

sEMG measurements of the tongue for classification of tongue movement

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Important data for these biomechanical models to create a virtual look-a-like are the neural motor commands. How do individual patients control their functional movements. The tongue is an important organ in speech and swallowing and often impaired...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON45261

Source

ToetsingOnline

Brief title

sEMG of tongue movements

Condition

- Head and neck therapeutic procedures

Synonym

virtual therapy

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biomechanical modelling, head and neck cancer, sEMG

Outcome measures

Primary outcome

The main study parameters are the measured sEMG signals and corresponding 3D movement of the tongue. The study endpoint is when all data is gathered per patient.

Secondary outcome

not applicable

Study description

Background summary

Head and neck cancer treatments can have serious side effects which under circumstance can be debilitating. When tumour board members discuss possible treatments, they often have to make important decisions with limited insight into the extent of such consequences. As a result, patients and physicians have to rely on the personal experience and intuition when selecting between possible (surgical) interventions or organ sparing radiotherapy. To give evidence-based foundations to such choices, we will construct a personalized, detailed, high resolution functional digital model of each individual patient, a genuine virtual look-alike. This virtual patient will combine data obtained from medical imaging and other biomechanical technologies in one functional model. High quality 3D animations incorporate the anatomy, physiology, and neuron-musculature of the virtual patient.

Physicians will *apply* the curative treatment options to this virtual patient to realize an audiovisual dynamic representation of the functional sequelae of treatment. The virtual patient will simulate the effect on important functions, e.g., mastication, swallowing, and audible speech in head and neck cancer. This gives the tumour board and the patient direct access to the use of a functional predictive tool, to realize evidence based decisions on treatment proposals. Furthermore, it enables tailoring of the proposed treatment to the individual patient, to improve functional outcome and decide on additional pre- and post-treatment therapy. It will also clarify the individual functional consequences of the proposed treatment in an audiovisual manner during the

counselling procedure. In ten years, we want to be able to construct a digital model not only for head and neck cancer patients, but for each cancer patient where treatments could impair mechanical functions.

These digital models will store all medical images, physiological data, and all state-of-the-art knowledge of therapy consequences and functional side effects. High quality 3D animations will visualize the likely outcomes of treatments, and their development over time, to the tumour board and patients. Before treatment, these visualizations will guide important decisions about treatment options and selection.

Study objective

Important data for these biomechanical models to create a virtual look-a-like are the neural motor commands. How do individual patients control their functional movements. The tongue is an important organ in speech and swallowing and often impaired due to surgery of tongue carcinomas. Obtaining indirect estimates of the neural motor commands using the surface electromyography technique is of great importance. Hopefully individual neural motor control can be distilled. And these so called activation patterns can be used in the biomechanical models, not only to control tongue movements in a personalized fashion, but also to be able to calculate residual movement after therapy, when certain nerve branches or muscles are affected. The main objective of this study is to test the feasibility of the sEMG approach. To test whether the acquired signals are able to classify standardized tongue movements. And eventually can control a biomechanical tongue model.

Study design

The study is an observational study

Study burden and risks

There is a minimal burden for the healthy volunteers. Only a maximum participation of 1.5 hours will be asked of each individual in one session. There is a small chance of an allergic reaction to medical adhesives. Therefore beforehand the participants will be asked about allergies and the medical adhesive will be tested on the skin of the underarm before using it intra-orally.

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

1. Age > 18 years
2. Healthy volunteer
3. Written informed consent

Exclusion criteria

Allergic reaction to medical adhesives

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO	
Date:	09-02-2017
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO	
Date:	30-05-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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

NL59701.031.16