Reliability and Reproducibility of the Eye Check Tonometer pressure measurements as measured by patients

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Purpose of the Study

To investigate whether the new applanation tonometer (Eye Check monitor) can provide intraocular pressure (IOP) measurements comparable to those of traditional tonometers such as the Goldmann applanation tonometer.

Background & Significance

Glaucoma is a disease that is usually caused by increased pressure in the eye which damages the optic nerve. It is a leading cause of blindness for people over 60 years old. Blindness from glaucoma can often be prevented with early treatment. The global prevalence of glaucoma for population aged 40-80 years is 3.54 percent. In 2013, the number of people (aged 40-80 years) with glaucoma worldwide was estimated to be 64.3 million, increasing to 76.0 million in 2020 and 111.8 million in 2040. The damage to the optic nerve can be prevented or slowed down by reducing the intraocular pressure (IOP). The ophthalmologist bases his/her decisions on IOP readings performed in the office with a tonometer. However, the values obtained during office hours have been shown to be unable to identify IOP peaks and variations. Therefore, IOP measurements in the office provide limited and potentially misleading information in planning the management of new patients and the evaluation of drug therapy or surgery intervention in patients already under care. Moreover, studies have shown that short-term IOP fluctuations and inter-visit IOP variations are prognostic factors for glaucoma progression. Therefore IOP monitoring by the patients, in their natural environment, referred to as home or self-tonometry, would provide reliable data of clinical importance for the management of glaucoma.

The Goldmann applanation tonometer is the gold standard for measuring the IOP. It measures the force necessary to applanate (flatten) the central cornea. As shown in the figure, to perform a measurement the subject is seated in front of a slit-lamp microscope. The operator places a drop of fluorescent dye and anesthetic on the eye and asks the patient to look straight ahead, open both eyes wide, fix his/her gaze and keep perfectly still. The operator gently holds up the patient's top eyelid, taking care not to put any pressure on the eye and moves the tonometer forward and perpendicular to the cornea until the prism rests gently on the center of the subject’s cornea. With the other hand, the operator turns the calibrated dial on the tonometer thereby increasing the force applied by the probe on the cornea. The operator continues to increase the force until the tear film at the periphery of the probe (seen as a fluorescent ring) reaches a preset diameter. The probe is then withdrawn from the eye and the value on the dial, corresponding to the force necessary to applanate the cornea (calibrated in mmHg units of IOP) is recorded in the notes. The calibration takes into account the force to deform the cornea when the IOP is absent and the opposite capillary force generated by the meniscus of fluid.

Despite the availability of self-tonometers and the proof of their clinical value, IOP monitoring by patients, in their own environment, has not been used widely. As stated in the Liang review, the economical hurdles have prevented the commercialization of this technology: the lack of reimbursement for the instrument cost (e.g. $2150 for the iCare Home tonometer https://www.howmuchisit.org/icare-tonometer-cost/), the training of the patient and data processing has deterred clinicians from implementing IOP home monitoring in their routine clinical practice. The

experience so far indicates that, to be adopted clinically for IOP monitoring, a self-tonometer must be: usable by most patients, require no corneal anesthetic, safe, require no or minimal training by ophthalmologists' clinical staff and capable to yield values that correlate well with gold standard tonometry.

The EYE Check Tonometer satisfies all the above-mentioned criteria necessary for practical large-scale implementation of home IOP monitoring. The instrument comprises of an optical head, a flexible arm and a power and control unit. The optical head is similar to the Goldmann tonometer. It is composed of an acrylic transparent probe connected internally to a force sensor and an optical monitor which monitors the contact of the probe with the cornea. In addition, it contains a light pattern for self-alignment.

In operation, the subjects, seated in front of a table on which the device is placed, move their head to center the visible pattern in the optical head by adjusting the flexible arm. An audible message informs them when their eye is aligned with the optical head. Upon confirmation of adequate centering, the subjects bring the cornea in contact with the probe by leaning towards the probe. The probe moves and activates the force sensor while the area of contact is recorded. When a preset safe pressure is registered, an audible signal informs the subject to lean back and the fixation light is turned off. The output the force sensor and the optical monitor are sampled frequently and transmitted to a laptop computer (to be replaced by a smartphone in the future). Following the procedure, the IOP is derived and quality control assessments are performed.

Design & Procedures

Prospective consecutive series of 50 adult patients. Consecutive patients coming to the Duke Eye Center will be approached by a research coordinator for the possibility of participating in the study. Subjects will be screened based on the inclusion and exclusion criteria (Selection of Subjects section). Eligible and willing patients will be asked to sign the consent form for the study.

Participants will be assigned a unique code number. The key to this code will be in a locked key file with the principal investigator. Both eyes will be evaluated in this study. The user (patient) will then be informed by a skilled technician, who is experienced with use of the Eye Check tonometer, on how to use it by themselves.

The subject will perform a self-alignment procedure that trains for alignment and assesses the results. During this procedure, no contact will be made with the probe. The progress with be monitored and recorded. Only subjects who to pass the alignment criteria will proceed to obtain IOP measurements. Prior to the instillation of any eye drops, five immediately consecutive readings will be obtained with the Eye Check tonometer. Each of these readings will be recorded in the Eye Check tonometer connected computer without any subject identifier other than the identification code. IOP measurements by a certified ophthalmic technician using the Goldmann Applanation tonometer, within 5 minutes after the use of the Eye Check tonometer will be performed. Other data such as age, pachymetry, refractive error, etc., will be recorded.

Patients will be provided with a questionnaire to assess comfort and ease of use.

Selection of Subjects

Inclusion criteria:
Age of 18 years or older,
Any glaucoma patient or glaucoma suspect patient

Exclusion criteria:
Arthritis affecting the upper extremity in the patient or caregiver
Patient unwilling or assessed to be unable to comply with the study protocol
Any corneal abnormalities such as opacities, scars, Fuchs dystrophy, map dot fingerprint dystrophy, history of recurrent corneal abrasion, corneal surgery such as Lasik, PRK, DSAEK, transplant or implant
History of any ongoing ocular symptoms such as eye pain or redness or discharge
History of recent ocular surgery (done in the past 3 months)
History of any filtering or tube surgery for glaucoma (to reduce risk of infection associated complications)
Recent eye infection (within the past 3 months)
History of diabetes for > 5 years duration
Monocular patient
Best corrected visual acuity< 20/70
Head or hand tremors

Subject Recruitment

Patients will be recruited from the glaucoma clinic who are already scheduled for a standard of care visit. Someone known to them will introduce the study to them and if interested a member of the study team will review the study and obtain consent before any study procedures are done. Approximately 50 subjects will be enrolled in this study.

Risk/Benefit Assessment

Risks: It is possible that the patient may abrade the cornea during a measurement resulting in a corneal abrasion. The likelihood of such an event occurring with the Eye Check tonometer is remote due to the disposable probe cover made out of contact lens material (thus protecting the cornea) during the measurement. Pain, redness, watering, and blurry vision are symptoms that would alert the patient immediately and they will be instructed to contact the principal investigator and stop the study. Such abrasions typically heal within 24-48 hours unless the patient is a diabetic in whom it may take longer and thus a history of diabetes is an exclusion factor. There is a remote possibility that the corneal abrasion can get infected.

Sanitation of device - The head of the unit will be bent so that the entire tip will be dipped in the standard cleaning solutions (those used for Goldmann tonometer tips), then dried (per the current

protocol), and then used on any subsequent patient in the study. The actual device will be wiped down with cavi wipe per standard clinic protocols.

Benefits: The physician will be able to assess the accuracy of the IOP measurements with the Eye Check tonometer, which has the potential to be used as a device by which the patients can check their own IOP at home in the future. This may lead to better management of their glaucoma.

Data Analysis & Statistical Considerations

The IOP readings from the Eye Check tonometer and the Goldmann will be compared. The Goldmann measurements are typically considered the gold standard. Mean IOP and standard deviation of IOP measurements using the two devices will be assessed.

If needed, for correlation analyses, data such as age, pachymetry, refractive error, etc., will be obtained by the clinical investigators from the charts.

The data of the Eye Check tonometer, which, as mentioned above, does not contain any subject identification or IOP data, will be analyzed. The IOP, Standard of Measurement, number of successful readings, and performance scores will be derived.

Data & Safety Monitoring

Patients will be advised to report any adverse event immediately to the principal investigator.

The investigating physicians will document and report the adverse events. A high rate of adverse reactions will prompt the termination of the study.

Adverse events could include corneal abrasions, corneal, or conjunctival infections if the probe is not handled in an aseptic fashion by the patient or caregiver. Thus, the patient would be asked to call if there was any redness of the eye, any discharge, excessive watering, blurry vision, or eye pain.

Reportable adverse events will be submitted to the DUHS IRB per policy.