Rethinking Glaucoma Management

Using Wearable Diagnostics From Heru re:Vive Visual Field

Key Messages

- re:Vive™ by Heru™ enables visual field testing on a portable, lightweight headset.
- The re:Imagine (re:I) Threshold strategy used by Heru's platform shows strong correlation with Humphrey SITA Standard, has excellent reproducibility, and a shorter testing time.
- The portable nature of the wearable device, along with features such as the patented Heru Active Track™ and no need for a dark room allow for more flexibility in visual field testing and may help expand the patient base and settings in which visual field testing can be performed.

Introduction

Visual field (VF) testing is an integral element of diagnosing and managing various ophthalmological conditions, most notably glaucoma, neuro-ophthalmological disorders, and retinal diseases such as drug-induced maculopathy. By quantifying the sensitivity of the patient's vision, VF testing allows clinicians to characterize and monitor visual function over time. Features important in VF testing include accuracy, reliability and repeatability, patient compliance, and provider convenience. Furthermore, having a secure, encrypted technology system that maintains patient privacy and confidentiality is vital.

The ZEISS Humphrey Field Analyzer (HFA) has evolved over the years to become the most universally used static perimetry system to measure and examine visual fields, especially for glaucoma management.[1] Despite its widespread use, the device has a few drawbacks. The HFA is bulky and costly, which may limit its adoption in certain settings; the tests are time consuming, which can slow clinic workflow and contribute to patient fatigue and worsen test reliability;[2] patients need to be positioned at the device in a certain way, which can be difficult or prohibitive for patients with reduced mobility. Unfortunately, mobility issues are more common in older patient populations who need VF testing the most. It is estimated that 50% of people with glaucoma today remain undiagnosed, and this number is even higher in minority and underserved populations.[3] With an aging global population, it is evident that the current state of glaucoma diagnostics is unable to adequately meet the need.[4]

The rapid introduction of telemedicine, and the rising prevalence of glaucoma worldwide,[5] most notably in third-world countries (predicted to surpass 111 million by 2040), illustrate the need for a portable and user-friendly platform that offers novel and more cost-effective means of testing the visual field to enhance patients' screening and compliance.

In this paper, we describe the development and studies performed using a novel visual field platform, the re:Vive visual field developed by Heru, Inc. (Miami, FL, USA), which uses a lightweight, wearable headset to perform visual field testing.

Background

The ability to measure the visual field using headsets was first developed at Bascom Palmer Eye Institute (University of Miami, FL, USA) to support visual field remapping to improve visual awareness and mobility in glaucoma patients. A study in 23 patients with visual field loss found that the ability to identify peripheral objects improved with the use of digital spectacles that tested the visual field and used a customized algorithm to remap the test image to intact areas of the visual field.[6] In this study, the comparability to HFA was also evaluated, and an error of 7.6% (standard deviation of 5.3%) was found, consistent with the known subjectivity of the test.[7] This was further tested in 2020 in 21 patients, where the researchers found that mobility and other measures of gaze accuracy improved overall.[8]

Development of Subjective Visual Field Test

The ability to perform subjective visual field testing was then integrated into re:Vive, Heru's ophthalmic diagnostic platform. There are several key differences between the HFA and Heru visual fields, which are summarized in Table 1 below:

	HFA 24-2 SITA Standard	**Heru 24-2 re:I Threshold**
Hardware	Perimetry bowl	Waveguide high-resolution display (1.3 megapixels per eye)
Stimulus	White light projected on perimeter bowl	White light displayed on dark AR background
Stimulus size	Goldman Size III	Goldman Size III (dynamic sizing available)
Background illumination	10 cd/m^2	1 cd/m^2
Brightest stimulus intensity	3183.1 cd/m^2	210 cd/m^2
Source of sensitivity differences	Luminance	Contrast & size
Gaze control	Blind spot monitoring, optional ability to monitor & report on gaze	Active real-time eye tracking (Heru Active Track™ 60 Hz), blind spot monitoring
Ambient light control	Dark room	None required
Test pattern	24-2	24-2
Test strategy	SITA Standard	re:Imagine (re:I) Threshold
Normative data	Proprietary	From Ref 9
Stimulus duration	200 msec	200 msec
Testing distance	30 cm	Infinity
Interstimulus time	Random	Adaptive
Fellow eye patched	Yes	No
Reliability indices	False positive, false negative (%)	False positive, false negative (%)
Refractive correction	Trial lenses	Trial lenses

Table 1. ZEISS HFA and Heru re:Vive comparison

To achieve a diagnostic capability similar to HFA, several considerations needed to be addressed. First, instead of having a bright white light projected onto the surface of a perimetry bowl, re:Vive by Heru uses the headset device to present a white stimulus on a dark virtual background. To test a wide dynamic range, the stimulus size is dynamically adjusted in the high end of retinal sensitivity thresholds.

While blind spot monitoring similar to the HFA is available, re:Vive employs an active eye tracking system (Heru Active Track™) as its primary fixation monitoring methodology. During the VF test, infrared LEDs in the device camera illuminate the eye and provide individual gaze coordinates at a frequency of 60 Hz, and stimulus lights are only presented when the patient is properly fixating (and will prompt the patient to regain fixation if improper fixation is detected), thus eliminating fixation loss errors and ensuring the reliability of each stimulus presentation in real time.

To limit the amount of ambient light entering the perimetry bowl, HFA requires that the test be performed in a dark room. In clinical practice, this means the device often needs to be in a dedicated room to ensure the rest of the clinic can continue undisrupted. The Heru platform uses a light shield that blocks light ingress points, allowing the VF test to be performed anywhere within the practice.

Finally, the testing distance between the two systems is different. The HFA has a testing distance of 30 cm, which represents approximately 3.3 diopters of accommodative demand. Because of this, the optical correction used for HFA testing changes based on the patient's age and presbyopic correction. Heru headsets present the stimuli at optical infinity, so the patient's distance correction is always used, and the testing is not affected by presbyopia or its associated image magnification differences due to changes in trial lens power.

Figure 1. re:Vive by Heru uses headsets that are lightweight and portable, allowing for more flexibility in VF testing.

Review of Studies

To further confirm the accuracy of the Heru re:I Threshold test strategy, a prospective study comparing the HFA 24-2 to re:Vive by Heru 24-2 was performed. The study included 47 eyes (21 healthy and 26 of patients with glaucoma and neuro-ophthalmic diseases) and found strong correlations between Heru VF mean deviation and threshold values and those of HFA in normal eyes ($R=0.91$, $P<0.001$) and eyes with glaucoma and other pathologies ($R=0.81$, $P<0.001$).[10] These correlations are better than those seen in other alternatives to bowl perimetry.[11,12] The study also found excellent reproducibility with ICC of 0.95 (95% CI 0.86-0.98) and 0.80 (95% CI 0.78-0.82) on normal and pathologic eyes, respectively. The re:I Threshold strategy was statistically significantly faster than the HFA SITA Standard (4.3 vs 5 minutes respectively; $P<0.001$), with a 15% gain in pathologic eyes and an 8% gain in healthy eyes. Additional data was added in a separate study, bringing the total eyes tested to 81 (40 normal eyes and 41 from eyes with pathology), showing similar results.[13]

Figure 2 below shows the comparison between 24-2 threshold visual field tests done on HFA and re:Vive by Heru for a healthy eye and an eye with glaucoma.

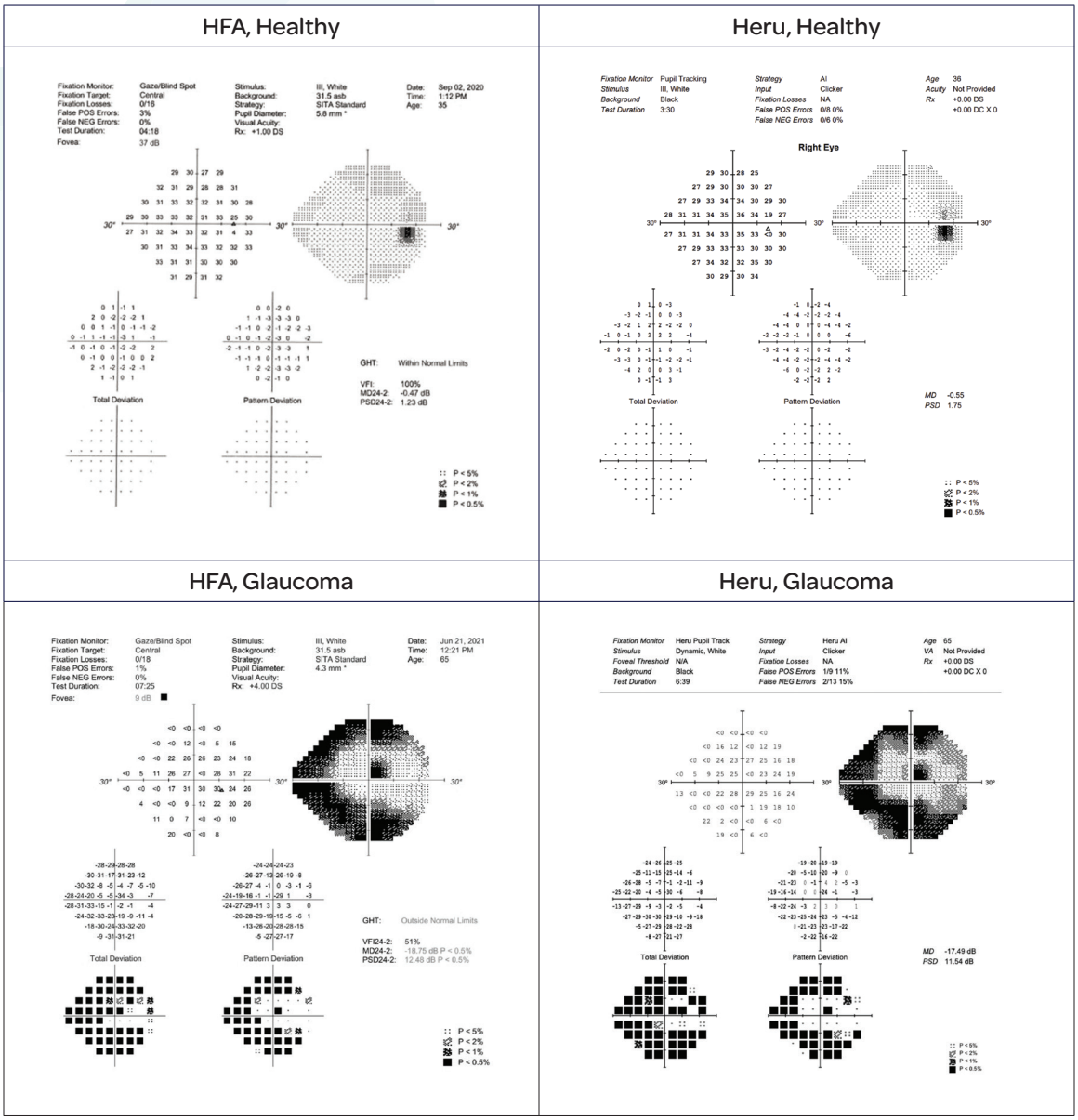

Figure 2. A healthy eye and an eye with glaucoma tested on the ZEISS HFA (left column) and re:Vive by Heru (right column). The similarity in the grayscale maps and deviation maps is evident. In the glaucoma case, superior and inferior arcuate scotomas as well as a focal paracentral defect can clearly be seen in both, with similar defect patterns and depth.

Conclusion

The rising prevalence of eye diseases, increasing demands for eye care and the current challenges in healthcare delivery necessitate new technologies to expand the reach of clinicians. The novel re:Vive by Heru visual field technology shows strong correlation with the Humphrey perimeter and excellent reproducibility, with a shorter testing time. In addition, its portable nature and use of a light shield allows the Heru VF to be performed in settings not suitable for traditional bowl perimeters. The re:Vive by Heru platform may enhance clinical care and telemedicine services provided to glaucoma and neuro-ophthalmology patients by enabling reliable VF testing on a portable, lightweight device.

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