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.

#### PURPOSE

To determine the reproducibility of abnormal visual fields observed during follow-up of patients in the OHTS

National Eye Institute Research Grant NIH EY09341, EY09307

Unrestricted Grant from Research to Prevent Blindness

Randomized, multi-center clinical trial to assess:

- Safety
- Efficacy of ocular hypotensive medication in preventing or delaying POAG

Enrollment Target: Achieved:

1,500 subjects 1,637 subjects

**<u>Clinics</u>** 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%</li>

## **ORIGINAL RETEST PROTOCOL**

- 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**

	#VF's	(%)	#VF's	(%)	#VF's	(%)
ABNORMALITY REPLICATED					<b>99</b>	(14.1)
ABNORMALITY NOT REPLICATED						
1. Normal			467	(66.4)		
2. Normal but with bordeline results						
GHT Borderline	39	(5.5)				
CPSD $p < 10\%$	29	(4.1)				
MD $p < 5\%$ (or lower)	22	(3.1)				
GHT Borderline, CPSD $p < 10\%$	13	(1.8)				
GHT Borderline, MD $p < 5\%$ (or lower)	2	(0.3)				
CPSD $p < 10\%$ , MD $p < 5\%$ (or lower)	4	(0.6)				
GHT Borderline, CPSD $p < 10\%$ , MD $p < 5\%$ (or lower)	3	(0.4)				
			112	(15.9)		
3. Initial Abnormality Not Replicated						
Different index	15	(2.1)				
Different location	1	(0.1)				
Artifact: heavy brow/droopy lid	6	(0.9)				
lens rim	3	(0.4)				
fatigue/drowsiness	0					
			25	(3.6)		
					604*	(85.9)
					703	(100.0)

\*Note: This is the sum of the 3 categoreis 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

Pupil Diameter: 4.0 m



GHT: outside normal limits CPSD: *p* < 0.5%



#### 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%



#### Figure 4: An Inferior Arcuate Visual Field Defect that Completely Clears Up on Retest



Rx Used: + 4.00 DS Pupil Diameter: 4.5 mm



GHT: Outside Normal Limits CPSD: *p* < 2%



#### 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%



#### 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

## X



GHT: Outside Normal Limits 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



Rx Used: + 3.00 DS Pupil Diameter: 4.0 mm

#### **Figure 8: An Inferior Temporal Vertical Step** (Etiology Unclear) that Resolves on Retest

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



**Rx Used: -3.50 DS** Pupil Diameter: 6.0 mm





**GHT:** Outside Normal Limits **CPSD:** p < 5%



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
- <u>85.9% (604 of the 703) of the abnormalities were not</u> <u>confirmed on retest</u>
- 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