Panel Discussion

Moderator: **Mark Blumenkranz**

Theodore Leng
Mays El-Dairi
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Brad Cunningham
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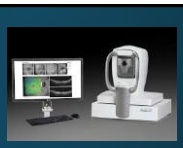
Felipe Medeiros
Lama Al-Aswad
Frank Brodie
Nadia Waheed

Panel Discussion Question 1

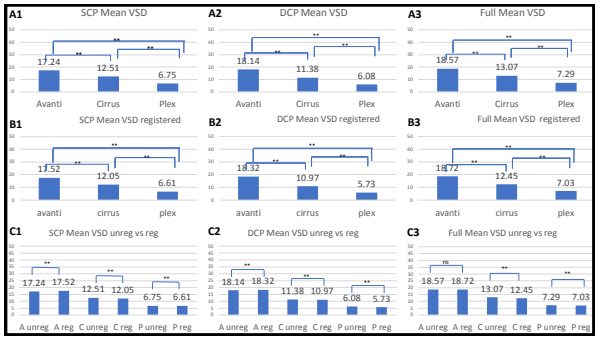
FDA is seeking to promote innovation and expedite the clinical development of optical coherence tomographers (OCTs). As new functionalities are introduced, typically, performance data is compared to a gold standard. Does a gold standard comparator exist for the following:

a. **Quantification of retinal vascularity?**
b. **Quantification of oximetry with visible light OCT?**
c. **Functional assessment of metabolic or indirect structure/blood flow changes?**
d. **AI-assisted segmentation?**





Parafoveal Vessel Density Assessment by OCTA in Healthy Eyes



Results-CoR Values

- coefficient of repeatability (CoR) calculated to assess repeatability
- lower CoR indicates a tighter dispersion and higher repeatability

Otsu VAD

Avanti			Cirrus			Plex		
SCP	DCP	Full	SCP	DCP	Full	SCP	DCP	Full
5.55	4.40	6.66	7.14	4.83	8.00	3.19	2.63	3.23

Otsu VSD

Avanti			Cirrus			Plex		
SCP	DCP	Full	SCP	DCP	Full	SCP	DCP	Full
2.84	1.79	3.11	2.28	1.41	2.68	0.49	0.36	0.63

Mean VAD

Avanti			Cirrus			Plex		
SCP	DCP	Full	SCP	DCP	Full	SCP	DCP	Full
2.33	1.73	2.23	2.86	2.62	3.32	1.635	1.64	1.63

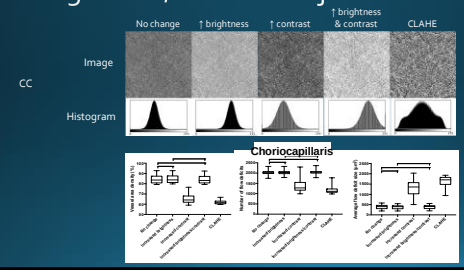
Mean VSD

Avanti			Cirrus			Plex		
SCP	DCP	Full	SCP	DCP	Full	SCP	DCP	Full
1.69	1.54	2.02	1.20	0.96	1.49	0.39	0.30	0.45

Conclusions

- Statistically significant variability exists among VD between the Avanti, Cirrus, and Plex Elite for a single normal imaged patient
- The Mean VSD method offered a more repeatable assessment of VD
- Less than 1% difference in VD existed between registered and unregistered images, which was statistically significantly different
- The ***clinical significance*** of this variability remains to be seen

Qualitative & Quantitative Effects of Brightness/Contrast Adjustments



Consensus

Research in current practice reveals several unmet needs:

- Standardization of the diagnosis of glaucoma
- Accurate algorithm for follow up and resolution of cases suspected of diagnosis of glaucoma
- Clear indications for treatment reducing both under- and over-diagnosis and treatment
- Foundational knowledge for research and development to standardize studies, protocol, inclusion and exclusion criteria, definition of populations and outcomes measures

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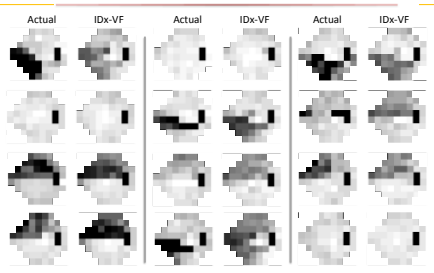
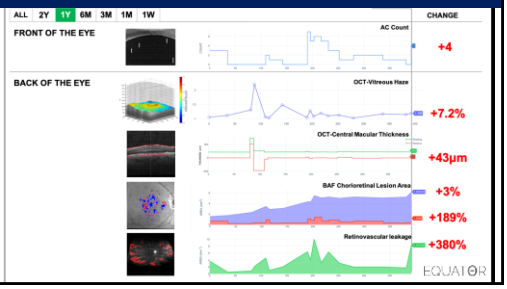


Uveitis Endpoints – A Vision for the Future



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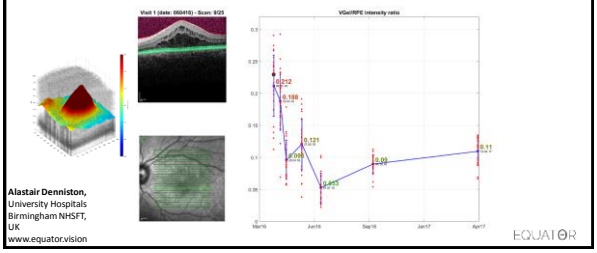
OCT Measurement of Vitreous Inflammation



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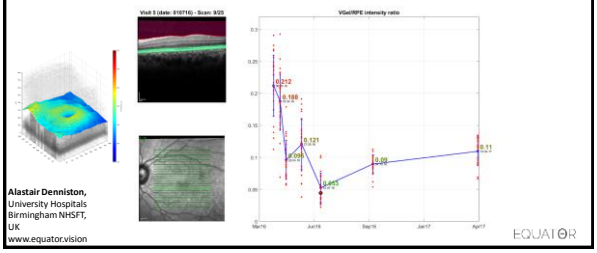

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