Evidence Table

Clinical Area: Optical Coherence Tomograph
Keywords: Glaucoma, diagnosis, sensitivity and specificity

Study Type: Comparison of diagnostic tests (prospective)
Study Aim: To compare the ability of the GDx, Heidelberg Retina Tomograph II (HRT II) and Optical Coherence Tomograph (OCT) to discriminate between healthy eyes and eyes with glaucomatous visual field loss.

Outcomes
• **Primary**: Area under the receiver operating curve (ROC), sensitivities at fixed specificities.

Design
• **Number of subjects**: N=183 (n=107 with glaucomatous visual field loss, n=76 with healthy eyes). N=141 (77%) had acceptable images and were included in the analysis.

• **Description of study population**: Patients were evaluated at the Glaucoma Center at UCSF between April, 2002 and November, 2003. (Of study completers): Mean age of patients with glaucoma=68 ± 10 years; mean age of patients with healthy eyes=65 ± 8 years.

• **Inclusion and exclusion criteria**: Patients with glaucoma: Best-corrected visual acuity of 20/40 or better in the affected eye; spherical refraction within ± 5.0 dipters (D); cylinder correction ± 3.0 D; open angles on gonioscopy. Excluded patients with coexisting retinal disease, uveitis or nonglaucomatous optic neuropathy. Patients with healthy eyes: Intraocular pressure ≥21 mm Hg; no history of increased intraocular pressure; normal visual field test; healthy appearance of the optic disc and retinal nerve fiber layer (RNFL).

• **Procedure**: One eye from each patients was randomly selected for study. All patients underwent imaging using 3 commercially available instruments within 6 months: the GDx (software version 5.01), HRT II and Status OCT.

Validity
• **Independent blind comparison with a gold standard or follow-up of those not receiving the gold standard test**? The visual field test was the gold standard.

• **Was “normal” defined?** Yes.

• **Appropriate spectrum of disease?** Patients were previously known to be have glaucomatous or healthy eyes, so the instruments were not used for screening.

• **Consecutive patients?** Not specified.

• **Methods described in enough detail to enable you to replicate the test?** Yes.

• **Reproducible results?** Yes.
Conclusions regarding validity of methods:
The study design is reasonably valid for its stated purpose. It is not valid for determining
the usefulness of the OCT for detecting early glaucoma, before visual field loss. A
limitation is that images were unacceptable for about one-third of the study participants.

Results

Note: ROC curves were used to describe the ability of each parameter from each
instrument to differentiate glaucomatous from normal eyes. An area under the ROC curve
(AUC) of 1.0 indicates perfect discrimination, an area of 0.5 indicates chance
discrimination.

No statistically significant difference was found between the area under the curve for the
best parameters from each instrument:
GDx (nerve fiber indicator, NFI, AUC=0.91)
OCT (inferior thickness, AUC=0.92)
HRT II (Bathija function, AUC=0.86).

At specificities of at least 95%, no significantly significant differences were found among
parameters with the highest sensitivities from each instrument:
GDx (NFI, sensitivity=61%)
OCT (average thickness, 71%)
HRT II (Bathija function, 59%)

At specificities of at least 80%, a statistically significant difference was found between
the HRT II and GDx parameters with the best sensitivity, and between the HRT II and
OCT parameters with the best sensitivity. The values for the HRT II and OCT
comparison were: HRT II (Mikelberg function, sensitivity 73%) and OCT (inferior
thickness, sensitivity=89%), p=0.01. There was no statistically significant difference
between the GDx and OCT parameters with the best sensitivity.

Note: kappa measures chance-corrected agreement. It ranges from 0 to 1. 0-.2=slight
agreement, .21-.4=fair agreement, .41-.6=moderate agreement, .61-.80= substantial
agreement; kappa between 0.81-1.0=almost perfect agreement.

Overall classification of participants into glaucomatous vs. healthy eyes
GDx and OCT agreed in 89% of cases (kappa=0.72)
GDx and HRT II agreed in 81% of cases (kappa=0.50)
OCT and HRT II agreed in 81% of cases (kappa=0.55)

Authors’ Conclusions
“The AUCs and the sensitivities at high specificities were similar among the best
parameters from each instrument….”
Reviewer’s Conclusions
The investigators found that the GDx, HRT II and OCT were similar in their ability to discriminate between glaucomatous eyes. The study does not address the ability of any of these instruments to identify early glaucoma, before visual field loss, or monitor the progression of disease.