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Towards Bidirectional Lower Limb Prostheses: Restoring Proprioception Using EMG Based Vibrotactile Feedback

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Current lower limb prostheses lack bidirectional communication and the ability to generate power. As a result, they do not effectively replace the lost limb. Electromyography (EMG) control has been widely implemented in upper limb prostheses but is still underdeveloped in lower limb prostheses. The aim of this thesis is to design, develop, and evaluate a novel vibrotactile feedback system in combination with an EMG-controlled powered knee or ankle prosthesis to restore proprioception. This thesis demonstrates that discrete localised vibrations enable proprioceptive sensing for the user through the described sensory feedback system. Three subjects with a major lower limb amputation performed level ground and inclined walking tests under various conditions. The experiments reported in the thesis compare the effects of EMG control with and without sensory feedback on temporal gait symmetry and psychosocial metrics, i.e. cognitive workload assessment, prosthesis embodiment, and confidence. The key results from this thesis are the following: temporal gait symmetry and psychosocial measures tended to improve within and between session, though the results varied widely between subjects. Interference in the rest EMG signal was found when the vibrotactors were activated. Further, subjects were able to distinguish between sensory feedback levels. EMG control initially reduced gait symmetry, but gait symmetry was later increased with sensory feedback. Higher symmetry scores were measured after sensory feedback was turned off, demonstrating learning retention. Similar trends were measured in psychosocial metrics, indicating that the sensory feedback system contributed to perceived improvements of the prosthesis. In summary, results show promising effects of using vibrotactile feedback in combination with EMG control in lower limb prostheses, despite the need to improve system robustness. Longer training with EMG and sensory feedback might improve quality of life of prosthesis users even more.

Keywords: sensory feedback, vibrotactile stimulation, EMG control, proprioception, gait symmetry, embodiment, lower limb prosthesis

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1 Introduction

Lower-limb amputation (LLA) is a life-changing event that affects the physical and mental health of an individual. In high income countries, the majority of limb amputations is caused by dysvascular diseases. Due to the high risk of dysvascular diseases in aging populations, the incidence rate of limb amputations is expected to increase over the years (Ziegler-Graham et al., 2008). In younger populations and lower income countries, limb amputation as a result of traumatic events or infections is more common (Desmond et al., 2012).

To counteract the functional and cosmetic loss after a limb amputation, prostheses are prescribed. However, a prosthesis does not entirely replace the lost limb. People with a lower limb prosthesis show a dissimilarity in gait, which often results in a reduced walking speed, chronic lower back pain, and a higher metabolic consumption while ambulating (Gailey et al., 2008; Nolan et al., 2003). LLA has also been correlated with an increased risk for cardio-vascular diseases (Naschitz & Lenger, 2008). User needs regarding lower limb prostheses vary widely and cover areas such as functional needs, psychological and cognitive needs, ergonomic needs, and other needs. A commonly mentioned need is the reduced cognitive workload, such that different tasks can be done in parallel, e.g. talking and walking (Manz et al., 2022).

Most commercially available lower limb prostheses on the market target the functionality level of the user. For lower functionality levels, mechanical prostheses are usually prescribed, whereas for more active users, microprocessor controlled devices are usually preferred. All mechanical prostheses and most of the microprocessor controlled lower limb prostheses are passive, meaning that they cannot generate energy. As a result, users have to rely on their intact limb when ascending stairs, walking on inclined slopes, or when getting up from a chair (Fluit et al., 2020). This results in a higher load on the intact side and associated lower back pain, osteoporosis, etc. (Gailey et al., 2008). In addition to the lack of active microprocessor controlled prostheses, the control mechanisms of the microprocessor controlled devices are often not intuitive or adaptable to changing environments. Sometimes, several steps are required before the activity mode is changed or a non-intuitive action needs to be performed (Fluit et al., 2020). As a result, some users avoid specific environments, such as stairs, as it is too bothersome to change to the correct activity mode (Valgeirsdóttir et al., 2021).

Finally, no communication pathways are established between the prosthetic user and the device itself. As a result, the user sometimes does not feel 'in control' of the actual limb replacement, nor are they aware of what is happening. Current prosthetic devices do not have a feedback loop implemented through which the user can be aware of the position of their prosthetic limb or the environment it is interacting with through their prosthesis. Most information about the prosthesis' position and environment is acquired through visual information, auditory information from prosthesis' motors, and a limited amount of sensory information through the socket (Manz et al., 2022; Valgeirsdóttir et al., 2021).

1.1 Motivation

Motivated by the limitations of current prosthetic devices as described above, this thesis aims to explore the benefits of vibrotactile feedback on myoelectric active lower limb prostheses. In the experiments outlined in this thesis, active prostheses have been used as these enable more symmetrical and natural movement, reducing the load on the intact side of the body (Hunt et al., 2021; Valgeirsdóttir et al., 2021). Furthermore, the active prostheses used here have been designed to allow for proportional direct electromyography (EMG) control. For this purpose, both the liner and the socket have been customised to incorporate surface electrodes to record EMG signals from the remaining muscles in the residual limb. The control of the active prostheses have been adapted to allow for proportional direct EMG control, such that the user has voluntary control of the prosthesis both in stance and in swing phase.

Driven by the lack of research in sensory feedback and myoelectric controlled lower limb prostheses, we developed a feedback system as an add-on for direct EMG control for lower limb prostheses. The novel feedback system provided proprioceptive information through vibrotactors placed on the residual limb. The use of direct EMG control is hypothesised to ameliorate phantom limb pain (PLP) and boost the feeling of agency among other factors. The addition of the vibrotactile feedback on top of the direct EMG control is hypothesised to improve the prosthesis control as well as psychosocial metrics. In addition, it is expected that the metrics that are improved by adding direct EMG control are enhanced even further by the addition of proprioceptive vibrotactile feedback. Such sensory feedback is considered to increase the effectiveness and efficiency of the prosthesis control.

The added benefit of this novel set-up has been evaluated against the standard active prosthesis, as well as the direct EMG controlled prosthesis without feedback before and after the addition of the feedback. Because of this, the learning effect and retention as a result of the feedback system can be measured. A mobile system has been developed that provides vibrotactile feedback in real-time informing the user about their EMG activation in the residual limb. This mobile set-up allows for more ecologically valid tests while ambulating on level ground as well as on an inclined ramp. On the inclined ramp, the advantage of an active prosthesis is hypothesised to be more pronounced when compared to level ground walking. The benefit of the feedback is possibly larger, though, the physical workload and energy expenditure are also higher in this setting.

1.2 Research questions and hypotheses

The lasting effect of sensation stimulation is largely unknown (Escamilla-Nunez et al., 2020). Graczyk et al. (2018) showed that sensory feedback improved both functionality as well as psychosocial measures when a sensorised upper limb prosthesis was used in home environment. However, for some metrics the performance boost disappeared when the sensory feedback was discontinued. Functional improvement and increase in confidence was also demonstrated with a sensorised lower limb prosthesis during three consecutive CYBATHLON competitions (Basla et al., 2022). Though, it is unclear to what extent the sensory leg was used between the competitions and how this sensory leg compares with a traditional leg in these tasks.

The aim of this research is, therefore, to find out to what extent EMG control and sensory feedback benefit prosthesis use and to explore the degree of knowledge retainment outside of the experimental session. It is important to know if there is learning retention from training with sensory feedback when designing sensory systems for prostheses. With enough learning retention outside the experimental environment, it might not be necessary to implement sensory feedback in each individual prosthesis. This could result in a more cost-effective and attainable method to improve quality of life for all individuals with a major LLA.

In this research, prosthesis performance is measured during several days using a combination of walking tasks as well as subjective measures. The users participated in level ground walking and inclined walking trials. The tasks were selected as the benefit of a powered prosthesis is hypothesised to be more pronounced while ascending a ramp. In general, people with LLA have better control in stance because they receive some feedback from the ground through the socket. However, in swing phase, such connection between the ground and the socket does not exist, causing an increasing importance for feedback on knee joint position (Hoover et al., 2013). As a result, better performance is expected in sensory feedback trials when compared to non-feedback trials. Better performance and perceived user confidence is also expected in the EMG controlled prosthesis trials. As a result of the learning effect, performance is expected to increase over time. On the other hand, the difference between the conditions is expected to decrease between consecutive sessions, due to a non-linear learning effect.

The formulated research questions are as follows:

1. How does the addition of EMG control affect temporal gait symmetry?

2. How does the addition of EMG control affect perceived user confidence, workload, and embodiment?

3. How does vibrotactile feedback on muscle contraction affect temporal gait symmetry?

    (a) Is there a lasting effect after the feedback is turned off?

    (b) To what extent does vibrotactile stimulation affect EMG signals and thus EMG control?

4. How does vibrotactile feedback on muscle contraction affect perceived user confidence, workload, and embodiment?

    (a) Is there a lasting effect after the feedback is turned off?

1.3 Contributions

The main contribution of this thesis is the design, development, and pre-clinical evaluation of a mobile sensory feedback system that can be added to an existing EMG controlled prosthesis as shown in Figure 1. The activities towards the pre-clinical trials consisted of:

- design and implementation of custom firmware developed for the Seeed Studio XIAO nRF52840 Sense microprocessor, for real-time reading and processing EMG data as well as activating the vibrotactors accordingly; and
- development of an experimental protocol, data collection, and data analysis.

In addition, the following work has been performed to contribute towards the research described in this thesis.

- research and design of a novel feedback paradigm for proprioception;
- development of custom firmware for EMG signal calibration and processing;
- creation of firmware for familiarisation, reinforcement training, and validation of vibrotactile feedback for the user;
- amendment of clinical instance for the experiment protocol;
- collection and analysis of subjective measures; and
- collection and analysis of temporal gait symmetry measures.

All code related to this thesis is available on GitHub[1] (Tilleman, 2023).

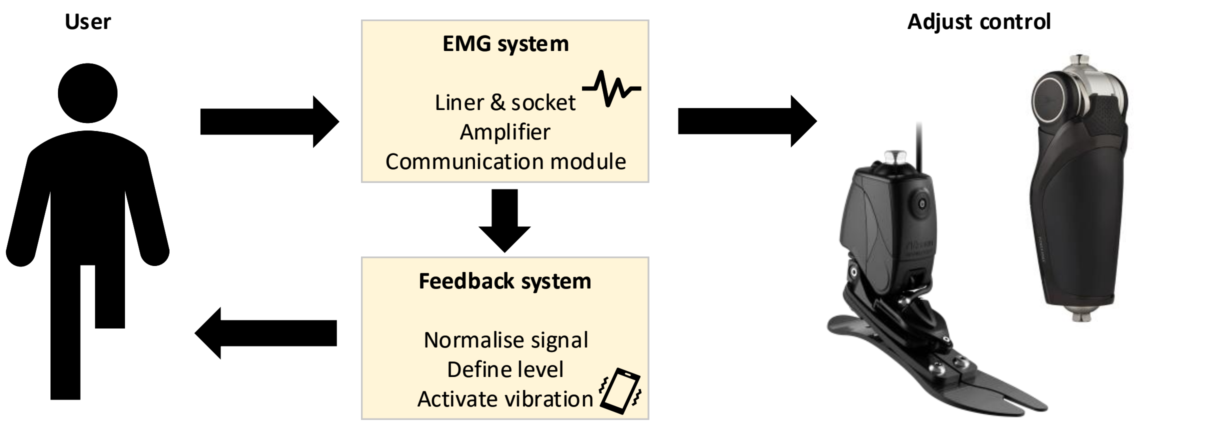


Figure 1: High level schematic overview of the closed-loop system between the user, the EMG and feedback system, and the bionic prosthesis.

[1] https://github.com/MyrtheTi/sensory_feedback

1.4 Outline

Section 2 reviews the consequences of a limb amputations and the challenges that come with a prosthetic device. In section 3, the materials and methods of the experiments are described. In section 4, the main results are presented, which are discussed in section 5. Finally, a conclusion is drawn in section 6.

2 Background

In this section, we first give an overview of different types of limb amputations and prosthetic devices in section 2.1. Then, we summarise current control strategies used in section 2.2. Section 2.3 describes interrupted neural pathways accompanying limb amputations and current methods to restore those. Section 2.4 reviews the various feedback strategies used. Finally, methods to evaluate prostheses are discussed in section 2.5.

2.1 Lower limb amputation

Major lower-limb amputations can be performed at several levels: 1) below-knee or transtibial, 2) through the knee or knee disarticulation, and 3) above-knee or transfemoral, see Figure 2. In general, individuals with a transfemoral amputation (TFA) have a higher asymmetry in gait than people with a trans-tibial amputation (TTA) (Nolan et al., 2003).

(a) Below-knee or transtibial amputation (TTA).

(b) Through the knee or knee disarticulation (KD).

(c) Above-knee or transfemoral amputation (TFA).

Figure 2: Overview of major lower limb amputation types (Össur, 2023a).

A lower limb prosthesis consists of the following parts: 1) a soft liner, 2) a prosthetic socket, 3) a prosthetic foot, and in case of a TFA 4) a prosthetic knee. Pylons are added between the prosthetic socket, knee, and/or foot to allow for variations in length of the residual leg and to adapt the prosthetic leg to the high of the user.

Most commercially available prosthetic knees and ankles are passive and therefore, they cannot generate energy. Level ground walking can be achieved well with passive devices and more complex daily life activities such as stair or slope ascension can be achieved with passive devices as well after sufficient training. However, an active prosthesis would allow users to perform higher energy activities with less exertion and allow for more symmetrical movements as well as less strain on other parts of the body (Manz et al., 2022).

After an amputation, around 64% of the individuals with a limb amputation experience pain related to their amputated body part (Limakatso et al., 2020). This phenomenon is called phantom limb pain (PLP) and it is a common problem for people with an amputation. A proximal amputation site,

(a) A prosthetic liner. (b) Prosthetic socket for a TTA or a TFA. (c) Bionic foot and knee.

Figure 3: Overview of the lower limb prosthesis components (Össur, 2023b).

stump pain, and phantom sensations are risk factors for PLP among other factors (Limakatso et al., 2020). The addition of sensory feedback seems to reduce both the frequency and intensity of PLP (Dietrich et al., 2018; Limakatso et al., 2020; Manz et al., 2022). PLP and prosthetic embodiment, as well as trust and self-efficacy seems to be positively influenced by using neurally controlled prostheses, enabling users to participate in a more active social life (Raspopovic et al., 2021; Valgeirsdóttir et al., 2021).

2.2 Control strategies

The control strategy is an important factor in prosthetic devices and defines how 'natural' the prosthesis moves. Intent recognition defines which activity mode needs to be used. In most commercially available microprocessor knees, a heuristic rule-based approach is used to define the activity mode based on information of mechanical sensors, such as inertial measuring units (IMUs) or force sensors. A combination of neural and mechanical signals has proven to better differentiate between activity modes than EMG or mechanical sensors alone (Fluit et al., 2020).

The commercially used control strategies are sufficient for cyclic movements in predictable environments, but they are not suitable for dynamic environments. Switching activity modes dynamically and a correct classification of user intent are still aspects that need to be developed further. In order to make the system resemble natural control and simultaneously increase adaptability to the desires of the user, neural signals from peripheral motor nerves or the central motor cortex can be used for the control of the prosthesis and could provide a direct communication pathway from the user to the bionic device (Dillen et al., 2022; Fleming et al., 2021).

Movements are planned by the motor cortex and signals are sent down to muscle spindles that activate parts of a muscle to contract. There are fast and slow muscles for coordinated control and gradual contraction. After amputation, the remaining muscles in the limb still exist and can be activated. Signals can be recorded from the brain all the way to the muscles, either through invasive or non-invasive methods (Bear et al., 2020).

A common noninvasive method to measure muscle activity is through the use of surface electromyography (sEMG). With sEMG muscle activity is recorded using electrodes on the skin. Commercial myoelectric prostheses are already available for people with an upper limb amputation and have improved the energy expenditure and degrees of freedom when compared to cosmetic or body powered devices (Guan et al., 2016). However, no such devices are commercially available at the moment for people with a LLA.

In order to measure sEMG signals from the muscles in the residual leg, the surface electrodes should be in stable contact with the skin. This could be achieved by attaching the electrodes to the skin or embedding electrodes in the liner and socket of the prosthesis. EMG signals normally contain a high noise level, and the signal can vary throughout the day due to fatigue, sweat, and/or movement of the electrodes. By applying filters to the raw EMG signal and personal calibration, a high quality signal can be achieved (Fleming et al., 2021; Nasr et al., 2021).

The joint can be continuously modulated by muscle activity in direct control. Using this method, there is no limitation to cyclic movements or specific activity modes. Ha et al. (2011) demonstrated that subjects with a TFA were similarly effective in following various knee trajectories using volitional EMG control with their residual limb as with their intact limb while sitting. Direct EMG control can also be added proportionally to the already existing heuristic rule-based approaches used in commercial devices as has been done previously by Hunt et al. (2021). Using proportional EMG control, a single subject proved capable of adequately controlling a powered knee prosthesis during weight bearing activities. Though, difficulties were experienced during the swing phase as no sensory feedback was provided or retrieved through the ground-socket interface (Hoover et al., 2013). Another common challenge for people with an amputation is the involuntary contractions of their muscles or involuntary co-contractions, where a person contracts both the antagonist and agonist muscle simultaneously (Fleming et al., 2021; Hoover et al., 2012). Finally, the training required for usage of a myoelectric prosthesis can be demanding because of the possible increase in cognitive workload (Fleming et al., 2021).

It is expected that these challenges can be mitigated through the addition of sensory feedback to the prosthesis. Sensory feedback can provide information about muscle contraction to the user and improve training outcomes. Ultimately, users might restore more natural and automatic patterns for limb control that require a limited amount of cognitive effort. However, there are no studies that examine the use of myoelectric controlled lower limb prosthesis systematically during training with or without feedback.

2.3 Proprioception

In an intact limb, muscle receptors in muscle spindles and the Golgi tendon organ transfer information about the muscle activity and tendon load to the central nervous system. In addition to these muscle receptors, skin receptors send information about skin stretch, touch, pressure, etc. The combination of this information, allows us to be aware of our body parts, the location, and the position they are in (Bear et al., 2020). However, after an amputation, these pathways between the peripheral nervous system and the central nervous system are disconnected. Therefore, people with an amputation do not have similar proprioception. As a result, people with an amputation often have to rely upon other input to know where and in what position their residual limb and prosthesis are.

Information regarding the position of the prosthesis is commonly based on auditory feedback, sensory feedback, and visual feedback. Auditory feedback is often based on the sound of the motors in the prosthesis or through for example a click that the knee is locked and can be loaded with weight. Some coarse pressure feedback can be experienced through the socket when the prosthesis is placed on the ground. Another form of sensory feedback, is the terminal impact that is perceived by some users with TFA. When they swing the prosthesis forward, they feel when their knee is fully extended as they throw their prosthesis forward to make sure it does not buckle when they land on it. This is especially common for those who have had non-microprocessor controlled knees. However, most users do not experience such sensory feedback during swing phase, and thus rely mainly on visual feedback. Visual feedback quickly shows where their prosthesis is and whether users can put their weight on the prosthesis. However, relying on visual feedback is not always preferred or available, e.g. when carrying something, or when walking in a dark environment (Valgeirsdóttir et al., 2021).

Clites et al. (2018) presented an agonist-antagonist myoneural interface (AMI). This comprises an invasive intervention where the agonist and antagonist muscle tendons are connected in series. The natural mechanism where an agonist muscle contracts and the antagonist is stretched is restored. As a result, proprioceptive feedback from the muscles is reestablished. Such interface has shown improved proprioception and muscle control in the residual limb in people with a TFA as well as a TTA (Clites et al., 2018; Srinivasan et al., 2021).

2.4 Sensory feedback

Sensory feedback about the knee joint angle and tactile information has shown to improve gait similarity (Basla et al., 2022) while also reducing the mental workload and metabolic cost of the primary task, such that the participant can focus better on the secondary task (Petrini et al., 2019). User confidence has also been rated higher in feedback trials compared to trials without feedback (Basla et al., 2022; Petrini et al., 2019).

Escamilla-Nunez et al. (2020) found that visual feedback was the most common and effective method studied to improve gait symmetry. However, this only seemed to hold for specific settings, where visual attention is not required elsewhere. Therefore, other types of feedback might be more effective in everyday use. Guémann et al. (2022) confirmed that visual feedback is strong compared to vibrotactile feedback. They also found that vibrotactile feedback is advantageous when no visual feedback is available. Furthermore, they found that multimodal feedback is the preferred method of feedback.

Regarding placement of vibrotactors on a limb, circular placement is prefered over longitudinal placement when spatial discrimination is important. Guemann et al. (2019) found that spatial discrimination was best when vibrotactors were placed along a transversal axis around the upper arm when compared to placement alogn a longitudinal axis. Longitudinal placement might also be more practical as the length of the residual limb limits the space for placement.

2.5 Testing prosthesis use

The performance and usability of a prosthesis can be tested in various ways. Previously, walking tests as well as subjective measures on for example embodiment, cognitive workload, and confidence have been used. Most of these walking tests record some quantitative measures such as distance travelled, or time taken to walk a certain distance. These tests, therefore, do not indicate qualitative performance of the users. Furthermore, as described by Park and Zahabi (2022) and Valgeirsdóttir et al. (2022) there are no tests usable for every scenario. In addition, the standardized walking tests are not ecologically valid and there is a ceiling effect for highly active users.

As a result, some challenging scenarios of daily living have been recreated for the CYBATHLON Leg competition. This competition is organised by the ETH in Zurich to challenge teams around the world to test and showcase assistive technologies for people with disabilities to overcome daily challenges[2]. In the leg race, participants with a TFA perform challenging tasks based on daily life. In these tasks, the participants have to cross obstacles such as stairs or step between boxes often while focussing on a secondary task, for instance balancing a small item on a plate. Therefore, all the exercises contain a primary task and a secondary task. The primary task is crossing the obstacle in each task, while the secondary tasks are for example balancing a cup on a saucer or carrying a bucket. The combination of these two tasks increases the cognitive load compared to each of the tasks alone. The goal of the tasks in the CYBATHLON is to complete the tasks correctly and as fast as possible. A detailed description of each task at the CYBATHLON 2024 competition is presented in the Races & Rules (Jaeger, 2022) and the dimensions and materials have been described in Races & Rules Appendix I (Baur, 2022). As a result, these exercises can be replicated with precision. Nevertheless, as described by Jaeger et al. (2023), the winner of the competition is defined by the time it takes to complete the task rather than the quality of movement. As a result, users with simpler prostheses have performed better in the previous competitions than users with more complex prostheses. Even though, more advanced prosthesis allow for more natural movement, and are therefore expected to allow for more benefits on the long term. Hence, movement quality will also be evaluated in future competitions.

There are several methods to evaluate movement quality. Often, gait symmetry is evaluated. However, there exists a wide variety of gait symmetry measures that each have their benefits and

[2]https://cybathlon.ethz.ch/en/cybathlon

drawbacks. Gait measurements can be recorded through motion capture, ground reaction force and pressure force plates or sensors, or through for example EMG signal analysis. Gait symmetry has been evaluated regarding temporal features of gait, such as swing and stance phase, but also regarding biomechanical measures, such as joint angles. Other studied features include step length, muscle activation, and acceleration (Viteckova et al., 2018). When evaluating gait, symmetric movement and load is usually assumed for simplicity. Yet, limb dominance and functional differences have been shown during normal gait. This functional difference seems to expose itself in healthy humans in the different contribution of each limb to stability and propulsion (Sadeghi et al., 1997; Sadeghi et al., 2000).

The symmetry index (SI), or sometimes called Robinson index, is calculated with the following formula:

$$SI = \frac{(X_R - X_L)}{0.5 \times (X_R + X_L)} \times 100 \tag{1}$$

where X_R corresponds to the gait variable of the right leg, and X_L to the gait variable of the left leg (Robinson et al., 1987). A score of zero indicates perfect symmetry. This is a simple and easy to interpret index to evaluate gait symmetry. Though, one of the drawbacks of this equation is that it does not indicate asymmetrical behaviour when there is similar abnormal behaviour in both legs. Furthermore, the SI is calculated from average values over several gait cycles and therefore do not reflect occasional irregularities in gait (Viteckova et al., 2018). In able-bodied subjects, asymmetry seems to limit itself to a maximum of $\pm$ 10%, depending on the selected variable and its absolute range (Herzog et al., 1989). Subjects with a major leg amputation experience an increased gait asymmetry of up to 65% in case of a TFA. Generally, the stance phase is longer, and the swing phase is shorter for the intact limb when compared to the prosthetic side. This shows more strain on the intact side in comparison with able-bodied subjects (Nolan et al., 2003).

Štrbac et al. (2017) tested force feedback using electrotactile stimulation in a myoelectric hand prosthesis. They showed short-term and long-term learning effects, resulting in a similar performance with and without feedback after 5 days of training. This shows promising effects for training with sensory feedback. However, long term effects and different situations and tasks need to be tested as well as the customisability of the feedback to the prosthesis and user. It is unknown whether these effects are transferable to people with TFA.

The cognitive load of using a prosthesis can be measured with physiological measures, subjective measures, or through the addition of secondary cognitive tasks such as counting backwards while walking. Despite the fact that such standardised secondary cognitive tasks are effective in increasing cognitive load, the ecological validity is not high (Valgeirsdóttir et al., 2022). It is expected that the addition of sensory feedback to prostheses reduces the cognitive load of using a prosthesis after an initial learning period.

In addition to the experimental tasks, subjective measures of cognitive workload, confidence, agency, and embodiment can also be recorded. NASA-TLX (Hart & Staveland, 1988) is commonly used as a subjective measure to analyse cognitive workload in prosthetic experiments (Park & Zahabi, 2022). The raw-TLX has been used in this experiment as this is easier to attain than the weighted subscales and it has been previously validated (Hart, 2006). Embodiment characterises the multifacetet effectiveness of a prosthesis regarding four domains, namely: sensory, motor, postural, and psychosocial. Combined, these domains influence the ownership and agency of users that create the concept of embodiment (Eftekari et al., 2023). Bekrater-Bodmann (2020) developed the prosthesis embodiment scale for lower limb amputees (PEmbS-LLA) to measure a selection of these aspects using a Likert questionnaire.

3 Materials and methods

3.1 Participants

Three subjects participated in this research, see Table 1 for participant information. Two subjects had a TFA and one a TTA. The participants with a TFA were fitted with an active microprocessor-controlled knee prosthesis (Power Knee, Össur, Iceland) if they did not use an active knee prosthesis in their daily life. The participant with a TTA was fitted with a prototype of an active ankle (powered ankle prosthesis protoype, Össur, Iceland). For each participant a customised liner with embedded surface electrodes and a socket had been created and reliable EMG signal acquisition was validated by a Certified Prosthetist/Orthotist (CPO). Inclusion and exclusion criteria are listed in Table 2. The experiment was approved by the Icelandic Medicines Agency (IMA), and all participants signed an informed consent prior to participating.

Table 1: Participant characteristics. M = male, TF = transfemoral, TT = transtibial, R = right, L = left, PLP = phantom limb pain

Subject	Sex	Age (years)	Level	Side	Cause	Post-amputation time (years)	K-level	PLP frequency	PLP intensity
S1	M	56	TT	R	Trauma	19	3-4	Weekly	High
S2	M	43	TF	L	Cancer	24	4	Monthly	Medium
S3	M	51	TF	R	Cancer	1	3	Almost always	Low

Subjects S1 and S2 had been testing EMG controlled prostheses on and off for 2 years. Subject S3 had no experience with EMG controlled prostheses. Furthermore, subjects S1 and S3 had some testing experience with powered ankle and powered knee prostheses, respectively. Subject S2 had extensive experience with powered knee prostheses and previously tested them in everyday life. None of the subject had extensive experience with sensory feedback in prostheses. Subject S2 had been testing the prototype several times throughout the development phase. Subject S1 had tried the non-mobile set-up once before the experiment, while subject S3 had no experience with sensory feedback prior to this experiment. All subjects mainly use a passive microprocessor controlled prosthesis in daily life. However, the specific device changes regularly as the subjects test different prostheses. None of the subjects had any areas with a lack of sensation.

3.2 Materials

The investigational device consisted of three major components: (1) an EMG system that collected and preprocessed the EMG signal; (2) the feedback system, that converted the EMG signals to a feedback level and activated vibration motors; and (3) the active prosthesis that were controlled proportionally by the EMG signal. A high level overview of the system is shown in Figure 1.

The subjects with a TFA were wearing an active microprocessor-controlled prosthetic knee (A-MPK) (Power knee, Össur, Iceland). The control of the A-MPK was adapted to allow for proportional direct

Table 2: Inclusion and exclusion criteria for participants.

Inclusion criteria:	**Exclusion criteria**:
50Kg < body weight < 166Kg	50Kg > body weight > 166Kg
Cognitive ability to understand all instructions and questionnaires in the study	Users with cognitive impairment
Age $\geq$ 18 years	Age < 18 years
Above ankle or above knee major lower limb amputation	Pregnancy
Willing and able to participate in the study and follow the protocol	Insufficient number of muscles suitable for EMG measurements evaluated by an investigator
Ability to produce reliable EMG signals from the remaining muscles in the residual limb	Neurological conditions or muscular disorders (e.g. multiple sclerosis, myasthenia gravis, muscle dystrophy)
	Pain, tissue- or nerve damage that can potentially prevent EMG measurements
	Major injury or signs of injury on residual limb
	Use of medication likely to influence neural-, neuromuscular or myoelectric signals
	Active skin infection on residual limb
	Limited ability to participate, as evaluated by an investigator
	Users with an agonist-antagonist myoneural interface (AMI)

control based on sEMG, where the degree of muscles contraction directly influenced the torque on the bionic joint. The participant with a TTA was fitted with a powered ankle prosthesis which was controlled through sEMG proportionally similar to the Power Knee.

The sensory feedback system consisted of six main components, see Table 3. EMG signals were recorded from two sets of two differential electrodes and a ground (one set for each muscle). The electrodes were embedded in a personal custom made prosthetic liner, which connected to a custom made socket through six dome electrodes (Sverrisson & Sigurðardóttir, 2022). The electrodes were connected with an amplifier and a custom made control board (Össur, Iceland), and a battery (ABP Technology Co. Ltd., China). The placement of the electrodes was defined through skin palpation and EMG recording during muscle contraction. The EMG signal acquisition and socket fit were verified by a CPO.

The feedback was provided through seven 9mm vibration motors (307-103, Precision Microdrives Limited, United Kingdom) placed vertically in a custom-made adjustable band at an interval of approximately 4.5 cm. This band was placed on top of the brim of the prosthetic liner, above the prosthetic socket. The centre vibrator was placed in the middle of the lateral side. The other vibration motors were then folded around the residual leg towards the anterior and the posterior side. As a result, there were no vibrotactors located on the medial side, this area is close to the groin for

Table 3: Materials and set-up of the sensory feedback system

Feedback Unit	Device	Location	Function
1) Vibrating Unit	Seven vibrotactors	On the liner above the socket, anterior to posterior sides of the thigh of the residual limb	Provide vibrotactile feedback
2) Control Unit	Microprocessor and custom electronic board	Housing case attached to the prosthetic socket	Data processing and activating vibration motors
3) EMG Sensors	Six surface EMG sensors	Embedded in the prosthetic liner and socket	Data acquisition
4) EMG Processor	Amplifier and custom made control board	Housing case attached to the prosthetic socket	EMG preprocessing
5) Power Supply	2 cell lithium-polymer battery (1300 mAh, 9.62Wh)	Housing case of the EMG processor	Power supply for the control boards and vibrators
6) Communication Unit	Bluetooth low-energy Module	Housing case of the EMG processor	Real-time wireless communication
	Össur Toolbox	Laptop	Real-time data collection and storing of logs

individuals with a TFA, and is therefore not suitable for vibrotactile feedback. The vibration motors were connected to a custom electronic board through two drivers consisting of an array of four bipolar (BJT) transistors (STA471A-ND, Sanken Electric USA Inc.), a battery, and a microprocessor (Seeed Studio XIAO nRF52840 Sense, Seeed Technology Co., Ltd, China). See Figure 4 for an overview of the hardware connections of the feedback system and see Figure 5 for an experimental set-up of the different components.

A standard laptop (Lenovo ThinkPad P53s, Intel Core i7 @ 1.90GHz, 32GB RAM), running Windows 10 Enterprise, was used to program the microprocessor with a custom-made program written in CircuitPython 8.0.5 using Asyncio 0.5.19 libary for running concurrent tasks. CircuitPython is a lightweight programming language based on Python with the necessary hardware support to run on microcontroller boards ("CircuitPython", n.d.). The microprocessor was connected to the control board of the EMG amplifier using a serial cable (UART). The EMG calibration and data analysis program was written in Python 3.10.8. The Power Knee or powered ankle prosthesis was connected to the laptop via WiFi and this connection was used to log data through the Össur Toolbox.

A Zebris FDM-T gait analysis system was used during the walking exercises to measure gait features. The system consisted of a treadmill with built-in force plates and software to record and process measured gait features. Recorded gait features included, among others, stance and swing time for each limb. After recording, the mean and standard deviation of each measured feature was calculated and presented in a comprehensive report. Raw data of the individual gait cycles was not available.

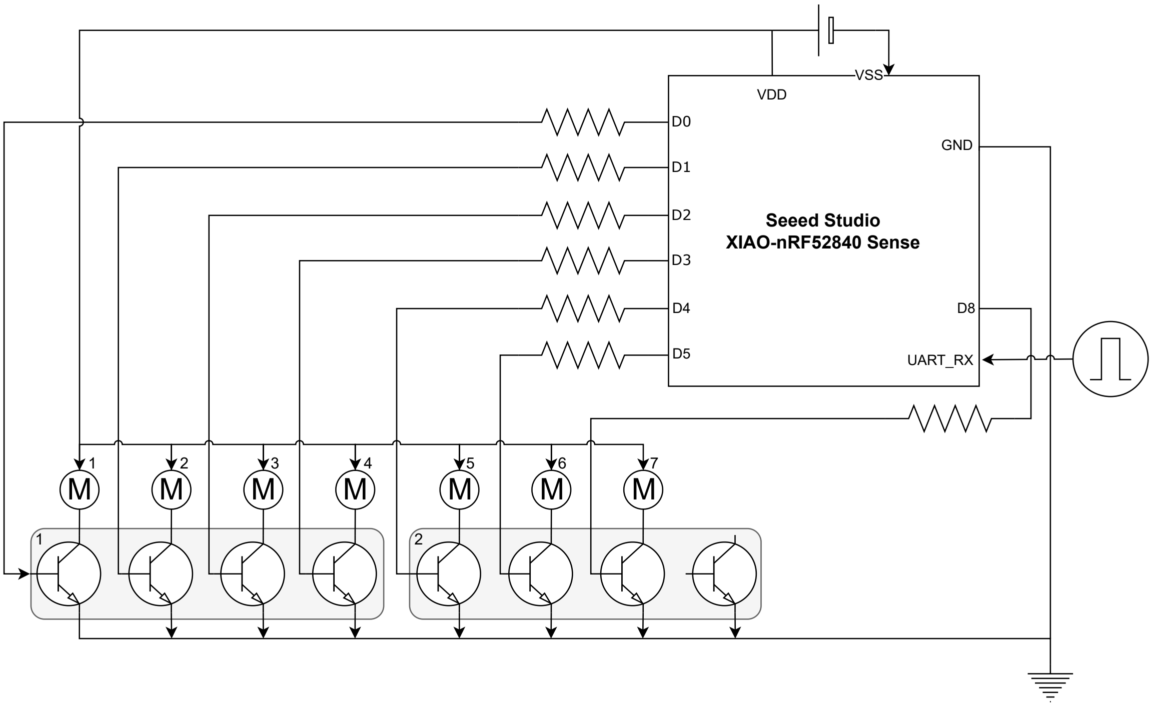


Figure 4: Overview of the hardware electrical circuit used for the feedback system. The Seeed XIAO-nRF52840 Sense is displayed in the middle and is connected to a battery. The microprocessor receives input from the EMG system through the UART_RX port in the form of serial data. The microprocessor sets the pin values of port D0 to D5, and D8. These I/O ports are connected to two drivers (shown in grey at the bottom) that regulate the power to the connected vibration motors (M).

3.3 Experimental set-up

3.3.1 EMG calibration

First, signal quality was reviewed by contracting the flexor and extensor muscle alternately. When the signal quality was deemed sufficient, calibration of EMG signals was performed. The participant was asked to contract their extension and flexion muscle three times to 80% of their maximum power and hold for a short period followed by a short period of total rest. This procedure was performed in both a sitting and standing position. The EMG signal was recorded at 100 Hz during the calibration. The rest activity was defined as the lowest magnitude of contractions during the EMG calibration. The rest levels were subtracted from all subsequent EMG measures for the feedback system. The maximum voluntary contraction (MVC) for each muscle was defined as the maximum value reached. The EMG signals used for sensory feedback were normalised to the MVC during the following experiments.

3.3.2 EMG processing

The EMG signals were collected at 1000 Hz from the surface of the residual limb through differential electrodes embedded in the liner. After collection, the signal was amplified and sent to the custom made control board for further EMG processing. Then, a 50 Hz notch filter and a 20 Hz high pass filter were applied. A second order Butterworth high-pass filter of 75 Hz and a second order

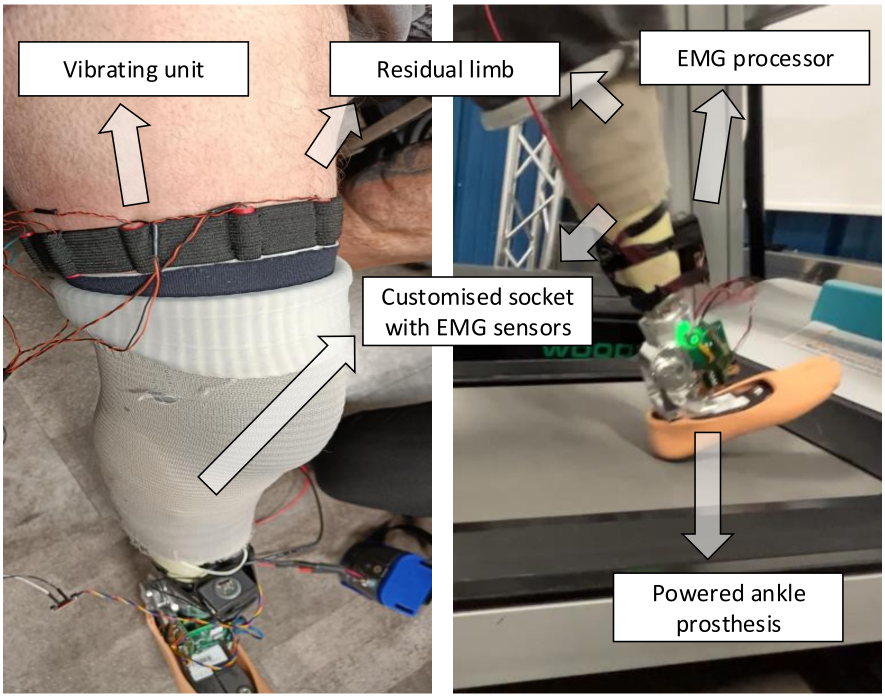


Figure 5: Experimental set-up with the EMG and sensory feedback system. The belt with the vibrotactors is placed on the thigh at the brim of the liner for individuals with a transtibial amputation (TTA). The EMG signal is collected through six electrodes in a customised set-up.

Butterworth low-pass filter of 400 Hz were applied. Then, the change in each channel was calculated. Motions artifacts were subsequently identified and removed with the EMG Error Checker. Finally, a Butterworth low-pass filter of 2 Hz was applied to get the EMG Control Signal (Sverrisson & Sigurðardóttir, 2022). Then, the signals were sent at a frequency of 100 Hz to the powered prosthesis and to the feedback system for joint angle control and sensory feedback, respectively.

For the feedback system, the EMG values were clipped to 0 and 500 to reduce noise. Then, the signals were processed by subtracting the rest activation and the signals were normalised against the MVC. When the normalised signal of one or both muscles was above 0.1, the feedback system was activated. The activation of the flexion muscle was subtracted from the extension muscle in order to define the level for the vibratory feedback.

3.3.3 EMG control

The control of the powered prostheses was adapted to allow for a proportional control based on sEMG signals (Einarsson et al., 2021). The EMG control was implemented on top of the existing protocol to ensure the safety of the participant. The control of the knee was divided into two modes: swing and stance. In the swing mode the foot was lifted off the ground. In this phase, the control was based on the difference in contraction between the flexor and the extensor muscle. For example, when the extensor is contracted more than the flexor, the leg extends and vice versa. In the stance mode, only the activation of the flexor was used for the control of the knee. Stronger contractions, resulted in a higher measured voltage, and more power was provided to the knee or ankle (e.g. when squatting) (Hunt et al., 2021). The control was personalised and calibrated for each person according to the MVC. The control was only activated when the EMG contraction reached a predefined threshold and when there were no or negligible co-contractions present.

3.3.4 Feedback paradigm

The paradigm used to activate the vibrotactors was based on the paradigm used by Tchimino et al. (2022). Nine discrete EMG activation levels were identified, from -4 to 4. The positive levels represented extension, while the negative levels indicated flexion. Each vibration motor was assigned one level from -3 to 3 and was activated accordingly. Level -4 and 4 corresponded to the activation of all three motors indicating flexion or extension, respectively. The activation level was based on the differential EMG signals received from the flexor and the extensor muscle, see Figure 6 for a schematic overview of the feedback paradigm.

The activation level was calculated through the difference in activation of the flexor and extensor muscle and was given a discrete level. The boundaries were defined similarly as Tchimino et al. (2022), i.e. [0.1, 0.2, 0.4, 0.65] in both directions. When both muscles had less than 0.1 normalised contraction, no vibration motor was activated. When both muscles were contracted to a similar level, i.e. in the case of co-contraction, the vibration motor of level 0 was activated.

The vibration motors were always activated on full power. By turning the vibrators on for only a short period, a short haptic stimulation was created. Such short haptic stimulations were generated repeatedly with a rest period of 100 ms between each stimulation. When the same level was activated for two seconds or longer, this rest period was increased to 500 ms. Initially, the vibrating duration was set at 10 ms per vibration motor. This was increased or decreased according to the participant's perception and wishes.

After the feedback system was donned, a familiarisation session was performed where each level was activated sequentially for 2 seconds followed by a 1 second pause, starting at level -4. The familiarisation was repeated until the user and researcher were satisfied with the vibration strength and EMG signal disturbance level. The vibration time for subjects S1 and S2, were set at 10 ms. For subject S3 the vibration time was reduced to 5 ms for all levels.

A reinforcement learning session was performed afterwards. The participant was in a static position, 2 rounds standing and 2 rounds sitting. Each level was activated 4 times in a random order for 2 s after which there was a pause of 1 second. After each activation, the participant was asked to indicate which level was activated. The researcher then confirmed the level when correct or provided the correct feedback level when incorrect.

After the reinforcement learning, a validation of the levels was performed. The previous process was repeated, however, this time, the correct answer was not known to the researcher. When 70% or more levels were identified correctly or when 90 % or more of the level groups were identified correctly as extension, flexion, or co-contraction, the validation was deemed successful. Otherwise, the process was repeated.

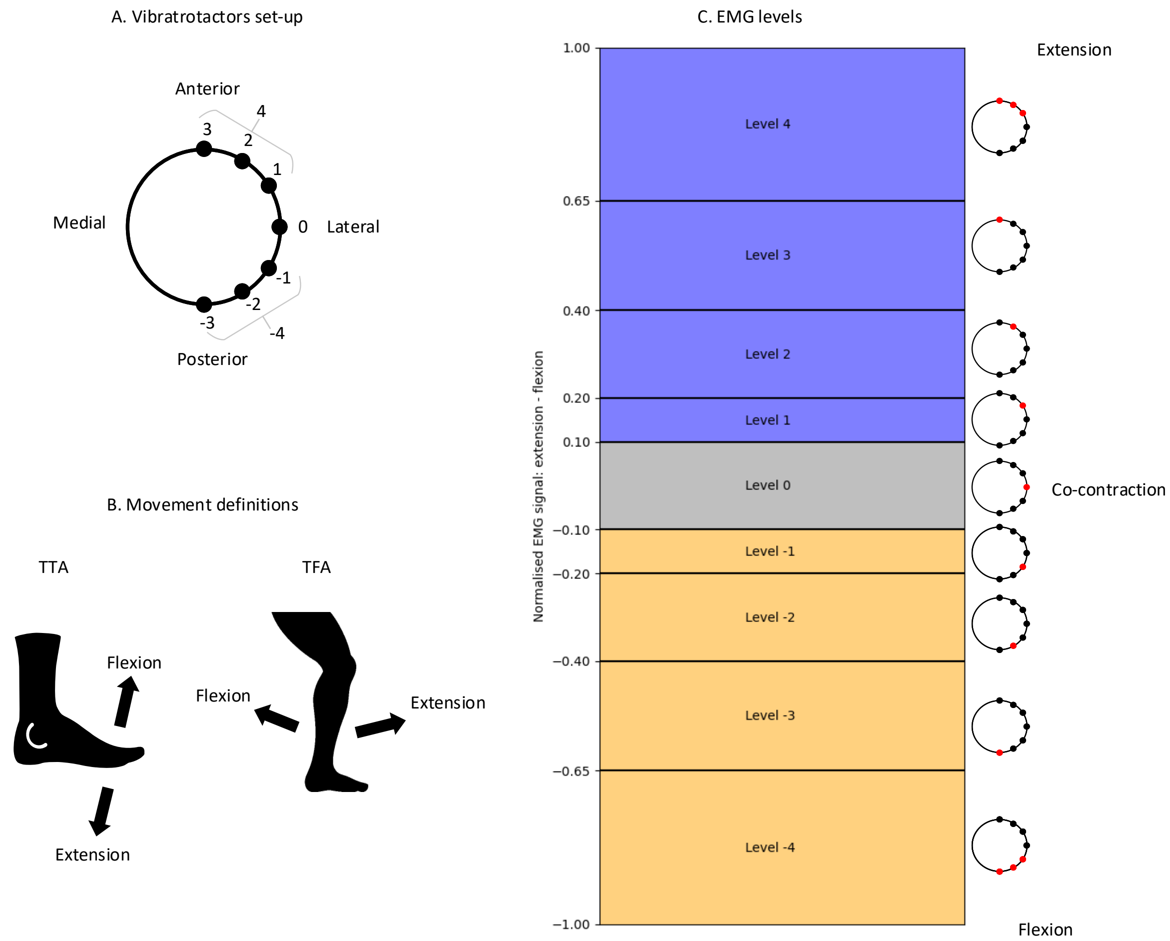


Figure 6: The feedback set-up and paradigm. A: vibrotactor placement and level locations on the leg are illustrated. The set-up of the vibrotactors is shown for persons with a transfemoral amputation (TFA). B: The direction of flexion and extension movement in regards to the body is reversed for TTAs, therefore, the levels of the vibrotactor on the thigh are reversed for TTAs. C: vibrotactile level is defined by subtracting the normalised flexor activity from the extensor activity. The red and black vibrotactors correspond to the active and inactive tactors in each level, respectively.

3.3.5 Online feedback system

The online feedback was turned on by running two tasks concurrently with the Asyncio library on the microprocessor of the feedback system: (1) to read and process the serial data, and (2) to set the pin outputs of the microprocessor to activate or deactivate the corresponding vibration motors according to the vibration level and duration. When starting the online feedback loop, the user calibration data regarding the MVC and rest values as well as the vibration duration were loaded. Then, three main classes were initialised: (1) serial reader, (2) EMG preprocessor, and (3) motor activator. See Figure 7 for an overview of the components of the online feedback system.

Serial data was received at a frequency of 100 Hz through the UART connection with the EMG system. The EMG data was sent in byte arrays and enveloped by specific byte arrays containing information about the EMG signal. The first task repeatedly checked whether a new byte array was received. It did this with a timeout of 0.01 ms. Once a byte array was received, the correct byte encoding the EMG data needed to be identified and converted. Then, the signal was processed further. First, the signal was clipped, then the rest signal was subtracted, and finally, the signal was normalised against the MVC. Then, the threshold for activating the feedback system was calculated. If the threshold was reached, the feedback level was defined and saved in the motor activator class as well as the corresponding pin(s) connecting to the motors.

The second task continuously checked the status of the vibration motors and turned the motors on or off according to the active duration time. Based on the feedback level that was set by the first task, it activated the corresponding motor. Before setting the pin outputs, it checked whether the same level was activated previously and whether the rest period between the vibrations needed to be adapted.

These two tasks ran concurrently and indefinitely until the battery would run out. The minimum time a vibration motor could be activated was 2.5 ms. The code for the online feedback system can be found in `run.py` on the corresponding GitHub repository (Tilleman, 2023).

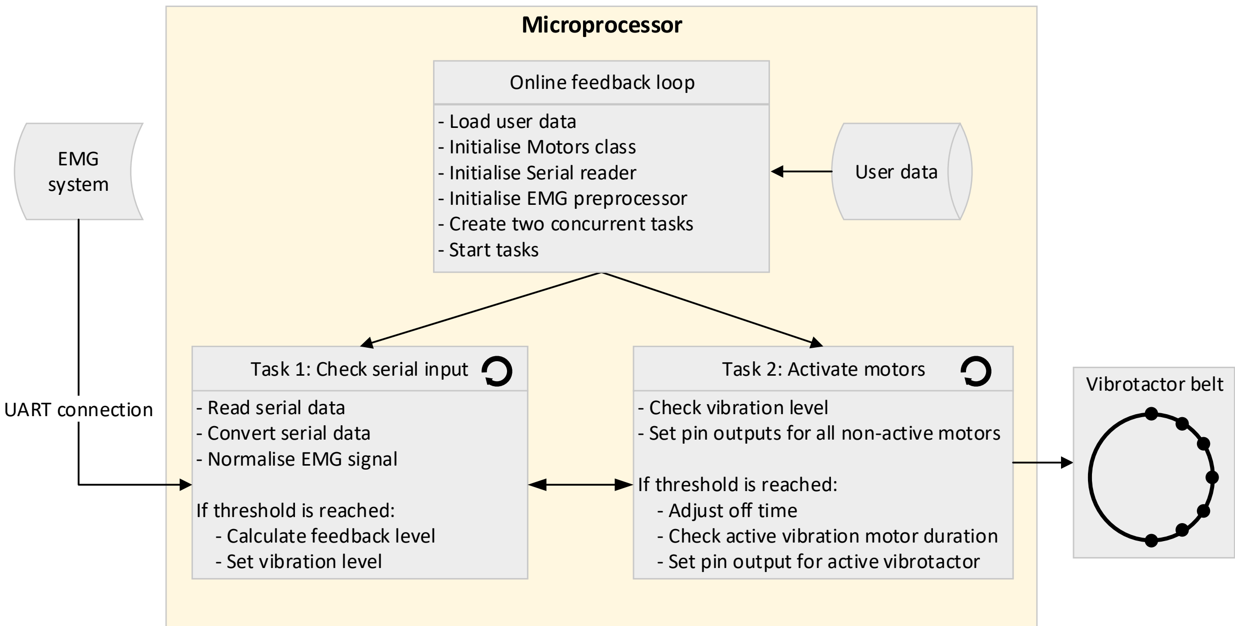


Figure 7: Overview of the software of the online feedback system.

3.4 Experimental tasks

The experimental tasks consisted of two types of walking tests. The first task consisted of two minutes walking on level ground. The second task consisted of two minutes of inclined walking on a slope of 5%. The walking tasks were performed on a Zebris FDM-T gait analysis treadmill with incorporated force plates. During the walking tasks, force measures, walking speed, and stance and swing time of both the sound limb and the prosthesis side were recorded. The mean values of stance and swing time for each limb were used to calculate the absolute symmetry index (ASI).

The ASI was calculating by adapting the symmetry index defined in Equation 1 to the following:

$$ASI = \frac{(I - P)}{0.5 \times (I + P)} \times 100 \tag{2}$$

where I corresponds to the stance/swing ratio of the intact limb, and P to the stance/swing ratio of the prosthetic limb. An ASI deviating from zero indicated asymmetrical gait. A score higher than $\pm 10\%$ represented asymmetrical gait.

3.5 Subjective measures

3.5.1 Mental workload

The raw NASA-TLX scale was filled out immediately after each trial. The values were recorded in steps of five and rounded up when a mark was put between two vertical tick marks. For each scale the score was digitised to a number from 0 to 100, where zero corresponded to a very low load and one hundred to a very high load. The scores were then rescaled and inversed to a score between 0 and 10, indicating a high mental workload and a low mental workload, respectively. Then, the mean score was calculated and reported as 'Ease of use'. The questionnaire is included in Appendix A.1.1.

3.5.2 Prosthesis embodiment scale

Prosthesis embodiment scale for lower limb amputees (PEmbs-LLA) was filled out directly after each trial to measure embodiment and agency. For each of the following statements, the user indicated how much they agreed (positive values) or disagreed (negative values). The questionnaire was filled out immediately, without the additional explicit observation and usage of the prosthesis. Item 1-5, and 7 were related to ownership, item 6 and 8 were related to Anatomical Plausibility, and item 9 and 10 were related to agency. See Appendix A.1.2 for the questionnaire. The mean score for embodiment was calculated and the scores were rescaled afterwards to a score between 0 and 10.

3.5.3 Confidence

Perceived user confidence was measured after each trial using a 10 cm long Visual Analogue scale. The participants were asked to mark on the scale how confident they felt during the trial from 'extremely confident' to 'not confident at all'. This scale was previously used by Basla et al. (2022) and Petrini et al. (2019). See Appendix A.1.3 for the scale. The scores retrieved were digitised afterwards from 0 to 10, where zero corresponded with 'not confident at all' and ten corresponded to 'extremely confident'.

3.6 Experimental procedure

The experimental procedures consisted of several sessions. Each session included four blocks of walking experiments. A block consisted of ten minutes familiarisation, followed by two minutes ground level walking, and two minutes walking on a slope of 5%. After each walking trial, subjective measures were filled out and a break was taken if necessary.

The blocks were performed in various configurations: (1) with the standard control of the powered prosthesis, (2) with proportional EMG control, (3) with proportional EMG control and sensory feedback (SF), and (4) with the proportional EMG control. Before the walking tests were performed, the participants were allowed to familiarise themselves to the system and practise daily life activities, such as level ground walking, inclined walking, sit-stand transitions, etc. After each block a break was taken according to the user's needs. See Figure 8 for an overview of a session.

During the first session, the experiment was explained and the informed consent was signed. Then, the participant information was filled out and the custom made liner and socket with the sEMG electrodes were donned. At the start of the first session, the preferred walking speed of the participants was selected by the participants. The participants were instructed to select a comfortable walking speed that was maintainable for two minutes in each walking task. The recorded speed was kept the same for one participant for each trial in this study. Subject S1 selected a speed of 3.8 km/h, subject S2 selected 3.5 km/h, and subject S3 selected 2.3 km/h.

After the first block, EMG signals were verified and EMG calibration was performed. When successful, the second block with the proportional EMG control was started. After the second block, the vibratory system was donned. During the first session, the vibration duration was adjusted to the user if necessary. The selected settings were then used for the entire block and the following sessions. After the feedback calibration, familiarisation, reinforcement training, and validation were performed. If the validation was completed successfully, block 3 was started. After block 3, the sensory feedback system was turned off and doffed. Finally, block 4 was completed with only EMG control.

Subject S1 performed all walking tests for three minutes instead of two and completed three and a half block. The fourth block was stopped after the level ground walking trial due to user fatigue and time constraint. Subject S2 completed three sessions on consecutive days. The second session only consisted of the first 2 blocks due to time constraint. Subject S3 completed one full session.

3.7 Data analysis

First, a Friedman test was performed on the combined subjective measures for each block. Then, a Wilcoxon signed-rank test was used for comparison between two blocks using a Bonferroni correction. The statistical significance was set at $\alpha = 0.05$ for all statistical tests. As a result, a p-value less than 0.008 indicated a significant difference when comparing between two blocks within

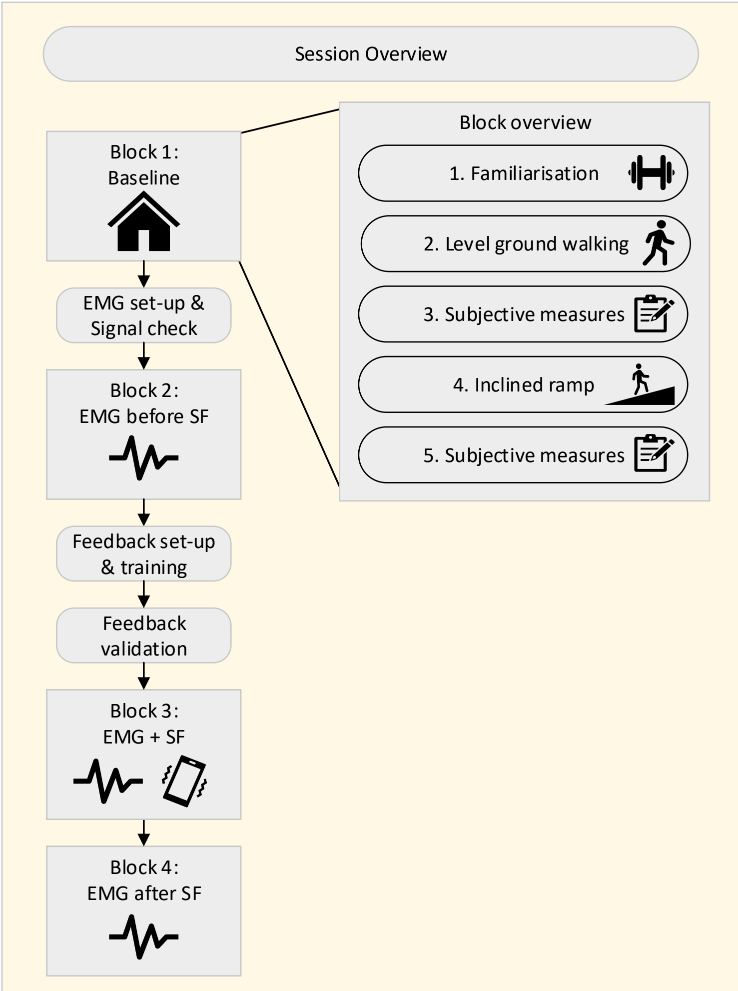


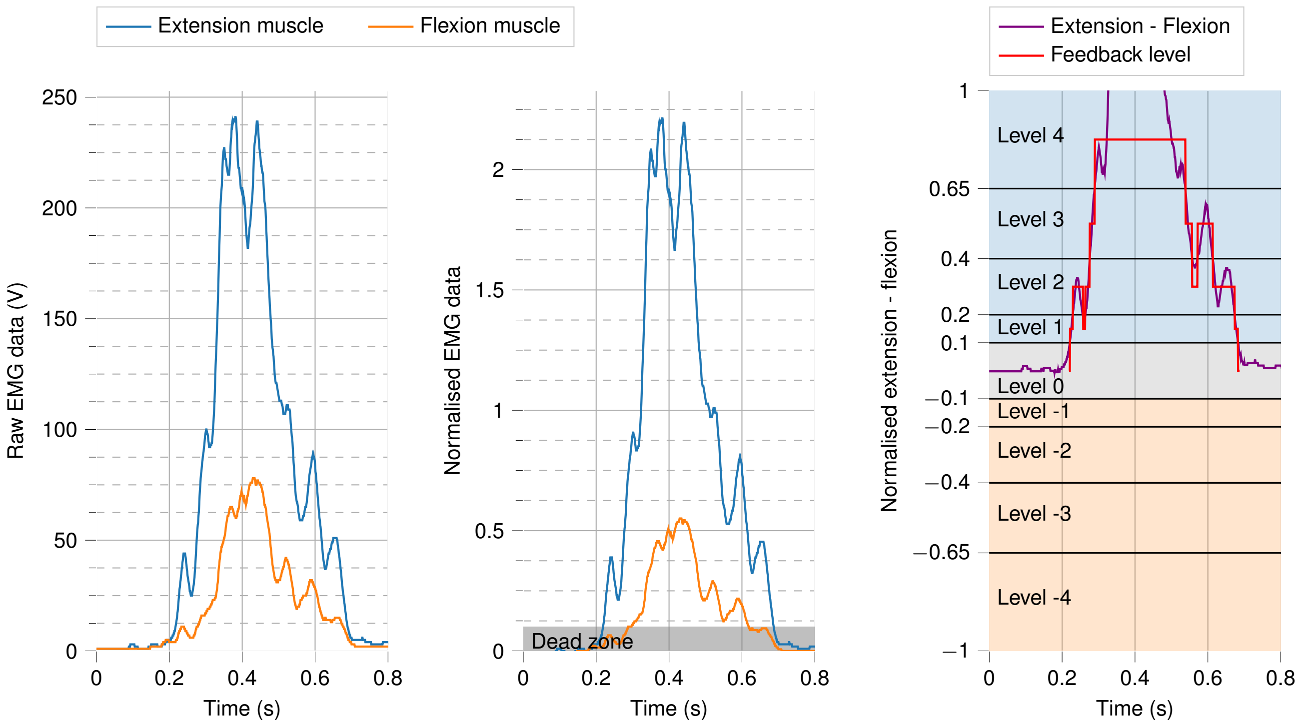
Figure 8: Flowchart of the experimental procedure of a session. After each block and trial a break was taken according to the user's needs. SF = sensory feedback

one session, and a p-value less than 0.017 indicated a significant difference when comparing between sessions. All statistical tests were performed using Python 3.10 and the scipy.stats module 1.10. No statistical tests were performed on the gait analysis data from the participants, due to the limited availability of the raw data recorded through the Zebris FDM-T gait analysis system. Therefore, only the calculated ASIs were reported.

4 Results

4.1 EMG signal

An overview of the EMG signal process is presented in Figure 9. The signal shown was collected from S1 during plantar flexion. The raw signal is shown in Figure 9a, then the normalised signal is shown in Figure 9b, and finally, the subtracted EMG signal and the corresponding feedback level are shown in Figure 9c. The deadzone in Figure 9b was defined as 10% of the MVC. When the activation of both muscles was within this zone, none of the vibrotactors were activated, as shown in Figure 9c at the beginning and end of the recording. While the subject was building up the plantar flexion, the vibrotactors were activated from level 0 to level 4, as the participant was holding the muscles contracted. Then, as the participant slowly relaxed their muscles, the feedback level was decreased step wise as well. In this recording, co-contraction in the flexor muscle was present. Though, the difference in contraction between both muscles was large enough that the highest feedback level was activated during maximum contraction. Only, at the start and end of contraction, the feedback level indicating co-contraction (level 0) was activated briefly.



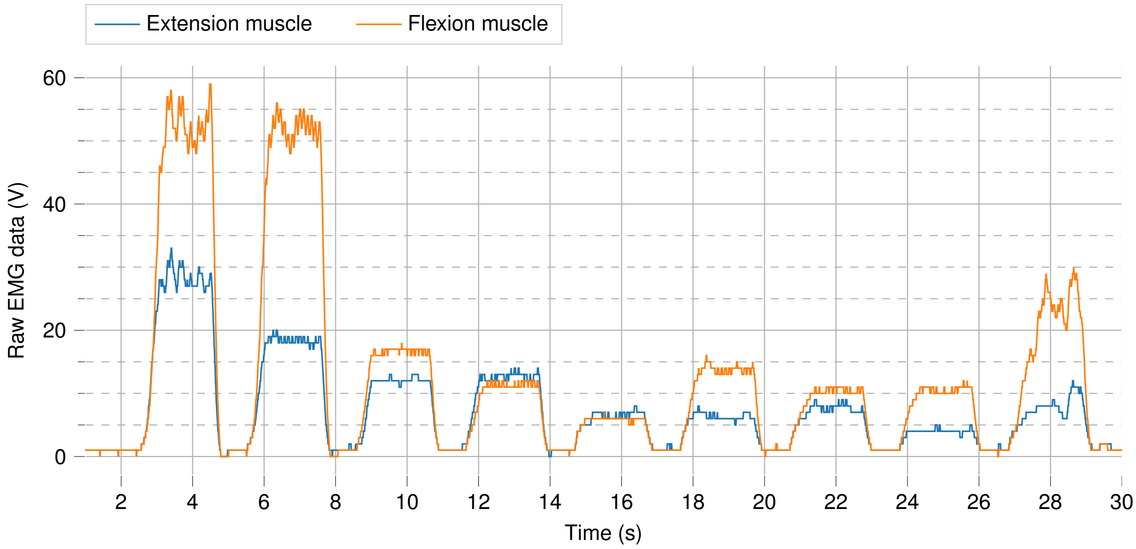
(a) Raw EMG signal.

(b) Normalised EMG signal.

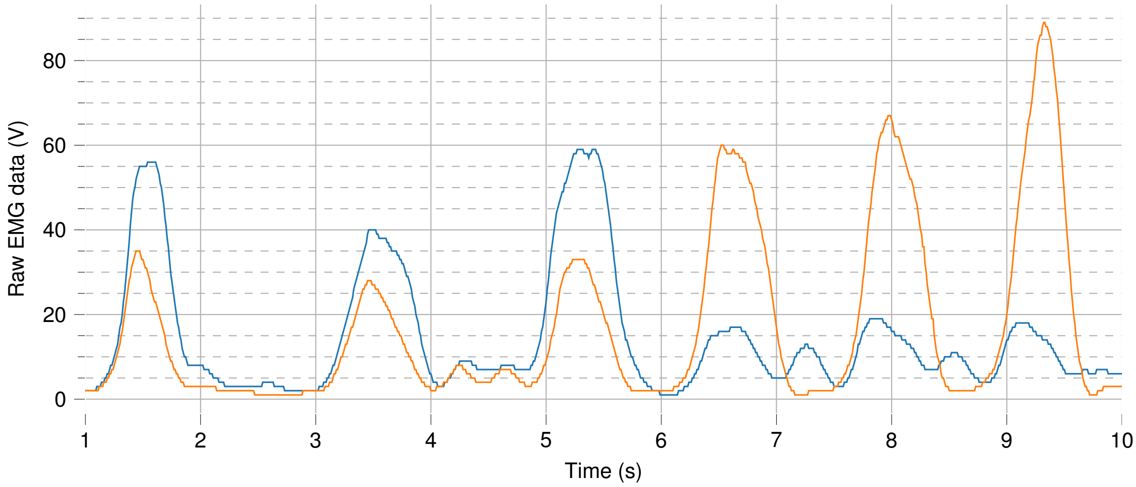
(c) Level discretisation.

Figure 9: Overview of EMG signal process. When the normalised activation of both muscles is under 0.1, no vibration motor is activated (dead zone).

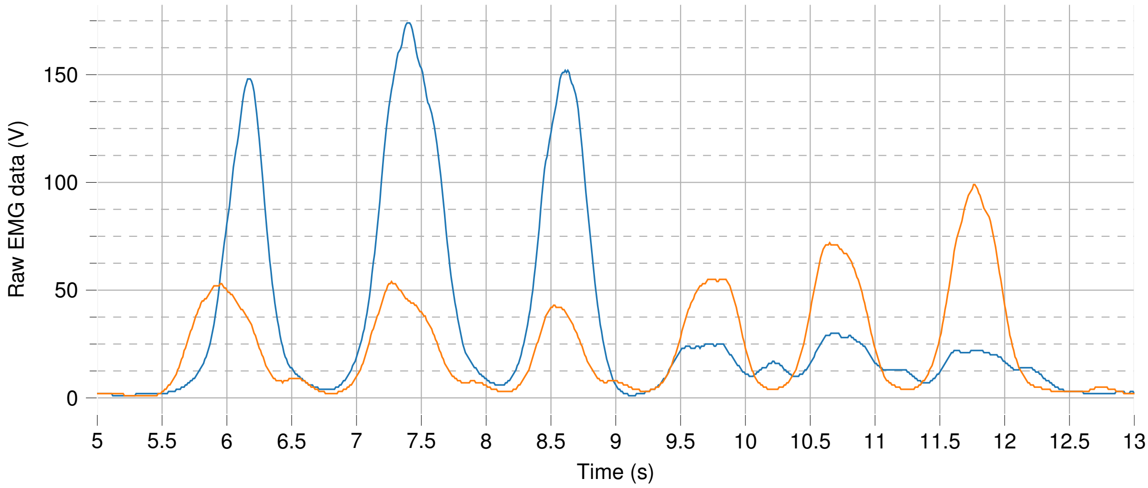
An overview of the influence of the vibrotactory feedback on the raw EMG signals of subject S2 in rest as well as during a signal check is shown in Figure 10 while in sitting position and in Figure 11 while in standing position. For Figure 10a and Figure 11a, the subject was at rest while the familiarisation procedure as described in Section 3.3.4 was performed. The activation of each level is



(a) Raw EMG signal from S2 while sitting during rest. Each level is activated for 2 seconds followed by 1 second rest starting with from -4 (flexion) to 4 (extension).

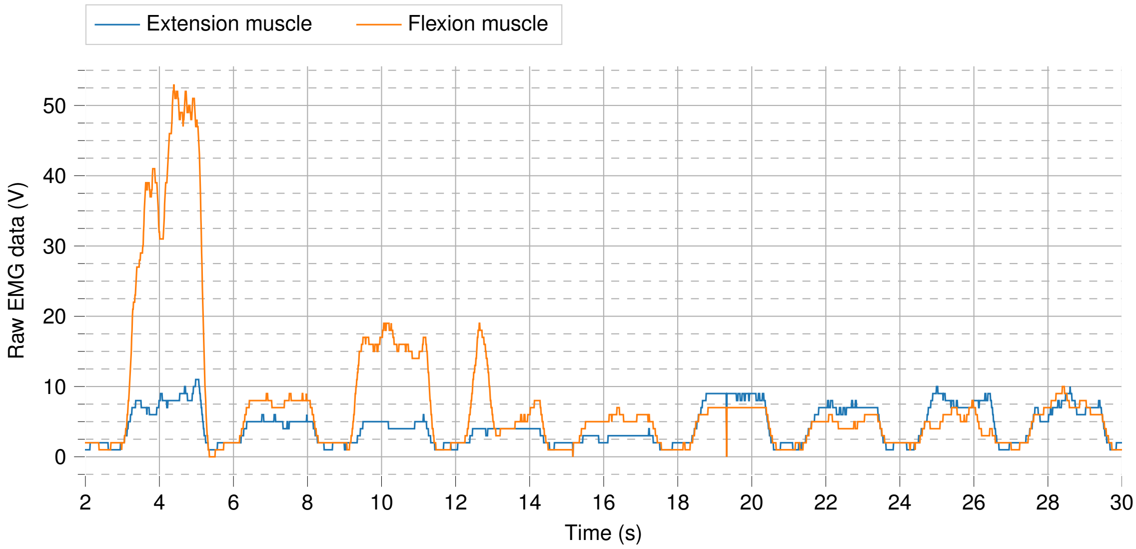


(b) Raw EMG signal from S2 while sitting during signal check. Voluntary contraction of the extension muscle three times, followed by three times voluntary contraction of the flexion muscles.

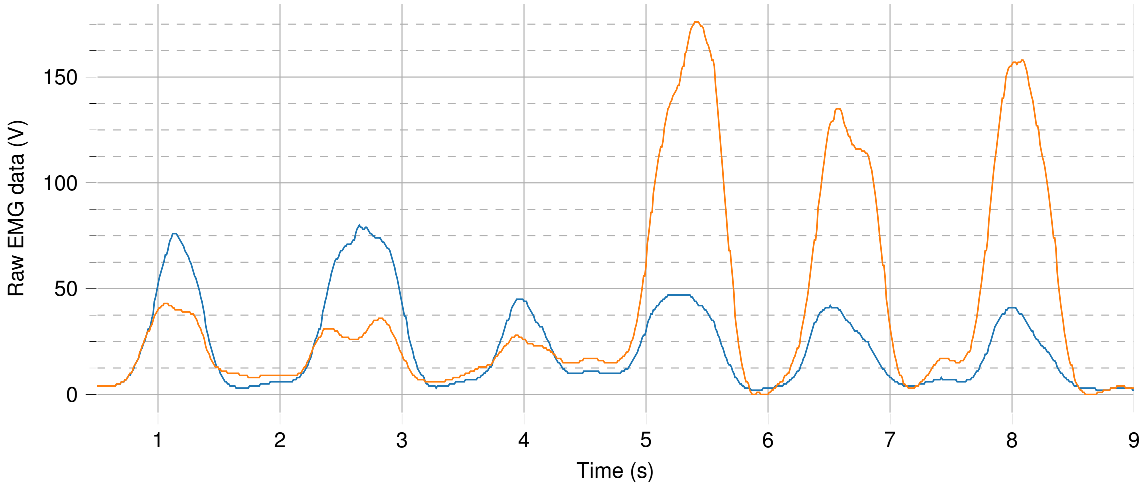


(c) Raw EMG signal from S2 while sitting during signal check with the feedback system activated. Voluntary contraction of the extension muscle three times, followed by three times voluntary contraction of the flexion muscles.

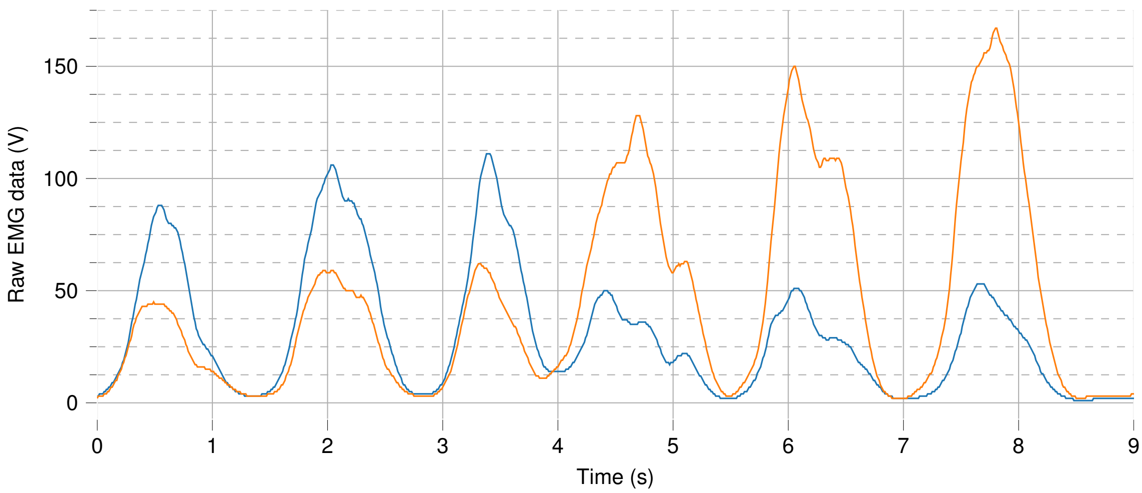
Figure 10: Overview of the influence of the vibrotactile feedback on the raw EMG signals in S2 while sitting during rest and voluntary muscle contractions.



(a) Raw EMG signal from S2 while standing during rest. Each level is activated for 2 seconds followed by 1 second rest starting with from -4 (flexion) to 4 (extension).



(b) Raw EMG signal from S2 while standing during signal check. Voluntary contraction of the extension muscle three times, followed by three times voluntary contraction of the flexion muscles.



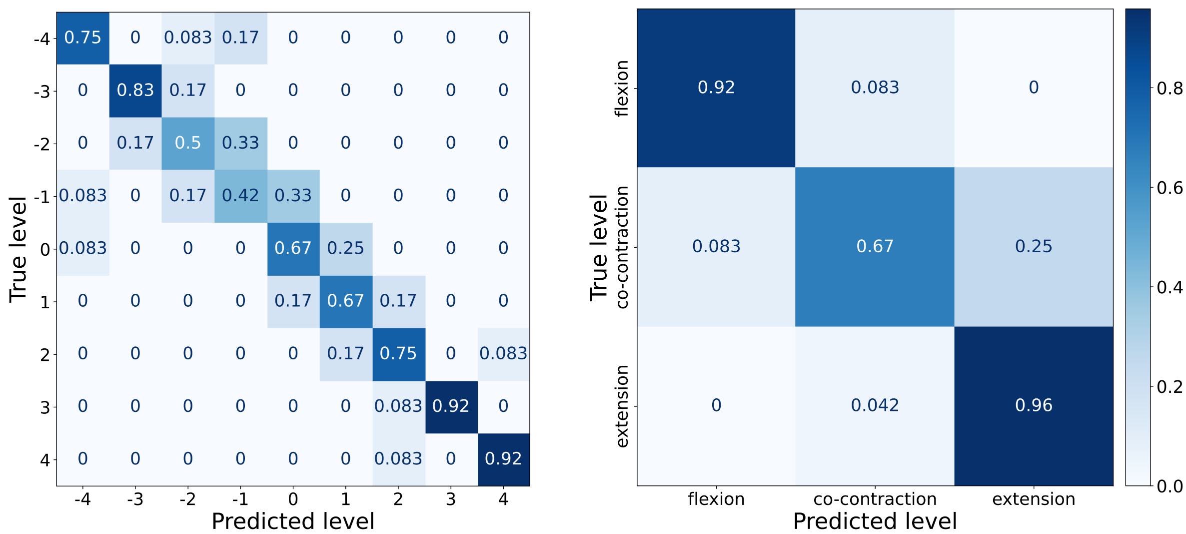
(c) Raw EMG signal from S2 while standing during signal check with the feedback system activated. Voluntary contraction of the extension muscle three times, followed by three times voluntary contraction of the flexion muscles.

Figure 11: Overview of the influence of the vibrotactile feedback on the raw EMG signals in S2 while standing during rest and voluntary muscle contractions.

clearly displayed by the increase in voltage for both electrodes, with periods of low voltage between the activation of two levels. The voltage recorded at the electrodes on the posterior side of the body was higher for most activated levels. In a sitting position, the pressure of the skin on the electrodes was higher in the posterior side than on the anterior side of the leg, resulting in higher voltages than recorded at the anterior side. In Figure 10b and Figure 11b, regular recordings for EMG calibration of S2 are presented in a sitting and standing position, respectively. For Figures 10c and 11c, the same process was repeated, however, during this recording, the feedback system was active. When comparing the raw EMG signals, the recorded voltage at the electrodes on the extension muscle were increased. The magnitude of the flexion muscle remained similar.

4.2 Feedback validation

All users achieved a discrimination accuracy of at least 70% for the individual levels or 90% for the combined levels during the first trial at the first session. The results from all users combined are shown in Figure 12. Most mistakes were made at adjacent vibrotactors, or with the maximum and minimum level. Subject S2 performed the validation test twice, once during the first session and once during the second session. No statistical difference was found between these two sessions (W=78.0, p=0.48).



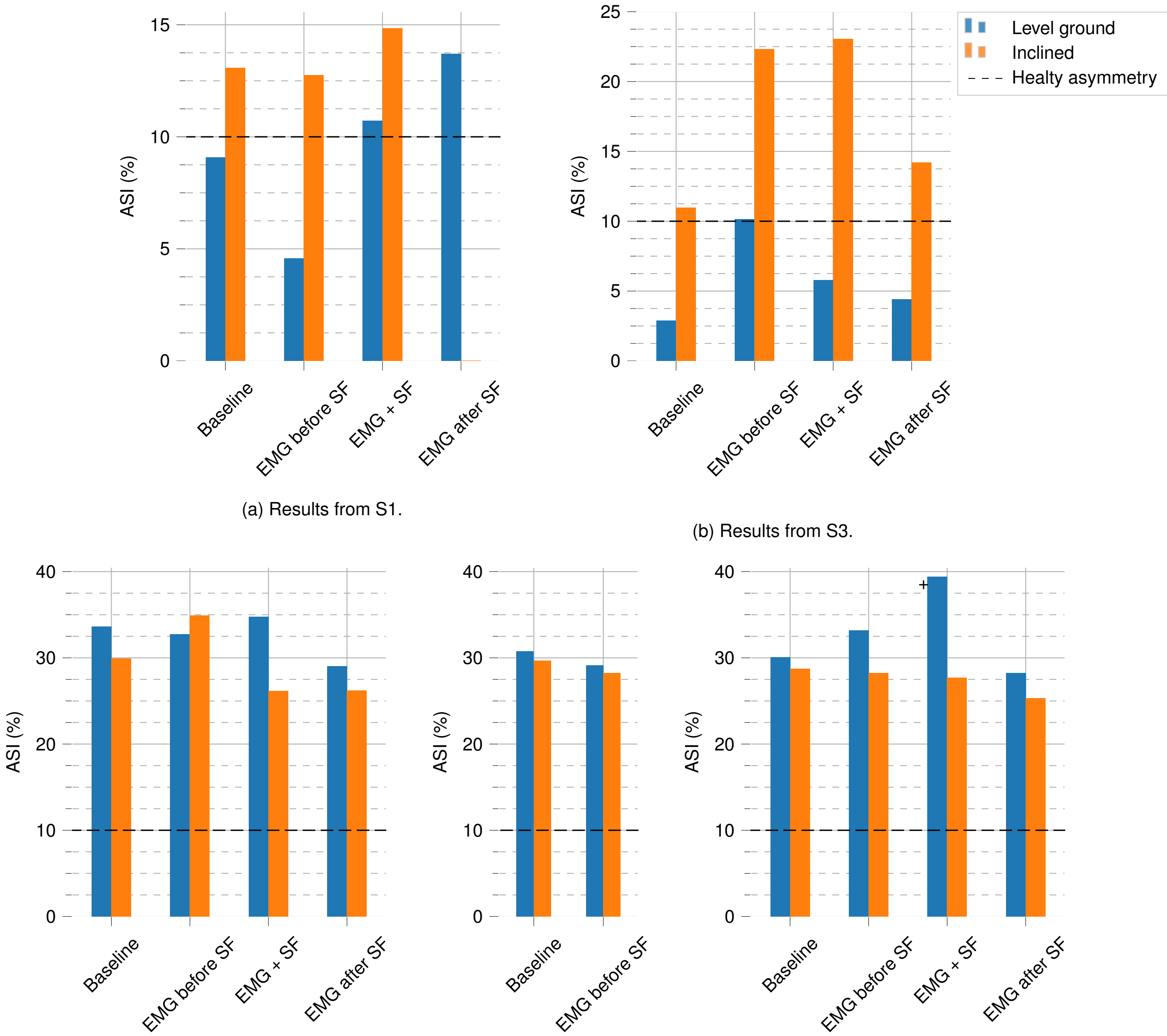
(a) Accuracy for discriminating individual feedback levels. Overall accuracy is 0.71.

(b) Accuracy for discriminating combined feedback levels. Overall accuracy was 0.91.

Figure 12: Confusion matrices of the feedback validation with scores of all subjects during the first session combined.

4.3 Gait analysis

The results of the gait analysis are shown in Figure 13. The ASI was calculated using the stance/swing ratio of the intact and prosthetic side. Generally, the asymmetry was higher than found for able-bodied subjects, though the results differed between the participants. No statistical tests were performed on the ASIs, due to the nature of the collected data from the treadmill. Subject S1 and S3



(a) Results from S1.

(b) Results from S3.

(c) Results from S2 of the first session.

(d) Results from S2 of the second session.

(e) Results from S2 of the third session.

Figure 13: Overview of the absolute symmetry index (ASI) score for each subject. A score of zero indicates perfect symmetry. The dashed line indicates the maximum asymmetry found in able-bodied subjects. SF = sensory feedback, + = prosthesis configuration was reset during this trial

showed a lower ASIs for level ground walking when compared to the inclined walking, see Figure 13a and Figure 13b. Subject S1 showed a decrease in asymmetry with the EMG control, especially in the level ground walking trial. However, in the third and fourth block, the asymmetry was increased again. All trials of this subject were performed for three minutes instead of two, and the subject got noticeably exhausted throughout the session.

The gait symmetry of subject S3 improved with the feedback during level ground walking, reaching a similar asymmetry degree as healthy subjects. The temporal asymmetry of subjects S1 and S3 increased with a few percentages when sensory feedback was added on top of the EMG control during inclined walking. Nevertheless, S3 showed a decrease in asymmetry in the last block, resulting in a lower ASI than the first EMG block.

The ASI of S2 tended to decrease during all sessions for both level ground walking as well as inclined walking. In the third block of the third session, during level ground walking, the asymmetry was increased. During this trial, the settings of the Power Knee were reset unintentionally, resulting in a non-customised configuration. After this trial, the user settings were applied again. The session was completed using the personalised settings, resulting in a lower ASI for both level ground and inclined walking.

4.4 Subjective measures

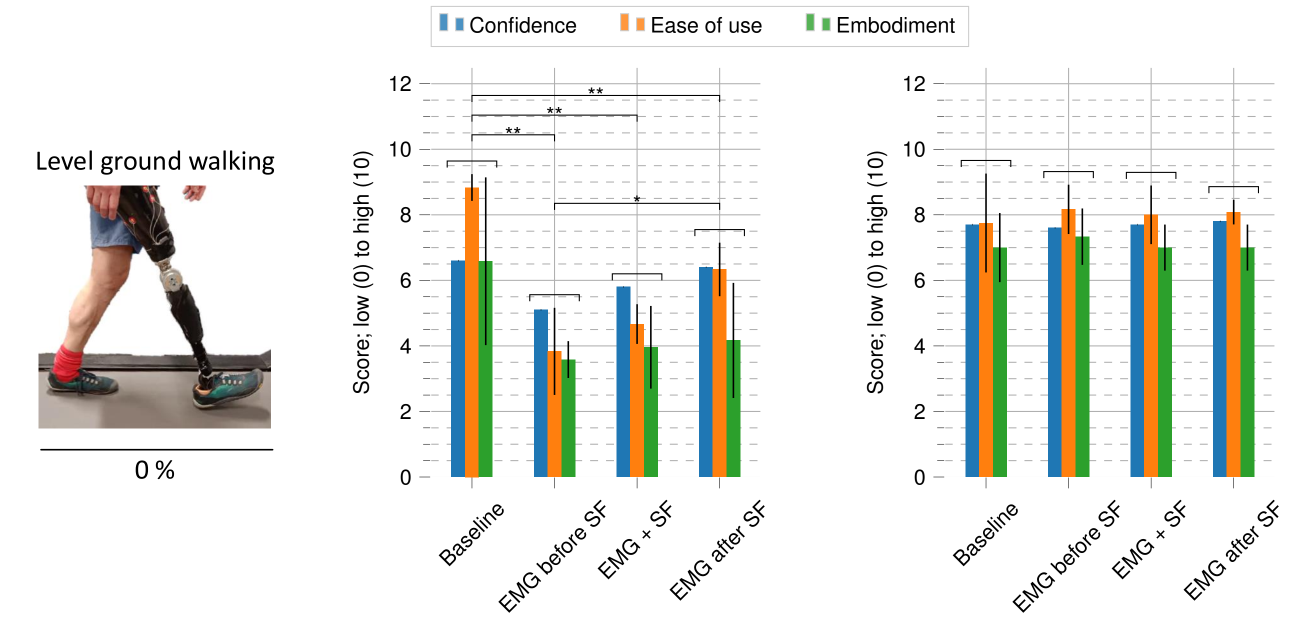
Questionnaires about confidence, cognitive workload, and prosthetic embodiment were filled out after each experimental trial. The results of all questionnaires were rescaled to a value between zero and ten. The scores for cognitive workload were inversed and are presented as 'Ease of use' in the following diagrams. A score of zero indicated low confidence, difficulties in use, or low prosthetic embodiment, whereas a ten indicated high confidence, simple in use, or high prosthetic embodiment. The scores of all questionnaires were combined to perform statistical tests between blocks and sessions.

The results from the recorded subjective measures of S1 and S3 are shown in Figure 14, while the results from S2 are shown in Figure 15. Subject S1 showed a significant decrease in psychosocial measures between the baseline and all other blocks during level ground walking, (baseline vs. EMG before SF: $W = 2.0, p < 0.001$; baseline vs. EMG + SF: $W = 2.0, p < 0.001$; baseline vs. EMG after SF: $W = 3.0, p < 0.001$). A significant increase was found between the EMG controlled blocks, 2 and 4, before and after the feedback was applied ($W = 0.0, p < 0.001$), see Figure 14a. No statistical differences were found for subject S3 during either level ground walking nor inclined walking.

Subject S2 showed a significant difference for level ground walking between the block with sensory feedback and the EMG controlled blocks without sensory feedback during the first session, where the psychosocial measures for the block with sensory feedback block were lower than the EMG controlled blocks (EMG before SF vs. EMG + SF: $W = 0.0, p < 0.001$; EMG + SF vs. EMG after SF: $W = 5.0, p = 0.002$), see Figure 15a. A similar pattern was found during level ground walking in the third session, where the subjective measures were rated significantly lower for the block with sensory feedback when compared to the other blocks (baseline vs. EMG + SF: $W = 0.0, p < 0.001$; EMG before SF vs. EMG + SF: $W = 0.0, p < 0.001$; EMG + SF vs. EMG after SF: $W = 0.0, p < 0.001$), see Figure 15c.

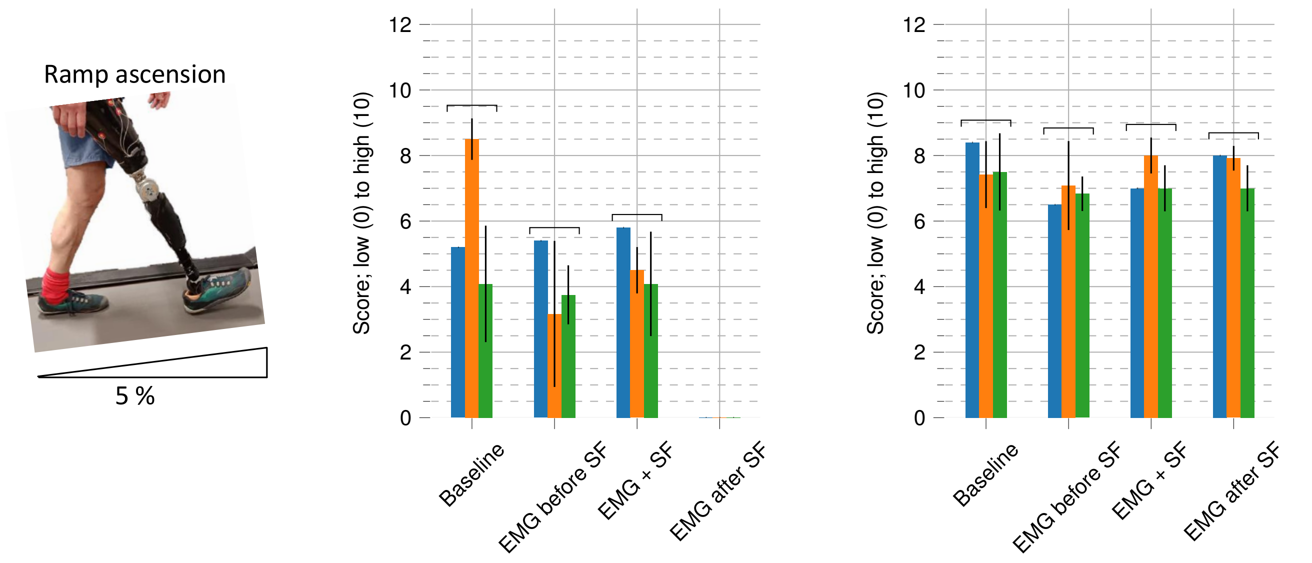
For inclined walking, a significant decrease in psychosocial measures was found during the first session between the baseline and the first EMG controlled trial ($W = 2.5, p = 0.002$) as well as between the baseline and the SF trial ($W = 0.0, p = 0.001$), see Figure 15d. No statistical difference was found during inclined walking between the baseline and the EMG controlled trial after SF had been taken away. During the first session, subjective measures were significantly higher in the last EMG controlled block when compared to the EMG controlled block before SF ($W = 5.0, p = 0.003$), as well as when compared to the EMG controlled block with SF active ($W = 0.0, p = 0.003$). During the third session, the psychosocial measures collected during the feedback block were significantly lower than all other blocks (baseline vs. EMG + SF: $W = 0.0, p = 0.002$; EMG before SF vs. EMG + SF: $W = 0.0, p = 0.002$; EMG + SF vs. EMG after SF: $W = 0.0, p = 0.002$), see Figure 15f. No significant differences were found during the second session, see Figure 15b and Figure 15e.

Subject S2 completed the baseline block and the EMG-controlled block before sensory feedback three times on three consecutive days. When comparing the subjective measurements recorded of these blocks, no significant difference was found for level ground walking. For inclined walking, a significant increase was found between the EMG controlled block of the first session and the two following sessions (EMG before SF, session 1 vs. EMG before SF, session 2: $W = 3.0, p = 0.005$; and EMG before SF, session 1 vs. EMG before SF, session 3: $W = 3.0, p = 0.005$. No significant difference was found between the baseline of each of the sessions, nor between the EMG controlled block of the second and third session ($W = 4, p = 0.34$). When comparing the walking trials with sensory feedback and EMG control after SF recorded on the first and third day, a significant increase was found for EMG control after SF during level ground walking ($W = 0.0, p = 0.007$).



(a) Results from S1 during level ground walking.

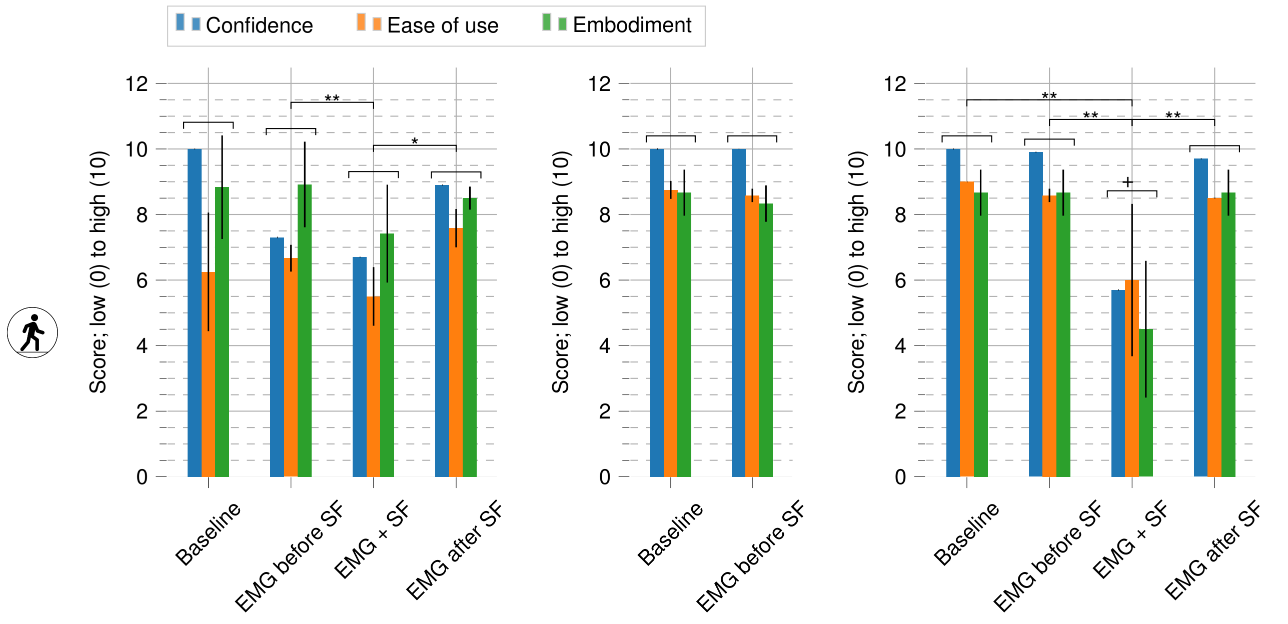
(b) Results from S3 during level ground walking.



(c) Results from S1 during inclined walking.

(d) Results from S3 during inclined walking.

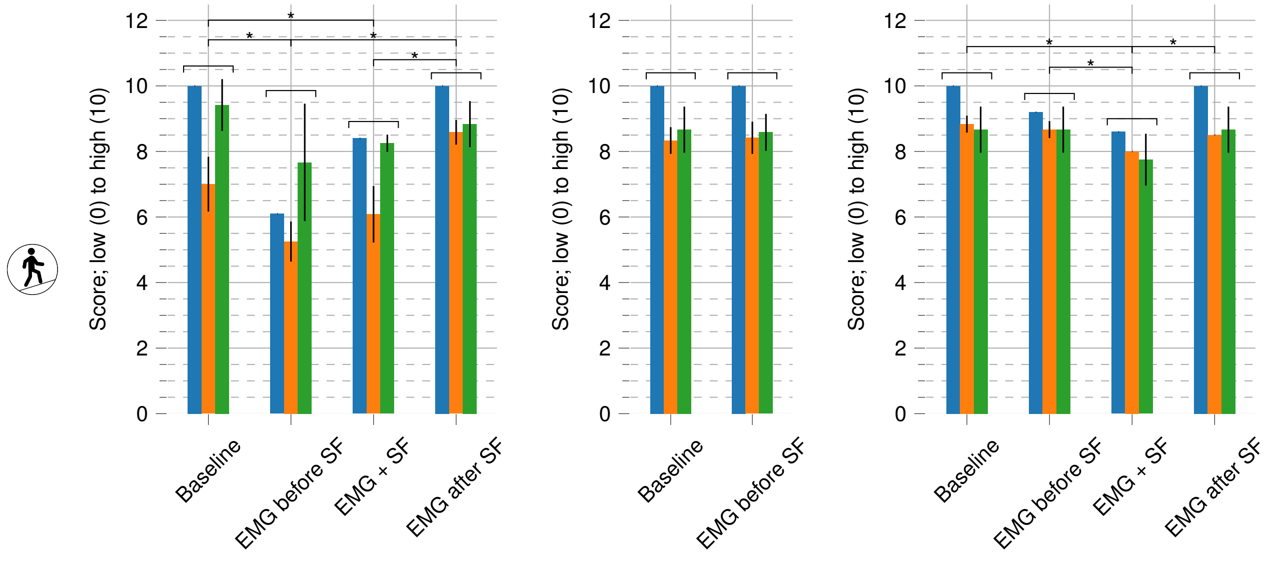
Figure 14: Overview of the results of the subjective measures recorded from S1 and S3. The horizontal bars with asterisk indicate a significant difference between all subjective measures in two blocks tested using the Wilcoxon signed-rank test (*, p<0.0083; **, p<0.001). SF = sensory feedback



(a) Results from S2 during level ground walking during the first session.

(b) Results from S2 during level ground walking during the second session.

(c) Results from S2 during level ground walking during the third session.



(d) Results from S2 during inclined walking during the first session.

(e) Results from S2 during inclined walking during the second session.

(f) Results from S2 during inclined walking during the third session.

Figure 15: Overview of the results of the subjective measures recorded from S2 during three sessions. In the second session, only the first and second block was performed. The horizontal bars with asterisk indicate a significant difference between all subjective measures in two blocks tested using the Wilcoxon signed-rank test (*, p<0.0083; **, p<0.001). SF = sensory feedback, + = prosthesis configuration was reset during this trial

5 Discussion

This thesis described the design and assessment of a novel bidirectional set-up that restores proprioception using vibrotactile feedback for EMG controlled lower limb prostheses. This is the first sensory feedback system that has been tested in conjunction with EMG controlled lower limb prostheses. The feedback system was able to deliver real-time vibrotactile feedback on muscle activities in the residual limb. The system was evaluated using gait analysis and subjective measures during level ground and inclined walking and was tested with three users, two who had a TFA, and one who had a TTA. The post-amputation time varied between 1 year and 24 years. The results varied widely between subjects, but generally, indicated that vibrotactile feedback has the ability to improve user confidence, cognitive workload, and embodiment as well as the symmetry of gait when using EMG controlled prostheses.

5.1 EMG signal

As seen in Figure 9, the sensory feedback was able to following the contractions of the muscles. The activation of muscles was processed into discrete feedback levels of increasing range, resulting in a minimal change in feedback level during gradual muscle contraction. This allowed the system to be comfortable, while clearly indicating the degree of contraction. The co-contraction present during this recording was considerable as the flexion muscle reached an activation over 50% of the MVC. The activation of the extensor muscle was much higher, over 200% of the MVC. Therefore, the difference between the muscle contractions was large enough and it did not considerably influence the control or the feedback system. In the event that substantial co-contractions are present, where muscles are contracted to a similar degree, the proposed feedback system could be helpful for learning to identify and to reduce such co-contractions. However, substantial co-contractions were not observed in this study and further research is required to explore the effect of proprioceptive feedback on co-contractions.

The vibrations of the vibrotactors influenced the EMG signals as shown in Figure 10 and 11. The disturbance was most pronounced in the electrodes measuring the flexor muscle activity. This could be caused by the increased pressure on the electrodes and the vibrator motors on the posterior side of the body. Another possible explanation is that the electrodes placed on the posterior side of the residual limb were placed in the same material as the brim of the socket. As the vibrator motors were placed between the brim and the liner, the vibration motors were pressed against the brim. It is likely that the activation of the vibration motors caused the material to vibrate locally and that these vibrations travelled through the material vibrating the electrodes in result.

Surprisingly, while contracting, the disturbance seemed to be largest on the electrodes measuring the extensor activity. The influence of the vibrotactors on the EMG signals while standing seemed to be less pronounced than while sitting. It is unclear how the vibrotactors affect the EMG signal quality during ambulation. The pressure of the vibrotactors on the residual limb changes during ambulation.

Simultaneously, the contact and pressure between the skin and the electrodes changes while ambulating. How both factors influence the EMG signal quality while moving needs to be researched further.

The level of noise generated by the vibrotactors also varied between users and is probably dependent on socket fit and vibrotactor placement. Verbal feedback from the users indicated that the feedback was 'spot on' when contracting. However, when resting after contraction, some of the vibrotactors stayed active even though no muscle contractions were measured. This 'random' activity only presented itself in subject S2. As the vibrotactors were placed further from the EMG electrodes in persons with a TTA, the noise generated by the vibrotactors in the EMG signal is presumably lower. For subject S3, the degree of noise was also recorded during rest, however, the level was much lower than for S2 (maximum 8 V). Another potential source of this 'random' activity is the generation of noise in the hardware or a miscommunication between the different devices. This could be investigated through logging the received bytearrays on the microprocessor chip. However, due to limited time, this was not realised. Nevertheless, these results clearly indicate that the EMG signal is affected by the vibrotactor activation and that it is necessary to reduce this noise.

5.2 Feedback validation

The result from the feedback validation indicated that the subjects were able to distinguish between the sensory feedback levels, see Figure 12. When combining the results from all subjects, an average accuracy of 71.3% was reached when identifying each individual level and an accuracy of 90.7% was reached when the levels indicating extension or flexion were combined. This was above the necessary 70% or 90% accuracy to continue with the experiment for individual and combined levels, respectively. Mistakes were most common between adjacent levels or with the minimum and maximum levels, where three vibration motors were activated simultaneously.

The feedback system was developed as an add-on to the EMG system, and it needed to be placed separately from the socket and liner. Therefore, repeatedly same placement could not be ensured and small changes between placement were inherent. Though, as seen with subject S2, the discrimination ability between levels did not differ significantly between sessions. As a result, small changes in placement can be overcome with retraining.

5.3 Gait analysis

The baseline ASI score of the subjects varied from 3% up to 34%, showing large differences between level ground walking and inclined walking, see Figure 13. Subjects S1 and S3 had an ASI around the asymmetry score found in healthy adults. Their ASI during level ground walking was generally lower than 10 %, while the ASI during inclined walking was higher than 10 %. As mentioned previously, S1 performed all walking exercises for three minutes instead of two, resulting in a higher fatigue. The increase of asymmetry during the last two blocks could be a result of this fatigue. Four to five percent of ASI score was dropped in the second block of level ground walking when compared to the baseline. This decrease shows a clear benefit of the EMG control for this subject, even though his subjective measures are significantly lower in this block. While the ASI increases during the following blocks, the subjective measures improve, showing an opposite pattern. In addition to these results, the subject verbally expressed that the feedback helped him with the timing of the push-off as well as with finding the necessary muscle activation for the push-off. As a result, he indicated that he was more effective in activating the push-off at a beneficial time without overactivating his muscles.

The ASI score of subject S3 increased with around 7% and 10% for level ground walking and inclined walking when using the EMG control compared to the baseline. Especially during inclined walking, the subject had some difficulties with fully extending the knee before heel strike with the EMG control. This subject was given more control over the prosthetic knee in swing phase than subject S2, which could result in these difficulties. However, after adding the feedback, the ASI dropped around 5% for level ground walking and remained at a similar level during inclined walking. After removing the feedback system, the ASI score dropped further for both conditions to a few percentage points higher than measured for the baseline. This subject did not have a lot of experience with EMG controlled prostheses and the improvement seen during the session could, therefore, be a result of a general learning effect. The feedback system might have played a beneficial role during this learning.

Subject S2 had a relatively consistent though slowly decreasing ASI score of about 30% during all sessions. The ASI score was slightly higher during level ground walking when compared to inclined walking. The subject verbally indicated that the incline helped him with the push-off. If he was able to benefit more from the push-off during inclined walking, this possibly resulted in more symmetry in gait during these trials. During and between the sessions, the ASI scores seemed to decrease with a few percentage points, resulting in the lowest ASI scores for level ground and inclined walking during the last EMG after SF trial. The EMG control and the sensory feedback system seemed to help decreasing the asymmetry below the baseline values. This indicates that learning retention takes place during and between the sessions. One outlier in these results is the ASI score measured during the EMG with SF during level ground walking in the third session. As indicated previously, the configuration of the Power Knee was reset and therefore, the knee went into full extension while walking every few gait cycles. As a result, the toes of the prosthetic foot hit the treadmill during swing when this happened. This incident shows the importance of personalised calibration of prosthetic devices to function properly.

5.4 Subjective measures

The results of the questionnaires measuring subjective confidence, ease of use, and prosthetic embodiment were presented in Figure 14 and Figure 15. Subjects S1 and S2 showed a decrease in subjective measures when comparing the baseline with the first EMG controlled trial during level ground and inclined walking, respectively, see Figure 14a and Figure 15d. This indicates that the use of myoelectric lower limb prosthesis decreased user confidence, embodiment, and ease of use, when compared to the baseline. Even though subjects S1 and S2 have elaborate experience testing these prototypes, the personal configuration and EMG control are still under continuous development and testing. Surprisingly, no statistical differences were found between the baseline and other trials during inclined walking for S1, level ground walking for S2, and all trials for S3. As a result, the effect of myoelectric control seems to have a varied effect on different subjects and activities.

With the addition of sensory feedback, the psychosocial metrics improved for S1 during level ground walking. When comparing the EMG controlled blocks before and after SF, a significant improvement was found even though the asymmetry was increased during this trial. The ASI score of subject S3 varied greatly during the session, while his subjective measures remained constant throughout the session. These discrepancies demonstrate the need for multimodal and interdisciplinary evaluation of prosthetic devices.

It could be hypothesised that the addition of sensory feedback decreases the simplicity of use as more information needs to be processed and integrated. This could be the cause for the decrease in psychosocial measures recorded from S2 during level ground walking in the first session, see Figure 15a. However, a similar pattern is not found during inclined walking in the first session. Specifically, during inclined walking, the psychosocial measures improved with the feedback and after the feedback was removed again. The subjective measurements of the last trial of the first session differed significantly from the EMG before SF and EMG with SF trials in the same session. No significant difference was found between the baseline and the last trial. This indicates that this participant felt that he learnt to control the prosthetic device throughout the session possibly with the help of the feedback system. The participant reported that he felt the feedback occasionally on the side and back of his residual limb while ambulating. Subject S3, on the other hand, reported that he mostly felt the vibrations at the anterior side of his residual limb. Only when placing his hand on the stimulated area, he felt the vibration motors on the medial and posterior side of the limb while ambulating. Even though the feedback was not felt consciously at all times by these subjects, automatic integration of the feedback could have had a positive influence on the change in symmetry or psychosocial metrics.

5.5 Connection to literature

Controlling a powered prosthesis with EMG can be a difficult task, especially when it has been a long time since the amputation has taken place. Yet, improvement can be made and sensory feedback seems to be a promising tool to facilitate this process. As presented in the results, learning is retained and continued even after the feedback system has been removed as both subjective measures as well as gait symmetry tend to improve within sessions as well as between sessions. Štrbac et al. (2017) found that electrotactile feedback improved routine grasping throughout various sessions in myoelectric upper limb prostheses. Learning was retained within and between sessions, reducing the performance difference between the trials with and without feedback. Though it is not certain whether such learning would be retained over longer time without regular retraining with feedback. Helm and Reisman (2015) showed increased gait symmetry in stroke patients using a split-belt walking paradigm. Long-term effects were sustained through repetitive short training sessions. Basla et al. (2022) demonstrated the benefit of electrotactile feedback of knee angle as well as pressure areas on the sole on user confidence and gait symmetry. This was validated through several evaluation of CYBATHLON challenges over the course of several years.

Even though not all previous studies included participants with a LLA, the observed learning effects of this thesis are similar. The improvement in control and subjective view seen within and between sessions is likely to be sustained through repetitive and regular retraining. However it remains unclear whether sensory feedback should be available as a training tool or for everyday use; user preferences also remain elusive. The feedback system could be designed as an add-on as done in this study, or further integrated with the prosthetic devices. Further studies focusing on learning retainment and multimodal effects of sensory feedback need to be completed in order to get a better overview of the costs and advantages of such systems.

5.6 Validation of hypotheses

Based on the results presented above, the formulated research questions and accompanying hypotheses will be answered and assessed. First, the effect of proportional EMG control is assessed when compared to standard control methods. Temporal gait asymmetry decreased non-significantly in six out of the ten trials. Psychometric measures decreased significantly in two out of the ten trials, demonstrating the possible increase in difficulty of use.

Secondly, the added benefit of vibrotactile feedback for proportional EMG control is compared to the EMG control and the baseline. The ASI was lower in two out of the eight trials when comparing EMG + SF to the baseline and three out of the eight trials when comparing EMG + SF to EMG before SF. Five out of the seven trials showed a decrease in ASI when comparing EMG after SF to EMG before SF and six out of the seven trials showed a decrease in ASI when comparing EMG after SF to EMG + SF. When comparing EMG after SF with the baseline, four out of seven trials resulted in a lower ASI. The data of subject S2 were collected throughout several days and demonstrated a reduction of up to 6.7% in ASI. These results provide evidence for the validation of the hypotheses that sensory feedback can be used to reduce gait asymmetry and that learning is continuous and retained throughout several days.

When evaluating the psychometric measures, a significant decrease was found between the baseline and EMG + SF in four of the eight trials. Only three trials significantly decreased when the baseline was compared to EMG before SF. Psychometric measures from EMG after SF were significantly higher for two trials out of seven when compared to EMG before SF. Four trials out of seven showed a significant increase in psychometric measures when comparing EMG after SF to EMG + SF. These results present evidence to accept the presented hypotheses that the addition of SF improves the subjective experience and that acquired skills are retained. When comparing the EMG after SF condition with the baseline, only one trial showed a significant decrease in psychometric measures.

When comparing sessions, the subjective performance of the EMG controlled prosthesis improved significantly in three of the five trials, confirming the hypothesis that SF improves psychometric measures and learnt skills are retained within and between sessions.

From the results described in Section 4.1, it is clear that the activation of the vibrotactors influence the EMG signal in rest and to some degree during contractions in static positions. However, it is unclear to what extent the sensory feedback affects the EMG signal during ambulation. In the following section, the limitations are explored further and ideas on how to improve the presented prototype are discussed.

5.7 Limitations

A major limitation of this study is the number of participants tested. In the field of prosthetics, it is hard to find an adequate number of participants that is representative of the population of people with an amputation. The user needs and characteristics vary widely between amputation cause and activity level. As a result, it is hard to generalise results gathered from subgroups to the entire amputee population.

The subjective sensation of the vibrotactile feedback varied between type of amputation. Subject S1 was able to feel all vibrotactile levels while ambulating. However, subjects S2 and S3 reported that the feedback sensations were falling to the background. Subject S3 reported to feel the vibrotactors at the front sometimes or when focusing on it. For individuals with a TFA, the vibrotactors were placed at the brim of the socket. Therefore, the vibrotactors do not have much space to move and activate the skin receptors. The pressure on the vibrotactors is also higher for subjects with a TFA, when compared to TTA, due to this difference in placement of the vibrotactors. It is speculated that the area around the brim is less sensitive than other parts of the residual limb as pressure and friction forces are applied daily to this area by the prosthetic device. Therefore, another area might be more suitable for vibrotactile stimulation. However, this needs to be explored further.

In general, EMG signals are known to be noisy. The EMG signals vary throughout the day and the quality is influenced by the skin contact, muscle fatigue, electrode movement, etc. It is unclear to what extent these factors influence the EMG signal quality and thus the control of the powered prostheses. In addition to that, it is practically impossible to repeatedly place the liner and socket in exactly the same place. As a result, the electrode locations vary slightly between days, influencing signal quality. Another variable factor is the residual limb size. Through muscle contractions, blood flow to the residual limb increases, resulting in an increased limb size. As a result, the skin is pushed against the electrodes and this could result in better electrode contact over time. On the other hand, muscle fatigue increases over time and reduces the signal quality. Therefore, it is probable that the signal quality increases during the first part of the session, but later decreases with muscle fatigue.

Aside from the vibrotactile feedback, the vibration motors generated auditory output while activated. Depending on the surfaces the motors were vibrating against, as well as the duration the motors were active, the auditory effect was more or less audible. During the experiments, the subjects were not shielded from this additional feedback as it might help them interpret or use the vibrotactile feedback. As the prostheses used during these experiments were active prostheses containing a motor, the prostheses themselves also generated audible noise. Therefore, it is not certain to what extent the audible effect of the vibrotactors was perceptible as well as to what extent this additional form of feedback was used by the subjects.

Furthermore, the duration that the vibrotactors were activated, varied between -0.7 and 1.5 ms of the actual programmed duration. In addition to this varying duration, the voltage supplied to the vibration motors depended on the remaining voltage of the connected battery. This battery was charged before each session. Yet, as a result, the feedback was not always of a similar strength. Whether this variability changed the perception of the vibrotactile feedback or the perceived feedback level is uncertain. The sensations could also differ between sessions or throughout sessions, due to for example small displacements of vibrotactors caused by muscle movement and shape change of the residual limb.

In addition to limitations regarding the vibrotactile feedback and the EMG signals, there were some limitations regarding the measurement tools used in this study. For the objective analysis of gait evaluation, the Zebris FDM-T gait analysis system was used. Unfortunately, this system compiled all data of a single recording and only reported the average values. Therefore, it was not possible to analyse individual gait cycles or symmetry variance throughout the experiment. It also prevented us from performing statistical tests on the collected results. In further studies, it is recommended to use a system in which individual gait cycles can be identified and analysed. Then, occasional irregularities may be found through qualitative evaluation in addition to general asymmetry evaluation calculated with the SI.

Further, it is unclear to what extent fatigue and learning effect influenced the results in this study. Subject S1 clearly showed signs of fatigue throughout the experiment and as a result, the last block was ended prematurely. The duration of the trials with the other users were also reduced from three to two minutes to prevent fatigue in the other users. In addition to fatigue through experimental procedures, general user fatigue and the amount of sleep influences the learning capabilities of user. As no measures were recorded regarding sleep or wakefulness, no conclusions can be drawn regarding the influence of this on the experiments.

Finally, the lack of comprehensive literature makes comparison of results exceedingly difficult. While some aspects of the present work, such as learning dynamics and sensory feedback, are relatively well-documented in literature, other aspects, are lacking. Concretely, the effects of frequency and duration of feedback on learning over time. Further, EMG control in lower limb prostheses is inadequately researched. Lastly, the combination of EMG control and sensory feedback is almost entirely unstudied.

5.8 Future research

Based on the current study and literature review, the following two main research directions can be identified: first the current prototype can be developed further to improve EMG signal quality, increase robustness, and to improve the usability of the system; secondly, further research can be targeted towards identifying the multimodal effects of sensory feedback and EMG controlled prostheses on a wider population and in more challenging environments.

5.8.1 Feedback prototype

The current prototype needs to be developed further in order to make it more robust and to improve the usability of the system. Several aspects of the prototype have been identified that need to be improved: 1) EMG signal quality; 2) EMG control; 3) vibrotactor placement; 4) feedback integration.

First, EMG signal quality could be improved further. EMG signal quality is known to be noisy and it has been shown that the EMG signals are influenced by electrode movement, sweat, and skin contact. Especially skin contact could be improved through an adjustable socket. With the use of EMG signals, muscles in the residual limb are activated more and there is an increase in blood flow. As a result, the socket becomes tighter. A size adjustable socket could keep the skin contact at a constant level throughout a day and be more comfortable for the user.

Another aspect that could be improved is the variability in electrode locations. The electrode locations are slightly different after each donning and therefore it can be hard to get a good quality signal that is consistent with previous signals. One solution would be to integrate multiple electrodes into the liner and socket instead of customising the location for each user. Then, the locations with the highest signal quality could be selected for the EMG control automatically. As a result, the system would be more adaptable if the muscle mass changes, or when the liner is donned slightly rotated. The system would also be more generalisable between users as locations would not have to be selected for each individual before creating the liner and socket, resulting in a cheaper system.

Secondly, the EMG control of the powered prostheses could be improved. The noise and variability of the EMG signal could be reduced by using an average of a rolling window. The control and feedback would become less reactive as a result of this, whether this negatively influences the system needs to be studied. Another aspect of the EMG control consists of the continuous need for recalibration. As the signals can vary significantly between days and throughout days dependent on fatigue, and signal quality, there is a need for automatic and simple recalibration of the control. Such automatic recalibration could be implemented through storing the maximum and minimum values of muscle contraction during a specific window as the MVC and rest values, respectively. Using the direct EMG control, co-contraction could also be used as an indication to stiffen a joint.

Additionally, the safety of the EMG controlled lower limb prostheses needs to be researched. Specifically, to what proportion the addition of direct EMG control benefits the user and how to guarantee the safety of both the user and the electronic components. It needs to be defined what configuration is most appropriate for a user and this needs to be easily adaptable. Furthermore, the electrical connections of the device need to be verified. In our system, the user was grounded to the powered prostheses through the EMG system. As a result, the prostheses turned off when the user received a static electric shock. The cause of this incident needs to be investigated in order to prevent the device from turning off unintentionally and/or frying electric components. The device needs to be electrically safe, and predictable in order to prevent falls.

Thirdly, the vibrotactor placement needs to be improved in order to increase both the signal to noise ratio of the EMG signal as well as the ease of use. The current system was designed as an add-on to the available EMG controlled prostheses. However, as repeatedly similar placement of the vibrotactors was not guarantueed and the space for placement was limited for subjects with a TFA, we propose to integrate the system with the current prosthetic device. If vibrotactors could be integrated with the prosthetic socket, the placement would be more consistent and donning and doffing would be easier.

As described before, the skin area around the brim is assumed to be less sensitive than other areas on the residual limb. By integrating the vibrotactors in the socket, other areas could be stimulated that are more sensitive. More sensitive areas would require a shorter vibration duration, and therefore the battery could last longer. The areas could possibly be matched with phantom areas in order to create more somatotopical stimulation. The circular position of the vibrotactors seems intuitive and discernible in the current set-up. The positions of the vibrotactors could be more personalised by using a proportional circular positioning of the vibrotactors. Guemann et al. (2019) presented that different locations of vibrotactor stimulation were more distinguishable in upper limb of able-bodied participants using such proportional circular positioning compared to absolute circular positioning. Whether the same applies for the residual lower limb after amputation needs to be investigated.

Another important aspect to investigate is the interference of the vibrotactors on the EMG signal. This could be reduced by decreasing the strength or activation duration of the vibrotactors. However, this would reduce the perceivability of the feedback by the users especially when focusing on other tasks. In the current set-up, the users with a TFA already reported that they barely felt the vibrations while ambulating. Therefore, reducing the strength further does not seem promising. Another solution would be to change to placement of the vibrotactors such that they are placed further away from the EMG electrodes and do not vibrate the socket. An option that was considered was to stimulate the intact limb or hip instead of the residual limb. Nevertheless, this would make the system less intuitive and decrease the usability as multiple systems need to be placed in several places.

The most promising option seems to be to integrate the vibrotactors in the socket. This would increase the usability of the system as it would be possible to don and doff the system directly as a whole. However, when integrated, it needs to be studied how EMG signal acquisition can be shielded from the vibrotactile stimulation. Furthermore, it should be avoided that too much pressure is applied onto the vibrotactors by the socket in order to make sure that the feedback is still perceivable and to prevent the socket from vibrating. A viable strategy would be to create holes in the socket with soft placeholders for the vibrotactors, such that the vibrotactors are able to move freely without touching the socket directly. For such design, other types of vibrotactors need to be tested that are smaller. The locations of the vibrotactors would also need to be above the vacuum to not compromise the suspension method of the prosthetic device.

Finally, the feedback system as a whole could be integrated more with the other prosthetic components. In the current system, both the feedback system and the EMG system need to be calibrated manually. The EMG signals are also processed separately after the initial preprocessing. The system could be more efficient when the feedback system is more integrated with the EMG signal. Though, this would probably reduce the adaptability of the feedback system, it is supposed to increase the usability of both systems together. In order to integrate the systems, more communication is needed. Therefore, it would be necessary to connect both control boards and convert the code of the microprocessor of the feedback system to C. This would not only improve the communication, it would also increase the processing speed of the EMG signals and thereby reduce the iteration time and the variability of the vibrotactor stimulation.

The feedback system needs to be tested for a longer time to investigate the long-term use of the vibrotactor feedback to test for skin irritation and sensitivity over time. A method also needs to be implemented to turn off the feedback. In the current set-up, the feedback can only be turned off by disconnecting the battery, or by changing the code on the microprocessor. Therefore, it would be advantageous to implement a power button to turn off the feedback. The feedback should also turn off automatically when the microprocessor has not received EMG signals for a specific amount of time, for example due to an empty battery of the EMG system. The power connections to the vibration motors could be made more stable to reduce the variability in feedback strength. Finally, the battery of the feedback system needs to be tested to know how long the system can run under which circumstances.

5.8.2 Sensory feedback

Future research in providing vibrotactile feedback that is not specifically targeted towards the described feedback system, should be aimed at identifying the general multimodal effect of sensory feedback, the long-term learning retention, and finally, other possible paradigms.

Primarily, the general effect of vibrotactile feedback for EMG controlled lower limb prostheses needs to be researched in a representable population of people with a major lower limb amputation. Then, specific target groups that would benefit from such intervention could be defined. Research could also indicate where knowledge would be transferable to other populations and use-cases for example in stroke patients, or in exoskeleton use. In order to get a clearer overview of the effects of vibrotactile feedback for everyday life, a wider variety of experiments need to be performed. Such experiments could include ascending and descending stairs and slopes, sit-stand transitions, CYBATHLON challenges, and more. Furthermore, a wider range of metrics would improve the knowledge on the multimodal effects of vibrotactile feedback and EMG control. Measures that could be recorded throughout training periods include phantom limb pain intensity and frequency, residual limb volume, muscle control, co-contraction levels, confidence, workload, oxygen consumption, prosthesis embodiment, gait symmetry, and other physiological and psychosocial metrics.

In the second place, the long-term learning retainment needs to be investigated in order to define whether a sensory feedback system is most appropriate for training purposes or for everyday life. This is best researched with multiple groups for comparison over a timespan of days to months. Such research would indicate the additional benefit from using the device for training only or everyday purposes and would demonstrate the magnitude of effect. The results could then be used to further argue the integration of such a device into daily prostheses or training programs and for the reimbursement of costs by insurance companies.

Finally, other types of signals could be communicated through similar vibrotactile feedback paradigms. For example knee or ankle angle could be communicated through the same vibrotactile feedback paradigm for non-EMG controlled prostheses. Another option would be to add feedback about touch to heel or toe areas of the prosthetic foot. Such paradigms should be developed further and the potential additional benefits need to be studied separately as well as in combination with the current proprioceptive feedback. Other types of sensory feedback could also be considered. For example, electrotactile feedback or invasive intraneural stimulation have been used in non-EMG controlled lower limb prostheses.

6 Conclusion

Lower limb amputation has a multifaceted effect on an individual's life. Contemporary prostheses intend to facilitate users' active participation in society. Yet, there is a lack of powered prostheses, resilient and adaptive control strategies, and bidirectional communication between the user and the prosthetic device. This thesis presented the design and pre-clinical evaluation of a prototype that aims to mitigate these shortcomings. A bidirectional vibrotactile feedback system for proprioception was developed as an add-on to a proportional direct EMG controlled powered knee or ankle prosthesis. The developed prototype was tested by subjects that had either a transfemoral or transtibial amputation during level ground and inclined walking. Experimental sessions included recording of objective measures concerning temporal gait symmetry as well as subjective measures regarding confidence, cognitive workload, and prosthetic embodiment. In general, the addition of the described sensory feedback system tended to improve both temporal gait symmetry and psychosocial metrics. The subjects showed learning retention within and between sessions, demonstrating the added benefit of using a sensory feedback system during rehabilitation training. Overall, the benefits of direct EMG controlled prostheses combined with sensory feedback are promising in the mitigation of current shortcomings of lower limb prostheses. Further development should be directed towards integrating such feedback system with prosthetic devices to increase device and signal robustness. Future clinical evaluations are required to assess the benefit of a bidirectional prosthesis during challenging diverse activities and to identify the sustainability of the learning effect.

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Appendices

Appendix 1 Subjective measures

A.1.1 NASA Task Load Index

User ID: ______ Block: ________ Activity: _______ Date: ________

Figure 8.6

NASA Task Load Index

Hart and Staveland's NASA Task Load Index (TLX) method assesses work load on five 7-point scales. Increments of high, medium and low estimates for each point result in 21 gradations on the scales.

Name	Task	Date

Mental Demand How mentally demanding was the task?

Very Low Very High

Physical Demand How physically demanding was the task?

Very Low Very High

Temporal Demand How hurried or rushed was the pace of the task?

Very Low Very High

Performance How successful were you in accomplishing what you were asked to do?

Perfect Failure

Effort How hard did you have to work to accomplish your level of performance?

Very Low Very High

Frustration How insecure, discouraged, irritated, stressed, and annoyed wereyou?

Very Low Very High

A.1.2 Prosthesis Embodiment Scale for Lower Limb Amputees

User ID: ______ Block: ________ Activity: _______ Date: ________

Prosthesis Embodiment Scale for Lower Limb Amputees (PEmbS-LLA)

□ I have put on my prosthesis.

Instruction: Please make sure that you can look directly at your prosthesis (for instance, by wearing shorts). For each of the following statements, please indicate how much you agree or disagree with it. If you agree with the statement, mark one of the positive numbers (1, 2, 3): the more positive the number, the more you agree with the statement. If you disagree with the statement, mark one of the negative numbers (-1, -2, -3): the more negative the number, the more you disagree with the statement. You should select the zero (0) only if you neither agree nor disagree with the statement. Please reply spontaneously, without thinking twice, and do not skip any statement. There are no right or wrong answers.

Please look at your prosthesis for about 60 seconds.

□ I have looked at my prosthesis for about 60 seconds and I am ready to continue.

		strongly disagree						strongly agree
1.	I feel as if I was looking directly at my own leg, rather than at a prosthesis.	-3	-2	-1	0	1	2	3
2.	The prosthesis belongs to me.	-3	-2	-1	0	1	2	3
3.	It feels as if I had two legs.	-3	-2	-1	0	1	2	3
4.	The prosthesis is my leg.	-3	-2	-1	0	1	2	3
5.	The prosthesis is a part of my body.	-3	-2	-1	0	1	2	3
6.	The posture of the prosthesis corresponds to that of a real leg.	-3	-2	-1	0	1	2	3
7.	My body feels complete.	-3	-2	-1	0	1	2	3
8.	The prosthesis is in the location where I would expect my leg to be, if it was not amputated.	-3	-2	-1	0	1	2	3

Please stand up and walk around the room for about 30 seconds.

□ If you are not able to walk around the room, mark here and skip the following items.

□ I have walked around the room for about 30 seconds and I am ready to continue.

		strongly disagree						strongly agree
9.	The prosthesis is moving the way I want it to move.	-3	-2	-1	0	1	2	3
10.	I am in control of the prosthesis.	-3	-2	-1	0	1	2	3

A.1.3 Confidence

Confidence

User ID: __________ Date: _________

Block: ________

Activity: _______

Please mark on the following scale how confident you felt during the task:

Extremely confident Not confident at all