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Title
Development of a tool to optimize individual alignment of lower leg prostheses. A combined in vitro, in silico and in vivo approach

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Summary
A personalized configuration and alignment of lower leg prostheses is paramount to obtain patient comfort and functionality. It is our aim to optimize the alignment procedure by developing a tool based on a combination of mechanical tests with a robot, musculoskeletal modeling and gait measurements.

Introduction
If a lower leg prosthesis is not well aligned or its configuration is not adapted to the patient's anatomy and characteristics, this will result in pain, discomfort and, ultimately, loss of function. Despite the clear importance of the alignment process, it is currently based primarily on the expertise and experience of the orthopedic technologist. Usually, he or she tries to reach an optimal solution through a static alignment procedure at first, followed by dynamic fine-tuning. It is a typical trial and error procedure, which is quite time consuming and a satisfying outcome is not guaranteed.
To scientifically underpin the whole procedure and thereby make it more efficient and effective, a project was started combining experimental tests with a robot, musculoskeletal models and extensive gait analyses. Using these techniques, the full space of alignment and configuration possibilities will be explored and related to the resulting pressures in the stump, gait asymmetries and comfort.

Methods
At first, in vivo measurements of the gait cycle of 10 subjects, with different settings for the alignment of their lower leg prosthesis will be performed to provide input and data for validation

for the next two parts. Kinematics, EMG signals, ground contact forces and stump-prosthesis pressure distribution are all recorded as well as subjective impressions regarding pain and discomfort.

Secondly, standardized in vitro tests of typical gait will be performed with a robot. The lower leg prosthesis is fitted onto an artificial stump which is connected proximally to the robot end-effector. The end-effector simulates the kinematics of the stump during gait and pressure sensors between the stump and the prosthesis register pressure distribution, while a force plate under the foot registers ground reaction forces.

Finally, musculoskeletal simulations will be performed to calculate muscle forces during the different gait trials.

Results

The combination of all gathered data will lead to an algorithm to guide and optimize the alignment procedure.

A feasibility test with one subject was already performed. We measured three gait trials in five different configurations of the lower leg prosthesis (about one quarter of the total number which will be investigated during the validation phase). Kinematics, ground reaction forces and EMG signals in the stump were recorded. The full test took about two hours. Figure 1 shows knee flexion angle at the amputated side during gait. Different configurations lead to differences mainly during the stance phase. For this subject, bench alignment leads to the most normal gait pattern. Based on this preliminary assessment, we concluded that a clinical validation of the simulation outcomes is feasible.

Currently, the design of an artificial stump is well underway. Based on FEM, the appropriate materials for bone and stump were identified and different kinds of liquid rubbers have been tested to obtain the optimal combination of softness and fatigue resistance. The stumps will now be produced and equipped with pressure sensors after which the tests with the robotic gait simulator can start.

Conclusion

It goes without a doubt that improvements are necessary in terms of both efficiency and efficacy of the personalized configuration and alignment process of lower leg prostheses. We believe that a combination of advanced technological tools which are available nowadays will help achieve these improvements.

In this project we will try to develop an algorithm to guide the orthopaedic technologist in his endeavour to reach an optimal solution for each patient. This will be done by using a combination of a robotic gait simulator, musculoskeletal modelling. The algorithm will then be extensively validated with gait analyses.

If successful, the resulting tool will also greatly improve the comfort of patients and their quality of life.

References

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Image: knee angle amputated side_1496.jpg

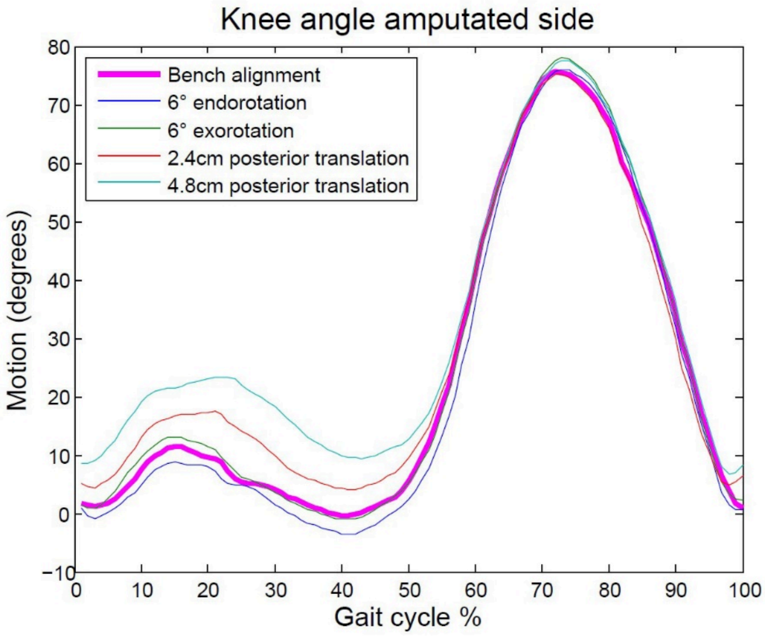

Figure 1: Knee flexion angle during gait at the amputated side for different configurations in one subject.