DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Corneal hysteresis (CH) measurement assesses corneal resistance to deformation and is the difference in the inward and outward pressure values obtained during the dynamic bi-directional applanation process. CH has been proposed as a possible indicator of the viscoelastic properties in the cornea. The Ocular Response Analyzer® is currently the only device that has been developed to measure the intra-ocular pressure and the biomechanical properties of the cornea. It indirectly assesses corneal hysteresis (CH), which may be a measure of ocular viscous properties reflecting the tissue capacity to absorb and dissipate energy, and corneal resistance factor (CRF), which may be a measure of overall ocular rigidity. Low CH demonstrates that the cornea is less capable of absorbing (damping) the energy of the air pulse. Abnormalities in corneal hysteresis have been detected in a variety of corneal diseases, including glaucoma, keratoconus, Fuchs' dystrophy, and in post-LASIK patients. The preferred method of measuring intraocular pressure is using a contact applanation method such as a Goldmann tonometer.

The Ocular Response Analyzer (Reichert, Inc.) was FDA approved in 2004 to measure intra-ocular pressure of the eye and the biomechanical response of the cornea for the purpose of aiding in the diagnosis and monitoring of glaucoma. A second FDA approval in 2008 was granted to measure intra-ocular pressure of the eye and biomechanical response of the cornea.

RECOMMENDATION

Corneal hysteresis (CH) measurement with the Ocular Response Analyzer is considered investigational/experimental and unproven for ocular disorders due to insufficient evidence in the peer reviewed medical literature that have not established safety, efficacy and effect on net health outcomes.

SUMMARY OF MEDICAL EVIDENCE 3-18

There is insufficient published evidence to assess the role of corneal hysteresis (CH) measurement for the diagnosis and/or monitoring of ocular disorders. Studies do not demonstrate that the measurement of corneal hysteresis impacts health outcomes such as improving vision or increasing the detection of ocular disorders. The current published literature consists of several controlled comparison studies, systematic review and meta-analysis, controlled studies, and retrospective controlled studies. The majority of the studies summarized conclusions regarding specific biomechanical corneal measurements (such as corneal hysteresis) obtained using the Ocular Response Analyzer. Number of participants in these studies varied from 60 to over 400. The studies reported measurements and outcomes pertaining to a specific group of patients or in relation to other, similar, biomechanical measurements associated with the cornea (such as intraocular pressure [IOP] or central corneal thickness [CCT]). There are no randomized controlled trials published in the literature that compare corneal
hysteresis with the ocular response analyzer to other tests measuring intraocular pressure. A summary of the most relevant studies is outlined below.

A large comparison controlled study by Sullivan-Mee et al (2013) examined factors that influence intraocular pressure (IOP) measurement agreement between Goldmann applanation (GAT), Ocular Response Analyzer (ORA), and Pascal Dynamic Contour tonometers (DCT). In subjects who were diagnosed with primary open-angle glaucoma, ocular hypertension, glaucoma suspect, and normal, ORA, DCT, and GAT were used to obtain corneal hysteresis (CH), corneal resistance factor (CRF), ocular pulse amplitude, and 4 IOP values (ORA-IOPcc; ORA-IOPg; DCT-IOP; and GAT-IOP.) Corneal curvature, corneal thickness, axial length, retinal nerve fiber layer thickness, visual field parameters, diabetes diagnostic status, and topical IOP-lowering treatment data were obtained. In 243 eyes of the 243 subjects, mean DCT-IOP (18.73+/−4.92) was not different from mean ORA-IOPcc (18.96+/−5.41) but both were significantly higher than ORA-IOPg (16.97+/−5.49) and GAT-IOP (16.37+/−4.97). In multivariate regression models, intermethod differences between IOPg, IOPcc, and DCT-IOP were explained almost completely by variations in CH, CRF, and level of IOP (r=0.98 to 0.99); conversely, intermethod variability between GAT-IOP and the other 3 IOP metrics was only partially explained by the factors evaluated in this study (r=0.31 to 0.65). The authors found that the 4 IOP variables examined in this study are not interchangeable. The most consistent confounders of IOP measurement agreement were the ORA-measured corneal parameters, CH and CRF. Thus, accounting for these factors may be important in efforts to obtain accurate transcorneal estimates of IOP. 13

Cook et al. (2012) assessed the agreement of tonometers available for clinical practice with the Goldmann applanation tonometer (GAT) in a systematic review and meta-analysis. A total of 102 studies, including 130 paired comparisons, were included, representing 8 tonometers: dynamic contour tonometer, noncontact tonometer (NCT), ocular response analyzer, Ocuton S, handheld applanation tonometer (HAT), rebound tonometer, transpalpebral tonometer, and Tono-Pen. The agreement (95% limits) varied across tonometers: 0.2 mmHg (-3.8 to 4.3 mmHg) for the NCT to 2.7 mmHg (-4.1 to 9.6 mmHg) for the Ocuton S. The estimated proportion within 2 mmHg of the GAT ranged from 33% (Ocuton S) to 66% and 59% (NCT and HAT, respectively). Substantial inter- and intraobserver variability were observed for all tonometers. The authors concluded that the NCT and HAT seem to achieve a measurement closest to the GAT. However, there was substantial variability in measurements both within and between studies. 5

The purpose of another systematic review by Terai et al. (2012) was to correctly interpret the underlying biomechanics of Ocular Response Analyzer (ORA) data and provide a compendium of factors influencing these measurements, with discussion of possible explanations for ORA measurement results. Several ORA biomechanical parameters of the cornea - corneal hysteresis (CH) and corneal resistant factor (CRF) - characterize the viscoelastic properties of the cornea, especially those of the ground substance. The impact on CH and CRF values of various independent factors, e.g. intraocular pressure (IOP), age, central corneal thickness (CCT), and corneal swelling, are discussed. The impact on CH and CRF of treatment-related structural changes of the cornea, i.e. those occurring after refractive surgical procedures, placement of intracorneal rings, and collagen crosslinking (CXL), as well as pathological changes of the cornea, e.g. those resulting from keratoconus, edema, and glaucoma, are discussed. The review concluded that changes in CRF and CH may be reflective of structural changes in the ground substance of the cornea. 16
Nessim et al. (2012) analyzed the relationship between measured intraocular pressure (IOP) and central corneal thickness (CCT), corneal hysteresis (CH) and corneal resistance factor (CRF) in ocular hypertension (OHT), primary open-angle (POAG) and normal tension glaucoma (NTG) eyes using multiple tonometry devices. Right eyes of patients diagnosed with OHT (n=47), normal tension glaucoma (n=17) and POAG (n=50) were assessed. IOP was measured in random order with four devices: Goldmann applanation tonometry (GAT); Pascal (®) dynamic contour tonometer (DCT); Reichert (®) ocular response analyser (ORA); and Tono-Pen (®) XL. CCT was then measured using a hand-held ultrasonic pachymeter. CH and CRF were derived from the air pressure to corneal reflectance relationship of the ORA data. Compared to the GAT, the Tonopen and ORA Goldmann equivalent (IOPg) and corneal compensated (IOPcc) measured higher IOP readings, particularly in NTG. DCT was closest to Goldmann IOP and had the lowest variance. CCT was significantly different between the 3 conditions as was CH and CRF. The authors concluded that this study suggests that as the true pressure of the eye cannot be determined non-invasively, measurements from any tonometer should be interpreted with care, particularly when alterations in the corneal tissue are suspected.

A large prospective observational study by Narayanaswamy et al. (2011) evaluated corneal hysteresis (CH) and intraocular pressure (IOP) measured by the Ocular Response Analyzer in Chinese subjects with primary angleclosure glaucoma (PACG), assess their relationship with Goldmann applanation tonometry (GAT) measurements, and compare this with subjects with primary openangle glaucoma (POAG) and normal controls. 443 individuals with PACG and POAG without prior intraocular surgery were enrolled from glaucoma clinics. Normal subjects were recruited from an ongoing population-based study. One eye of each subject underwent standardized ocular examination and IOP measurement by GAT and the Ocular Response Analyzer. Corneal hysteresis and corneal compensated IOP were compared between groups. Corneal hysteresis was lower in PACG (9.1 mm Hg; 95% confidence interval [CI], 8.7 to 9.4 mm Hg) and POAG (9.5 mm Hg; 95% CI, 9.2 to 9.5 mm Hg) eyes compared with control eyes (10.4 mm Hg; 95% CI, 10.1 to 10.6 mm Hg; P<.001 for both), with no difference (P=.16) in CH found between PACG and POAG eyes. After adjusting for age, sex, and IOP measurement by GAT, CH persisted to be lower only in eyes with PACG in comparison with control eyes (9.4 vs 10.1 mm Hg; P=.006). Eyes with POAG had lower CH than control eyes but the difference was not statistically significant (9.6 vs 10.1 mm Hg; P=.06). Conclusions: Corneal hysteresis was lower in eyes with glaucoma. After adjusting for age, sex, and IOP measurement by GAT, a persistently lower hysteresis was noted in eyes with PACG compared with other groups.

The American Academy of Ophthalmology (AAO) does not address corneal hysteresis measurement in its Preferred Practice Pattern for the evaluation and management of Primary Open-Angle Glaucoma.

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**REFERENCES**

**Government Agencies**


**Peer Reviewed Publications**


Professional Society


Hayes


Other Resources

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There are no NCD’s found on the topic of corneal hysteresis (CH) measurement with the Ocular Response Analyzer.¹