Feasibility study protocol

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Abstract

1 Purpose and Objectives

We are planning a feasibility study, to demonstrate the added value of the solution TRUE REHAB is developing. The study has a cascaded set of objectives, and we aim at reaching as many of these objectives as possible.

- Identify person specific muscle parameters
- Prove that the robot can provide assistance-as-needed along specified trajectories
- Prove that muscle parameters change following rehabilitation
- Prove that such a rehabilitation scheme has advantages for specific group of patients

The final objective is an ideal scenario, but even if we are able to reach either of the two or three first objectives, we can claim that our robotic rehabilitator is one step forward.

Instead of the last two objectives, we could also consult our medical experts to define a more appropriate metric for evaluating the success of rehabilitation, something that could be compared to existing literature.

To maximize the relevance of our results, we should ideally test our device with patients. These patients should fit certain criteria, the main one being their need for rehabilitation. Since our project aims at developing a strategy for maximizing/minimizing the contribution of certain muscles in execution of tasks, we should ideally identify a patient group that would require such a rehabilitation scheme. Some possible groups would include post-surgical rehabilitation, where unnecessary strain should be avoided in certain areas close to the surgery.

2 Requirements

To reach the objectives defined in the previous section, we need to have accomplished the following steps:

- Implement sliding mode control with
- Define trajectories that maximize/minimize muscle participation
- Quantify the amount of assistance provided by the robot
- Be able to identify person specific muscle parameters
- Recruit patients

3 Protocol

The following steps define a possible scenario for a testing protocol

- Recruit participants, respecting inclusion and exclusion criteria defined in the following subsection
- Inform participant on the study protocol, risks, and benefits of the study, sign informed consent
- Perform basic movements for muscle parameter identification with both affected and unaffected arm
- Define the rehabilitation task(s) to be performed based on a pre-defined list of tasks
- Attach EMG electrodes on the relevant muscles of the participant, and verify clear signals
- Ask participants to perform a maximum voluntary contraction of muscles of interest
- Connect the participant to the robotic rehabilitator
- Perform several repetitions of the rehabilitation task
- Detach the participant from the robot and remove the EMG electrodes

If possible, we should aim at performing this protocol several times with the same participants and evaluate their progress over time. During the measurements, we should measure the following aspects:

- The actual trajectory of the end-effector of the robot and hand of the participant
- The wrench at the end-effector
- Muscle activation
- The 3d skeleton kinematics of the participant

Using these signals, we can quantify how close are we to fulfilling the objectives defined in Section 1. For instance, by observing the wrench and comparing its direction with the pre-defined trajectory, we can distinguish active vs passive movements, and quantify the level of assistance. By observing the muscle activation, we can quantify the participation of individual muscles. By measuring the kinematics of the participant and the muscle activation, we can re-calculate the new muscle parameters online.

3.1 Recruitment

A very important aspect of this study will be the recruitment of patients. For this, we need the assistance of our medical partners. We should ideally focus on a specific patient group, with a pathology that is relevant, for which our rehabilitation scheme is relevant. A possible group could be post-surgery patients that need to undergo rehabilitation of the upper arm. Such patients might benefit from rehabilitation schemes that minimize the participation of specific muscles, i.e., those that are traversing the surgical area.

For reaching the objectives defined in Section 1 we have defined the following inclusion and exclusion criteria:

Each participant should:

- Be in need of upper-limb rehabilitation
- Should be able only affected on one of the two limbs
- Should be able to perform basic movements with the affected limb
- Should exhibit activation of the relevant muscles on the affected limb