Rehaklinik Bellikon
Der Name für UnfallReha

«Descriptive Study of Receptive Fields in lower limb Amputees and the Effect of a related Stimulation System on selected Gait Parameters»

This Study is organized through:

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Dear Madam, dear Sir,

We kindly want to ask you to participate in your clinical study. Followingly we want to present you the study protocol. First in a summary, after in a more detailed manner.

Summary

1	**Purpose of the Study** The purpose of this study is to identify and describe so called receptive fields on your body. Following this, a medical device bearing CE approval which stimulates these fields is tested.
2	**Selection criteria** You have an amputation below the knee. This is the reason we want you to participate.
3	**General Information regarding the study** This study is set to last 4 months and include ca. 35 subjects. In a first phase we will describe receptive fields on your body. These already existing fields will be detected by brushing over your skin with a mild toothbrush. In a second phase a CE certified medical device is tested. The name of the device is «Phantom Stimulator» (Cort X Sensorics, Spaichingen; Germany).
4	**Procedure** In the first part of the study 7 meetings are planned of ca. 1 hour each. Here we want to detect and describe the receptive fields. In the second part of the study you will perform 3 gait analyses during one half-day. The first gait analysis is performed without the device, whereas the following 2 are performed with the previously mentioned device. In this setup the device is worn for about 3 hours over the whole study duration. Overall this study creates an expenditure of time of about 10 hours distributed over 1 month.

5	**Benefit of the study** Through your participation you permit the gain of important knowledge regarding the behavior of receptive fields in people with lower limb amputations. This knowledge is required to develop and safely apply medical devices as the one tested in the second phase of the study. Through the participation in this study you can test a new device in an early stage of development. Further, using this device, we expect improvements regarding Phantom pain, phantom sensations and gait parameters.
6	**Rights** You decide freely whether to participate in this study or not. Your decision has no influence on your medical care and you do not have to justify your decision.
7	**Responsibilities** If you participate we ask you to follow certain requirements. Firstly, we ask you to adhere to the set meeting dates and times. Secondly, we ask you to always be truthful during the meetings and respond honestly to our questions. This as false statements can bias the results.
8	**Risks** Risks related to the use of the device is only the possibility of skin irritations associated to the electrode glue. However, this glue is dermatologically tested and already used frequently. Associated with the other analysis there are no other risk factors we are aware of.
9	**Other treatment options** As of today, there are no comparable treatment options available.
10	**Results** You are informed of results of the study in advance if the results are of relevance for you own wellbeing. If you do not want to be informed, please refer to the tester.
11	**Privacy of the Data** We respect all legal rules of data protection and all personnel involved is subject to professional secrecy. Your personal and medical data are used in an encrypted and protected manner. The data is used for further research only if you give your consent separately.

12	**Withdrawal** You can withdraw at any time from the study and not participate anymore. The data collected up to that point is used for analysis.
13	**Compensation** You are compensated for travel expenses (basis SBB second class Halbtax or 0.7 Chf/km). if needed a room for the night is provided at the clinic. Further you can keep the collected data on your receptive fields as well as the results of the gait analysis.
14	**Liability** The public liability of the Rehaklinik Bellikon arises if damages occur and these are directly related to one of the testers or the infrastructure of the Rehaklinik Bellikon.
15	**Financing** This study is financed by the Rehaklinik Bellikon.
16	**Contact:** Pleus Michael und Dr. med. Groegli Marion Sportmedizin und Rehabilitation Rehaklinik Bellikon Mutschellenstrasse 2 5454 Bellikon Tel.: +41 (0)56 485 56 90 E-Mail.: Studie@rehabellikon.ch

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Detailed Information

1. Purpose of the study

The purpose of the first part of the study is to describe so called receptive fields on your body. These fields are tested for changes in size and position over the timespan of one month. Further we want to evaluate if differences exist If the testing is performed by different testers.

In the second part of the study we evaluate the efficacy of a medical device bearing CE approval ("Phantom Stimulator"). This device uses the receptive fields by stimulating them. The efficacy of this device is assessed through a gait analysis and a questionnaire.

2. In-/Exclusion

All people having an amputation below the knee can participate in the study.
For safety reasons we must exclude pregnant women, for this reason all women must perform a pregnancy test on the first meeting.

We must exclude from the second part of the study people with implanted devices as pacemaker or defibrillators. Further we must exclude people not having any receptive fields at the end of the first part of the study.
In those cases, you can however participate at the first part of the study without concerns.

3. General Information

It has been observed that patients subject to amputations of the lower extremities develop so called receptive fields. Timing and localization of the appearance of these fields is extremely subject related and poorly examined scientifically.

A receptive field is defined as a skin area, which if stimulated by others, causes a phantom sensation in the amputated limb. These fields originate as result of the reorganization of the somatosensory cortex and are randomly allocated on the amputated body side. They can also occur in the genital area although this is not common.
A phantom sensation is defined as a sensation of any kind concerning a body part not connected to the nervous system.

In a first part of the study, these receptive fields are found and recorded. This is done by a specifically trained person with a mild toothbrush and through the dialog with you.
The recording of the receptive fields is done by marking them on your skin with a normal eyeliner. These signs are then photographed and evaluated with the computer program Photoshop and Excel.
In this Analysis we record size and position of the detected fields.

In a second part of the study (day 31) we analyze the short time effects of the system called «Phantom Stimulator» (Cort X Sensorics, Spaichingen, Germany) on Gait, phantom sensations and phantom pain. This system has a CE conformity label and is therefore allowed on the swiss market.
This «Phantom Stimulator» consists of a pressure sensing insole, an impulse generator and TENS electrodes. The electrodes are attached on to the receptive fields representing heel and toes. Through the walking with the prosthesis, the electrodes apply a light electric impulse on to the receptive fields stimulating a rhythmic phantom sensation mimicking the rolling motion while walking.
As a result, we expect changes in phantom sensations and phantom pain as well as changes in the measured gait parameters (gait length, gait width, speed, cadence and ground contact time).

We perform the study as the swiss law prescribes it. We respect the international rules as well.
The responsible ethics committee has reviewed and approved the study.
You can find a description of the study on the website www.kofam.ch as well.

4. Procedure

Part 1:

As to collect the needed information on the receptive fields, the meetings are arranged as follows:

- At day 1 the receptive fields are measured at a predefined time of day by a tester X.
- At day 2 the receptive fields are measured at the same time of day by the same tester X.
- At day 7 the receptive fields are measured at the same time of day by the same tester X.
- At day 14 the receptive fields are measured at the same time of day by a tester Y.
- At day 21 the receptive fields are measured at the same time of day by the tester X.
- At day 28 the receptive fields are measured at the same time of day by the tester Y.
- At day 31 the receptive fields are measured at the same time of day by the tester X.

Part 2:

The Procedure in this part consists of the following phases:

- In a first phase (Familiarization-Phase) you will walk 1000 steps, answer a questionnaire and perform a gait analysis.
- In a second phase we will install the system which has to be tested and you will be randomly assigned to 2 distinct groups (A or B).
    - Group A: this group first walks with the functioning system 1000 steps, answers the questionnaire and performs a gait analysis. After, this group walks 1000 steps again but with the non-functioning system, answers a questionnaire and performs a gait analysis.
    - Group B: this group first walks with the non-functioning system 1000 steps, answers the questionnaire and performs a gait analysis. After, this group walks 1000 steps again but with the functioning system, answers a questionnaire and performs a gait analysis.

The collected parameters of the gait analysis are the step width, the step length, the ground contact time, the cadence and the speed.
The questionnaire asks questions regarding the presence, quality and quantity of your phantom sensations and pain.

It is possible that we must exclude you prematurely from participation at this study. This can be the case if your safety or well-being is at risk. Specifically, this includes skin irritation, psychological problems or pregnancy. In this case you are examined once more for your safety.
Your family doctor should be informed beyond study participation.

5. Benefit

By participating in this study, you enable the gathering of relevant information regarding the behavior of receptive fields in people with lower limb amputations. This information is required to support systems as the tested one in their development and application.

Thanks to this study you can test a new product in an early stage of development. Further we expect improvements in the areas of phantom sensation, pain and gait parameters from the use of the tested system.

Finally, the results of this study can be of relevant importance to people having the same fate.

6. Rights / Withdrawal

Your participation in this study is entirely voluntary. As a participant, you have the right to withdraw from the study at any time without needing to specify any reasons nor facing negative consequences. The project team informs you about possible changes of the study which would influence your written consent.

7. Duties

As participant to this study it is important that you:

- Respect the guidelines and requirements set by the study protocol and respect the instructions manual of the system.
- Inform the tester upon the course of your condition and inform him/her if new symptoms or discomfort arises.
- Inform the tester of eventual concomitant treatment or intake of pharmaceutics.
- Respect the accorded meeting times and dates.
- Try to be as honest as possible while answering our questions. This as false statements can bias the results.

8. Risks and Stresses for the participants

Side effects of the system: there can be allergic reactions to the glue used by the TENS electrodes. These can show as skin irritations. A discomfort which the system involves is the carrying of cables on the body.

Side effects of the examination: as the examinations are not invasive and not otherwise dangerous, we do not expect any side effects.

For women that can become pregnant:

There is no available data on the effect of the system on the unborn child.
If you become pregnant during the study, you have to inform your tester as soon as possible and cannot participate anymore.
In this case you will be asked to inform about the progression and outcome of the pregnancy.

9. Other treatment options

As of today, there are no comparable treatment options available.

10. Results of the study

Your tester will inform you of results during the study if this data could influence your safety and therefore your consent of participation. You will receive this information also in written form.

If a chance finding occurs which can help in prevention, detection or treatment of further diseases, you will be informed. If you do not want to be informed, please refer to your tester.

11. Data protection

The obtained data will be stored safely and reported in an anonymous form. Only the responsible investigators and/or the members of the ethical committee have access to the original data under strict confidentiality. Under no circumstances will your name be published in reports or publications of this study.

12. Compensation for the participants

You are reimbursed of incoming travel expenses (Basic SBB second class Halbtax or 0.7 Chf/km). If necessary, an overnight stay can be organized at the clinic.

Further you can keep the obtained data about your receptive fields as well as the evaluation of the gait analysis.

13. Liability

Possible damages to your health, which are directly related to the study and are demonstrably the fault of the Rehaklinik Bellikon, are covered by the general liability insurance the Rehaklinik Bellikon. However, beyond the before mentioned, the health insurance and the accident insurance (e.g. for the way to or back from the study locations) is in the responsibility of the participant.

14. Founding

The study is entirely financed by the Rehaklinik Bellikon.

15. Contact

In case of any questions or undesirable incidents, which occur during or after this study, do not hesitate to apply to any of the contacts below:

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Consent form for participants

Please read this form carefully. Please ask the investigator or the contact person if you have any questions.

Study title:	«Descriptive Study of Receptive Fields in lower limb Amputees and the Effect of a related Stimulation System on selected Gait Parameters»
Responsible Institution:	Rehaklinik Bellikon Mutschellenstrasse 2 5454 Bellikon
Study location:	Rehaklinik Bellikon Mutschellenstrasse 2 5454 Bellikon
Responsible Sponsor / Investigator:	Dr. med. Groegli Marion Sportmedizin und Rehabilitation Rehaklinik Bellikon Mutschellenstrasse 2 5454 Bellikon Tel.: 0041 56 485 56 90 Mail: Studie@rehabellikon.ch
Participant´s name and first name: **Gender:**	

- I participate in this study on a voluntary basis and can withdraw from the study at any time without giving reasons and without any negative consequences.
- I have been informed orally and in writing about the aims and the procedures of the study, the advantages and disadvantages as well as potential risks.
- I have read the written information for the volunteers. My questions related to the study participation have been answered satisfactorily. I have been given a copy of the information for the volunteers and the consent form.
- I was given sufficient time to make a decision about participating in the study.
- With my signature I certify that I fulfill the requirements for the study participation mentioned in the information for the volunteers.
- I have been informed that possible damages to my health which are directly related to the study and are demonstrably the fault of the Rehaklinik Bellikon, are covered by the general liability insurance of the Rehaklinik Bellikon. However, beyond the before mentioned, my health- and/or accident insurance (e.g. for the way to or back from the study location) will apply.
- I agree that the responsible investigators and/or the members of the ethical committee have access to the original data under strict confidentiality.

- I am aware that during the study I must comply with the requirements and limitations described in the information for the volunteers. In my own health interest, the investigators can, without mutual consent, exclude me from the study.

Location, Date	**Signature volunteer**
Location, Date	**Name and First name of the principal investigator:** **Signature investigator:**