2021 43rd Annual International Conference of the
IEEE Engineering in Medicine & Biology Society (EMBC)
Oct 31 - Nov 4, 2021. Virtual Conference

2021 43rd Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC) | 978-1-7281-1179-7/21/$31.00 ©2021 IEEE | DOI: 10.1109/EMBC46164.2021.9629989

Design of a stepwise safety protocol for lower limb prosthetic risk management in a clinical investigation

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***Abstract*— In research on lower limb prostheses, safety during testing and training is paramount. Lower limb prosthesis users risk unintentional loss of balance that can result in injury, fear of falling, and overall decreased confidence in their prosthetic leg. Here, we present a protocol for managing the risks during evaluation of active prosthetic legs with modifiable control systems. We propose graded safety levels, each of which must be achieved before advancing to the next one, from laboratory bench testing to independent ambulation in real-world environments.**

I. Introduction

Most lower limb prostheses are either entirely passive mechanical devices or microprocessor-controlled devices which are energetically passive, meaning that they do not provide net positive power to the user. This lack of compensation for the lost musculature in the missing limb limits the ambulatory ability and leads to compensatory movements with increased reliance on the biological limb [1]–[3]. Only few energetically active prosthetic devices are commercially available, of which the Össur PowerKnee and the Ottobock Empower are two examples. However, extensive research efforts are directed to this field and a range of active devices have previously been, or currently are, being developed and tested in research settings [4]–[10].

Adding active joints to the prosthesis increases the number of achievable ambulatory modes and the complexity of the prosthesis control scheme. Embedded or added sensors on the prosthesis, the contralateral limb, or electromyography (EMG) sensors placed on/in the residual limb may be used to infer ambulation mode, gait phase, and ambulation mode transitions to allow smooth locomotion for the user [11]–[17]. By combining these sources of information, the ambition is to enable increased prosthesis function with increased safety for the users. However, as the complexity of sensor integration and control schemes increase, so does the work required to test and verify function. Much of this work requires physical testing during actual prosthesis usage, and adequate safety precautions must be in place to avoid hazardous situations.

In contrast to individuals using upper limb prostheses, lower limb prosthesis users risk unintentional loss of balance due to intrinsic and extrinsic factors related to tripping, slipping or collision, all of which can lead to injury such as fractures [18]. Fear of falling and decreased confidence in the prosthetic leg can lead to a reduction of prosthesis use and to social withdrawal [19], [20]. Some lower limb prosthesis users report a need to concentrate while walking that has been associated with a fear of falling [19]. To minimize the risks, safety precautions should rely on well-designed rehabilitation and evaluation protocols in combination with the combined experience of healthcare and research professionals. To this end we are proposing a stepwise safety protocol for managing the risk when active prosthetic legs, with modifiable control systems, are used by individuals with a lower limb amputation. This protocol was designed owing to the need of our group to evaluate neuromusculoskeletal prostheses for the lower limb, (the neuromusculoskeletal interface is further described in [21], [22]), but it can be applied to any new leg prostheses and control strategies. The protocol is developed with focus on individuals with transfemoral amputation due to their increased risk of falling, but it is also applicable for the transtibial amputation level [19].

II. Structure of the Protocol

As per Good Clinical Practice guidelines a risk management plan (RMP) should be maintained throughout a clinical investigation [23]. This stepwise safety protocol can be seen as a part of the RMP and comprises prosthetic evaluations and mobility from the laboratory bench (without a

* Research supported by the Promobilia Foundation, the IngaBritt and Arne Lundbergs Foundation, the Swedish Innovation Agency (VINNOVA), the Swedish Research Council (Vetenskapsrådet), and the Swedish state under the agreement between the Swedish government and the county councils, the ALF agreement (ALFGBG-76480 and ALFGBG-725641).

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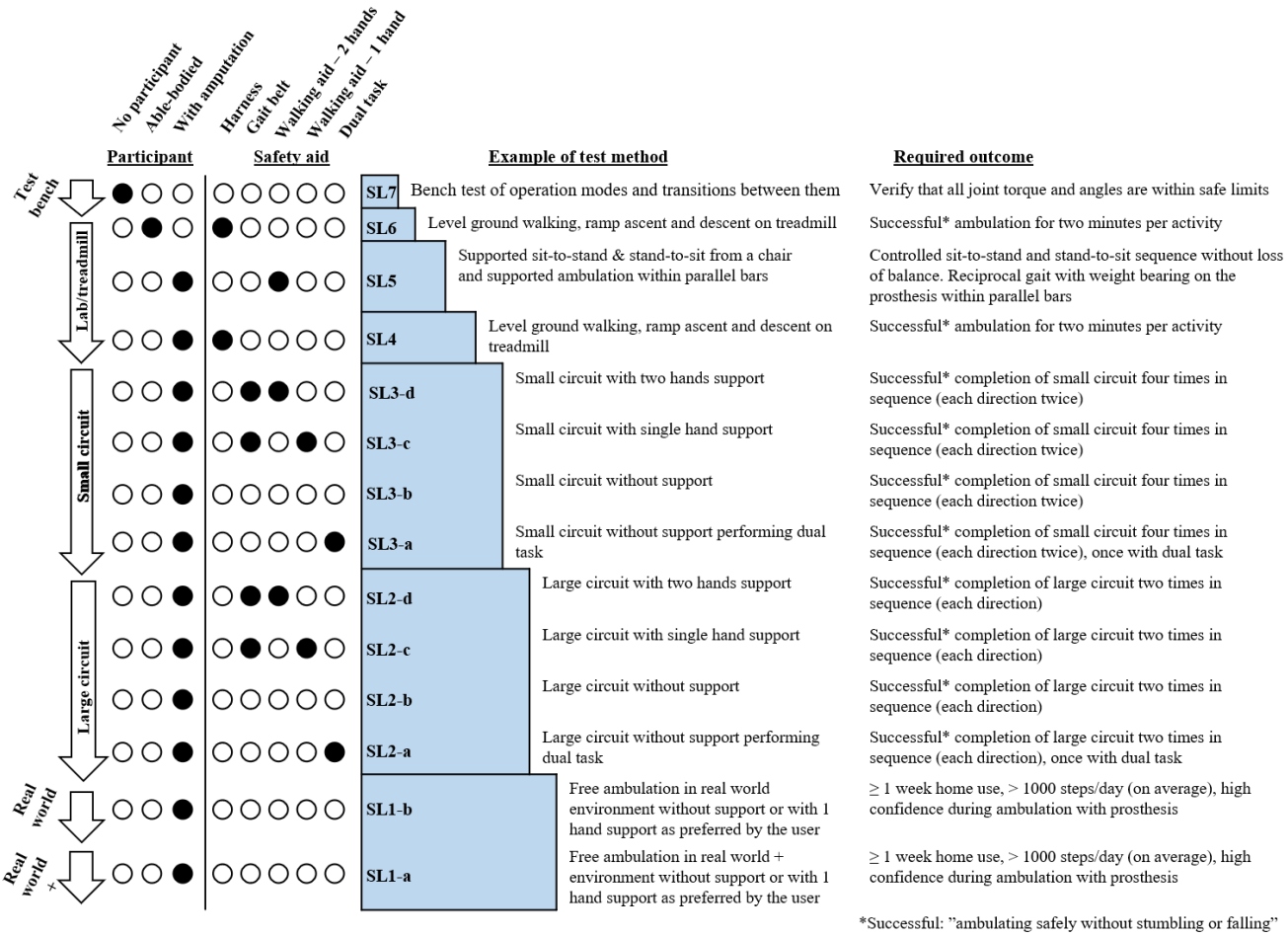

Figure 1. Stepwise safety protocol. The safety protocol is followed starting from the top and downwards through subsequently lower safety levels. From left to right the columns denote, test environments, participant, safety levels, examples of test methods and required outcomes

user), to use by an able-bodied individual (using a lower limb by-pass socket to attach the prosthesis), and finally to use by research participants with lower limb amputations. All tests and requirements per safety level must be achieved before advancing to the next level, as shown in Fig. 1.

III. SAFETY LEVELS

Seven safety levels are included in the protocol. Each level consists of at least one test method with required outcome(s) that must be met before advancing to the next level (or sub-level). Furthermore, specific precautions during ambulation, including potential walking aids, type of environment in which the tests should be performed, and cognitive workload tasks to simulate the user's need to concentrate, are defined per each level.

Requirements per safety level aim to complement each other while covering all major aspects for safe prosthetic mobility. By including safety levels involving bench tests and able-bodied participants, the reliability of novel or adapted prosthetic devices can be established before implementing them with research participants with amputation.

A. Safety precautions during ambulation, physical environments, and cognitive workload tasks

Safety precautions during ambulation are defined per level or sub-level and involve the use of safety aids, as shown in Fig. 1. These aids include walking aids, gait belts, and harnesses (see Fig. 2). Walking aids include crutches, canes, parallel bars, or other assistive equipment, which provide support to the research participant during ambulation. A gait belt is worn by the research participant and is securely held by an assistant, who follows the participant to prevent the individual from impacting the ground in the case of loss of balance. A harness is suspended from above, either mounted to the ceiling or to free-standing equipment, and prevents the participant from falling.

Figure 2. Example of assistive devices. a) crutch. b) gait belt. c) harness

Physical environments are also defined in the safety protocol. The test bench is where the prosthesis can be mounted and tested, disconnected from the participant. The mounting and placement of the prosthesis should be done in a manner by which the safety of the research staff is ensured, preferably inside a cage or in an otherwise shielded-off environment. Laboratory environments include ambulation on a treadmill or in a small circuit in a clinical laboratory room, with minimal distractions and even surfaces. Outside lab environments are separated into "real-world" and "real-world +" environments where the latter is defined as environments which are challenging to navigate with a lower limb prosthesis, for example due to uneven terrain, slippery surfaces, or crowds. Examples of real-world and real-world + environments are shown in Fig. 3.

Figure 3. Examples of real-world environments (a and b) and real-world + environments (c and d).

Lower limb prosthesis users report the need to concentrate during ambulation [19], [24]. This is incorporated in the safety protocol by including dual-task paradigms such as serial subtraction, in which the participant is asked to count backwards by threes or sevens from a random starting number while performing another task such as standing or walking [25]. Advancing from a less to more challenging environment, for example from the small circuit in the laboratory setting to the larger circuit in the real-world setting, also considers the cognitive workload of the individual as an important safety component.

B. Requirements for transition to lower safety level

In order to transition to a lower safety level, one or more tests must be completed to a specified outcome, as detailed in Fig. 1. A transition can only be made from one safety level at a time and both the research participant and the responsible professional must agree to make the transition to the lower safety level.

To confirm the reliability of active prosthetic devices with modifiable control systems, outcomes are categorized depending on the use of the prosthesis:

- For no user (bench testing), all joint torque and angles must be within safe limits.
- For ambulation on a treadmill with safety harness, the user must ambulate safely without stumbling or falling for 2 minutes per activity (defined below).
- For ambulation in a circuit, the user must complete the circuit (Fig. 4) without stumbling or falling a specified number of times (four times for the small circuit and two times for the large circuit), divided per direction, to confirm fluency using the device. For users who want to use a preferred walking aid such as a crutch, cane, or a walking stick, in the real-world environment a slight adaptation of the safety levels is made. These users will not be required to walk without support in the ambulatory circuits, but may use the preferred walking aid for transition to a lower safety level. To verify the ability of safe ambulation without excessive cognitive effort, the last trials in the circuit before transitioning to a lower safety level must be completed while performing a dual task, such as serial subtraction.

- Users who would like to use their device in real-world + environments, must first exhibit safe ambulation in real-world environments (minimum 1 week, with more than 1000 steps/day on average) without any stumbles and/or falls. The user must also have a high confidence in ambulation with the prosthesis, to maximize research participant safety in a variety of physical settings.

Activities for ambulation on a treadmill include gait initiation/termination, level ground walking and ramp/descent at two different speeds. Activities for ambulation in a circuit start from a seated position at the starting point, continues to level walking, ramp ascent/descent, stairs ascent/descent, and transitions between level walking, before finishing the circuit by sitting on a comfortable chair at the end point.

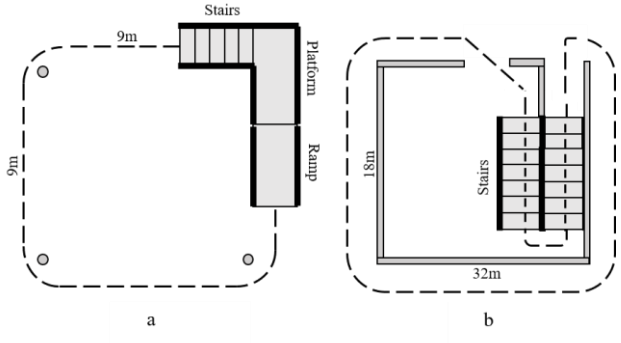

Figure 4. Example of walking circuits. a) Small circuit, b) Large circuit

IV. Conclusion

Employing a stepwise safety structure aims to minimize the risk to participants and research staff, thus maximizing the safety during testing and training to use active, prosthetic legs with modifiable control systems in individuals with lower limb amputations. In the proposed protocol the prosthesis must undergo bench testing and weight-bearing ambulation assessment by able-bodied users before research participants with lower limb amputation may begin testing such prosthetic devices. If a user is unable to achieve the specified tasks of a safety level, they will not be allowed to advance to the next safety level, thus minimizing the risk of potential injury. The protocol design requires that the safety level structure is followed to maximize safety for participants.

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