Gaze stability as a measure of vestibular function: Deficits and corrective strategies of 3D gaze stability in singel sided vestibular loss

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To validate the method of measuring torsional eye movementsTo measure 3D eye movementsTo assess the age dependency of the responsesTo measure the gain of eye-versus headmovement and retinal slip velocity in clinical diagnosis by comparing patients...

Ethical review	Not approved
Status	Will not start
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational invasive

Summary

ID

NL-OMON53988

Source ToetsingOnline

Brief title Gaze stability in 3D

Condition

- Inner ear and VIIIth cranial nerve disorders
- Neurological disorders of the eye

Synonym

Cerebellopontine angle tumor, vestibular schwannoma

Research involving

Human

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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, corrective saccade, Head impulse test, visuo vesibulo-ocular reflex

Outcome measures

Primary outcome

Retinal slip velocity in deg/sec in 3 dimensions

Eye and head position in 3 dimensions

Eye and head velocity in 3 dimensions

Eye and head acceleration in 3 dimensions

Timing correction saccades relative to head movement, misalignment after

correction saccade

Secondary outcome

Study description

Background summary

The vestibular system contributes to body balance, gaze stability and spatial orientation, both in stationary position and during movement. Sudden, single sided loss of function leads to vertigo and instability and to symptom related to reduced gaze stability as oscillopsia and visual lag. Dizziness and instability may also arise as result of neurological and cardiological disease. It may be difficult to distinguish between causes. Single sided vestibular loss will usually be readily compensated for, reducing symptoms. On clinical examination nystagmus disappears and corrective saccades develop.

The commonly used clinical tests calculate the ratio of eye versus head

movement, which yields a relative measure, not aimed at setting criteria for compensatory strategies. Retinal slip velocity, which is is not commonly calculated, is an absolute measure of the difference between head and eye movement. increase of retinal slip velocity increases misalignment between head and eye direction.

Furthermore, only horizontal and vertical eye movements are analysed, due to methodological limitations. However, torsion is a component of virtually every eye movement. We will use a new technique to measure eyeball torsion with the help of a contact lens.

Study objective

To validate the method of measuring torsional eye movements

To measure 3D eye movements

To assess the age dependency of the responses

To measure the gain of eye- versus headmovement and retinal slip velocity in clinical diagnosis by comparing patients with single sided vestibular disease to normal subjects.

To describe the amplitue and timing of corrective saccades as a function of misalignment, to correlate the ability to correct for loss of vestibular function to symptoms

Study design

Pilot study, with 3 experiments:

- 1. Validation of the measurement method for torsional eye movements
- 2. Obtain age dependent normal values for accuracy of gaze stabiisation

3. Assess gaze stability in single sided vestibular loss and in stationairy retinal dysfunction syndrom

All participants will fill out the dizziness handicap inventory and the questionnaire from the Rotterdam study. The questionnaire has been slightly adapted for this experiment. The questionnaires serve to investigate the correlation between symptoms and compensatory eye movement strategies.

Study burden and risks

The horizontal, vertical and torsional will be measured by a infrared camera, mounted on a pair of goggles, held in place by a tight fitting headband. Torsional eye movement will stand out more clearly when the subject wears a structured contact lens, approved by METC (MEC*2016*327),

In the validation experiment the head movements are generated by a motion platform, the head is immobilised by supports and a bite board. This equipment has been assessed and approved by the METC (METC-2003-82).

For registering eye movements a contact lens, or a scleral coil (approved by METC (MEC*2016*327)) will be used

For experiment 2 and 3 a standard clinical protocol will be used. Low frequency movements are generated by a rotatory chair, high frequency head movements are generated by head impulses that are manually applied.

The bite board, the lenses, the scleral coils and het video goggles all generate some discomfort without causing a risk.

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

- age 16 and up,

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- Normal hearing in the unaffected ear
- Fuctional vision in both eyes
- Informed concent (toestemmingsformulier).
- Solitary vestibular schwannoma for experiment 3
- 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 invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	0
Туре:	Anticipated

Medical products/devices used

Generic name:	imprinted scleral lens
Registration:	Yes - CE intended use

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Ethics review

Not approved Date: Application type: Review commission:

07-03-2023 First submission 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 CCMO ID NL82792.078.23