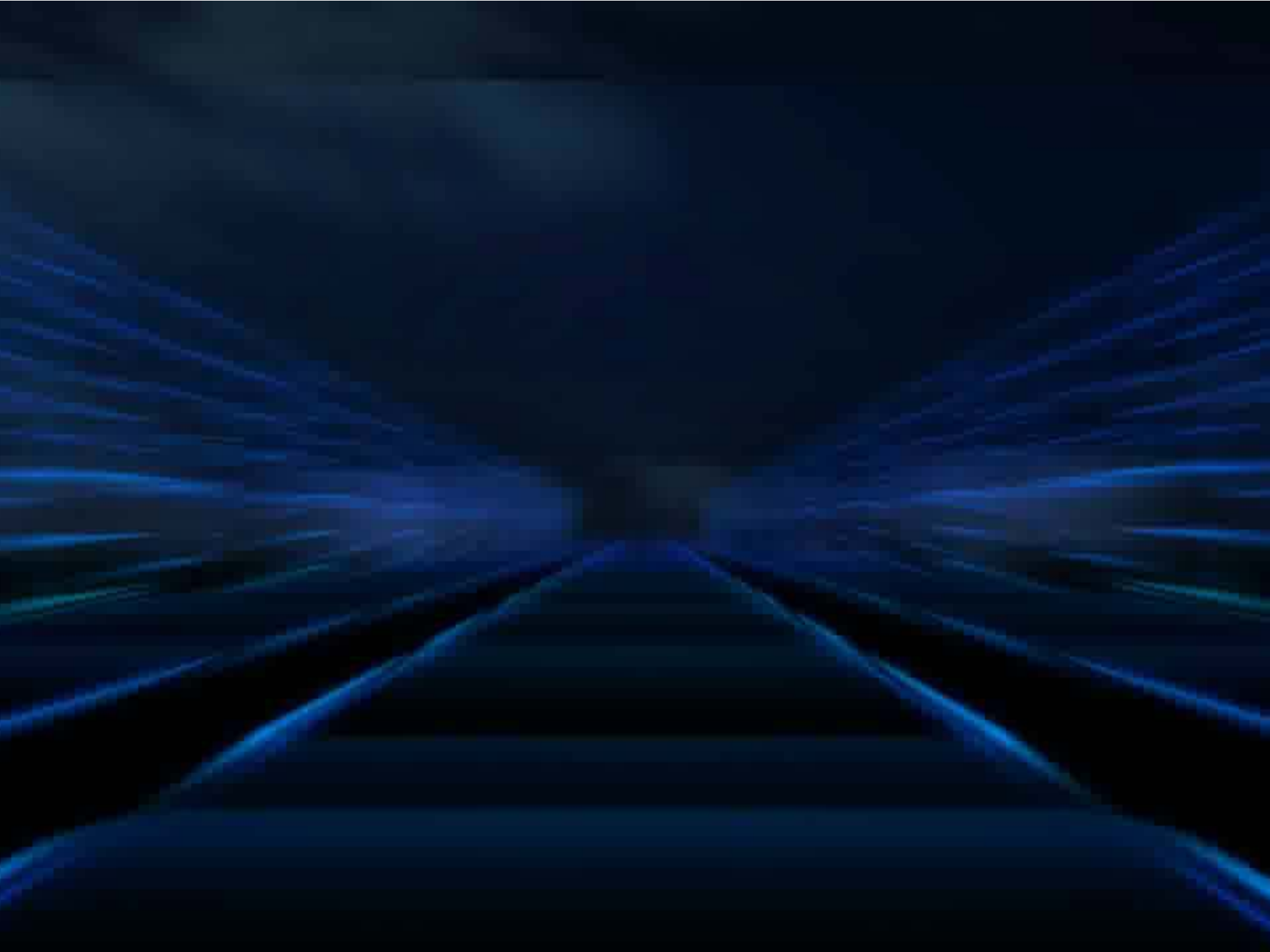


Beyond the Amsler Grid: Current Trends in Vision Self-Monitoring Approaches for AMD

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Disclosures

- Dr. Bittner is a co-investigator on an NIH/NEI phase II SBIR grant:
"Visual & Memory Stimulating (VMS) Grid Self-Monitoring Tests" R44EY018990

Outline

- Visual disability due to neovascular AMD
- Delay in the start of anti-VEGF treatment & worse vision outcomes
- Primary factors associated with delay in patient presentation
- Home vision monitoring options for patients

Optometrists' Role

Why should ODs learn about strategies & tools for AMD self-monitoring?

- Your AMD patients may be using these tools and may ask for your assistance or opinion
- Your AMD patients may not be using any self-monitoring tool and you have an opportunity to educate and offer recommendations
 - Busy ophthalmology/retina specialists offices may not have the time or resources to educate the patient
- *You can play a vital role in preventing vision loss in AMD patients who convert from dry to wet!*

Dry to Wet AMD

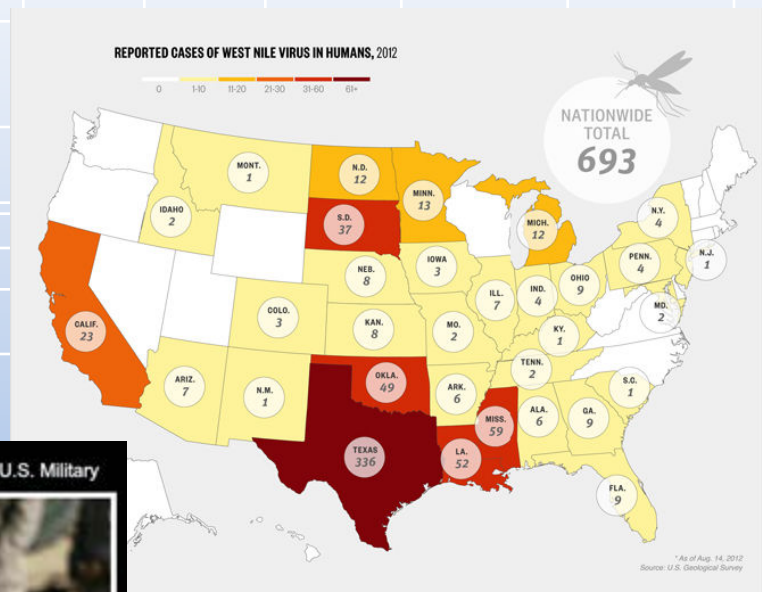
- Over 25% prevalence of atrophic (dry) AMD in elderly over age 85
- Wong et al. 2008: 10-15% of dry AMD will convert to wet (neovascular) AMD
- Even an improvement from current 94% to 99% efficacy in anti-VEGF therapy would not eliminate vision loss because many patients present weeks or months late, after significant loss of vision

Visual Signs & Symptoms

- The effects of choroidal neovascularization can be quite subtle:
 - Lines may look wavy due to the retina being deformed (metamorphopsia)
 - Small areas of vision may look blurry due to swelling of the retina
 - Areas may look washed out if photoreceptor function deteriorates
 - Only in late stage will areas be missing altogether due to photoreceptor dropout (scotoma)
- *Of course advanced dry AMD patients may have scotomas before CNV occurs...*

Treatment Delay & Vision

- Can you think back to these headlines?



Treatment Delay & Vision

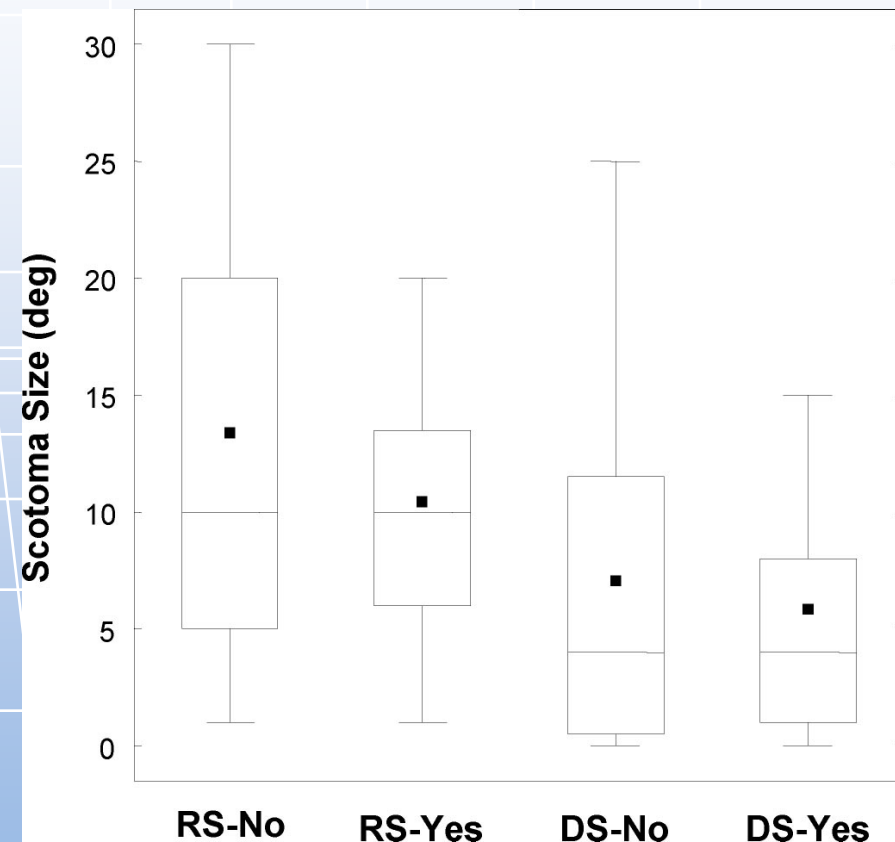
- Delay in the start of anti-VEGF treatment by several months (>21 wks. vs. <7 wks.) is significant risk factor for worse vision outcomes (Lim et al. AJO 2012)
- Typical delay in presentation to an eye care professional following newly developed neovascular AMD has been estimated as ~5 months based on typical progression of lesions over time (Vander et al. Ophthalmology 1989)

Factors assoc. w/ delay

- Various initial symptoms: blurry vision, wavy lines, &/or colored or blank spots
- Symptoms may be:
 - subtle,
 - away from fixation,
 - appear gradually enough to go unnoticed,
 - masked by filling-in phenomena,
 - intermittent,
 - in non-dominant eye... further adding to lack of confidence
- Patients may incorrectly attribute symptoms to non-urgent causes (cataracts, a need for new glasses, or just dry AMD progression)

Factors assoc. w/ delay

- Fletcher et al., 2012:
 - 88% of AMD patients referred for low vision rehab had binocular scotomas near fixation, & >50% were totally unaware of their presence
 - In patients with scotoma, awareness of scotoma is almost exclusively related to scotoma location, but not to size, density, VA, patient age, or duration since onset



Factors assoc. w/ delay

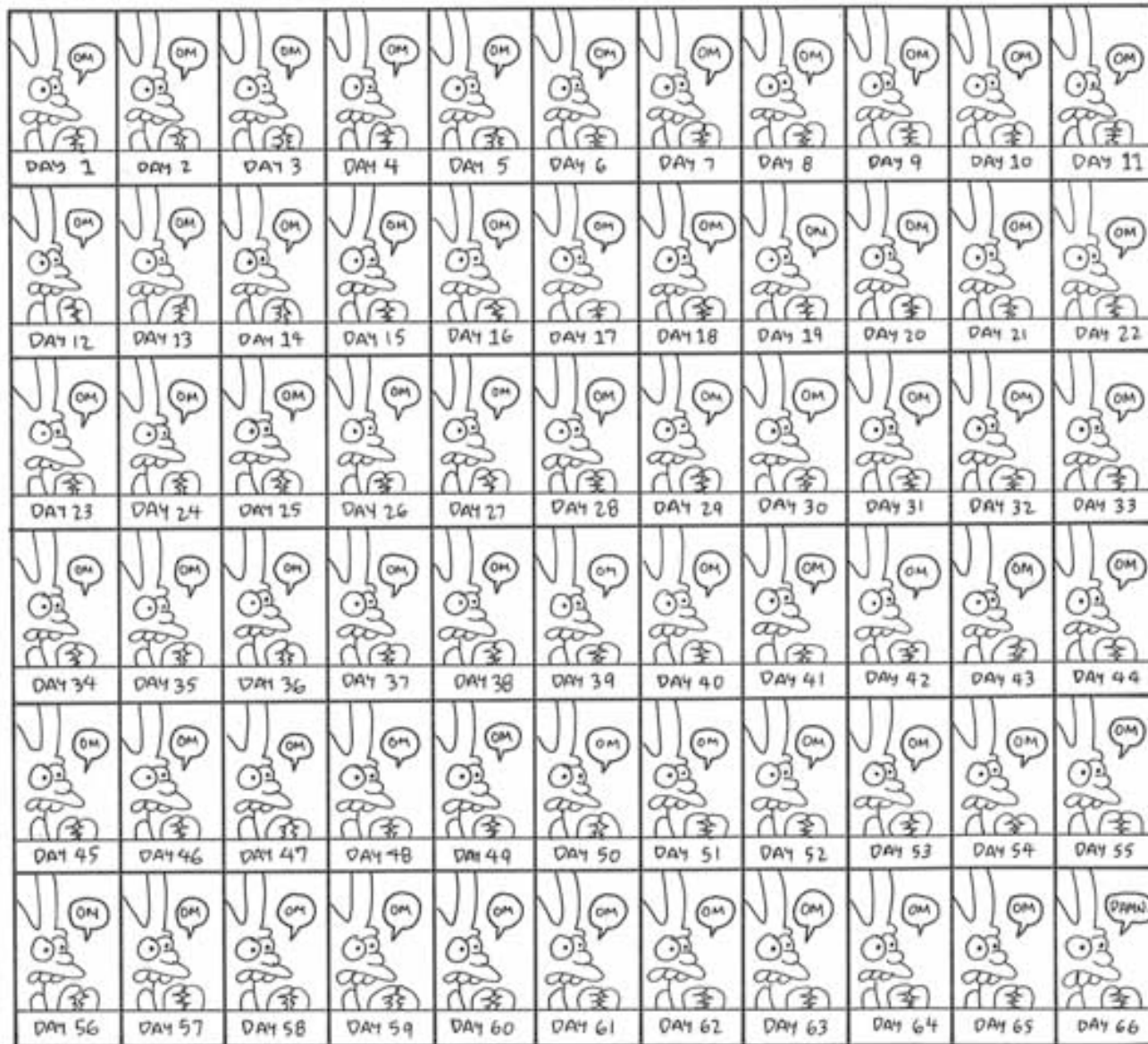
- Factors influencing the decision to schedule an appointment:
 - primary was lack of confidence in symptoms
 - 2nd was lack of urgency associated with symptoms

(Unpublished Study conducted in 2010;
focus groups with AMD patients seen in CT
retinal specialist's private practice)

LIFE IN
HELL

©1989 BY
MATT
GROENING

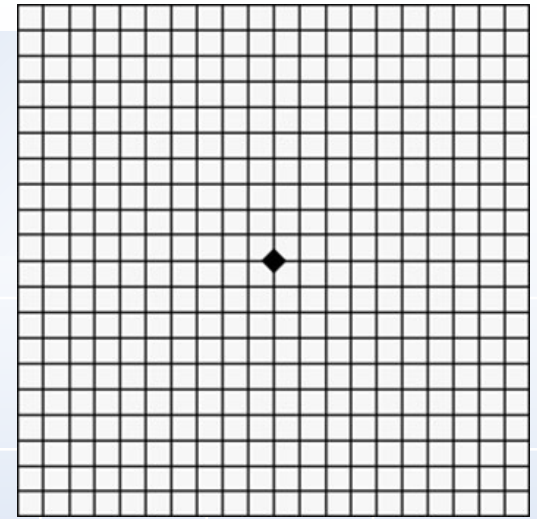
BINKY'S SEARCH FOR ENLIGHTENMENT



How effective is the
gold-standard
Amsler Grid?

Amsler Grid

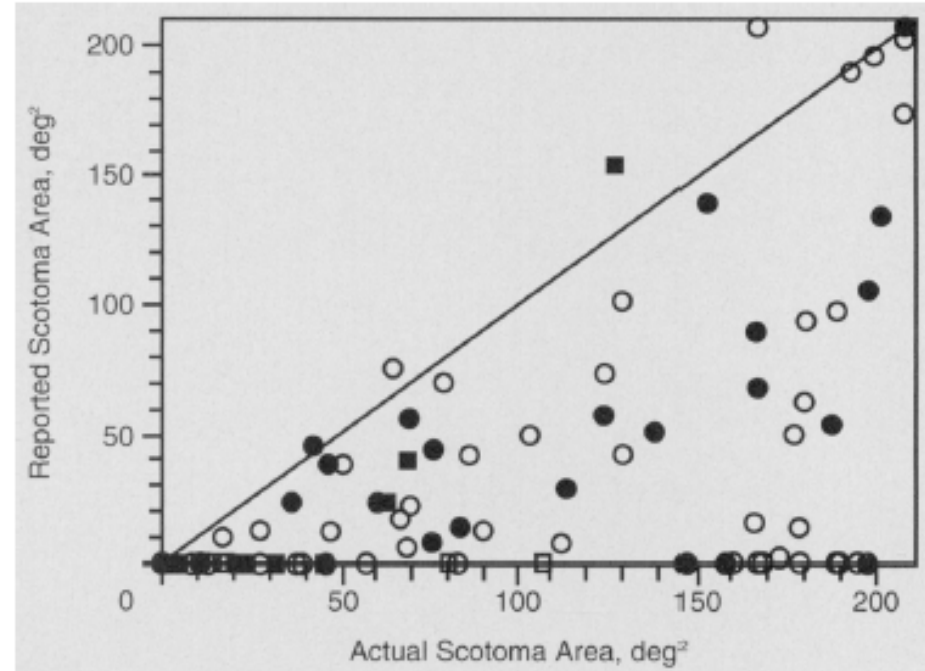
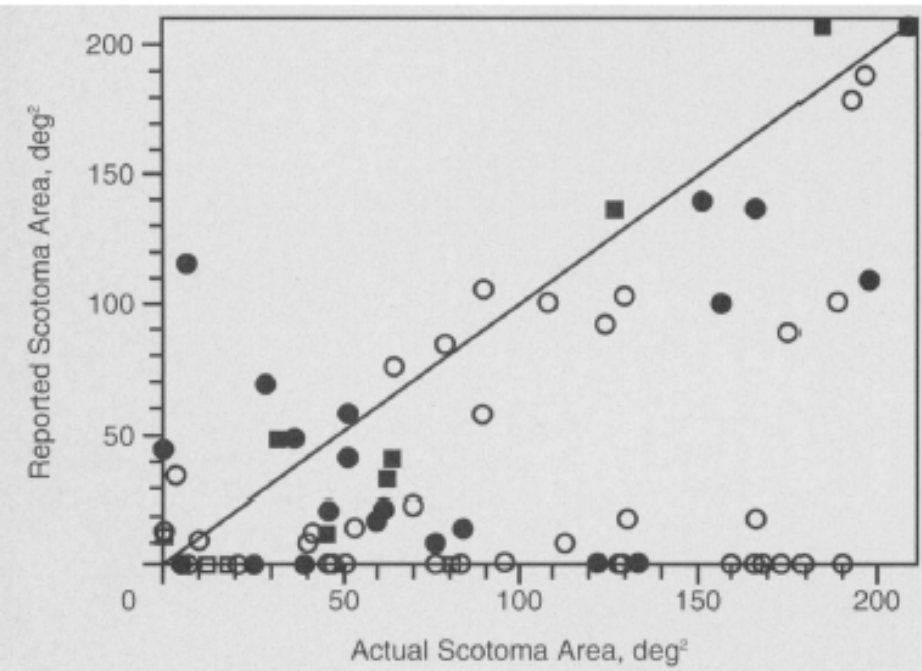
Amsler Grid



- Suboptimal performance of the Amsler grid for detecting scotomatous areas of macular vision loss reported by several investigators for nearly 20 years
- Schuchard, 1993: 77% of standard & 87% of threshold scotomas were not detected by Amsler
 - Amsler-based distortion may arise from perceived lines filling-in across scotomas or from non-scotomatous retinal impairments
 - No gap in Amsler incorrectly interpreted as no scotoma

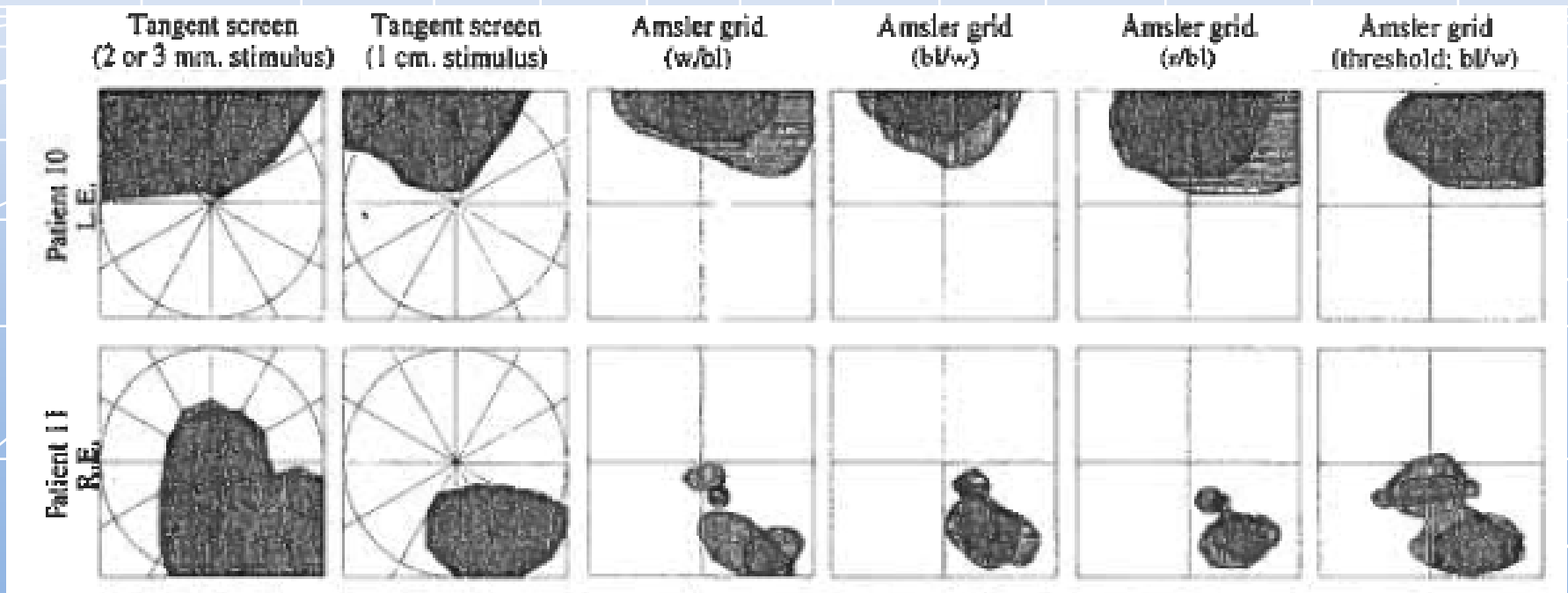
Amsler Grid

- Schuchard 1993:



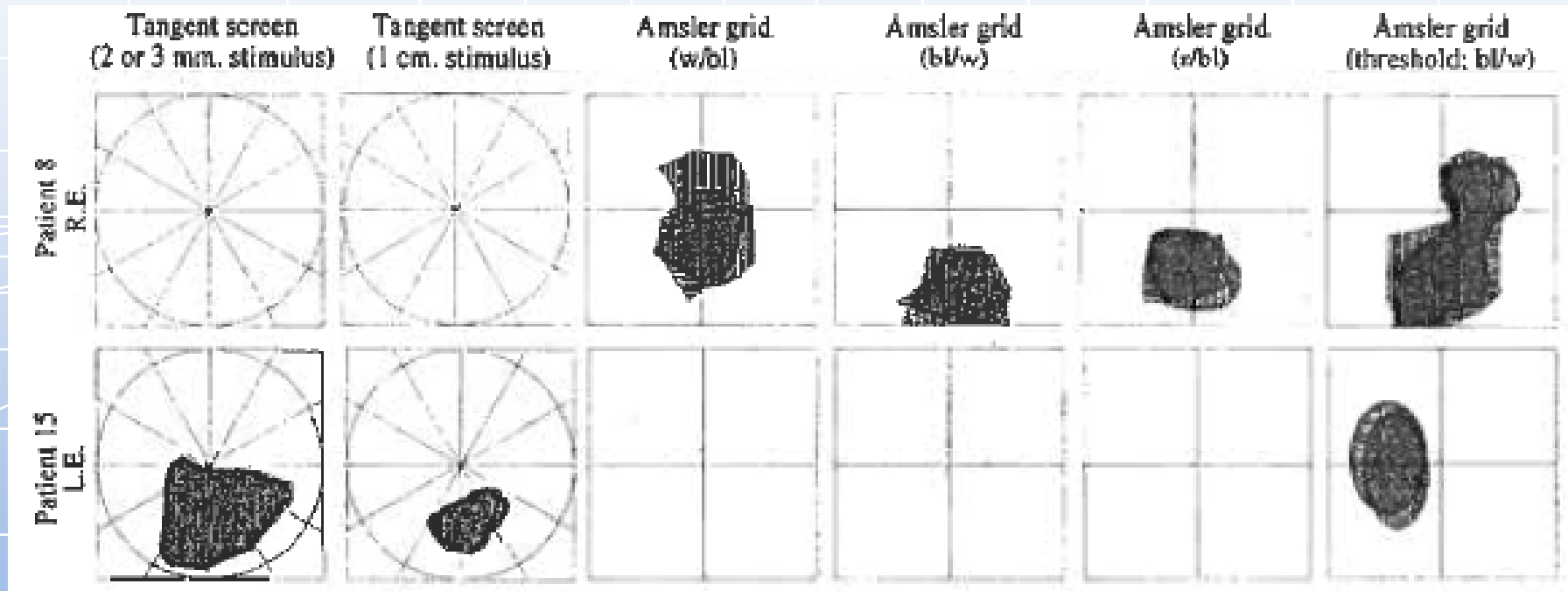
Amsler Grid

- Achard et al., 1995: Results of 2 successively administered Amsler tests were variable in size, shape & location, & therefore not comparable



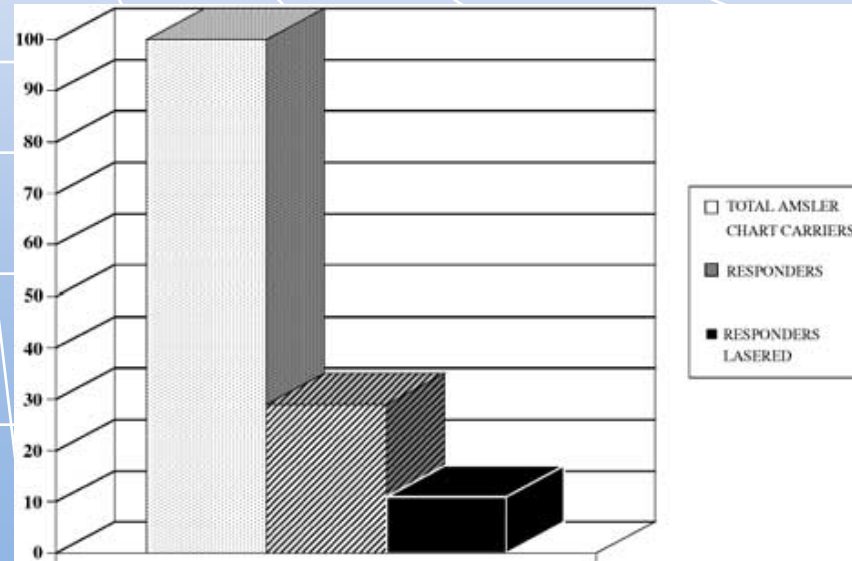
Amsler Grid

- Achard et al., 1995:



Amsler Grid

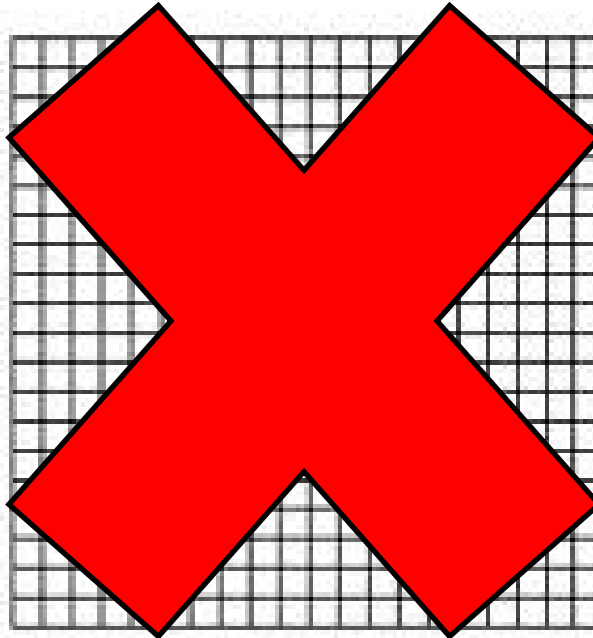
- Zaidi, 2004:
 - Amsler detected choroidal neovascularization in 29/100 patients, 11 of whom received laser treatment
 - Amsler was less effective in older patients
 - Patients with 2nd eye involvement were not more likely to be detected by Amsler



Amsler Grid

- Most likely explanation for the failure of the Amsler grid is that changes are easily missed
- The grid is regular, high contrast, & lacking in distinguishing features, making it hard to remember changes in irregularity
- The Amsler grid does nothing to educate or engage the patient

AMSLER GRID



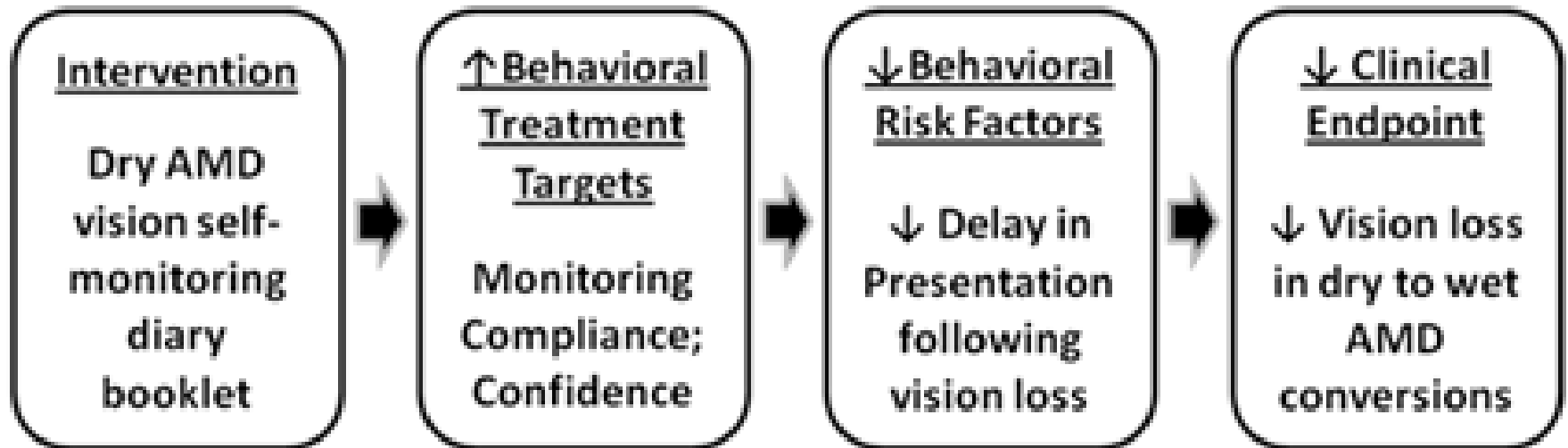
1. Test vision with one eye at a time, and use normal glasses for reading.
2. Hold chart at normal reading distance.
3. Store or control dot and look for distortion or blind spots in the grid.

Prerequisites

- New approaches to AMD self-monitoring should:
 - address the reasons for patients' delay in presenting after new-onset wet AMD
 - be low-cost & low-tech, i.e., amenable to distribution across large populations
 - include interactive elements to enhance compliance
 - foster appropriate and timely action

Conceptual Model

Increased Significance as you travel along the model to the Clinical Endpoint



Future Outcomes require ↑ follow-up time

**What are the latest
strategies and
technologies for AMD
self-monitoring?**

self-monitoring?

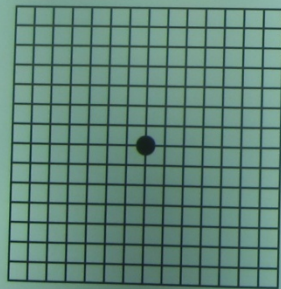
Approach in Metrostation Exit 2, Taipei, Taiwan



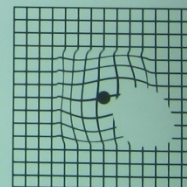
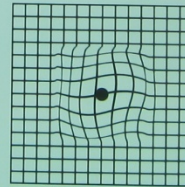
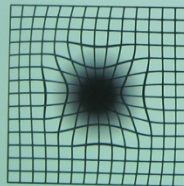
Approach in Metrostation Exit 2, Taipei, Taiwan

世界看起來很扭曲？ 小心是你快失明了！

若你的視覺中心有**模糊**、**扭曲**、**變形**，
這是**黃斑部病變**的徵兆，
快詢問“視網膜專科醫生”，尋求專業諮詢。



1. 眼睛距離方格表約30公分
2. 一次用一隻眼看方格
3. 若有老花，請佩戴老花眼鏡檢查



若看見：

線條模糊、扭曲變形，甚至有黑影，請儘速向“視網膜專科醫生”
尋求專業諮詢，把握黃金就診期。

Preview/Foresee PHP

- Preferential Hyperacuity Perimeter (PHP)
- 1st generation of the PHP technology in 2004 was the Preview PHP, used by patients in the eye doctor's office



PHP

- Uses Vernier hyperacuity – ability to perceive minute differences in relative spatial localization of 2 objects in space
- Analyzes responses to "dot deviation signals" flashing on a screen
- A series of closely spaced dots in a single straight line w/ ≥ 1 dots out of alignment, displayed on screen for 160 ms.
- Patient uses stylus pen to touch screen to identify the most prominent distortion in the line
- Typical 3-5 minute test measures 500 retinal data points covering central 14° of macula
- Requires stable fixation

Preview PHP

- Retina, 2011 - Sensitivity twice as high as Amsler
- Goldstein et al. 2005, Alster et al. 2005, Isaac et al. 2007: Sensitivity and specificity were superior to the Amsler grid
- Stur et al. 2010: Low false positive rate for detecting dry to wet AMD conversions

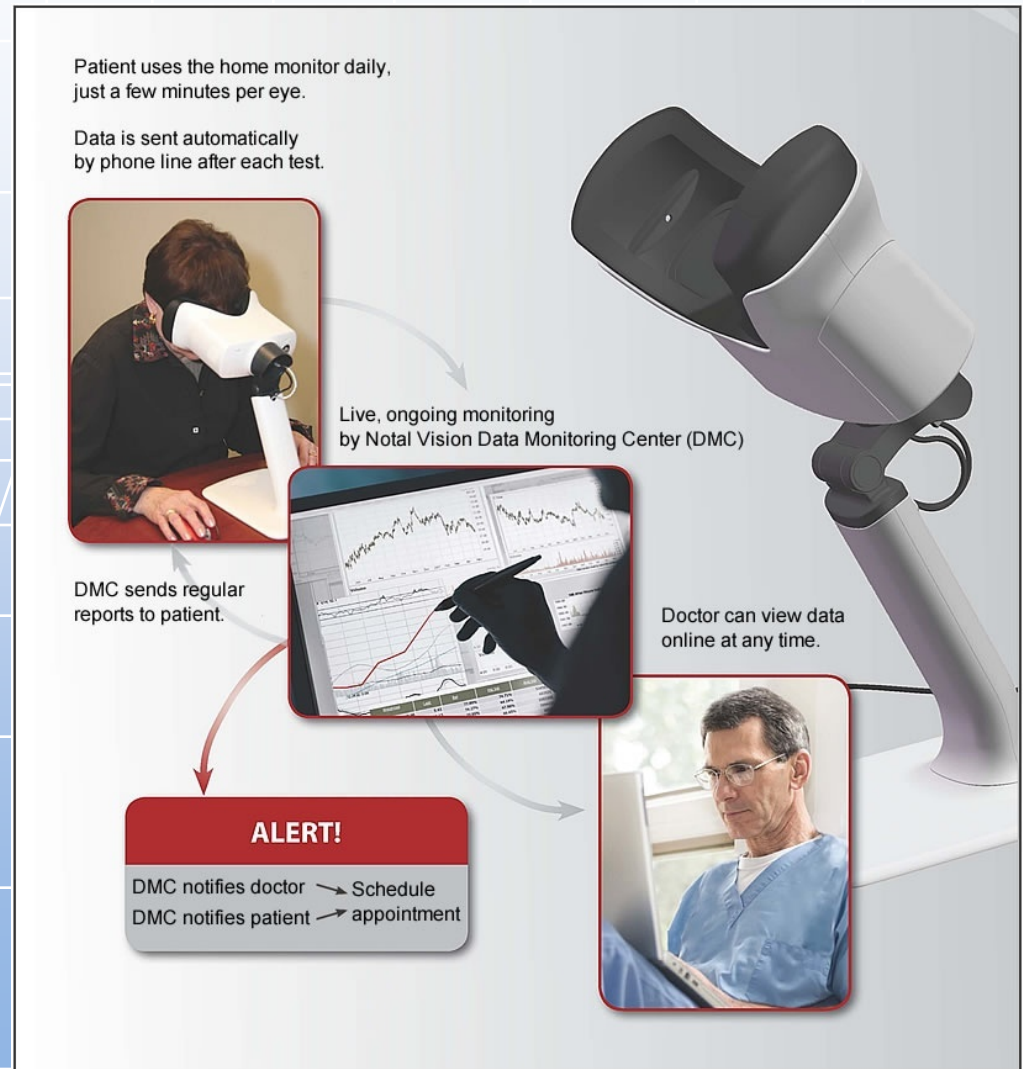
ForeseeHome PHP

- Notal Vision received FDA clearance for the ForeseeHome AMD Monitor in Dec 2009
- In 2010, began pre-launch marketing clinical trial, still ongoing
- Teleconnected home-based monitoring system
- Requires stable fixation



ForeseeHome PHP

- sensitivity & specificity have only been established for in-office monitoring
- high false negative rates may occur during in home monitoring



ForeseeHome PHP

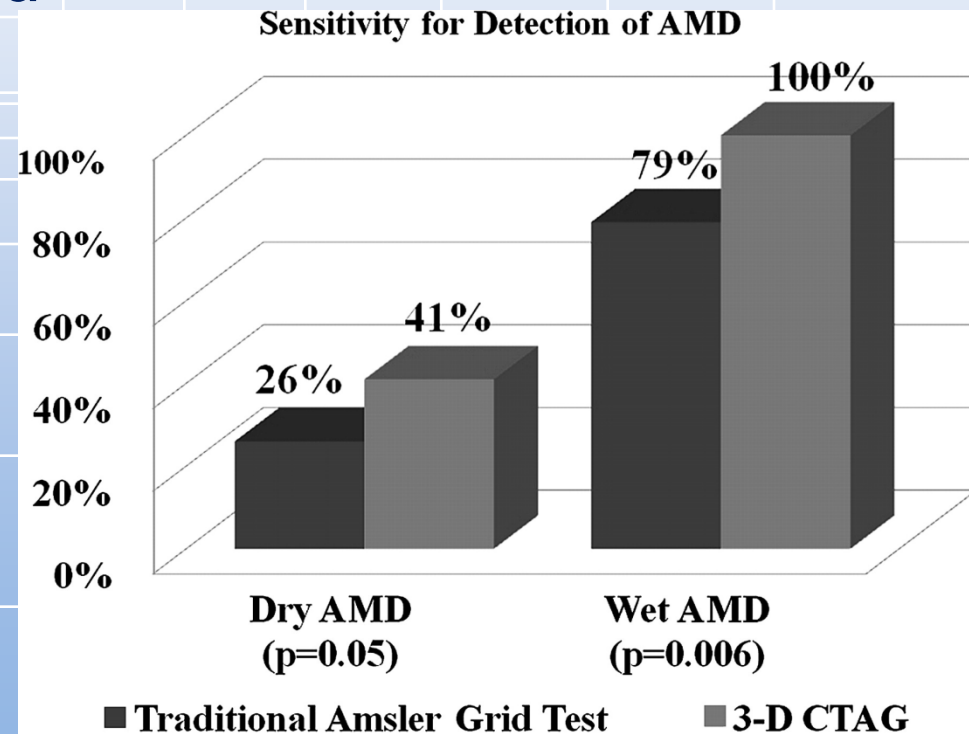
- Potential limitations: expensive, not readily portable, not easy to distribute
- Acceptance by large elderly population is questionable
- Any technological approach like this will require a complex support network

3D-CTAG

- three-dimensional, contrast modulated, Computerized Threshold Amsler grid
- Operating principle: By lowering the contrast of a dark Amsler grid against a white background, scotomas begin to reveal themselves as “white-out” areas as the contrast goes down
- Notice that this test aims to detect scotomas, not metamorphopsias or blurring

3D-CTAG

- Jivrajka et al., 2009: 24% of wet AMD had a scotoma detectable with the computer test but not with the Amsler grid
- Robison et al., 2011: 100% of wet AMD patients & 20% of dry AMD patients had a scotoma detectable with 3D-CTAG but not with the Amsler



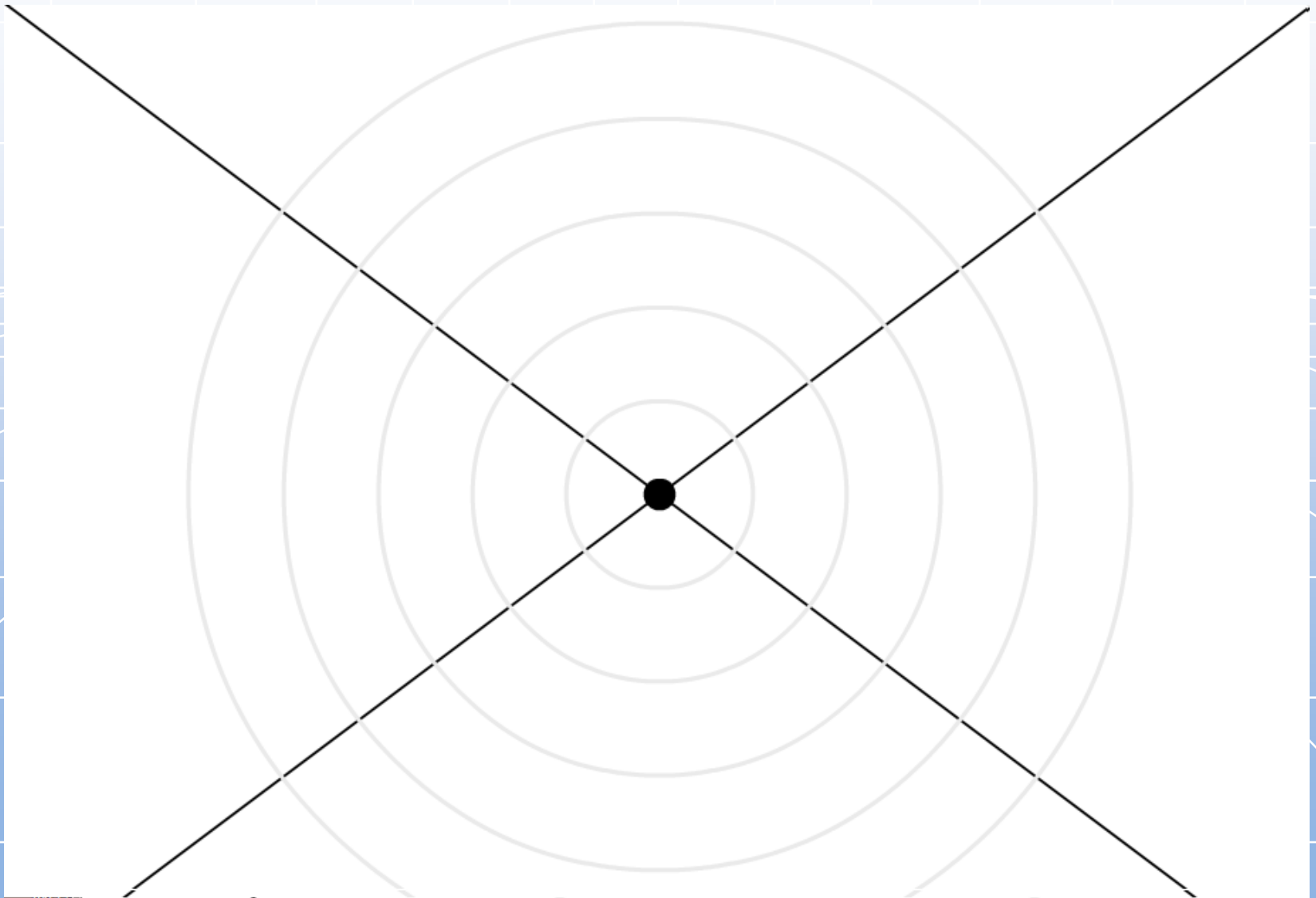
3D-CTAG

- Potential limitations:
 - previous studies had small sample sizes
 - did not demonstrate value of 3D-CTAG for:
 - detecting dry to wet AMD conversions or
 - whether patients are capable of self-administering this test at home
- Unlikely to detect early /subtle changes such as metamorphopsias

BCVFT

- Berkeley Central Visual Field Test (BCVFT)
- Developed by Ian Bailey, OD, MS at Berkeley
- PC-based Static VF test with 50 points in central 10°
- 20 points in superior field & 30 in the inferior
- 10 meridians : 25, 65, 115, 155, 195, 225, 255, 285, 315, 345
- Eccentricities of 1°, 3°, 5°, 7°, 9°
- Goldmann size III target in black on white
- 1.5 minutes to administer

BCVFT



BCVFT

- No repeats & no variations in target size or contrast during test
 - Option to reverse contrast to white on black
- Saved data records points that were missed & gives a score of points seen
(good central field = 48/50; bad = 12/50)
- Patients self-administer tests
 - Patients can self-monitor their scores & report changes to their doc
 - Or patients can periodically send their accumulated data file of all completed tests to their doc

PCVTS

- PC-based Vision Test Suite (PCVTS)
- Developed by Gislin Dagnelie, PhD, at JHU
- Monitoring tool in supplement trials for RP
 - Interim vision testing in-between study visits
- Used for screening and monitoring in retirement communities

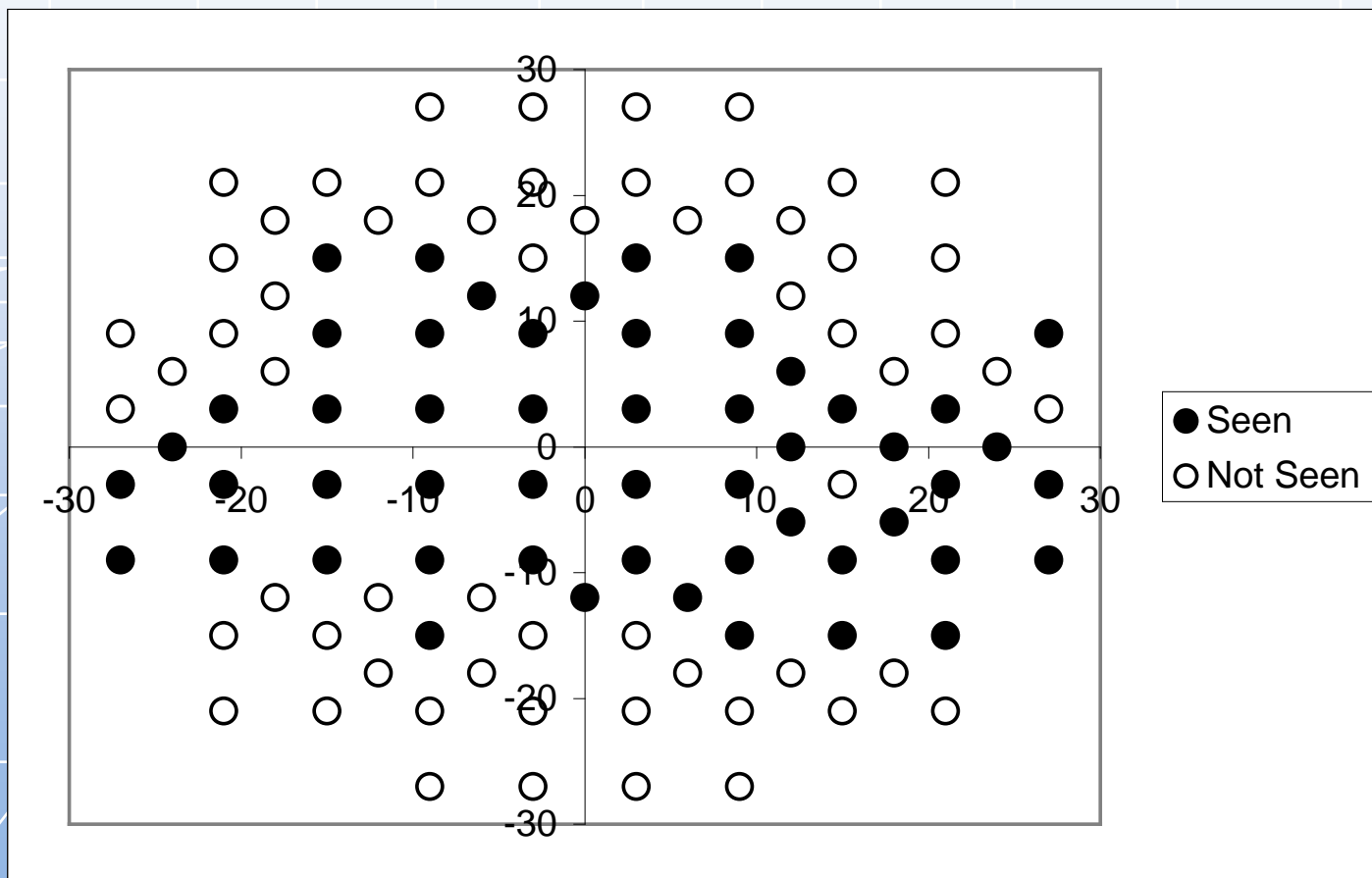
PCVTS Central Field Test

- Configurable for selection from over a dozen tests
- Central VF test suitable for AMD scotoma screening
- Default: 6° square grid (80 points)
- 2 out of 3 detection criterion
- Intermediate test points inserted around any missed points

JHU & Erickson Vision Test Report

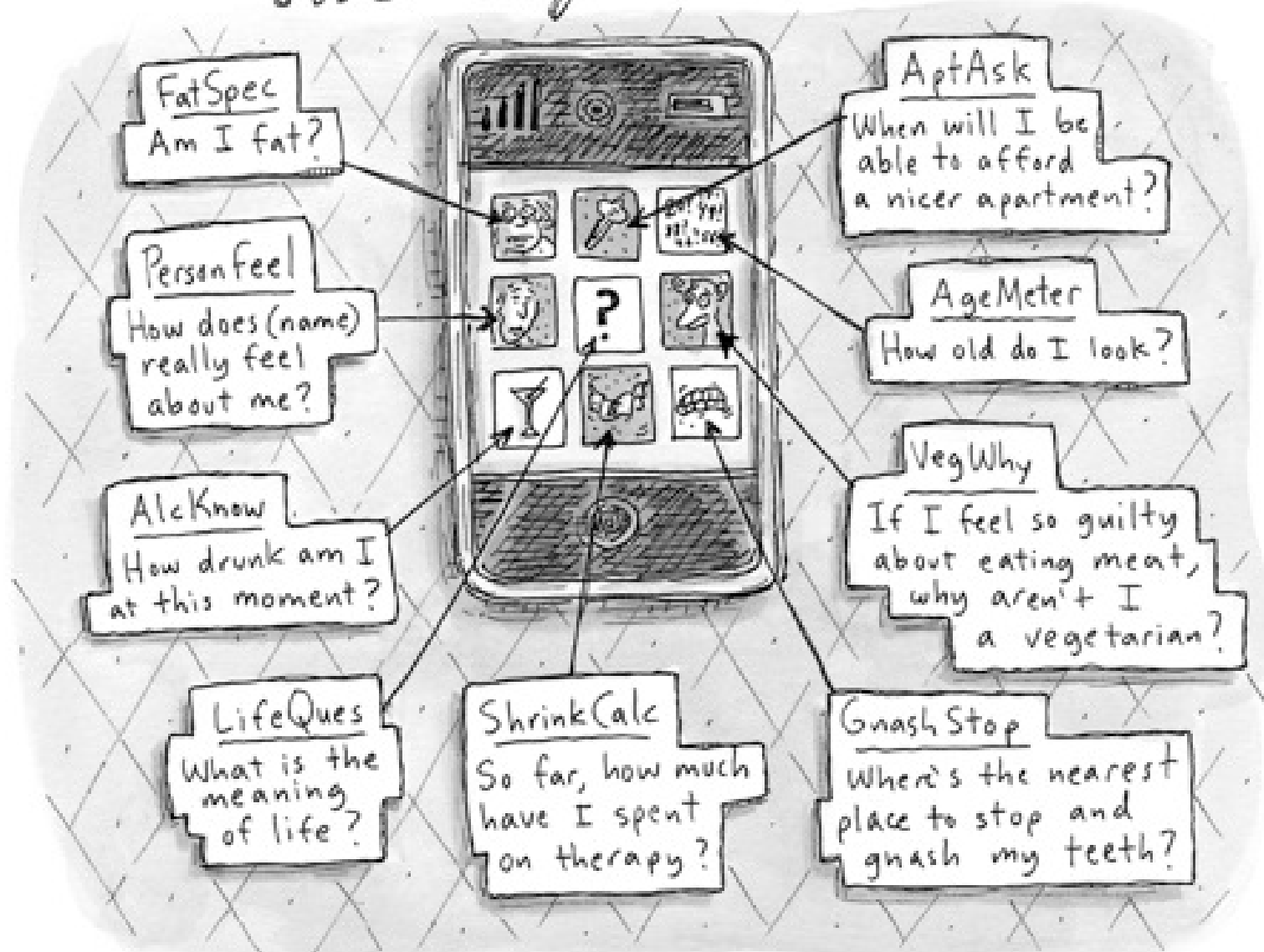
10/26/2012 12:46

Name	108299			Age	82.8		Viewing Distance
TestDate	August 02 2010						
Right Eye					Age Limit	Result	Viewing Distance
Acuity	Snellen = 20 / 51	logMAR=	0.41	0.36	SUSPECT		150
Contrast	4.0%	logCS=	1.39	1.11	PASS		
Field	Total dot= 111	Not seen=	58		Poor		



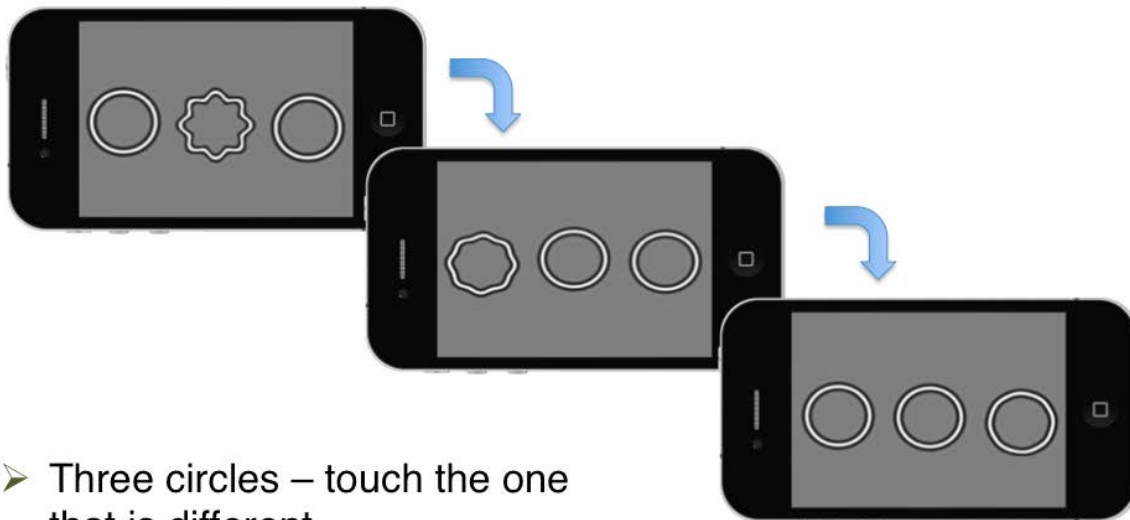
introducing ...

The myPhone.

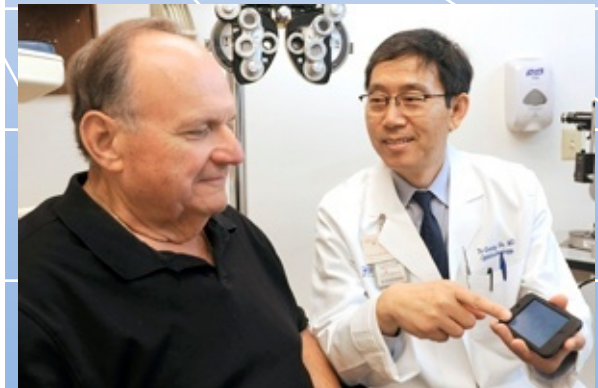


myVisionTrack™

- iPhone/iPod app with shape discrimination test conceived by Dr. Yi-Zhong Wang at the Retina Foundation of the Southwest
- NIH/NEI funded, now marketed by Vital Art and Science, Inc.



- Three circles – touch the one that is different



myVisionTrack™



- Self-test in <math>< 90</math> sec.
- Displays 3 circles on a screen, one different from others, patients touch odd-shaped circle.
- With each click, the differentiation becomes more subtle.
- Results stored in device
- If significant vision change detected, patients instructed to see their doctor



myVisionTrack™

- Currently recruiting AMD subjects for NIH-sponsored study using iPad
- Submitted 510K application to FDA for approval of iPhone version of myVisionTrack
- Potential limitations:
 - Technology barrier
 - Validation study



VMS Booklet

Key features:

- multiple vision tests (enhanced grid test with colored & dashed lines, near VA, home objects reference test with baseline)
- specific instructions with diagrams on how to correctly use the tests & understand the results



VMS Booklet

Key features (continued):

- AMD-related education, including lifestyle changes to reduce risk of vision loss
- specific help-seeking steps to take if a change in vision is detected
- weekly calendar sticker system to boost and track compliance
- quotations and games to boost long-term interest and enjoyment of the process
- Low tech, large print

VMS Booklet

Today's date:

Words of WISDOM from Mark Twain

1. Check the circle next to each line you can read.

Left Eye		Right Eye
1 ○	N C K Z O	○ 1
2 ○	R H S D K	○ 2
3 ○	D O V H R	○ 3
4 ○	C Z R H S	○ 4
5 ○	O N H R C	○ 5
6 ○	D K S N V	○ 6

Compare to your acuity baseline test.

- Left eye Better Same Worse
- Right eye Better Same Worse

Always do right. This will gratify some people and astonish the rest.

2. Look at objects in your home with straight lines

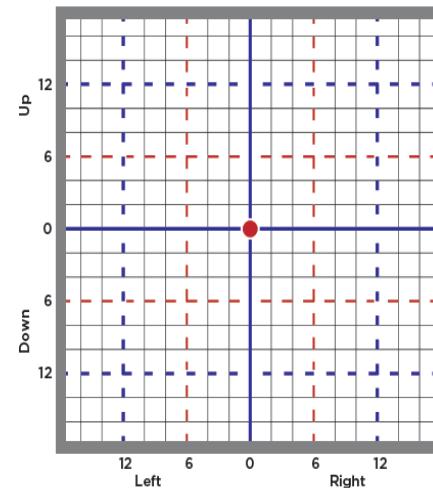


Compare to your home object baseline test.

- Left eye Better Same Worse
- Right eye Better Same Worse

3. Focus on the center dot.

Look for wavy, blurry or spotty lines



Compare to your grid baseline test.

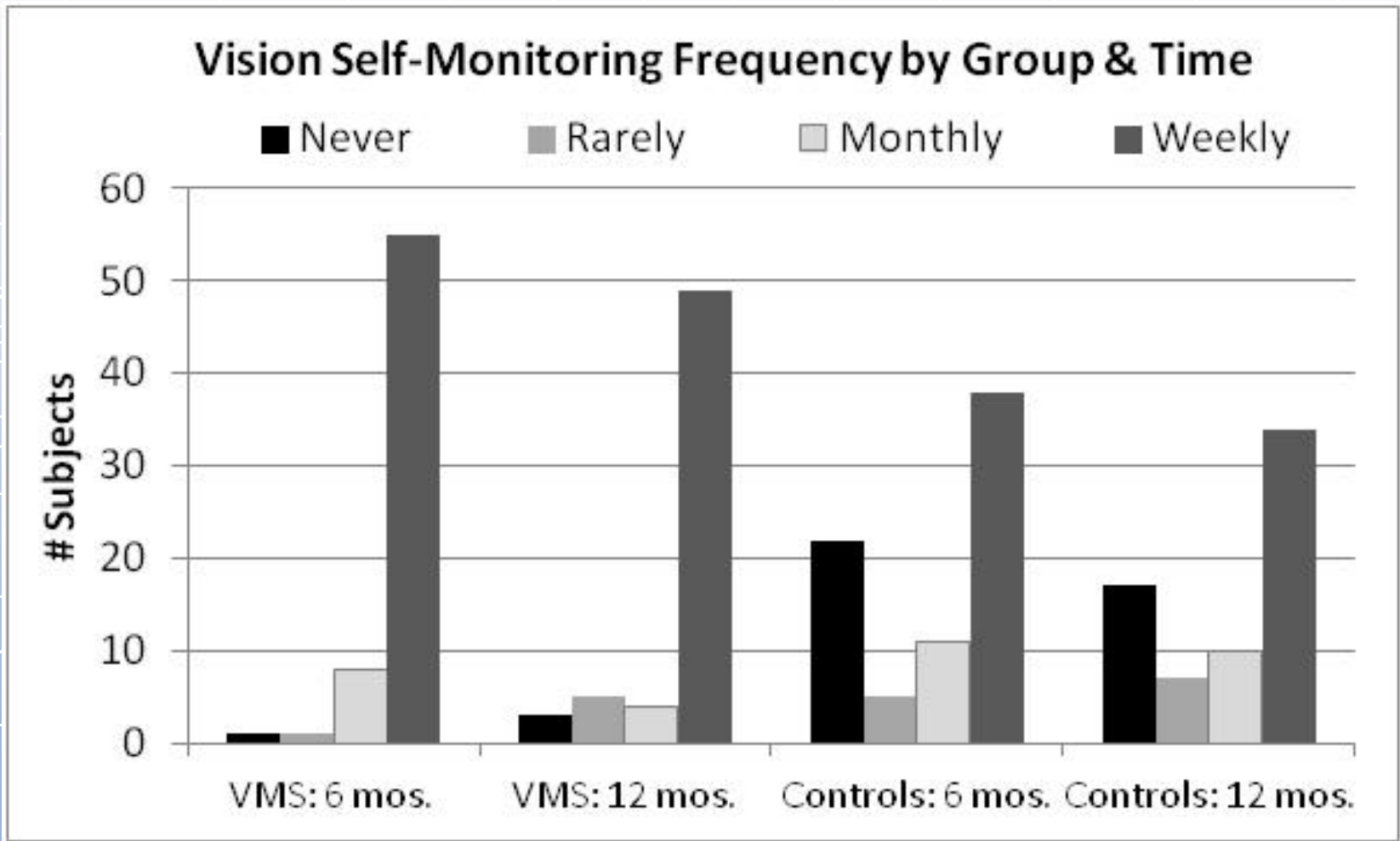
- Left eye Better Same Worse
- Right eye Better Same Worse



VMS Booklet

- RCT with 198 enrolled subjects found significant difference in subjects who reported monitoring their vision at least weekly at 6 & 12 months, respectively: 85% & 80% of the VMS booklet subjects vs. 50% of controls at both follow-ups ($p < 0.001$)
- At 6 and 12 months, respectively, 29% & 25% of controls ($n = 22$ & 17) had not checked their vision in the past 6 mos., while only 1.5% & 5% ($n = 1$ & 3) of the VMS booklet subjects reported they did not check their vision

VMS Booklet



VMS Booklet

- No statistically significant change in weekly vs. less frequent self-monitoring between groups ($p=0.68$), with 81% of all subjects reporting no change in their frequency between 6 and 12 mos.
- VMS booklet promotes persistence in weekly monitoring over the course of a year

VMS Booklet

- Significant difference in self-monitoring confidence:
at 6 and 12 mos., respectively, only 15% & 13% of the VMS booklet subjects vs. 53% & 44% of controls did not feel confident they were taking care of their sight by monitoring their vision ($p < 0.001$)

VMS Booklet

- Potential limitation: cannot objectively measure frequency of vision monitoring; must rely on self-report
- Longer-term follow-up will need to determine efficacy for promoting appropriate self-referrals when vision loss is detected
 - Too few conversions thus far

Checklist: Which Tools meet the Criteria?

Criterion	PHP	3D-CTAG	myVisionTrack	VMS	BCVFT PCVTS
Education	No	No	No	Yes	No
Interactive	No	No	Yes	Yes	Yes
Auto-alert	Yes	?	Yes	No	Maybe
Low-cost	No	Maybe	Maybe	Yes	Maybe
Low-Tech	No	No	No	Yes	No
Foster action	Yes	Yes	Yes	Yes	Yes
Proven detection	Not yet	Not yet	Not yet	Not yet	Not yet

Clinicaltrials.gov

- **Get your patients involved in these trials!**
- PHP (FORESEE HOME): NCT01314430 (AREDS2)
- VMS: NCT01337414

- **Contact the investigators for these tools:**
- 3D-CTAG: jsebag@VMRinstitute.com
- myVisionTrack: yiwang@retinafoundation.org
- BCVFT: ibailey@berkeley.edu
- PCVTS: gislin@jhu.edu

Conclusions

- New, emerging field of tools for vision self-monitoring
 - Need additional long-term research to see which is most effective
 - Likely that any or all will be superior to Amsler
 - May need to match to patient's individual needs
 - OD's are the first line of defense in saving vision