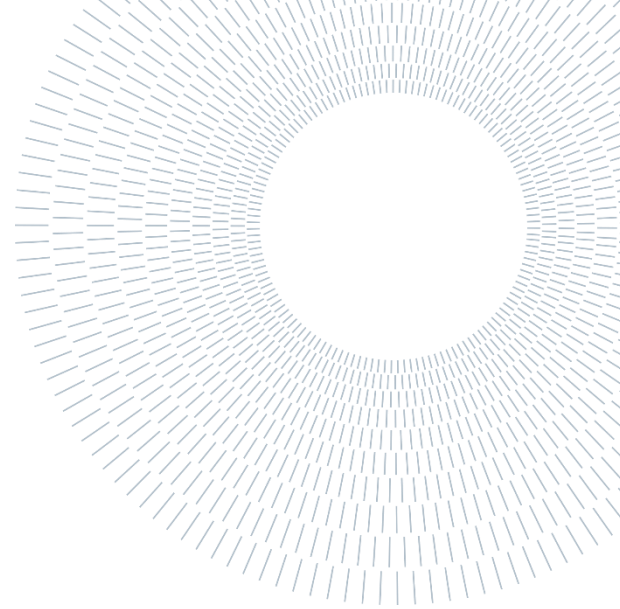




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EXECUTIVE SUMMARY OF THE THESIS

Development and validation of a trip-eliciting system: towards trip detection and fall avoidance for lower limb amputees

TESI MAGISTRALE IN BIOMEDICAL ENGINEERING – INGEGNERIA BIOMEDICA

AUTHOR: LORENZO PITONI

ADVISOR: ALESSANDRA LAURA GIULIA PEDROCCHI

CO-ADVISOR: SILVESTRO MICERA

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1. Introduction

Lower Limb Prosthesis (LLP) users are at risk for fall-related injuries, as more than 50% report falling at least once a year [1]. This can lead to the development of fear of falling and participation avoidance. The inactivity can further compromise balance and increase the risk of future falls [2].

One in five falls reported by LLP users can be attributed to a trip [1], so reducing the probability of one of these events could improve their quality of life. A possible solution could be the development of an active prosthesis with trip reaction capabilities. INAIL's MOTU++ project focused on the development of such a device.

To implement trip reaction, trip detection is necessary. The device needs to implement a trip detection algorithm needs, using sensors that could be placed on a prosthesis. This project focused on the development of an experimental setup for collecting data useful to the development of said algorithm.

To produce the data, we had to simulate realistic trips in a consistent manner. Tripping events have been investigated in various papers and different setups have been developed to this end. Three kinds of setup are present in literature: tether-based [3], consisting of a tether or rope being attached to the subjects' ankles becoming taut during the swing phase; treadmill-based [4] consisting of sudden accelerations and decelerations to the support foot and obstacle-based [5], where an obstacle is actuated to halt the progression of the foot.

2. Material and methods

Concept

The need to record data from life-like trips introduced some requirements: the forces acting on the subject should be comparable to a real-life situation; the gait should be close to the natural gait of the subject; the trips should be unexpected. An additional requirement we introduced was the minimization of fall risk during the experiments, for safety reasons.

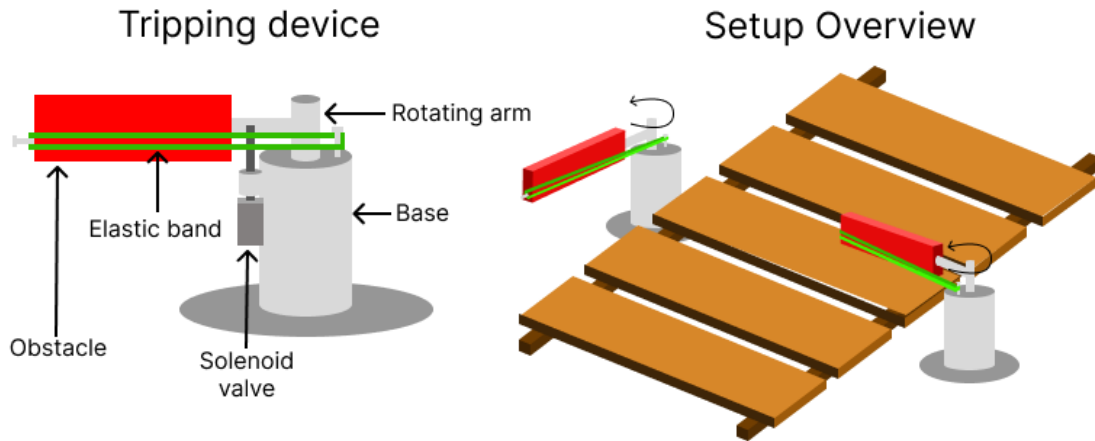


Figure 1, schematic representation of the tripping setup: on the left, the individual tripping device; on the right, the overall setup, with the walkway and the obstacle attached to the side.

To fulfill the first requirement, we decided that the tripping setup should be obstacle-based, employing spring-loaded obstacles with automatic release. Due to the second requirement, we could not use a treadmill, so we decided to create a walkway along which the subject could walk.

The obstacles were rotating bars, placed on the side of said walkway. Their activation was based on the subject's gait phase and position on the walkway. When the tripping foot was in the swing phase and approaching the obstacle, this was released and went on to obstruct the tripping foot. Figure 1 shows an overview of the walkway and the obstacle, while Figure 2 displays the flow diagram for the deployment of the obstacle.

To reduce the likelihood of a fall, the subject was secured with a harness to a winch. We also decided



Figure 2, flow diagram of the control system for the tripping setup.

that the obstacle should be compliant. This way, the obstacle would not completely block the foot and we could also simulate trips with different kinds of obstacles, like rugs or branches.

To fulfill the unexpectedness requirement, multiple obstacles were placed along the walkway. This way we increased the chances of activation and made the tripping attempts less predictable. Having more obstacles made it harder for subjects to anticipate when and which obstacle would be released, introducing a randomization factor to the trials.

Hardware

The setups comprised a walkway, four obstacles, four distance sensors, two Force Resistive Sensors (FSR), a Sessantaquattro (by OT Bioelettronica), four solenoid valves, eight IMUs, an Arduino, and a PC.

The walkway was constructed from 2-meter wooden boards, fixed on an elevated aluminum frame. The obstacles, fixed on the frame, consisted of a base, a rotating arm, and the obstacle itself. Elastic bands were employed to actuate the obstacle. This allowed us to obtain compliant obstacles and adjustable strength. An IMU was placed on the distal end of each obstacle, for reasons explained in Analysis.

The distance sensors served to identify the position of the subject with respect to the obstacle. They were placed close to the obstacle and detected if the subject was passing in front of them, by evaluating the distance measured. To obtain fast and accurate readings, we selected a laser-based, time-of-flight distance sensor, the VL53L0X.

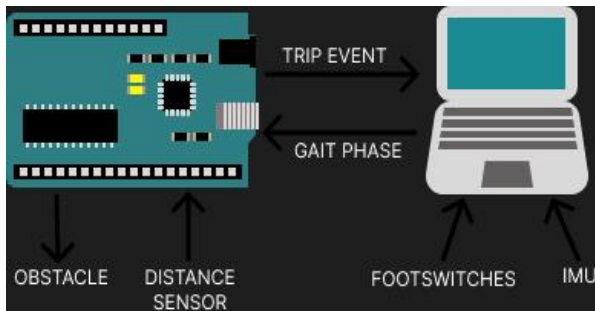


Figure 4, schematic of the interactions between the control units.

To identify the gait phase two FSRs were employed as Footswitches (FS): they were placed under the tripping foot, one under the heel and the other under the toes. Using them it was possible to identify which part of the foot made contact with the ground, thus allowing discrimination between the swing phase and the stance phase.

Since the FSRs needed to be placed on the subject, to avoid having meters of cables connecting the subject and the control units, we employed an OTB Sessantaquattro. The Sessantaquattro is a portable device for EMG recording capable of wireless connection with a PC. We used it to supply the voltage necessary to read the signal of the FSRs and to wirelessly send the data from the subject to a PC.

Obstacles were locked in their loaded configuration by a metal pin. This was pulled away by a solenoid valve (model B14HD-257-B-4) chosen because of its high pulling strength and speed. The valves were activated by supplying them with 12 V.

To study the elicited trips, we used IMUs, to measure accelerations and angular velocities acting on the subject. More specifically, we employed the Xsens MTw Awinda system. This system had portable measurement units that wirelessly connected to an Awinda Station. The Awinda Station acted as the interface between the PC and the IMUs. It was possible to send triggers to the Station, which would then record the event together with the IMU measurements. This became useful for the Analysis.

Finally, all the electronic elements in our setups were controlled by two control units, an Arduino Uno and a PC. The Arduino Uno connected with the distance sensor and the solenoid valve, and it was responsible for the release of the obstacle. The PC read the FS signal and recorded it, together with the IMU signal. The PC also performed analysis on the FS signal, identifying the instant of

toe-off and heel strike and communicating to the Arduino the gait phase. So in the setup, the Arduino decided whether the obstacle should activate, while the PC provided the information necessary to make this decision. A schematic of the flux of information is shown in Figure 3.

In reality, there was one Arduino Uno for each obstacle, totaling four Arduino Uno. This was done for a series of reasons: the number of ports of a single Arduino Uno was not sufficient to control all the solenoids and the distance sensor; connecting all the necessary components to a single Arduino would have meant running meters of thin cables, affecting the signals' transmission; reading the value from the distance sensors introduced a delay, and since readings could not be performed in parallel using a single Arduino would have significantly slowed the system.

Obstacle activation algorithm

For the setup to work we had to develop two scripts: one running on the Arduino, to control the release of the obstacle, and the other on the PC, to analyze the gait and inform the Arduino of the gait phase. The first algorithm is described by the flow diagram in Figure 4.

Before describing the Arduino script, a clarification is necessary. Most of the studies we found on tripping simulation tried to cause trips in the early- and mid-swing. For this reason, we decided that the obstacles could be released only during early- and mid-swing.

To release the obstacle, the Arduino script checked that two conditions were verified: that the tripping foot was either in the early or the mid-swing, and that the distance sensor recorded a distance under a certain threshold.

At the beginning of each iteration, the Arduino checked the content of the serial port. The script

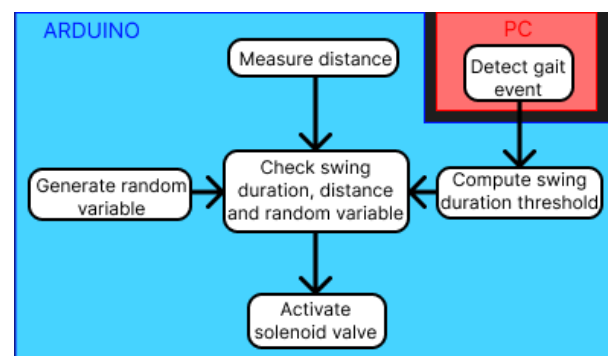


Figure 3, flow diagram for the activation algorithm

running on the PC communicated the occurrence of gait events through the serial port. This way the Arduino script knew when a new gait phase had begun.

To verify that the tripping foot was in the right portion of the swing, the current swing duration was compared with a threshold. This was computed at the end of each swing phase and was equal to 60% of the median duration of ten consecutive swings. This way we obtained an adaptive threshold marking the end of the mid-swing phase for the subject. When the tripping foot was in the swing phase, the script checked that it had lasted less than the threshold.

Then, the script read the distance sensor measurement. Since this was affected by noise, the median value of three consecutive readings was taken as the actual distance. If the distance was under 20 cm it meant that the tripping foot was nearing the obstacle. This threshold guaranteed that only the tripping foot would trigger the system, as explained in the Experimental Protocol.

To reduce anticipatory movements a randomization factor was also introduced in the script, which prevented the device from activating each time the first two conditions were met. This was obtained by performing a check on a randomly generated variable.

If all three checks were verified, the obstacle was released. At the same time, the Arduino communicated to the PC the activation of the obstacle, so that the activation instant could be recorded. It also sent a trigger to the Awinda Station: these messages would allow later (Analysis) to synchronize the IMU measurements with the FS signal.

Gait analysis algorithm

While the activation script ran on the Arduinos, another script ran on the PC during the trials. This script performed three tasks: it collected the Footswitches' signal from the Sessantaquattro; it analyzed the gait and communicated the gait phase to the Arduino; it stored the FS signal for future analysis.

These tasks had to be performed in parallel, to avoid losing data recorded by the Sessantaquattro. For this reason, the script was divided into three subprocesses: an acquisition subprocess, a control subprocess, and a save subprocess.

The acquisition subprocess retrieved the FS signal from the Sessantaquattro and made it available to the other subprocesses, while the save subprocess saved the signal in the PC.

The control subprocess was responsible for the gait analysis and communication with the Arduinos. To detect the events of toe-off and heel strike, it quantized the FS signal and then computed its derivative. The quantization was needed to standardize the values the derivative could assume, thus simplifying discrimination.

Whenever a toe-off or a heel strike was detected, a message was sent to all Arduinos. At the same time, the control process checked for messages coming from the Arduinos. If a message concerning the activation of one obstacle arrived, the process recorded the instant the message was received. This information was later used to synchronize FS and IMU tracks, as explained in Analysis.

Experimental Protocol

The trials followed a rigorous procedure to guarantee the consistency of the data.

1. The subject was introduced to the experimental setup and the experiment was explained.
2. The FS were fixed under the tripping foot, one under the heel and the other under the toes. The tripping leg was always the right leg for healthy subjects and the prosthetic one for amputees. In the validation trials, only healthy subjects were involved.
3. The Sessantaquattro and the IMUs were fixed on the subject using elastic bands. Four IMUs were placed on the subject, as shown in Figure 5.
4. The subject was asked to walk on the walkway, to check the correct placement of the FS and to familiarize themselves with the setup.
5. Each trial started by having the subject standing still on one side of the platform. The subject was instructed to start walking after hearing an acoustic signal. During the trials, the subject had to walk a circuit on the walkway and had to keep walking until an

- obstacle was deployed or the trial was stopped by one of the operators.
6. When the trial ended, a questionnaire was given to the subject to fill out.
 7. Steps 5 and 6 were repeated until five successful tripping trials were recorded. Afterward, the sensors were removed from the subject and the experiment was interrupted.

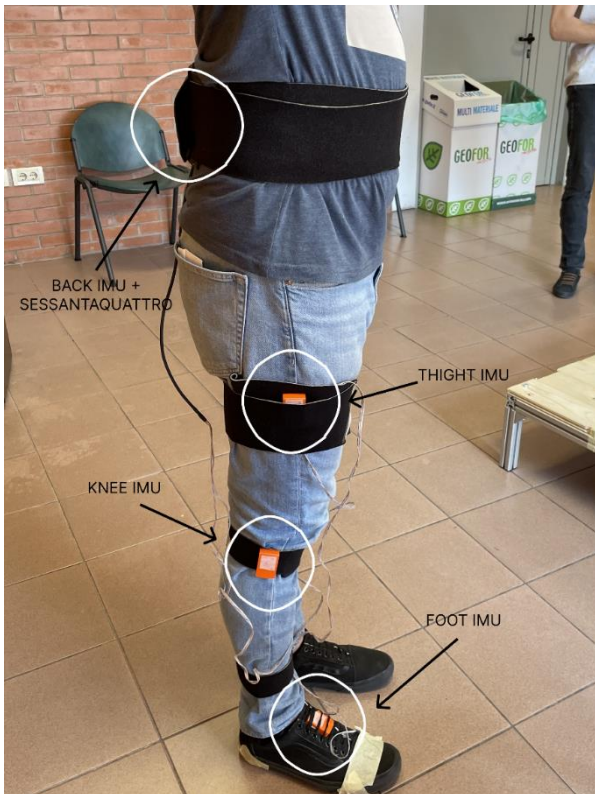


Figure 5, placement of the 4 IMUs on the subject. Regarding the circuit, two lines were drawn on the walkway, parallel to the longer side. The subjects were instructed to walk astride one of the lines when walking in one direction and astride the other one as they went back. The lines were positioned so that the tripping foot would always be at most 20 cm from the side, while the support foot would be further away. This way we guaranteed that only the tripping foot would trigger the distance sensor and that the foot would always be in the range of the obstacles, which were fixed to the sides of the platform.

The questionnaire given at the end of each trial was devised to gauge the level of adaptation of the subjects and to evaluate the realism of the stumble. It contained four questions:

1. On a scale from 1 to 5, how much were you surprised by the obstacle activation?
2. On a scale from 1 to 5, how close to a real-life stumble was your impact with the obstacle?
3. On a scale from 1 to 5, do you feel that your reaction to the stumble was natural?
4. On a scale from 1 to 5, did you feel any discomfort upon impacting the obstacle?

Analysis

The output of each trial was a track from the FS and eight IMU tracks. Each IMU measured six quantities: the accelerations and the angular velocities along the three Cartesian axes, for a total of six signals per IMU track.

We were interested in analyzing each step taken by the subject during the trials. Two MATLAB scripts were then developed: one to synchronize the data tracks and one to cut the IMU tracks into smaller tracks, each containing a single step.

The synchronization algorithm had two tasks: to synchronize the tracks and to identify the tripping instant. The first task was accomplished in two steps. First, the IMU signal was resampled to have the same sampling rate as the FS signal, raising it from 100 Hz to 1kHz. At this point, the two signals were aligned, by matching the samples corresponding to the trip: for the FS, this was the sample recorded at the time the Arduino signaled the activation of the obstacle; for the IMUs, it was the sample recorded when the trigger was sent to the Awinda Station. The FS and the IMU signals were resized to have the same signal length and to have the two samples coincide.

This first alignment was not extremely accurate, as both samples had a variable delay with respect to the tripping instant. To eliminate the residual mismatch, the angle of the foot with respect to the transverse plane was computed from the corresponding angular velocity. According to [6] the toe-off corresponds to the values of local maxima for the angle. By inspecting the angle it was possible to identify the toe-off in the IMU track. By matching the first toe-off in both tracks it was possible to eliminate the mismatch from the

first alignment process. After this, the synchronized and resampled tracks were saved.

To identify the tripping instant, the IMUs on the obstacles were used. Before the trials, ten tracks of the obstacle being activated without impact were recorded. The assumption was that the acceleration of the obstacle during a trip-less activation would be similar to the acceleration during activation with a trip until the impact with the foot occurred. So we computed the mean and the standard deviation of the tangential acceleration of the obstacle from the ten trip-less trials. The synchronization script then analyzed the tangential acceleration of all obstacles during the trials: the tripping instant was identified as the instant when this had a significant deviation from the mean trip-less acceleration.

The step extractor algorithm took the aligned FS and IMU tracks as inputs. First, it isolated the steps, by extracting slices of signal from the IMU track that went from one toe-off instant to the next. To make them comparable, each slice was resized to be 2,000 samples long. The individual swing phase and stance phase of the step were resampled to be 800 and 1200 samples long, respectively. This way, the heel-strike sample would coincide in all steps, and the proportions of a natural step were maintained. A tail of five values was added to the end of the resampled array, to store information related to the step: the trip instant, the original number of samples of the swing phase and the stance phase, the trial to which the step belonged and a tag for the individual step. Having extracted

the individual steps, all steps from all trials for a single subject were stored in a single tridimensional array.

Results

We aimed to collect data from 10 subjects, to obtain a robust database. In the end, we recorded 11 subjects, as one of the experimental sessions had problems due to equipment malfunction and would be excluded from the analysis. After synchronization and step extraction, another subject was excluded because the foot angle did not present the expected profile in all steps. This left us with 9 subjects to analyze. In total, 42 useful trips were recorded. Over 50% of them took place in the early swing, 40% happened mid-swing and only 2 took place in the late swing.

Since the objective of the project was validating the experimental setup, analysis of the obtained data was mainly carried out through qualitative evaluation of the IMU tracks.

We compared the trip steps with the trip-less steps. Trip-less steps were condensed in a single signal for each quantity recorded, by computing its mean and standard deviation. Steps following a trip were excluded from this computation. This was done for both individual subjects and then combining all the subjects together. The signals associated with a trip were then plotted together with these condensed signals for visual comparison. An example of the plots generated considering all subjects is shown in Figure 6.

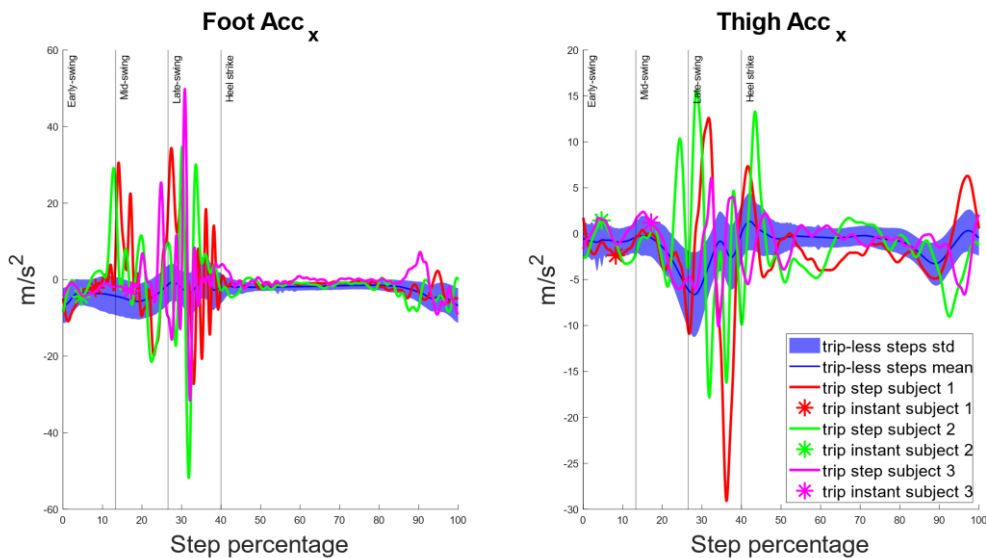


Figure 6, x-acceleration of the foot and of the thigh during trips versus trip-less steps for all subjects. The instant the trips happened are signaled by stars on the graphs.

Concerning the trip-less steps, the mean value of acceleration and angular velocity maintained a similar profile across subjects. Even when considering all subjects together, the profile did not significantly change. The standard deviation of all trials combined was instead on average greater than the standard deviation for a single subject.

The signals associated with a trip showed perturbation not displayed by their trip-less counterparts, as shown in Figure 6. These signals were not comparable, as trips' signals present extremely different profiles across trials. It was still possible to compare them across different IMUs though. For the same event, the perturbations recorded by IMUs further from the point of impact (i.e. the foot) had a smaller maximum amplitude compared to those recorded closer. Furthermore, the onset of the perturbations was delayed when the signals were not recorded close to the foot. This is shown in Figure 6.

The results of the questionnaire were investigated too. We were particularly interested in the realism of the trips and the adaptation of the subject to the setup as the experiment went on. To study the second, we considered the median and the IQR plots of the answers given by the subjects as a function of the trials. The median value of surprise for the first and second trials were respectively 4.5 and 4 and as the experiment progressed the level of surprise decreased, albeit slowly. For trials 5 and 6, the median level of surprise had decreased to 3 and 4 respectively.

To investigate the realism of the trip, we considered the answers given to question 2 of the form. More than 60% of the trips were reported to have a level of realism of at least 4, while no subject attributed a value of 1 to the realism of the trip.

3. Conclusions and future works

The objective of the project was the development of an experimental setup capable of consistently causing realistic trips. By simply observing the trials, it was already possible to say that we achieved our objective. Still, other metrics were investigated to gauge the overall quality of our work.

The questionnaire confirmed that the subjects attributed a high degree of realism to the trips and that they remained consistently surprised by the activation of the obstacle. The decrease in the

surprise was slow enough to say with confidence that our system did not significantly lose effectiveness for the first six trials.

The investigation of the IMU signals served to verify that the setup developed could provide useful data for future work on the trip detection algorithm. The visual analysis confirmed that signals associated with a trip significantly deviated from the average signal associated with a trip-less step. The deviation is significant enough to suggest that some feature could be extracted to detect a trip. This means that the setup constitutes a solid foundation for the development of the parent project.

From the same signal, some educated guesses can also be made concerning the algorithm for trip detection. First of all, the magnitude of the perturbation was much greater for accelerations than for the angular velocities, suggesting that sensors integrated into the prosthesis could simply be accelerometers. As described in the Results, the IMU positioning affects the magnitude and the delay of the perturbation. The sensors should then be placed closer to the point of impact with the obstacle, i.e. the foot. This should facilitate the identification of the trip and guarantee a faster detector.

Given the result of the analysis, we consider the setup ready to be employed in the collection of the data for the development of the detection algorithm. Furthermore, the preliminary analysis of the data produced by the validation trials has given useful insight into how the detector could be implemented. While this project was a preliminary step of the parent project, I believe the work done could impact the future development of LLPs: the development of trip-reacting prostheses could increase the faith of amputees in active prostheses, in a world where improvement in mobility is often sacrificed in favor of simplicity of use. Not only that, but this setup could also be replicated to reliably study trips for a variety of subjects, as increasing our knowledge in the field could aid in reducing fall risk.

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