EX3D

Exophthalmometry With 3D Face Scanners

NCT-Nummer:
NCT04704414

Studienbeginn:
August 2019

Letztes Update:
12.01.2021

Wirkstoff:
-

Indikation (Clinical Trials):
Orbital Fractures, Eye Diseases, Graves Ophthalmopathy, Exophthalmos

Geschlecht:
Alle

Altersgruppe:
Erwachsene (18+)

Phase:
-

Sponsor:
University of Zurich

Collaborator:
-

Studien-Informationen

Detailed Description:

BACKGROUND: Accurate and reproducible measures of abnormal eyeball protrusion are important for diagnosing different causes of exophthalmos, as well as following patients with Grave's orbitopathy and retroorbital tumors. The current clinical gold standards for measuring abnormal eyeball protrusion is the Hertel exophthalmometer, which is prone to reading errors

and inconvenient to use.

OBJECTIVE: The purpose of the EX3D-project is to replace the historic Hertel Exophthalmometer with a state-of-the-art mobile smartphone app that every ophthalmologist can carry in his pocket.

METHODS: The investigators developed an accurate and easy to use method for measuring abnormal eyeball protrusion using the TrueDepth camera of the iPhone 11 in comparison with a high-resolution 3D scanner as a reference to compare with the Hertel Exophthalmometer.

OUTCOMES:

1. Accuracy and precision of 3D face-scanner and iPhone in comparison to Hertel Exophthalmometer.

2. Test re-test reliability in comparison to Hertel Exophthalmometer.

3. Inter-operator reliability against Hertel Exophthalmometer.

4. Patients before and after exophthalmos changing treatment.

5. Applicability in daily clinical practice.

BROADER IMPACT: The invention makes exophthalmometry quick, easy and objective. A mobile smartphone application would replace measurements with the traditional Hertel Exophthalmometer, which are cumbersome, prone to reading errors and have a poor inter-rater reliability as well as test-retest reliability.

Ein-/Ausschlusskriterien

Inclusion Criteria:

- Written informed consent

- Able to cooperate with the study investigations (hearing, comprehension)

- Exophthalmos (Grave's disease, orbital tumors, orbital inflammation, orbital fractures, rare causes (congenital, e.g. microphthalmos)

- health controls

Exclusion Criteria:

- Unable to sign informed consent

- Unable to cooperate with the examinations (hearing loss, neurological deficits)

Studien-Rationale

Primary outcome:

1. Accuracy of the smartphone face scanner (Time Frame - On average 2 weeks):
Accuracy of iPhone exophthalmos measurements (measured in mm for each eye) compared to measure with 3D face scanner and Hertel Exophthalmometer

2. Test-retest-reliability of the smartphone face scanner (Time Frame - On average 2 weeks):
Repeated measures (measured in mm for each eye) of the same subjects with iPhone 11, Hertel Exophthalmometer and 3D face scanner

3. Inter-operator reliability of the smartphone face scanner (Time Frame - On average 2 weeks):
Measurement (measured in mm for each eye) of the same patients by 3 different operators

4. Smartphone face scanner measures before and after treatment with the smartphone face scanner (Time Frame - On average 3 months):
Measurements (measured in mm for each eye) with the smartphone face scanner before and after exophthalmos-changing treatment

Geprüfte Regime

- Exophthalmos measurement:
Exophthalmos measurement with iPhone 11 vs Artec Space Spider 3D Scanner vs Hertel Exophthalmometer.

Studienlocations (1 von 1)

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Status: Rekrutierend

Quelle: ClinicalTrials.gov