Development of a method to obtain a long term load profile of the shoulder joint, under daily conditions.

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON34130

Source
ToetsingOnline

Brief title
Ambulatory method to estimate Shoulder Loading

Condition

- Other condition

Synonym
mechanical loading of the shoulder joint

Health condition

Onderzoek naar ambulante meet techniek, en procedures

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: SenterNovem

Intervention

Keyword: Ambulatory, Musculoskeletal model, Neural Networks, Shoulder joint load

Outcome measures

Primary outcome

Part 1: Accuracy of the NN method compared to output of a musculoskeletal model, over subjects.

Part 2: Feasibility of the longterm measurement of upper extremity kinematics using IMMS and surface EMG under daily conditions, the application of the NN method on large datasets, descriptives of a first impression of ambulatory obtained shoulder joint load profile of healthy subjects.

Part 3: Feasibility of the NN-method on subjects with a shoulder endoprothesis under daily conditions, descriptives of the first impression of ambulatory obtained shoulder joint load profile of subjects with a shoulder endoprothesis.

Secondary outcome

Part 1: The minimization of activities needed to generate `sufficient` training data for the Neural Network. `Sufficient` means here without degrading the initial performance of the Neural Network performance. This minimized set of activities will be used in part 2 and 3 of the experiment to train the NN under daily conditions.

Study description

Background summary

To facilitate the development of enhanced shoulder endo protheses, a long term loading profile of the shoulder joint under daily conditions is needed. This joint load, in terms of estimated muscle forces, joint reaction forces (JRF), forces on ligaments etc. can be estimated by musculoskeletal models, using 3D kinematics and external forces as input. For long term ambulatory measurements, 3D kinematics can be measured by means of Inertial Magnetic Measurement Systems (IMMS). However, recording of external forces under daily conditions is not practicable.

This study addresses the feasibility and accuracy of a Neural Network (NN) approach in predicting shoulder joint load. The input is based upon arm kinematics and shoulder muscle surface EMG, as an ambulatory obtainable measure of exerted force. Output of the NN are variables that represent joint load directly (JRF), and variables that can be used as input for a musculoskeletal model to calculate mechanical loading of the shoulder joint in full detail.

Study objective

The study can be divided in three parts
1. A laboratory based experiment to addresses the accuracy of the Neural Network based method. A secondary objective is the minimization of activities needed to generate training data for the Neural Network.
2. Technical feasibility of the NN-method outside the laboratory, in *True Life*, for healthy subjects. A method in handling large datasets will be evaluated. Given the accuracy obtained in part 1, a first impression of joint loading of the shoulder under daily conditions will be described.
3. Feasibility of the NN method under daily conditions for subjects with a shoulder endo-prothesis. A first impression of a shoulder endo-prothesis* load profile in Real Life will be described.

Study design

Feasibility study

Study burden and risks

The risks for the participants are limited to a minimum. The tasks to be performed for calibration of measurement equipment, and generating training data for the Neural Network are functional movements with low external loading, within the normal daily range of movements. In part two and three the additional measurements comprise the performing of the normal daily routine of

the subject, observation with non-invasive measurements.

The measurements comprise motion analysis and recording of surface EMG with portable, battery operated equipment, and pose no risk or inconvenience for the subjects. Part 1 of the study requires a one day-part (4 hours) visit to a motion laboratory, part two and three require initial preparation time of about 45 minutes before actual measurement of the daily routine can start.

Due to the explorative nature of the study, there is no direct personal benefit for the subjects, but their support in this explorative pilot will help in determining the accuracy and feasibility of the method, and in accessing exemplary Real Life data, which is needed to further develop the described method.

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

For part 1 and 2 of the study:
Healthy male
right handed
over 50 years of age
no history of shoulder complaints
active in ADL
ability to understand and follow instructions
ability to complete measurement session;For part 3 of the study:
Healthy male
right handed
over 50 years of age
with a shoulder endoprotheses (right shoulder)
at least 6 month after completion of the rehabilitation process (concerning implant)
active in ADL
ability to understand and follow instructions
ability to complete measurement session

Exclusion criteria

For part 3:
Co-morbidity of disorders affecting use of the upper extremity, like rheuma.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Ethics review

Not approved

Date:	08-08-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL32115.044.10