**Evidence Table**

**Clinical Area:** Heidelberg Retina Tomograph for the diagnosis of glaucoma  
**Keywords:** glaucoma, visual field changes  

**Study Type:** Comparison of diagnostic tests (retrospective)  
**Study Aim:** To determine the agreement between the Heidelberg Retinal Tomograph (HRT) and visual field examinations in differentiating normal from glaucomatous eyes; evaluate the sensitivity and specificity of HRT in detecting eyes with glaucoma.

**Outcomes**  
- **Primary:** Agreement between HRT and visual field examinations (kappa statistic); sensitivity and specificity of HRT.

**Design**  
- **Number of subjects:** N=359 (n=209 with ocular hypertension, n=55 normal, n=95 with primary open-angle glaucoma).  
- **Description of study population:** Retrospective chart review of data from consecutive patients attending a clinic in Italy. Age range=35 to 77 years. The study included patients with normal eyes, patients with ocular hypertension (OHT) which increases the risk of developing glaucoma, and patients with primary open-angle glaucoma (POAG). Mean age: normal=60.8 ±9.2 years; OHT=63.4 ± 10.0 years; POAG=60.8 ± 9.2 years.  
- **Inclusion criteria:** 20/20 visual acuity, clear lens, normal retina. The diagnosis of POAG was based on the presence of an abnormal visual field consistent with glaucoma--outside normal limits if the glaucoma hemifield tests and a statistically significant corrected pattern standard deviation of more than 4 dB. The defect needed to be shown in two different visual fields repeated within 6 months. The clinical appearance of the optic disc was not considered. Normal was defined as an IOP <21 mmHg (under topical medical treatment). OHT was defined as an IOP >21 mmHg (without topical medical treatment).  
- **Exclusion criteria:** Myopia more than –6 diopters (D), optic disc abnormality (i.e. drusen or a tilted disc), history of neuroophthalmologic disease, diagnosis of low-tension glaucoma.  
- **Procedure:** One eye was randomly chosen from each patient. All patients underwent a complete ophthalmologic evaluation. Biomicroscopy of the anterior segment and intraocular pressure (IOP) measurements were done before pupillary dilation. Indirect ophthalmoscopic fundus oculi evaluation and HRT examination were done after dilation. The HRT examinations were performed using a 10° angle view where possible, otherwise a 15° angle view was used. The HRT data discriminating between normal and glaucomatous eyes were analyzed in several ways, multivariate discriminant analysis (MDA) and ranked-section distribution (RSD) curves.

**Validity**  
- **Independent blind comparison with a gold standard or follow-up of those not receiving the gold standard test?** The gold standard was not specified. It appears to be visual field loss.  
- **Was “normal” defined?** Yes.  
- **Appropriate spectrum of disease?** Appears to be.  
- **Consecutive patients?** Yes.  
- **Methods described in enough detail to enable you to replicate the test?** Yes.  
- **Reproducible results?** Yes.
Conclusions regarding validity of methods:
The study design (retrospective chart review) is weaker than a prospective comparison of diagnostic tests. With a retrospective design, it is harder to ensure that a standard protocol was followed. Visual field loss may not be appropriate gold standard since HRT is designed to detect changes before they are observable in the optic field.

Results
Test characteristics of the Heidelberg Retina Tomograph, using two methods of analyzing HRT data (whole sample)

<table>
<thead>
<tr>
<th>Test Characteristics</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivariate discriminant analysis</td>
<td>80%</td>
<td>65%</td>
<td>45%</td>
<td>90%</td>
</tr>
<tr>
<td>Ranked segment distribution curves</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rim to disc area ratio</td>
<td>50%</td>
<td>92%</td>
<td>70%</td>
<td>84%</td>
</tr>
<tr>
<td>Rim volume</td>
<td>51%</td>
<td>91%</td>
<td>69%</td>
<td>84%</td>
</tr>
<tr>
<td>RNFL cross-sectional area</td>
<td>31%</td>
<td>92%</td>
<td>59%</td>
<td>79%</td>
</tr>
<tr>
<td>At least one HRT parameter positive for glaucoma</td>
<td>81%</td>
<td>62%</td>
<td>44%</td>
<td>90%</td>
</tr>
</tbody>
</table>

PPV=positive predictive value; NPV=negative predictive value

Agreement between the visual field-based and HRT definitions of glaucoma
Kappa ranged between 0.48-0.28=fair to poor agreement

Note: Kappa measures the degree of agreement beyond chance.

Authors’ Conclusions
“In a broad clinical setting including normal, OHT and glaucoma patients, the HRT and visual field tests have fair to poor agreement in detecting glaucoma. The HRT demonstrated a lack of specificity when using Mikelberg’s multivariate discriminant analysis and a lack of sensitivity when using cumulative frequency distribution (ranked-segment distribution) curves. These values did not change when normal or OHT patients were excluded from the analysis. In the clinical setting, caution should be used when interpreting HRT results on the basis of multivariate discriminant analysis or cumulative frequency distribution curves.”

Reviewer’s Conclusions
The sensitivity and specificity of the Heidelberg Retina Tomograph depends on the analysis method and parameter used. No analysis method had both high sensitivity and high specificity. The HRT is designed to detect glaucomatous changes before visual field loss occurs. This may at least partially explain the poor agreement between visual-field based and HRT definitions of glaucoma.