

Trial Description

Title

The role of the somatosensory system in the balance control of lower-limb amputees

Trial Acronym

BCinA

URL of the trial

[---]*

Brief Summary in Lay Language

We are studying how the body controls posture when a person is missing a lower limb and has to use a prosthetic device. We will measure how the body sways when it is in a quiet upright position. We will also perform standardized clinical balance tests. By extending the experimental conditions (EMG images and use of electrical surface stimulation) further insight on the balance control in humans with leg amputations will be obtained. The updated course of study was defined by an amendment to the original study protocol and received a positive vote from the Ethics Committee of the University of Freiburg on May, 7th, 2019.

Brief Summary in Scientific Language

The dynamics of the adjustment of center of pressure (CoP) has been utilized to study human pathologies characterized by impairments in balance control. This research will investigate the CoP adjustments that occur during upright standing in amputees wearing a prosthesis. The complexity of the CoP adjustments of unilateral transfemoral amputees and healthy participants will be quantified. These measures will be correlated to clinical data (i.e., Berg Balance Scale and the timed up-and-go test), to assess the neuromuscular status of the controlled limb. This allows to: (1) analyze compensatory mechanisms in amputees wearing a prosthetic device, and (2) evaluate new stimulation paradigms designed to restore sensory feedback. In addition to the quantification of CoP adjustments, information about the interaction of involved muscles during balance control can be analyzed via the recording of EMG signals. Electrical surface stimulation will be used as a first step towards the enhancement of balance control through the restoration of sensory feedback.

Organizational Data

- DRKS-ID: **DRKS00015254**
- Date of Registration in DRKS: **2018/09/20**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
-

DRKS-ID: **DRKS00015254**

Date of Registration in DRKS: **2018/09/20**

Date of Registration in Partner Registry or other Primary Registry: [---]*

Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **230/18** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- Free text: **Lower-limb amputation**
- ICD10: **Q72.0 - Congenital complete absence of lower limb(s)**
- ICD10: **Q72.9 - Reduction defect of lower limb, unspecified**
- ICD10: **S78.1 - Traumatic amputation at level between hip and knee**
- ICD10: **S78.9 - Traumatic amputation of hip and thigh, level unspecified**
- ICD10: **T13.6 - Traumatic amputation of lower limb, level unspecified**

Interventions/Observational Groups

- **Arm 1: Patients with unilateral lower-limb transfemoral amputation wearing a prosthesis will be tested in two standard clinical balance tests (Berg-Balance-Scale: 14 different short mobility tasks; Timed-Up-and-Go-Test: simple mobility test of balancing ability). Furthermore, the changes of the center of pressure (CoP) and the synchronization of muscle activity (EMG measurements) will be measured while patients are standing still on a force measurement platform. The complexity of CoP adjustments will be correlated to the clinical assessments of the first two tasks and data will be compared to participants without amputation (see arm 2). Patients with transfemoral amputation will further get transcutaneous electrical surface stimulation.**
- **Arm 2: Healthy participants without an amputation (control group) will be tested in two standard clinical balance tests (Berg-Balance-Scale: 14 different short mobility tasks; Timed-Up-and-Go-Test: simple mobility test of balancing ability). Furthermore, the changes of the center of pressure (CoP) and the synchronization of muscle activity will be measured while participants are standing still on a force measurement platform. The complexity of CoP**



adjustments will be correlated to the clinical assessments of the first two tasks and data will be compared to participants with lower-limb amputation (see arm 1).

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

While participants are standing still on a force measurement platform, data will be obtained about the changes of the center of pressure in their feet and the synchronization of muscle activity. This data will be analysed to be able to compare the complexity of CoP adjustments in participants with lower-limb amputation and the control group. Additionally, amputees will get transcutaneous electrical surface stimulation to take a first step directing to an enhancement of balance control by restoring sensory feedback.

Secondary Outcome

General body balance abilities of the participants will be assessed with two standard clinical mobility tests (Berg-Balance-Scale and Timed-Up-and-Go-Test). The results of these tests are in the following correlated with the results from the CoP measurements.

Countries of recruitment

- **DE Germany**

Locations of Recruitment



- University Medical Center **Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/10/05**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

Unilateral transfemoral (above the knee) amputations

Exclusion criteria

Participants diagnosed with neurological diseases, cardiovascular or other orthopedic disorders, cancer, pace maker, metall implants, acute inflammation, not yet healed fractures or wounds, feverish diseases, haemophilia, psychogene syndrome, known allergies against electrode gel or pregnancy will be excluded.

Addresses

- **Primary Sponsor**

Laboratory for Biomedical Microtechnology
Department of Microsystems
Engineering
University of Freiburg - IMTEK
Mr. Prof. Thomas Stieglitz
Georges-Koehler-Allee 102
79110 Freiburg
Germany

Telephone: **0761-203-747**

Fax: [---]*

E-mail: **stieglitz at imtek.uni-freiburg.de**

URL: **https://www.imtek.de/professuren/bmt/startseite**

- **Contact for Scientific Queries**

Laboratory for Biomedical Microtechnology
Department of Microsystems

Contact for Scientific Queries

EngineeringUniversity of Freiburg - IMTEK
Mr. Dr. Cristian Pasluosta
Georges-Koehler-Allee 102, Room: 102-00-208
79110 Freiburg
Germany

Telephone: **+49 761 203 7251**

Fax: [---]*

E-mail: **cristian.pasluosta at imtek.uni-freiburg.de**

URL: **Web: https://www.imtek.de/professuren/bmt**

■ **Contact for Public Queries**

Laboratory for Biomedical MicrotechnologyDepartment of Microsystems
EngineeringUniversity of Freiburg - IMTEK
Mr. Dr. Cristian Pasluosta
Georges-Koehler-Allee 102, Room: 102-00-208
79110 Freiburg
Germany

Telephone: **+49 761 203 7251**

Fax: [---]*

E-mail: **cristian.pasluosta at imtek.uni-freiburg.de**

URL: **Web: https://www.imtek.de/professuren/bmt**

■ **Collaborator, Other Address**

UNIVERSITÄTSKLINIKUM FREIBURG**Klinik für Orthopädie und Unfallchirurgie**
/Tumorzentrum Freiburg - Comprehensive Cancer Center Freiburg CCCF
Mr. Dr. med. Georg Herget
Hugstetter Str. 55
D-79106 Freiburg
Germany

Telephone: [---]*

Fax: [---]*

E-mail: **georg.herget at uniklinik-freiburg.de**

URL: **www.uniklinik-freiburg.de**

■ **Collaborator, Other Address**

Sanitätshaus Pfänder
Mr. Theo Falck
Munzinger Str. 5c
79111 Freiburg
Germany

Telephone: **+49 761 - 21 86 80**

Collaborator, Other Address

Sanitätshaus Pfänder

Mr. Theo Falck

Munzinger Str. 5c

79111 Freiburg

Germany

Telephone: **+49 761 - 21 86 80**

Fax: [---]*

E-mail: **theo.falck at pfaender-freiburg.de**

URL: **www.Pfaender-Freiburg.de**

Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

Laboratory of Biomedical Microtechnology, Department of Microsystems

Engineering - IMTEK, University of Freiburg

Georges-Köler-Allee 102

79110 Freiburg

Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ **Private sponsorship (foundations, study societies, etc.)**

Wissenschaftliche Gesellschaft in Freiburg im Breisgau

Löwenstr. 16

79098 Freiburg

Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

DRKS-ID: **DRKS00015254**

Date of Registration in DRKS: **2018/09/20**

Date of Registration in Partner Registry or other Primary Registry: [---]*

-
- Paper **Neuromuscular adaptations and sensorimotorintegration following a unilateral transfemoralamputation**

* *This entry means the parameter is not applicable or has not been set.*

*** *This entry means that data is not displayed due to insufficient data privacy clearing.*