## Summary

Robot-assisted gait training is rapidly evolving since the last two decades. However the use of robot-assisted gait trainers (RAGT) in clinical practice is limited. Main contributors hereto are the limited effectiveness and limited efficiency. The main challenges in the development of robot-assisted gait trainers are to allow for Assist As Needed (AAN) training and reduction of the idle time of training, i.e., time needed to (de-)install the patient in the RAGT (donning and doffing time). AAN training implies that the patient should have freedom in walking and only receives support on specific (affected) aspects of gait. This in it turn implies that the RAGT must allow for multiple Degrees of Freedom (DoFs) and that the powered DoFs are capable of following the patient's motion, i.e., the DoFs should be transparent, in order to display minimum impedance.

After extensive research on the requirements from the end users i.e., physical therapists, rehabilitation physicians, patients and researchers, the system requirements for the new RAGT, LOPES II, were established: a treadmill-based robot, with mechanics located behind the patient, with minimum amount of clamps. Furthermore the patient must be able to move freely in rotations and translations of all segments and joints, and arm swing must be unhindered. In a study, we have demonstrated that one can walk unhindered with up to 6 kg of inertia added to the pelvis, or 2 kg of inertia added to the ankle. Support must be supplied on the pelvis horizontal translations, hip abduction / adduction (leg sideways) and flexion / extension (swinging the upper leg forward/backward), knee flexion / extension, and foot plantar / dorsiflexion (foot push-off/toelifting).

During the concept phase, the end users frequently evaluated the concepts. This process not only improved the quality of the concepts, but also increased the involvement of the end users in the development process. The best concepts were integrated into a single-legged mechanical proof of concept. This integrated proof of concept for LOPES II uses a patented shadow leg approach, i.e., a mechanical leg located behind the patient. The patient leg and shadow leg are connected with push-pull rods. Contrary to conventional exoskeletons with a mechanical leg located at the side of the patient leg, the shadow leg requires little alignment. The number of clamps are minimum: a clamp at the pelvis (combined with a harness for safety and bodyweight support), clamps at the lower legs (below the knees), and clamps at the feet (foot brackets). For the clamps at the feet and pelvis we use patented gimbals which allow rotations of feet and pelvis, and make that supportive forces apply in the center of the ankle joints and hip joints. Furthermore the concept contains a seat on which patients can sit during the donning and doffing phase, and rest between trainings.

The integrated proof of principle, together with a list of system requirements, formed the input for the design of the mechatronic prototypes. The mechanical linkage is designed such that powered DoFs are largely decoupled, to avoid complexity in transformation calculations and to have an optimal range of motion for each DoF. The selected actuators are capable of providing sufficient support for severely impaired patients, and they are fast enough to follow motions of fast walking. For control of LOPES II we selected admittance control. This allows for both high impedance (high support) and low impedance (low support), by displaying a (low) virtual mass without friction. Custom-made force sensors located near the clamps provide input for the admittance controller. For safety, we added redundant force and position sensors to detect sensor failure. The development of the resting chair in the linkage has been postponed, in order to maintain focus on the primary function of LOPES II, i.e., assistance of gait.

Two mechatronic prototypes were built and installed in the Roessingh Rehabilitation Center in Enschede, the Netherlands, and the Sint Maartens clinic in Nijmegen, the Netherlands. The linkage for the foot plantar/dorsiflexion had a negative impact on the controllability of the remaining DoFs, due to its weight. Therefore the actuation for foot pushoff was removed. We added a passive toe lifter, to allow for gait training for patients with problems with toe lifting (e.g., due to weakness in the dorsiflexor muscles or spasms).

We then started the evaluation of LOPES II, starting with the verification of the system requirements. Measurements of the mechanical stiffness between the actuators and the force sensors showed that LOPES II is not as stiff as required. Furthermore we measured the position accuracy of LOPES II, i.e., how accurate can LOPES II measure the patient joint angles from the motor angle data. The measured position errors are less than the standard deviation of normal walking.

For most DoFs, the impedance of LOPES II is sufficiently low. In minimal impedance mode, the admittance controller displays a virtual inertia with minor damping. For ankle translations (anterior / posterior and mediolateral), LOPES II displays little over the allowable 2 kg. For the knee anterior / posterior translation, LOPES II displays 4.7 kg; little higher than the allowable 4 kg. However for the pelvis anterior / posterior and mediolateral translations, LOPES II displays 40 kg, whereas 6 kg is the allowable inertia to allow for free walking. Examining the gait patterns of healthy subjects, we see that walking in LOPES II in minimal impedance mode, resembles free walking on a treadmill. Particularly for the joint rotations, the correlation is high. For the pelvis translations the correlation is lower, which is also reflected in the relatively high interaction forces on the pelvis (peak-to-peak 100 N). This is attributed to the relatively high virtual mass at the pelvis.

In the next phase we performed pilot studies to evaluate the potential of LOPES II in the clinic. When patients were installed in LOPES II for the first time, the donning time varied from ten to fifteen minutes. For recurring trainings, the donning time varied from five to eight minutes. For first time training the patient limb sizes must be measured, and data must be fed in the computer. More severely impaired patient required longer donning times, due to the fact that they require help in standing. These donning time are considerably lower than the known donning times for existing devices, allowing for more efficient use of training time.

During pilot studies we tested the potential of LOPES II to assist as needed. For this we have developed a graphical user interface, with which the therapist can adjust gait patterns and the support levels for specific aspects of gait. LOPES II is powerful and stiff enough to enforce a walking pattern (high support on all aspects of gait) on a severely affected patient. We also demonstrated that, on the other side of the spectrum, LOPES II can provide selective support to a mildly affected patients.

LOPES II has the potential to perform Assist As Needed training in the clinic. Currently a randomized clinical trial is being performed to compare the effect training with LOPES II with conventional therapy.