

Trondheim 19.11.2020

Chennai 19.11.2020

Oslo 19.11.2020

**Video Oculography Device (VOG) BulbiCAM shows good to excellent agreement in the validation of inter-observer reliability between devices and stability of all measurements, during visual field testing, pupil testing and testing of eye ptosis in a population of glaucoma patients and normal controls.**

An orthogonal nested Latin square study design was performed, measuring six glaucoma patients and three normal controls at different age groups and at different disease stages, which gave a two dimensional study design. Selection of glaucoma subjects was classified according to the glaucoma criteria of The American Academy of Ophthalmology<sup>1</sup>.

Medical Research Foundation (Sankara Nethralaya Eye Hospital, Chennai, India) led by Director Ronnie George, MD, PhD Ophthalmology conducted the study under the collaboration of Professor Emeritus, Stig Larsen (Professor of Controlled Clinical Research Methodology and Statistics). The study was designed to measure the reliability, reproducibility and stability of two BulbiCAM VOG's, where subjects underwent a test-retest procedure up to six times.

Statistical analysis of the agreement index between devices and the stability index of agreement in both devices in all measurements were performed. Overall there was a good to excellent agreement and stability of the BulbiCAM during visual field testing, pupil testing and testing of ptosis between devices.

**Visual Field Test**

Two variables were measured in the trial: seen/unseen peripheral targets and Saccadic Reaction Time (SRT) in a Visual Field test based on Eye Movement Perimetry (EMP). Four sectors were tested: Central, nasal, superior and inferior visual field areas. The mean agreement index between devices of SRT, in all sectors, was 0,78 [0,69-0,83] for the right and the left eye. The mean stability index of all measured SRTs were 0,75 [0,63-0,86] for the right and the left eye. The mean agreement index of seen/unseen targets was 0,82 [0,63-1,00]. More information and details can be found in the statistical report of the *"Visual field testing based on Eye Movement Perimetry using video-based oculography"*.

**Pupil Test**

Six variables on pupil diameter during pupil constriction and pupil dilatation were measured in the trial. Two different pupil latencies and peak velocities during pupil constriction were also measured. The agreement index of the pupil variables between devices for pupil diameters for the left eye was on average 0,80. For the right eye, it was on average 0,87. The stability agreement index of all the pupil diameters for the left eye was on average 0,86, and for the right eye, it was on average 0,85. The agreement index of the pupil latencies for the left eye was 0,91. For the right eye, it was 0,86. The stability agreement index of all the pupil latencies for the left eye was on average 0,92. For the right eye, it was on average 0,89. The agreement index of the pupil peak velocities for the left eye was 0,81. For the right eye, it was 0,84. The stability agreement index of the all pupil peak velocities for the left eye was 0,85. For the right eye, it was 0,83. More information and details can be found in the statistical report of the *"Dynamic pupillometry in video-based oculography"*.

## **Ptosis Test**

One variable on the ptosis test was measured in the trial. This was the Marginal Reflex Distance 1 (MRD1), which is the distance from the upper eyelid to the centre of the pupil.

The agreement index of MRD1 between devices was 0,83 for the right eye and 0,73 the left eye. The mean stability index of MRD1 for the right eye was 0,80 and 0,79 for the left eye. More information and details can be found in the statistical report of the *“Automated eyelid ptosis measurement using video-based oculography”*.

<b>Agreement index</b>	<b>Degree of agreement</b>
< 0.20	Poor agreement
0.21-0,40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-1.00	Excellent agreement

<b>Visual Field test in Eye Movement Perimetry</b>	<b>Agreement Index</b>
Agreement index of Saccadic Reaction Time-SRT	0,78 [0,69-0,83]
Stability agreement index of Saccadic Reaction Time-SRT	0,75 [0,63-0,86]
Agreement index of seen/unseen peripheral targets	0,82 [0,63-1,00]
<b>Dynamic pupillometry</b>	
Agreement index of pupil diameter	0,84 [0,80-0,87]
Stability index of pupil diameter	0,855 [0,85-0,86]
Agreement index of pupil latency	0,89 [0,86-0,91]
Stability index of pupil latency	0,90 [0,89-0,92]
Agreement index of peak velocity	0,83 [0,81-0,84]
Stability index of peak velocity	0,83 [0,83-0,83]
<b>Ptosis</b>	
Agreement index of ptosis	0,76 [0,73-0,82]
Stability index of ptosis	0,795 [0,79-0,80]

## **Conclusion**

In conclusion, the preliminary results indicate that high-frame-rate VOG is a promising tool to measure and quantify individual pupillary values in a dynamic pupillometry. It is also possible to estimate reliable and stable individual ptosis values using VOG. Also, individual SRT values as well as seen/unseen visual targets in a visual field test using EMP seem reliable and stable in the device.

## **Discussion**

We would recommend planning a longitudinal multicenter intervention study to assess the clinical performance of the EMP test, by evaluating the functional progression of glaucoma. The EMP test, incorporated in a BulbiCAM VOG, includes fast testing of eye movements (fixations, saccades, smooth pursuits), pupil behaviour (constrictions and dilations) and a visual field screening protocol. Here, subsequent peripheral stimuli are shown to test the extent and the responsiveness to stimuli throughout the visual field. The outcome of the trial should include classification rules based on the existing structural and functional tests. Patient outcomes in follow-up treatments should be monitored during a period of a minimum of 1 year.

The results of the measurements should estimate:

1. The reproducibility, reliability and stability in a large glaucoma population using BulbiCAM EMP and pupillography
2. How well EMP and pupillography can identify early-stage glaucoma screening
3. The concordance between EMP and pupillography and the existing standard eye examination in monitoring disease progression

Such a study would provide data to estimate the potential benefits and harms of using EMP and pupillography to guide clinical decision making in glaucoma management. The observed proportion of discordant test results will help inform the design of future randomized controlled trials of the EMP and pupil test.

The overall aim of the study should be to assess the additional value of the EMP and pupil test in glaucoma management.

### **References**

1. Know the New Glaucoma Staging Codes; Ronald L. Fellman, MD, OCS, Cynthia G. Mattox, MD, Kim M. Ross, OCS, CPS, Academy Coding Specialist, and Sue Vicchilli, COT, OCS, Academy Coding Executive