

CORNEAL HYSTERESIS AND INTRAOCULAR PRESSURE MEASUREMENT

Guideline Number: MMG028.K

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[Instructions for Use](#) ⓘ

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Related Policies
None

COVERAGE RATIONALE

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- Measurement of corneal hysteresis
- Measurement of ocular blood flow using a tonometer
- Monitoring of intraocular pressure during vitrectomy
- Continuous monitoring of intraocular pressure for ≥ 24 hours in persons with glaucoma

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0198T	Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report
66999	Unlisted procedure, anterior segment of eye
67299	Unlisted procedure, posterior segment
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report

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DESCRIPTION OF SERVICES

Corneal hysteresis (CH) measurement assesses corneal resistance to deformation. CH has been proposed as a possible indicator of the viscoelastic properties in the cornea. The Ocular Response Analyzer® (ORA) is an instrument that measures CH by using a rapid air impulse to apply force to the cornea. An advanced electro-optical system then monitors the deformation. Two independent pressure values are derived from the inward and outward applanation events. The difference between these two pressure values is CH. Low CH demonstrates that the cornea is less capable of absorbing (damping) the energy of the air pulse. Abnormalities in CH have been detected in a variety of corneal diseases, including keratoconus, Fuchs' dystrophy, and in members who have had laser in situ keratomileusis (LASIK). Glaucoma is another potential indication for CH measurement. The preferred method of measuring intraocular

pressure (IOP) is using a contact applanation method such as a Goldmann tonometer (GAT). Corneal compensated IOP, derived from the CH measure has been suggested as a superior measurement of IOP compared to the GAT measurement.

The ocular blood flow (OBF) tonometer measures IOP and pulsatile OBF. It has been proposed that the IOP and OBF test results taken together increase the detection rate for glaucoma when compared to traditional tonometry, which measures only average IOP. The ocular Blood Flow Analyzer (BFA) is an electronic pneumotonometer that measures IOP 200 times per second over a period of 5-15 seconds and automatically measures OBF. The BFA is basically an OBF tonometer, using a pneumatic mode of operation.

IOP monitoring during vitrectomy may be accomplished indirectly by placing disposable blood pressure transducers into the line tubing utilized for vitrectomy infusion. It may also be monitored by inserting a catheter pressure transducer directly into the vitreous by an extra pars plana incision. In either approach, pressure measurements are obtained simultaneously during the various stages of the vitrectomy, including air-fluid exchange and gas-forced fusion. Monitoring IOP during vitrectomy surgery has been proposed to measure fluctuations in IOP that may have an adverse effect on retinal and optic nerve function and visual acuity recovery.

Devices, including contact lens sensors, are being developed to monitor eye pressure for 24 hours or longer in individuals with glaucoma. Currently, the Triggerfish[®] contact lens sensor (CLS) (Sensimed, Lausanne, Switzerland) is the only commercially available device that has been shown to be able to provide 24 hour IOP data. This device has received marketing clearance by the U.S. Food and Drug Administration (FDA). The Triggerfish CLS is a disposable silicone contact lens with an embedded micro-electromechanical system which measures changes in corneal curvature induced by variations in IOP. An antenna, mounted around the eye, receives the data, which are then transmitted to a recorder for analysis. These devices are being studied to determine if they improve detection and allow earlier treatment for individuals with glaucoma.

CLINICAL EVIDENCE

Corneal Hysteresis Measurement

Susanna et al. (2018) conducted a prospective observational cohort study to investigate the role of CH as a risk factor for development of glaucoma. Two hundred and eighty-seven eyes of 199 individuals suspected of having glaucoma were observed for approximately 4 years. Development of glaucoma was defined as occurrence of 3 consecutive abnormal standard automated perimetry tests during the follow-up period. At baseline and at each visit during follow-up, all participants underwent a comprehensive ophthalmologic examination including IOP measured using GAT, gonioscopy, stereoscopic optic disc examination, visual field testing, and central corneal thickness (CCT) measurements via ultrasound pachymetry. Based on the results of the study, the authors concluded that the decrease in CH measurements represents a risk factor for developing glaucoma. Study limitations included but were not limited to study design (observational versus interventional) as well as uncontrolled confounding by unmeasured factors, such as family history of glaucoma. Future studies, including randomization protocols controlling for treatment strategy, should be performed to further clarify this and other predictive factors.

A 2018 Hayes report identified 16 studies that evaluated CH testing for diagnosis of glaucoma, or for predicting the progression or response to treatment of glaucoma. Eleven prospective or retrospective cohort studies and 5 prospective case-control studies were examined, involving from 52 to 443 patients with follow-up times ranging from zero to 6.6 years. The report concluded that the test has some capacity to diagnose glaucoma, to predict risk for glaucoma progression, and to predict response of glaucoma to certain types of treatment; however, the evidence is of very poor quality and lacked the rigor to determine diagnostic or prognostic accuracy. The role of CH testing in the management of patients with glaucoma and its impact on long-term health outcomes could not be determined due to the lack of evidence on the clinical utility of this test. Additional studies are needed.

Murphy et al. (2017) conducted a cross sectional study with 123 patients (one eye each) to determine if CH differs between patients with glaucoma, ocular hypertension (OHT) and glaucoma-like optic discs (GLD). The secondary aim was to investigate whether corneal resistance factor (CRF) and CCT differ between these patient groups. A One-way Analysis of Covariance (ANCOVA) was conducted to evaluate the mean difference in CH between the 3 diagnostic groups (glaucoma, OHT and GLD), correcting for potential confounding factors, IOP and age. Analysis was repeated for CRF and CCT. There was a significant difference in mean CH across the 3 groups. Mean CH was significantly higher for GLD compared to glaucoma, and significantly higher for OHT compared to glaucoma. Mean CH was slightly lower in patients with GLD than those with OHT, but this difference was not statistically significant. A similar pattern was seen when the analysis was repeated for CRF and CCT. The authors concluded that higher CH in GLD and OHT compared to glaucoma suggests increased viscoelasticity of ocular tissues may have a protective role against glaucoma. Future research in the area of CH should focus on its role in other diseases characterized by altered tissue compliance such as diabetes and hypertension. These areas may reflect a further advantage for the addition of CH measurements into routine ophthalmological examinations.

To determine whether CH and CCT are independent risk factors for glaucoma, Carbonaro et al. (2014) conducted a cross-sectional population-based cohort study with 1754 twin subjects. CH, IOP, and CCT were measured; optic disc photographs were analyzed; and multivariable linear regression analysis was performed. Data were available on 1645 individuals. The authors found no relationship between CH or CCT and quantitative measures of optic disc cupping that suggest CH and CCT are independent risk factors for glaucoma.

Observational cohort studies have been conducted by Medeiros et al. (2013) and Zhang et al. (2016) to investigate the relationship between CH and progressive retinal nerve fiber layer (RNFL) loss/visual progression in patients with glaucoma followed prospectively over time. Medeiros' study group included 114 eyes of 68 patients with glaucoma who were followed for an average of 4 years. Zhang's group followed 186 eyes of 133 patients with glaucoma for an average of 3.8 years. Using the ORA to obtain CH measurements in both a univariable and multivariable models, both studies concluded that the CH measurements to be significantly associated with risk of glaucoma progression and that eyes with lower CH had faster rates of RNFL/visual field loss over time than those with higher CH. While Zhang concludes this study provides further evidence that CH is an important factor to be considered in the assessment of the risk of progression in patients with glaucoma, there is no information that these findings will affect patient management.

Shin et al. (2014) conducted a prospective, cross-sectional, comparative study to evaluate the effects of corneal biomechanical properties on IOP measured with the ICare, and to compare IOP readings obtained with ICare, ORA, and GAT in normal-tension glaucoma (NTG) and normal subjects. IOP was measured with ICare, ORA, and GAT. All subjects had CH and CRF, which were measured with ORA; and CCT, axial length, spherical equivalent, and keratometry. This study enrolled 97 eyes of 97 NTG patients and 89 eyes of 89 normal subjects. CCT, CH, and CRF in NTG patients were significantly lower than those in normal subjects. The difference in IOP between techniques was highly significant in NTG patients, while there was no significant difference in IOP values between techniques in normal controls. ICare readings were significantly lower than corneal-compensated IOP in NTG patients ($P = .014$). CH and CRF were significantly associated with IOP measurements with ICare in NTG and normal subjects ($P < .001$). The greater difference between IOPcc and ICare in NTG patients was significantly influenced by the lower CH ($P < .001$). The author concluded that ICare is a convenient way to measure IOP and is a reasonable option as an alternative tonometer in NTG patients. However, the clinician must consider that the corneal biomechanical characteristics in NTG can cause ICare to underestimate IOP. The findings of this study are further limited by the small size of the study group.

Mansouri et al. (2012a) conducted an observational cross-sectional study to identify whether there is an association between corneal biomechanical parameters and the severity of glaucoma as defined by the visual field and RNFL thickness. CH and CRF were measured using the ORA. CH is assumed to reflect the viscous properties of the cornea as well as its dampening and energy absorption capacity. The CRF seems to be an indicator of the overall "resistance" or elasticity of the cornea. This study included a total 299 eyes of 191 participants (151 suspect and 148 glaucoma eyes), with the mean age of the participants being 68.1 years (range 30–91 years). The authors found only a weak relationship between corneal biomechanical parameters of CH and CRF and measures of structural and functional damage in glaucoma. Prospective longitudinal studies are needed to investigate the relationship between corneal biomechanics and long-term risk of glaucoma progression.

A randomized comparative study with 106 normal subjects concluded that measurement of the biomechanical properties of the cornea using the ORA are repeatable and reproducible, affect Goldmann tonometry less than noncontact tonometry, and have a minimal influence on the difference in measured intraocular pressure between tonometers (Ogbuehi, et al. 2014).

In a systematic review and meta-analysis, Cook et al. (2012) assessed the agreement of tonometers available for clinical practice with the GAT, the most commonly accepted reference device. A total of 102 studies, including 130 paired comparisons, were included, representing 8 tonometers: dynamic contour tonometer (DCT), noncontact tonometer (NCT), ORA, 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.

Nessim et al. (2012) analyzed the relationship between measured IOP and CCT, CH and CRF in OHT, primary open-angle (POAG) and NTG eyes using multiple tonometry devices. Right eyes of patients diagnosed with OHT ($n=47$), NTG ($n=17$) and POAG ($n=50$) were assessed. IOP was measured in random order with 4 devices: GAT; Pascal[®] DCT; Reichert[®] 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 GAT IOP and had the lowest variance. CCT was significantly different between the 3 conditions as was CH and CRF. According to the authors, 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.

In a prospective longitudinal observational study, Sullivan-Mee et al. (2013) examined the factors that influence IOP measurement agreement between GAT, ORA, and Pascal DCT. The study included 243 eyes in 243 subjects. The authors identified 5 factors, including CH, by multivariate regression as being independently associated with disagreement in IOP results as measured by different types of instruments. The authors stated that further study is needed to explain the residual disagreements among these instruments.

Kaushik et al. (2012) evaluated corneal biomechanical properties across the glaucoma spectrum and studied the relationship between these measurements and IOP in a prospective cross-sectional study that included 323 participants. Based on the results of the study, the investigators concluded that IOP measurements from the ORA are not interchangeable with, and are unlikely to replace, GAT at the present time.

Touboul et al. (2011) estimated the ability of the ORA parameters to aid in the diagnosis of keratoconus in pre-laser in situ keratomileusis (LASIK) patients. The study group comprised 103 eyes and the control group, 97 eyes. CH had a sensitivity of 66% with a specificity of 67%. The authors stated that despite low sensitivity and specificity, some parameters provided by the corneal analyzer offered high negative likelihood ratios and deserve more study with bigger samples.

Schweitzer et al. (2010) evaluated the performance of the ORA in the screening of forme fruste keratoconus (FFKc) in a retrospective comparative study that included 180 eyes. ORA preoperative data were analyzed for 125 normal control eyes (64 patients) undergoing LASIK without corneal ectasia after 24 months of follow-up and 55 case eyes with unilateral keratoconus from a database. All eyes were matched in 4 groups of CCT. CH, CRF, the air pressure curve, and the infrared signal were compared between FFKc and normal eyes in each group. Based on the results of the study, the investigators concluded that the ORA provides additional information in the screening of FFKc, with an accurate analysis of the corneal biomechanical properties according to CCT, air pressure, and infrared curves. According to the investigators, further studies are required to confirm these results and to follow the corneal topography and the ORA parameters over time for both groups.

Professional Societies

American Academy of Ophthalmology (AAO)

The AAO Preferred Practice Pattern (PPP) for POAG states that CH, which is a measure of the viscoelastic dampening of the cornea, has been shown to be associated with the risk of glaucoma progression. In addition, it states that low CH is associated with glaucoma progression (Prum et al., 2016).

Measurement of Ocular Blood Flow by Intraocular Pressure Sampling

A prospective, cross-sectional, case-control hospital-based study was conducted with 614 participants to help identify which vascular data can be used as a clinical tool for screening and disease stratification. Patients with POAG, NTG, OHT, glaucoma suspects and healthy volunteers were recruited. Mean ocular perfusion pressure was higher in the glaucoma groups than in controls. Glaucoma groups had lower retrobulbar velocities, higher retinal venous saturation and choroidal thickness asymmetries when compared to the healthy group, in line with the current literature. Named the Leuven Eye Study, the authors concluded that the creation of this vast database may help integrate the vascular aspects of glaucoma into the clinical practice of glaucoma. The trial did not result in definitive information that would affect patient management (Abegão Pinto, et al. 2016).

In a cross-sectional study, Resch et al. (2011) correlated OBF parameters with parameters of optic nerve head (ONH) morphology and visual field performance. A total of 103 patients with POAG were included. Choroidal and ONH blood flow was assessed using laser Doppler flowmetry. Retinal blood velocities and retinal vessel diameters were measured with laser Doppler velocimetry and a Retinal Vessel Analyzer, respectively. Among all measured ocular hemodynamic parameters, the ONH blood flow was most strongly correlated to structural parameters of ONH damage and visual field loss. Reduced retinal vessel diameters were only slightly correlated with the degree of glaucomatous damage. The authors concluded that reduced blood flow in the ONH was associated with an increasing amount of visual field defect and morphological changes of the ONH. Retinal vessel diameters were only marginally associated with glaucomatous optic nerve damage. According to the authors, based on retinal vessel diameter determination alone, it is not possible to assess whether reduced retinal blood flow is causative or secondary in glaucoma.

Januleviciene et al. (2011) evaluated hemodynamic parameters as possible predictors for glaucoma progression in an 18-month randomized double-masked cohort study including 30 open-angle glaucoma patients. IOP, arterial blood

pressure, ocular and diastolic perfusion pressures, color Doppler imaging, pulsatile OBF analysis, scanning laser polarimetry, and Humphrey visual field evaluations were included. The authors concluded that structural changes consistent with glaucoma progression correlate with non-IOP-dependent risk factors. The authors stated that larger group studies with longer followup, standardization of measurement techniques for glaucoma progression, and OBF parameters are required to elicit a clear understanding of vascular risk factors in glaucoma progression.

Professional Societies

American Academy of Ophthalmology (AAO)

The AAO PPP for POAG does not address measurement of OBF for the evaluation and management of glaucoma (Prum et al., 2016).

Monitoring of Intraocular Pressure during Vitrectomy

Yang et al. (2017) conducted a prospective case series, monitoring IOP in vivo using 2 vitrectomy machines, with or without constant infusion pressure monitoring and control, to evaluate IOP fluctuation during vitrectomy. Among 61 eyes of 61 consecutive patients, 32 were assigned to the Accurus system (group 1) and 29 were assigned to the Constellation system (group 2). IOP fluctuated significantly during routine vitrectomy using both systems. Hypotony and partial ocular collapse were more frequently observed with the Accurus system than with the Constellation system, and both systems were vulnerable to IOP surge during indentation and intravitreal injection.

In a prospective, interventional, consecutive case series, Sugiura et al. (2011) measured ophthalmodynamometric pressure (ODP) during vitrectomy in 75 patients with proliferative diabetic retinopathy (PDR). Multiple regression analysis revealed that ODP had a significant correlation with diastolic blood pressure, presence of rubeosis iridis, and severity of PDR. There is no evidence from this study that this information will affect patient management.

Moorhead et al. (2005) conducted a clinical study of 10 patients to directly measure dynamic IOP during vitrectomy and to determine whether disposable pressure transducers placed in the infusion line can indirectly measure with accuracy the dynamic IOP during vitrectomy. The directly measured IOP varied between 0 and 120 mm Hg during vitrectomy. During fluid flow, the indirectly measured IOP, calculated from the infusion line pressures, accurately corresponded with the directly measured IOP. The investigators concluded that closed vitrectomy causes wide fluctuations in IOP. The IOP can be accurately measured during fluid flow with inline sensors. According to the authors, the physiologic significance of these findings requires further study.

There is limited evidence to support that intraoperative IOP monitoring will improve health outcomes in patients undergoing vitrectomy. Additional clinical trials are necessary to determine its benefit.

Monitoring of Intraocular Pressure for 24 Hours or Longer

Hayes performed a search and summary of peer reviewed literature published in the last 5 years studying the Sensimed Triggerfish (Switzerland) and glaucoma. 18 abstracts, including prospective studies, a retrospective study, and a systematic review were included, with numbers of participants ranging from 9-50. Various forms of glaucoma were studied, including NTG, POAG, primary angle-closure glaucoma, and glaucoma in general. Five studies received funding from the manufacturer, and there was considerable overlap of authors in the peer-reviewed abstracts. It was determined that while there is sufficient published evidence to evaluate this technology, the study abstracts presented overall conflicting findings regarding the use of the Sensimed Triggerfish System for continuous IOP monitoring in patients with glaucoma. Therefore, conclusions about the safety and efficacy of this technology cannot be made until a full assessment has been completed (2017).

In a review on the Sensimed Triggerfish CLS, Dunbar and colleagues concluded that overall, it is considered a safe and well-tolerated device for monitoring IOP-related patterns in healthy and glaucomatous individuals and greatly expands the available information to the clinician with regard to IOP-related patterns. Clinical studies continue to help advance understanding of how information obtained from the CLS can be analyzed, interpreted, and applied. The utility of this device in identifying high-risk patients and monitoring their response to treatment interventions continue to be areas of promising research (2017).

Mansouri et al. (2012b) examined the safety, tolerability, and reproducibility of IOP patterns during repeated continuous 24-hour IOP monitoring with the Triggerfish CLS. Patients suspected of having glaucoma (n = 21) or with established glaucoma (n = 19) were included in the study. Correlation between the 2 sessions was moderate, suggesting good reproducibility of the IOP recordings. There was also no difference in adverse events or survey scores for tolerability between those with established glaucoma compared with those with suspected glaucoma. Main adverse events were blurred vision (82%), conjunctival hyperemia (80%), and superficial punctate keratitis (15%). The authors concluded that repeated use of the contact lens sensor demonstrated good safety and tolerability. According to the authors, the recorded IOP patterns showed fair to good reproducibility, suggesting that data from continuous 24-hour IOP monitoring may be useful in the management of patients with glaucoma. However, this study did not

translate abstract research data into clinical guidelines that can be used to improve physician decision-making and patient care.

In a prospective, observational cohort of 15 patients, Mansouri and Shaarawy (2011) reported their initial clinical results with the Sensimed Triggfish for continuous IOP monitoring in patients with open angle glaucoma. A signal was recorded in all patients. Thirteen (87%) patients completed 24 hour IOP monitoring: one patient discontinued IOP monitoring due to device intolerance, and incomplete recordings were obtained in a second patient due to technical device malfunction. In 9/13 (69%) patients, the highest signals were recorded during the nocturnal period. No serious adverse events were recorded. According to the authors, the device shows good safety and functionality to monitor IOP fluctuations in patients over 24 hours. The significance of this study is limited by small sample size.

There are multiple clinical trials evaluating the Sensimed Triggerfish System. Additional information is available at www.clinicaltrials.gov. (Accessed March 26, 2019)

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

On January 20, 2004, the Ocular Response Analyzer® (ORA) by Reichert Inc. received FDA clearance for the intended use 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. More information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/K032799.pdf. (Accessed March 26, 2019)

On October 21, 2002 the Blood Flow Analyzer (BFA) received FDA marketing clearance. More information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf2/k023245.pdf. (Accessed March 26, 2019)

On March 4, 2016, the Triggerfish® contact lens sensor (CLS) received FDA marketing clearance. More information is available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/den140017.pdf. (Accessed March 26, 2019)

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GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
06/01/2019	<p>Coverage Rationale</p> <ul style="list-style-type: none"> Simplified non-coverage statement <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services, Clinical Evidence, and References</i> sections to reflect the most current information Archived previous policy version MMG028.J

INSTRUCTIONS FOR USE

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare West Medical Management Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.