Challenges in Adaptive Robot-Assisted Gait Training: The Balancing Act of Minimizing Assistance While Preserving Safety

Alejandro Melendez-Calderon and Serena Maggioni

Abstract To maximize functional outcomes, rehabilitation strategies must provide challenging environments that encourage active participation of the users. Robotic gait trainers can provide adaptive and personalized environments that guide the patient as needed and encourage the patient to be active during the whole therapy session. However, even though research in neurological recovery may favor such approaches, they may be highly difficult to implement in practice. Here, we share some challenges in implementing adaptive robot-assisted gait training in practice.

1 Introduction

Multiple evidence, from animal models to clinical studies in humans, has demonstrated that functional improvements after neurological injury are better achieved when the patient is encouraged to produce voluntary neuromuscular activity (active participation) and receives early and intensive therapy, i.e. high amount of movement repetitions, but without repetition, or in other words "repetitive attempts at the same task accompanied by variable trajectories of elemental variables" [1].

Robotic gait trainers (e.g. Lokomat, Walkbot, G-EO, Lexo, Gait Trainer GT II) are valuable tools for gait therapy after neurological injury. Such devices can provide intensive training with a high amount of repetitions, and encourage active participation and challenging training conditions by, for example, providing increased walking speed or decreased robotic assistance, and exer-games.

While commercially-available devices offer opportunities for personalization of these challenging environments, such parameters are typically adapted by the therapist via a user interface. This implies that the robotic assistance is left at the

A. Melendez-Calderon (✉)
Biomedical Engineering, School of ITEE, The University of Queensland, Brisbane, Australia
e-mail: alej.melendez@uq.edu.au

S. Maggioni
Hocoma AG, Volketswil, Switzerland
e-mail: serena.maggioni@hocoma.com

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discretion of the therapist, and it is typically ‘fixed’ for the duration of the therapy session—missing opportunities for challenging the patient at an optimal level.

To address the limitation of ‘fixed’ robotic assistance (which can be high, or low), several research groups have proposed the concept of “Assist-As-Needed” (AAN) control for robot-assisted training, e.g. [2–4]. In this case, the robotic assistance is no longer set by a therapist but adapts constantly, and automatically, based on the user’s performance. As a training approach, AAN is believed to be more effective than traditional assistive controllers, because it encourages the patient to be active during the whole therapy session.

In recent work, we implemented an ANN algorithm in the Lokomat (Hocoma AG, Switzerland), a commercially-available robotic gait trainer widely used in clinical practice [2]. The objective of this implementation is to investigate opportunities for using ANN control as a valid, reliable and sensitive assessment method of walking activity in a robotic gait trainer. While several aspects still need to be addressed to be able to reach this goal, preparation for and the conduction of a clinical study on 15 SCI patients with this algorithm has given us insights into the challenges of implementing adaptive robot-assistance that can be used for training in clinical settings. This paper summarizes those challenges with the aim of fostering transdisciplinary activities across multiple stakeholders (industry, research, healthcare provides, etc.) to find solutions to those.

2 Challenge I: Risk of Injury and Liability

In conventional locomotor training, a therapist (or more) is in direct contact with the legs of the patient; he/she can feel whether the patient needs more or less assistance to provide adequate foot clearance and prevent scuffing. If, for any reason, the patient is injured because of inadequate foot clearance, liability lies on the healthcare provider.

In the case of robotic locomotor training, the device guides the legs of the patient. When decreasing the amount of robotic support, potential hazards can come from unwanted interactions between the foot and the treadmill. For example, if there is no sufficient support to provide foot clearance or lift the body, but the robot continues to force movement on the legs, the device can seriously injure the patient. This situation can result because of improper implementation, or due to human error in selecting parameters and setting up a patient in the device. Liability in this case is not white or black and is typically shared between the medical device manufacturer and the healthcare provider. The medical device manufacturer is responsible for evaluating any possible risk of injury when operating the device in all possible configurations, and to provide necessary safety mechanisms to make sure that such risky situations are extremely unlikely. The healthcare provider is responsible for operating the device with trained personnel and according to the intended use and user manual.

The big responsibility for medical device manufacturers creates a very conservative approach for implementing novel robot-assistance techniques in commercial devices. Therefore, even though research in neurological recovery may favor challenging environments for training (e.g. more transparent, less guided movements), such approaches may be highly difficult to implement in practice. What works on a well-controlled, research trial, may result in injury to a patient when implemented in real clinical settings. For example, a therapist needs to take care of many more variables in a busy clinical setting which may result in to insufficient supervision, or due to the heterogeneity of the patients' characteristics, unstable circumstances may arise which may never have been encountered during testing.

3 Challenge II: Testing and Validation

Adaptive controllers pose challenges in guaranteeing stability and safety in human applications. A conservative approach for safety is usually adopted, because testing for certification of a medical device does not necessarily include all possible neuromechanical impairments that would make the device safety mechanisms fail (Fig. 1). This conservative approach to safety restricts opportunities for implementing novel training techniques that are more likely to result in better functional outcomes.

In [5], we propose the use of bio-inspired robotic testbenches, rendering biomechanical properties of human motion, as platforms for testing algorithms in a systematic way (Fig. 1). Although such testbenches may be a simplistic representation of

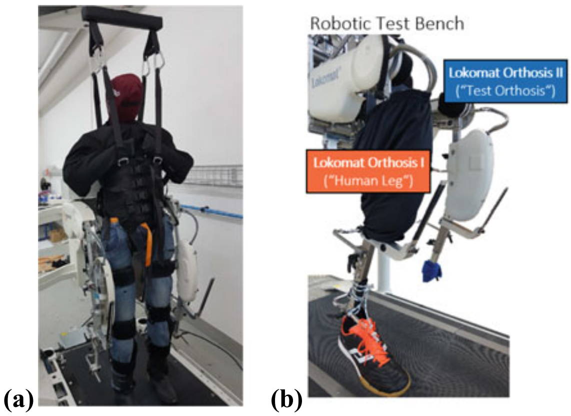

Fig. 1 **a** Manikins are typically used in life-cycle testing of medical robots. The figure shows a passive manikin on the Lokomat. Such manikins are passive and do not allow the testing of realistic conditions, e.g. spastic or voluntary activity, which may cause unsafe interaction with adaptive controllers. **b** Bio-inspired robotic testbenches [5] allow the testing of more realistic conditions. The figure shows one of the Lokomat orthosis acting as a 'human' leg as a possible configuration; but one could also envision full robotic manikins replacing passive manikins as in (**a**). This provides opportunities in testing the safety of adaptive robot-assistive training strategies and benchmarking across different devices

the complex biomechanics and control exhibit by patients, they provide a powerful method for simulating repeatable and controlled input, and identifying situations in which safety mechanisms can be 'relaxed' or need to be improved. Simulating known impairments reduces the causes of uncertainty and allows to perform tests in controlled conditions, and study the behavior of adaptive robot-assistive training strategies.

4 Challenge II: Intuitive Task Instructions

Assist-as-needed approaches vary robotic guidance based on a measure of user's performance on a given task. For instance, in our ANN implementation, subjects were instructed to follow the movements of a walking avatar while trying to remain inside two shaded rectangles around the thigh and the shank that indicate the reference position (Fig. 2a), or to follow the blue trajectory in space and in time (the blue dot indicated the desired position at every instant) (Fig. 2b). In both cases, the adaptation of robotic assistance (knee and hip stiffness, and body weight support) was driven by the kinematic error between the actual and 'desired' joint angle trajectories. However, feedback on leg segments was more difficult to follow by patients than feedback on endpoint positions. Moreover, the desired endpoint trajectory was based on a reference gait trajectory that may have been different from the patient's own trajectory, increasing thereby the difficulty of the task.

While such cognitive load may not be an issue in some patient population, e.g. SCI patients, the increased cognitive difficulty of the task might create undesired movement patterns in other patient population, e.g. stroke. When it comes to commercial implementation, the challenge here is in creating motivating environments that are suitable for the majority of users, which can include multiple populations.

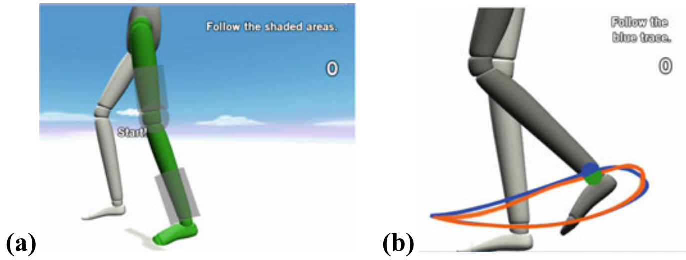

Fig. 2 **a** Visual feedback and instructions provided to the subjects in our RAGA implementation of ANN control [1]: **a** follow independent leg segments; or **b** follow an ankle trajectory

5 Conclusion

The concept of robot-aided neurorehabilitation has been around for more than 30 years, but first commercial robots for gait rehabilitation only became available until year 2000 (e.g. Lokomat, Hocoma AG, Switzerland). In these past 20 years, we have seen the flourishment of several commercial robotic gait trainers. While there have been enormous advances in research using these devices, the requirements needed for promoting recovery, e.g. active participation and challenging environments, may be extremely difficult to implement in commercial products. We see the need for gaining a better understanding on acceptable risks, and for dialogue between different stakeholders to determine legislation, liability and ethics around adaptive robot-assisted approaches to therapy.

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