Corneal Hysteresis

Section 1: Introduction to Corneal Hysteresis

What is Corneal Hysteresis (CH)?
- The only in-vivo measurement of corneal/ocular biomechanics
- CH specifically refers to the output of the measurement process performed by the Ocular Response Analyzer (ORA)\(^1\)
- Corneal Hysteresis reflects the ability of the corneal tissue to dissipate energy \(^2\)
  - Function of viscoelastic damping\(^2\)
  - Not a characterization of stiffness\(^2\)
- Provides insight into ocular properties that were not previously understood or conceived of

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1. High MI et al. (Ocular Response Analyzer). 2009: 2505-2525

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Section 1: Introduction to Corneal Hysteresis

CH: Average Values in Normal Subjects

<table>
<thead>
<tr>
<th>CH Values in Normals around the world</th>
<th>N</th>
<th>CH*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil1</td>
<td>105</td>
<td>10.3 ± 1.0</td>
</tr>
<tr>
<td>USA2</td>
<td>272 pairs</td>
<td>10.2 ± 1.2</td>
</tr>
<tr>
<td>China3</td>
<td>125</td>
<td>10.9 ± 1.5</td>
</tr>
<tr>
<td>Japan4</td>
<td>208</td>
<td>10.2 ± 1.3</td>
</tr>
<tr>
<td>Spain5</td>
<td>88</td>
<td>10.8 ± 1.5</td>
</tr>
<tr>
<td>USA6</td>
<td>88</td>
<td>10.5 ± 1.2</td>
</tr>
</tbody>
</table>

*CH units are mmHg

Section 1: Introduction to Corneal Hysteresis

CH Stability Over Time – Diurnal and Age

- CCT, IOP and CH were measured every 2 hours in 15 healthy volunteers (20-25 yrs)3.
- Nocturnal mean IOP and CCT were significantly higher than diurnal means5.
- CH did not display a 24-hour rhythm1.
- CH has been shown to decrease slightly with age2.

CH vs Age

Diurnal CH, CCT, IOP

Section 2: Clinical Evidence – Study 3

CH Associated with Asymmetric Glaucoma Progression

CH was the best discriminative index for the worse eye in asymmetric OAG.
- CH lower in 80% of worse eyes

Section 2: Clinical Evidence – Study 4

CH Associated with Rate of VF Progression

Our study adds information regarding rates of VF change and CH, showing that glaucomatous eyes with low CH not only reach event-based progression endpoints but also progress more rapidly (in dB/y).

* Note: CH is what caused CCT to fall out of the multivariate model

CH-related markers were ICC and CH-related macular macular pressure. CH in the study related CH (IC mean deviation, PSD quartile standard deviation, OAS visual field, OAS visual field glaucoma.)


Section 2: Clinical Evidence – Study 5
CH as a Predictor of Progression in the DIGS Cohort
Study Overview and Design
- Results from numerous retrospective studies suggested CH is associated with increased risk of glaucoma progression\(^1\)
- Investigated the relationship between baseline CH and rates of glaucoma progression in an observational study cohort to determine whether low CH is reflective of the disease process\(^2\)
- 68 glaucoma patients (114 eyes) were evaluated at 6-month intervals for 4 years\(^2\)
  - CH (ORA)
  - IOP (GAT)
  - CCT (ultrasound pachymetry)
  - VF (WFI)

\(^1\) Khawaja et al. OphthalmoLOGY. 2013;130:1331–1343.

Section 3: CH and the structural continuum
CH with the structural continuum
Evidence that CH is a biomarker for glaucoma risk
The Evidence suggests that CH is reflective of pressure-independent mechanisms involved in glaucoma pathogenesis and associated changes to the optic nerve

Section 3: Corneal Hysteresis and The Structural Continuum

WHY CORNEAL HYSTERESIS IS A BIOMARKER FOR GLAUCOMA: EVIDENCE


Section 3: CH and the structural continuum
Conclusion based on evidence in the literature

The eye is a mechanical structural continuum
The evidence suggests that CH is reflective of overall ocular tissue properties
CH appears is related to pressure-independent mechanisms involved in glaucoma pathogenesis and associated changes to the optic nerve.

Section 4: Ocular Response Analyzer Technology
The instrument

- 2002: Clinical research with ORA commenced
- 2005: The first generation ORA was launched
- 2012: Generation II ORA was launched
- 3rd Generation "ORA G3" introduced September 2015

Measures:
- Corneal Hysteresis (CH)
- Goldmann-correlated IOP (IOPG)
- Corneal compensated IOP (IOPcc)

Section 4: Ocular Response Analyzer Technology
Interpretation of measurement values

Section 4: Ocular Response Analyzer Technology
Bi-direction Applanation Signal

Section 4: Ocular Response Analyzer Technology
Personalized Glaucoma Risk Assessment

CH will help refine risk assessment
- Increase confidence in defining risk stratification based on CH values
- eg. "true," "medium," "high"
- Better information to decide who to treat; who to monitor
- Allocate resources to patients with highest risk of progression
- Decrease burden on patients at low risk for progression

NOTE: when CH is over 10 in absolute, CH will be reported lower than its true value due to deliberate limitations of the ORA delivery system. This should be taken into consideration.

As well, low CHs as a result of LASIK, Keratoconus, Sclera, or other alteration of corneal biomechanical properties should not be considered a risk factor for glaucoma. In these instances the IOPcc measurement is quite valuable.
Section 7: Implementing ORA in Your Practice

PRACTICAL ISSUES

Section 7: Implementing ORA in Clinical Practice

Implementing ORA in Clinical Practice

- Consensus guidelines needed for low/medium/high CH values
- How does the ORA best fit into practice workflow
- Where does ORA fit into the measurement process?
  - Prior to the patient getting into the chair
  - Prior to anesthesia (before measurement of CCT)
- IOP, advantages vs GAT
  - Saves time
  - Saves $ on drops fluorescence and anesthesia
  - No operator bias
  - Easily delegated to staff
  - Does not require sterilization
  - Less influence by corneal properties

Section 7: Implementing ORA in Your Practice

Reimbursement

- CPT code 92145 - code published January 1, 2015
  - 92145: Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral with interpretation and report
  - According to An Insider’s View published by the AMA: “this test achieved Category I status because the clinical utility has been established and usage has grown since 2007 when the Category II code was implemented”
  - Reichert is working with consultants, regional champion MDs, and MAC directors in strategic fashion to ensure positive payment policies (LCD5)
  - Bilateral reimbursement estimated to be approximately $16.00
  - Patient qualifications and frequency TBD

Section 7: Implementing ORA in Your Practice

Special considerations

In post-LASIK/refractive surgery and in Corneal Pathology (IC, Fuchs’)

- CH is not a reliable indicator of glaucoma risk due to modified biomechanics
  - In these situations there is increased importance of IOP

Is there a need to educate ORA users for correct interpretation of CH values?

- Children have significantly higher CH values than adults, which should be taken into consideration when determining glaucoma risk
- CH values are artificially low with very high IOP (3D+)

Section 5: Incorporating CH in Clinical Practice

CH is a More Powerful Glaucoma Risk Factor than CCT

In every study where CH and CCT have been compared, CH is more significantly associated with glaucoma than CCT

- CCT has limited sensitivity and specificity for differentiating ocular hypertension from POAG 1
- CH explained 17.4% of the variation in the rates of progression, CCT explained only 5.2%2
  - We found a moderate correlation between CH and CCT and that CH was the parameter most strongly associated with VF progression.3

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Progressing (n=29)</th>
<th>Non-progressing (n=120)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCT (mmHg)</td>
<td>525 (535) μm</td>
<td>542 (195) μm</td>
<td>0.04</td>
</tr>
<tr>
<td>CH (mmHg)</td>
<td>7.5 (3.4) mmHg</td>
<td>5.5 (1.9) mmHg</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

References:
2. Hayashi T et al. J Glaucoma 2011;20:1031-1036
3. Tsubota K et al. J Glaucoma 2002;11:359-361