3D gaze stability as a meausure for visual-vestibular function

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Ethical review	Approved WMO
Status	Pending
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56520

Source
ToetsingOnline

Brief title
Gaze stability in 3D

Condition

- Inner ear and VIIIth cranial nerve disorders
- Vision disorders

Synonym
Cerebellopontine angle tumor, vestibular schwannoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: compensatory eye movements, Head impulse test, retinal slip, visuo vesibulo-ocular reflex

Outcome measures

Primary outcome

Primary:

• Retinal slip velocity in °/s, the movement of the eye relative to the image.

Secondary outcome

Secondary:

• Saccade and smooth pursuit amplitude and latency as a reference for the accuracy of oculomotor response when viewing a moving image with a stationary head.

• Hearing threshold in dB as a reference for the integrity of the audiovestibular end organ.

• Speech discrimination in % as a reference for the integrity of the audiovestibular end organ.

• Visual acuity in % as a reference for the integrity of the input from the visual system.

• DHI score, ERGO score, and VAS score for documentation of the experience of balance complaints.

Study description

Background summary

Dizziness and instability are common symptoms. The primary cause is often

attributed to the vestibular system, which contributes to body balance by generating muscle reflexes. Additionally, the vestibular system aids in gaze stabilization through the vestibulo-ocular reflex (VOR). The VOR, along with the optokinetic response (OKR), is responsible for generating eye movements during head motions. Sudden loss of function in one vestibular organ, due to illness or accident leads to dizziness, gait instability, and disorientation. There are also complaints of visual disturbances during head movements, such as visual lag and oscillopsia. Unilateral vestibular loss will be compensation by the central nervous resulting in a reduction of symptoms. Complete compensation can even lead to the resolution of symptoms. Examination of eye movements in compensated cases reveals the disappearance of nystagmus and the development of compensatory saccades. This compensation can occur spontaneously or be facilitated by vestibular physiotherapy. A crucial prerequisite for complete compensation is a well-functioning visual system, as it calibrates the reflexes. Some patients with retinal abnormalities also experience dizziness due to reduced motion detection. The retinal abnormality prevents the proper use of visual signals for VOR adaptation. This condition affects patients with stationary retinal dysfunction caused by an inherited gene defect, which can cause night blindness or color blindness.

This study aims to measure both patient groups to comprehensively assess and compare the eye movements under altered visual and vestibular input with those of normal subjects. During the VOR test, a fixation point is presented, and the subject's head is moved using a rotating chair. Compensatory eye movements, generated by joint action of the vestibular system and the visual tracking system, are measured using an eye movement tracking system. In the OKR test, a moving visual stimulus is displayed on a screen while the subject's head remains still. Once again, eye movements are measured using the eye movement tracking system. Conventional clinical diagnostics typically tests the vestibulo-ocular reflex (VOR) and the optokinetic reflex (OKR) separately, using different stimuli. In the proposed experiment, the same stimuli are used for both conditions, so the difference in gaze stability between the OKR and compensatory eye movements is caused by the cooperation between OKR and VOR. The aim is to determine how this cooperation affects gaze stability. The hypothesis is that the ability of the vestibular system to improve the visual response is an indicator of vestibular function.

An important clinical outcome measure of gaze stability is the combination of gain and phase. Gain represents the ratio of head movements to eye movements induced by a moving target in a stationary environment or the ratio of eye movements to image movements with a stationary head. Phase refers to the temporal difference between them. Both measures are relative indicators of gaze stabilization. In this study, we will investigate retinal slip velocity as an absolute measure of gaze stabilization accuracy. Typically, only horizontal and vertical eye movements are measured, while torsion of the eyeball is a component of nearly every eye movement. However, due to methodological limitations in measuring torsion in patients, torsional movements are often

disregarded.

Study objective

The aim of this observational and exploratory study is to describe the accuracy of gaze stabilization in the presence of abnormal vestibular and visual functions. Visually induced image movements are used as the basis for gaze stability for each subject. Visuo-vestibular-induced eye movements generated by similar stimuli are superimposed on these baseline movements. The interaction between the visual tracking system and vestibular responses typically results in improved gaze stability compared to the optokinetic response.

Study design

The study consists of 2 different experiments to answer the primary and secondary research questions. During the first experiment, the participant remains stationary behind a computer screen, and we measure the characteristics and reflexes of eye movements while the head is still, inducing the OKR. During the second experiment, we utilize the motion platform and measure the characteristics and reflexes of eye movements during head movements, inducing the VOR. To document hearing and vision, visual acuity is measured, and a tone and speech audiogram is conducted. Two questionnaires, the Dizziness Handicap Inventory (DHI) and a version of a questionnaire used in ERGO, are administered to document the nature and severity of symptoms. Although some patients are measured before and after treatment, this study does not evaluate the treatment itself. Instead, it aims to determine whether the patient's perception (VAS score) regarding the nature and severity of their symptoms aligns with the 3D eye movements and questionnaires.

Experiment 1

During this experiment, the participant remains still in front of a monitor, with the head supported by a chin rest to measure eye movements during image motion. The visual tracking system and the balance system are thus decoupled. We measure the participant's eye movements during:

Saccade test, examining the relationship between saccade duration, saccade amplitude, and saccade velocity during shifts of a fixation target in horizontal and vertical directions with various amplitudes. In the horizontal direction, 10 amplitudes are tested 6 times, and in the vertical direction, 8 amplitudes are tested 6 times. A total of 108 trials (~7 min).
Smooth pursuit test in horizontal and vertical directions, where a fixation target moves sinusoidally at a constant speed. Both horizontal and vertical movements consist of 10 cycles at 3 different speeds. A total of 6 trials (~3 min).

Experiment 2

During this experiment, the participant sits on the motion platform and fixates on a stationary visual target in space while being moved by the platform. The platform's movements involve rotations around 5 different axes: roll, pitch, yaw, LARP, and RALP. The visual and vestibular systems now work together maximally for gaze stabilization. We measure the participant's eye movements during 2 different motion stimuli:

Sinusoidal movements: The platform performs a sinusoidal motion around one of the 5 main axes for 30 seconds. The sinusoidal movements are executed at 0.5 Hz (with amplitudes of 2, 4, and 8 degrees) and at 1 Hz with a fixed amplitude of 2 degrees. A total of 20 trials (~12 min).
Impulse movements: Within 2 seconds, the platform rapidly rotates around one of the 5 main axes to measure the vestibulo-ocular reflex in the first 100 ms of the movement. The impulse is a maximum of 150 degrees/s^2, and each axis is tested 3 times. A total of 15 trials (~5 min). Two different visual tasks are used during this experiment.

Experiment 3
This is a repetition of experiment 1, but now the visual target is attached to the platform, causing the target to move along with the platform. The platform's movements are the same as those in experiment 1 (~5 min).

We measure eye movements using a video-oculography (VOG) headset. This VOG headset measures horizontal, vertical, and rotational eye movements based on pupil detection and iris features. The headset also includes an accelerometer for precise measurement of the timing and magnitude of induced head rotations. The VOG headset is described in Chapter 6 of this application: investigational products and the IMDD. The use of the motion platform is described in Chapter 7 of this application and the corresponding IMDD. The total duration of the experiments, including preparations, is approximately 45-60 minutes.

Study burden and risks

For the recording of horizontal, vertical, and rotational eye movements, participants wear a video-oculography headset (see also the IMDD). This headset has a tight fit but does not hinder the ability to make eye and head movements. During Experiment 1, the participant sits in a chair in front of a computer screen. During Experiments 2 and 3, the participant is seated in a rotating chair setup. This setup is easily accessible for both young and elderly participants, with a specially designed staircase. The participant is secured "body-fixed" using a 5-point harness in a comfortable chair. The head is immobilized using a headrest and a biteboard. This reduces comfort but is not perceived as burdensome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Normal hearing in the unaffected ear
- Fuctional vision in both eyes
- Informed concent (toestemmingsformulier).
- Solitary vestibular schwannoma
- Stationairy retinal dysfunction syndrom

Exclusion criteria

- neurological or psychiatric disease
- dizziness due to side effect medication
- Alcohol or drug abuse up to 6 months previously

- HIV
- Hepatitis B
- History of *closed head injury*,
- Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2023
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-02-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84820.078.23