed on the brow to align the lid with the limbus. The device was activated when the signaling mechanism indicated the device was vertical.

**RESULTS**

Age range 3-91 years of age (mean 47.5 years). The average IOP with the Diaton was 16.24 (±/-5.11 mm Hg; range = 7-32 mmHg). The average IOP with the TonoPen was 16.37 (±/-4.90 mm Hg; range = 8-33 mmHg). The mean variation between the two modalities was 1.59 mmHg (±/-1.31 mm Hg; range = 0-6 mmHg). Eighty-one percent of all measurements were within 2 mmHg of each other (Table 1). There was no statistically significant difference in mean IOP values obtained with the two devices (p=0.87).
### Table 1

<table>
<thead>
<tr>
<th>Device</th>
<th>Mean IOP (standard deviation)</th>
<th>IOP Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonopen</td>
<td>16.37 (+/-4.90 mm Hg)</td>
<td>8-33 mm Hg</td>
</tr>
<tr>
<td>Diaton</td>
<td>16.24 (+/-5.11 mm Hg)</td>
<td>7-32 mm Hg</td>
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<tr>
<td>Variance between devices</td>
<td>1.59 (+/-1.31 mm Hg)</td>
<td>0-6 mm Hg</td>
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### CONCLUSIONS

The Diaton tonometer pressure measurements correlated well with Tono-Pen measurements in this retrospective review.

We did not find problems performing the exam in children, and many were reassured by the fact that no drops were needed.

There may be a notable benefit in patients after refractive surgery or with corneal pathology since the Diaton does not applanate the cornea.

The Diaton tonometer appears to be a clinically useful device in the IOP measurement of both children and adults.

### REFERENCES


Eisenberg DL, Sherman BG, McKeown CA, Schuman JS. Tonometry in adults and children: a manometric evaluation of pneumotonometry, applanation, and TonoPen


Experience of application of “Tangent Screen Examination” inspection system and transpalpebral scleral tonometry at home


Russian State Medical University, Ophthalmology Department of Medical Faculty *Academic Group of A.P. Nesterov, academician of the Russian Academy of Medical Sciences, Scientific Center of Cardiovascular Surgery of the Russian Academy of Medical Sciences

Grant of President of Russian Federation for state support of leading scientific school of Russian Federation NSH-3662.2006.7

PURPOSE

Designing and practical application in ophthalmology of the improved method of glaucoma patients’ medical examination with three level control system - outpatient, stationary and home.

METHOD

Inspection System «Tangent Screen Examination», assigned for field of view examination using PC display; for installation you need IBM-compatible PC and LCD display to cover central field of view in the range of 23-25°. Several tests are used for threshold sensitivity study and screening – test of field of view evaluation using over threshold strategy. Results can be presented – in grey scale shades, quantitatively – in Humphrey decibels, conventionally – in scotomas of three levels depth. In our study to realize tonometry by patients’ relatives transpalpebral scleral DIATON tonometer is assigned,
RESULTS

We are observing a stable group of 22 persons, controlling the field of view at home during the period from half a year to a year and a half using home version of «Tangent Screen Examination» program. The patients examine the field of view 1-2 times a month. Periodicity of IOP control is the same. During observations we registered IOP increasing in 4 patients which required treatment correction. At that we did not register deterioration of the field of view characteristics in these patients, which is connected with the regular IOP measuring and timely assuming the adequate medical measures. In other 18 persons during observations we registered stable parameters of Tangent Screen Examination and IOP.

CONCLUSION

Patients participating in active monitoring of their state using «home» methods of the field of view and IOP control provides comprehensive understanding of medical recommendations fulfillment necessity, which allows controlling the glaucoma process completely and sufficiently.

Clinical comparison of the Diaton and the Non-contact Tonometers with the Goldmann applanation tonometer in glaucoma patients

Nesterov A.P., Illarionova A.R., Obruch B.V.
Eye Diseases Department, Russian State Medical University, Moscow, Russia

PURPOSE

Study of intraocular pressure evaluation (IOP) reliability using non-invasive devices, which require no anesthesia: transpalpebral scleral Diaton tonometer and non-contact pneumotonometer (NCT).

METHOD

Here the prospective comparative case series clinical study is presented. 87 patients (146 eyes) suffered from glaucoma (m:f = 51:36; age distribution: 29-85 years) were examined. For comparison IOP values received with Goldmann applanation tonometer (GAT) using the traditional methodology and digital mean values received with Diaton and NTC were used.
**RESULTS**

Mean IOP was 17.4±7.6 mmHg with GAT, 16.7±5.58 mmHg with Diaton, 21.4±9.13 mmHg with NCT. Minimum IOP value was 6.0 mmHg with GAT, 6.0 mmHg with Diaton, 5.0 mmHg with NCT; maximum value was 40.0 mmHg with GAT, 36.0 mmHg with Diaton, 47.0 mmHg with NCT. There was no significant difference of IOP values (t =-0.51, p<0.001). The Pearson’s correlation coefficient was r=0.89, p<0.001 between GAT and Diaton; r=0.87, p<0.001 between GAT and NCT. There was observed high correlation of both tonometers with GAT in IOP range up to 30 mm Hg. In case of IOP significant increase NCT showed IOP overestimation up to 7 mm Hg; Diaton showed IOP underestimation up to 4 mm Hg.

**CONCLUSIONS**

The study shows high reliability of transpalpebral scleral Diaton tonometer enough for clinical purpose. It has both accuracy correlating with GAT and NCT’s safety and operating speed. Diaton advantage is the possibility to evaluate IOP in cornea pathology, which is very important in glaucoma patients after corneal including laser surgeries.


NO FINANCIAL INTEREST

**Clinical Use of Transpalpebral Scleral DIATON Tonometer in Pediatrics**

*Professor E.I. Sidorenko, E.Y. Markova*

*Russian State Medical University, Morozov Children’s Clinical Hospital, Moscow*

**PURPOSE**

Study of possibility of use and evaluation of transpalpebral scleral DIATON tonometer clinical use effectiveness in pediatrics.

**METHOD**

The prospective comparative case series clinical study was done in 60 children (120 eyes), age distribution 7-16 years. Existence of eyelids inflammatory diseases, their deformation, cornea pathology were exclusion criteria. During the study Goldmann tonometer and transpalpebral scleral DIATON tonometer were used. Intraocular pressure measuring was realized with three different DIATON devices at the same day time. Researchers’ experi-
ence of DIATON tonometry application in clinical practice was not less than 1 month.

RESULTS

For OD mean modified tonometry value with Golmann was 19,98±0,4 mmHg, mean IOP value measured with DIATON was 19,40±0,47 mmHg (t=0,65, df = 117, p> 0.05), for OS mean modified tonometry value with Golmann was 19,39±0,48 mmHg, mean IOP value with DIATON was 19,41±0,42 mmHg (t=0.99, df = 117, p> 0.05).

CONCLUSION

Clinical study of possibility of transpalpebral scleral DIATON application in children tonometer demonstrated its high accuracy. The recommended child’s age for IOP measuring with this tonometer is 7-16 years. The advantages are: simplicity of use without any additional medicines, psychological acceptability by children, significant time saving for ophthalmotonometry procedure.
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Dear Sir or Madam

We would like to take an opportunity and thank you for the interest in the unique Non-Corneal Diaton Tonometer. We are very much hope that collected articles were helpful and provided you with an initial overview of the medical and practical importance of the Diaton Tonometer.

Please do not hesitate to contact us if you have any further questions.

We will be happy to provide you with detailed information.

Yours sincerely,

Tonom GmbH

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