Confirmation of Visual Field Abnormalities in the Ocular Hypertension Treatment Study (OHTS)

The Ocular Hypertension Treatment Study Group (OHTS)
National Eye Institute, National Center for Minority Health and Health Disparities, NIH grants EY09307, EY09341, EY02687, Unrestricted Grant from Research to Prevent Blindness, Merck Research Laboratories and Pfizer, Inc.
Ocular Hypertension Treatment Study

PURPOSE

To determine the reproducibility of abnormal visual fields observed during follow-up of patients in the OHTS.
Ocular Hypertension Treatment Study

National Eye Institute
Research Grant
NIH EY09341, EY09307

Unrestricted Grant from Research to Prevent Blindness
Ocular Hypertension Treatment Study

Randomized, multi-center clinical trial to assess:

- Safety
- Efficacy of ocular hypotensive medication in preventing or delaying POAG
Ocular Hypertension Treatment Study

**Enrollment**
Target: 1,500 subjects
Achieved: 1,637 subjects

**Clinics**
22 Clinics nationwide
Definition of OHTS VISUAL FIELD ABNORMALITY

A reliable visual field is defined “abnormal” when...

- The GHT index is abnormal (Outside Normal Limits or General Reduction of Sensitivity), and or

- The CPSD index has a $p$ value of $<5\%$
If a reliable follow-up field is abnormal, the eye is retested.

If the retest is reliable and abnormal on the same indices and in approximately the same location, the abnormality is defined as confirmed.
Visual Field Abnormalities
Returning to Normal:

Between April 1, 1994, and March 1, 1999

21,603 visual fields were performed on 1,636 patients in the OHTS
Visual Field Abnormalities

Returning to Normal:

• 1,006 of 21,603 were follow-up retests performed because of abnormality (748) or unreliability (unacceptability) 258:

• 703 (94%) of the 748 visual fields were abnormal and reliable (acceptable)
Visual Field Abnormalities
Returning to Normal

• On retesting, abnormalities were not confirmed for 604 (86%) of the 703 originally abnormal and reliable (acceptable) visual fields
Abnormalities Replicated and Not Replicated

<table>
<thead>
<tr>
<th>ABNORMALITY REPLICATED</th>
<th># VF's (%)</th>
<th>ABNORMALITY NOT REPLICATED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>467 (66.4)</td>
<td>1. Normal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Normal but with borderline results</td>
</tr>
<tr>
<td>GHT Borderline</td>
<td>39 (5.5)</td>
<td>3. Initial Abnormality Not Replicated</td>
</tr>
<tr>
<td>CPSD ( p &lt;10% )</td>
<td>29 (4.1)</td>
<td>Different index</td>
</tr>
<tr>
<td>MD ( p &lt;5% ) (or lower)</td>
<td>22 (3.1)</td>
<td>Different location</td>
</tr>
<tr>
<td>GHT Borderline, CPSD ( p &lt;10% )</td>
<td>13 (1.8)</td>
<td>Artifact: heavy brow/droopy lid</td>
</tr>
<tr>
<td>GHT Borderline, MD ( p &lt;5% ) (or lower)</td>
<td>2 (0.3)</td>
<td>lens rim</td>
</tr>
<tr>
<td>CPSD ( p &lt;10% ), MD ( p &lt;5% ) (or lower)</td>
<td>4 (0.6)</td>
<td>fatigue/drowsiness</td>
</tr>
<tr>
<td>GHT Borderline, CPSD ( p &lt;10% ), MD ( p &lt;5% ) (or lower)</td>
<td>3 (0.4)</td>
<td>15 (2.1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Normal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Normal but with borderline results</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Initial Abnormality Not Replicated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Different index</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Different location</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Artifact: heavy brow/droopy lid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lens rim</td>
</tr>
<tr>
<td></td>
<td></td>
<td>fatigue/drowsiness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25 (3.6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>604* (85.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>703 (100.0)</td>
</tr>
</tbody>
</table>

*Note: This is the sum of the 3 categories above in which the abnormality is not replicated
Figure 1: The Quality Control Performance of OHTS Clinics for Visual Fields Performed Between July 1998 and June 2000
Figure 2: A Trial Lens Rim Artifact that Might be Misinterpreted as Glaucomatous Visual Field Loss. It is Absent on Retest.

TEST (5/20/97)
- Rx Used: + 5.00 + 0.50 x 180
- Pupil Diameter: 4.0 mm
- GHT: outside normal limits
- CPSD: p < 0.5%

RETEST (5/27/97)
- Rx Used: + 5.50 DS
- Pupil Diameter: 4.0 mm
- GHT: normal
- CPSD: normal
Figure 3: A Drooping Lid or Brow that is Absent on Retest

TEST (5/3/96)

- Rx Used: +3.00 DS
- Pupil Diameter: 4.0 mm
- GHT: normal
- CPSD: $p < 5\%$

RETEST (5/17/96)

- Rx Used: +2.00 DS
- Pupil Diameter: 4.0 mm
- GHT: normal
- CPSD: normal
Figure 4: An Inferior Arcuate Visual Field Defect that Completely Clears Up on Retest

TEST (4/2/97)

Rx Used: + 4.00 DS
Pupil Diameter: 4.5 mm

GHT: Outside Normal Limits
CPSD: p < 2%

RETEST (4/9/97)

Rx Used: + 4.00 DS
Pupil Diameter: 4.5 mm

GHT: normal
CPSD: normal
Figure 5: An Inferior Arcuate Defect with Central Depression that Resolves on Retest

**TEST (5/30/97)**
- Rx Used: + 3.25 DS
- Pupil Diameter: 4.0 mm
- GHT: Outside Normal Limits
- CPSD: $p < 10\%$

**RETEST (6/6/97)**
- Rx Used: + 3.25 DS
- Pupil Diameter: 4.5 mm
- GHT: *normal*
- CPSD: *normal*
Figure 6: A Superior Arcuate Defect with an Inferior Nasal Step that Resolves on Retest

TEST (5/1/96)
- Rx Used: -2.00 +1.50 x 175
- Pupil Diameter: 4.0 mm
- GHT: Outside Normal Limits
- CPSD: normal

RETEST (5/28/96)
- Rx Used: -2.00 +1.50 x 175
- Pupil Diameter: 4.0 mm
- GHT: normal
- CPSD: normal
Figure 7: A Generalized Diffuse Loss both Superiorly and Inferiorly with a Suggestion of a Double Arcuate Visual Field Defect that Completely Clears on Retest

TEST (7/12/95)

Rx Used: + 2.50 DS
Pupil Diameter: 5.0 mm

GHT: General Reduction
CPSD: normal

RETEST (7/28/95)

Rx Used: + 3.00 DS
Pupil Diameter: 4.0 mm

GHT: normal
CPSD: normal
Figure 8: An Inferior Temporal Vertical Step (Etiology Unclear) that Resolves on Retest

**TEST (7/30/97)**

- **GHT:** Outside Normal Limits
- **CPSD:** $p < 5\%$
- **Rx Used:** -3.50 DS
- **Pupil Diameter:** 6.0 mm

**RETEST (9/15/97)**

- **GHT:** normal
- **CPSD:** normal
- **Rx Used:** -3.50 DS
- **Pupil Diameter:** 5.0 mm
SUMMARY

• Of the 21,603 follow-up visual fields, 1,006 were follow-up retests performed because of abnormality (748) or unreliability (258)

• 94% (703 of the 748) visual fields were abnormal and reliable, and 45 (6%) were abnormal and unreliable

• 85.9% (604 of the 703) of the abnormalities were not confirmed on retest

• The majority of visual field abnormalities in OHTS patients were not confirmed on retest.
CONCLUSION

- Confirmation of visual field abnormalities is essential for distinguishing reproducible visual field loss from long-term variability.

- OHTS now requires 3 consecutive reliable abnormal visual fields with the same abnormal indices and location to confirm an abnormality (June, 1997).
OHTS Clinical Centers

- Bascom Palmer Eye Institute
- Baylor Eye Clinic
- Charles R. Drew University
- Devers Eye Institute
- Emory University Eye Center
- Eye Associates of Washington, DC
- Eye Consultants of Atlanta
- Eye Doctors of Washington
- Eye Physicians and Surgeons of Atlanta
- Glaucoma Care Center
- Great Lakes Ophthalmology
- Henry Ford Hospitals
- Johns Hopkins University
- Jules Stein Eye Institute, UCLA
- Kellogg Eye Center
- Kresge Eye Institute

- Krieger Eye Institute
- Maryland Center for Eye Care
- Mayo Clinic/Foundation
- New York Eye & Ear Infirmary
- Ohio State University
- Salus University
- Scheie Eye Institute
- University of California, Davis
- University of California, San Diego
- University of California, San Francisco
- University of Louisville
- University Suburban Health Center
- Washington Eye Physicians & Surgeons
- Washington University, St. Louis
OHTS Resource Centers

Study Chairman’s Office
&
Coordinating Center
Washington University
St. Louis, MO

Optic Disc Reading Center
Bascom Palmer Eye Institute
University of Miami
Miami, FL

Visual Field Reading Center
University of California, Davis
Sacramento, CA