

Providing time-discrete gait information by wearable feedback apparatus for lower-limb amputees: usability and functional validation

Simona Crea, *Member, IEEE*, Christian Cipriani, *Senior Member, IEEE*, Marco Donati, Maria

Chiara Carrozza, *Member, IEEE*, Nicola Vitiello, *Member, IEEE*

© 2015. Personal use of this material is permitted. Permission from IEEE must be obtained for all other uses, in any current or future media, including reprinting/republishing this material for advertising or promotional purposes, creating new collective works, for resale or redistribution to servers or lists, or reuse of any copyrighted component of this work in other works.

The DOI of the final edited version of this paper is: [10.1109/TNSRE.2014.2365548](https://doi.org/10.1109/TNSRE.2014.2365548).

Providing time-discrete gait information by wearable feedback apparatus for lower-limb amputees: usability and functional validation

Simona Crea, *Member, IEEE*, Christian Cipriani, *Senior Member, IEEE*, Marco Donati, Maria Chiara Carrozza, *Member, IEEE*, Nicola Vitiello, *Member, IEEE*

Abstract— Here we describe a novel wearable feedback apparatus for lower-limb amputees. The system is based on three modules: a pressure-sensitive insole for the measurement of the plantar pressure distribution under the prosthetic foot during gait, a computing unit for data processing and gait segmentation, and a set of vibrating elements placed on the thigh skin. The feedback strategy relies on the detection of specific gait-phase transitions of the amputated leg. Vibrating elements are activated in a time-discrete manner, simultaneously with the occurrence of the detected gait-phase transitions. Usability and effectiveness of the apparatus were successfully assessed through an experimental validation involving ten healthy volunteers.

Index Terms—Augmenting feedback, lower-limb amputees, vibrotactile stimulation, sensorized-foot insole, wearable technology.

I. INTRODUCTION

SOMATOSENSORY FEEDBACK provided by muscle and skin receptors in the leg is important for controlling balance and movement in humans [1]-[2]. Lower-limb amputees instead typically rely on haptic feedback from the stump-socket interaction to monitor ground contact and to stabilize balance. Unfortunately, skin irritation is common in the stump areas directly interacting with the socket resulting in poor haptic feedback and worsened gait performance [3]. Indeed, recent studies show that lack of adequate sensory information from a prosthetic leg leads to both poor balance and abnormal gait kinematics [4]-[6]. Amputees tend, for instance, to shift more weight and have a prolonged stance phase on the sound limb than on the prosthetic limb [7]-[9]. The abnormal kinematics and postural asymmetries can, in turn, lead to musculoskeletal diseases (e.g., osteoarthritis in the sound limb

[10]). Moreover, reduced sensory feedback increases the cognitive effort when using the prosthetic device [11], affecting its acceptability [12] and may reduce mobility [5].

The prospect of restoring dependable somatosensory feedback in patients affected by limb amputation and gait disabilities have inspired many research teams to develop technological aids [10]-[17]. Many of these were designed to enhance gait rehabilitation by providing signals that indicate that a certain biomechanically relevant variable is outside a pre-set range [18]-[25] and patients are instructed to pay attention to this during rehabilitation sessions. Other devices were instead conceived to be permanently used by patients affected by lower-limb impairments. Such devices encode a specific measured or computed variable (e.g., the foot-ground interaction force) into a specific stimulus (e.g., electrical stimulation on the thigh). Patients are expected to incorporate the stimulations into their body control scheme, with the ultimate goal to restore a more physiological walking pattern (e.g., more symmetrical) [26]. Fan *et al.* [27], for instance, developed a wearable system based on piezo-resistive force sensors under the prosthetic foot sole and pneumatically-controlled balloon actuators placed on the thigh. Usability of this system was validated with healthy volunteers, while only a pilot test was carried out with an amputee [28]. Sabolich *et al.* [26] presented a feedback system based on time-continuous electrical stimulations through electrodes placed inside the socket: the stimulus magnitude was proportional to the pressure recorded by force sensors under the prosthetic foot. Initial results showed that this system can restore a more symmetrical gait pattern. Orpyx® Medical Technology Inc. recently introduced a sensory substitution system that establish a relationship between force sensors under an instrumented shoe and vibrators placed on the user's back but the usability of this concept has not yet been tested [29].

Our objective is to introduce a novel feedback system for lower-limb amputees previously presented only in a preliminary form [30]. The system is embeddable into lower-limb prostheses and designed to convey sensory information from a prosthetic foot sole to the individual. It has been designed to be completely wearable, highly acceptable and with low encumbrance. It comprises a sensorized prosthetic foot sole, a data processing unit and three miniaturized vibrotactile (VT) units placed on the stump in skin areas

Manuscript received on September 24, 2013. This work was supported in part by the European Union within the CYBERLEGS Project FP7/2007-2013 under Grant Agreement 287894 and the WAY Project FP7/2007-2013 under Grant Agreement 287894. The work by C. Cipriani is also supported by the Italian Ministry of Education University and Research under the FIRB 2010 program (RBFRI0VCLD).

S. Crea, C. Cipriani, M. Donati, M.C. Carrozza and N. Vitiello are with The BioRobotics Institute, Scuola Superiore Sant'Anna, viale Rinaldo Piaggio, 34, 56025 Pontedera (Pisa), Italy. E-mails: s.crea@sssup.it, ch.cipriani@sssup.it, m.donati@sssup.it, carrozza@sssup.it, n.vitiello@sssup.it. S. Crea is the corresponding author.

N. Vitiello is also with Don Carlo Gnocchi Foundation, via di Scandicci, 269, 50143 Firenze, Italy.

minimally interacting with the socket [Fig. 1]. The VT units provide non-invasive, easily wearable and highly acceptable stimulations, and have been used for sensory feedback in upper-limb amputees [31], and are effective in both providing information to the user for manipulation control [32] and for inducing embodiment of a hand prosthesis [33].

The novelty introduced by this work is twofold: firstly, the feedback is provided in a time-discrete fashion, synchronously with specific gait-phase transitions detected through the sensorized foot insole. We propose a time-discrete strategy to avoid some limitations of time-continuous stimulation: time-continuous modulation of a tonic, high-power stimulation can be perceived as cumbersome and unacceptable by a user while adaptation is known to occur to low-power time-continuous stimulation [34]. In line with recent theories stating that the human brain is prone to control behaviours by processing and incorporating time-discrete somatosensory information in its internal models [32], [35]-[36], time-discrete stimulation is proposed to lead to the perception of a *rhythm* that the amputee can incorporate in his or her body control scheme and learn to associate with a physiological gait pattern, without having to pay continuous attention to the modulation of a time-continuous stimulation [37]. Secondly, we have investigated the capability of humans to spatially and temporally perceive and discriminate low-power vibrations in a dynamic condition, i.e., during ground-level walking. Only a few studies have investigated the perception of vibrations on the thigh [38]-[40], i.e., one of the least sensitive areas of the body. We also tested how delays in the wireless communication from the sensorized insoles (and consequently in the detection of the gait phase) affect the perception of vibrations. Finally, we analysed the most relevant temporal gait parameters—stance time, swing time and step cadence—to test if the mechanical stimulation of the surface nerves of the thigh could lead to undesired changes in gait biomechanics.

II. MATERIALS AND METHODS

In this section we describe the different modules of the proposed system. In particular, we overview: 1) the pressure-sensitive insoles; 2) the algorithm to process insole data in order to address the gait segmentation and identify the biomechanical events (i.e., heel-strike, flat-foot, and toe-off) that are then encoded in time-discrete stimulations through the VT units; 3) the VT stimulation units. This section is then completed with the description of the experimental protocol.

In the tested system the central processing unit (differently from the concept shown in [Fig. 1]) did not run on the same board driving the VT units but on a remote Windows 7 64-bit desktop PC. The data flow diagram of the system used in this study is explained in [Fig. 2(a)].

A. Pressure-sensitive insoles

The pressure-sensitive insoles used in this study were developed at Scuola Superiore Sant’Anna (Pisa, Italy), presented in [41], and used in previous experiments on gait segmentation [42]. Each insole comprises an array of 64

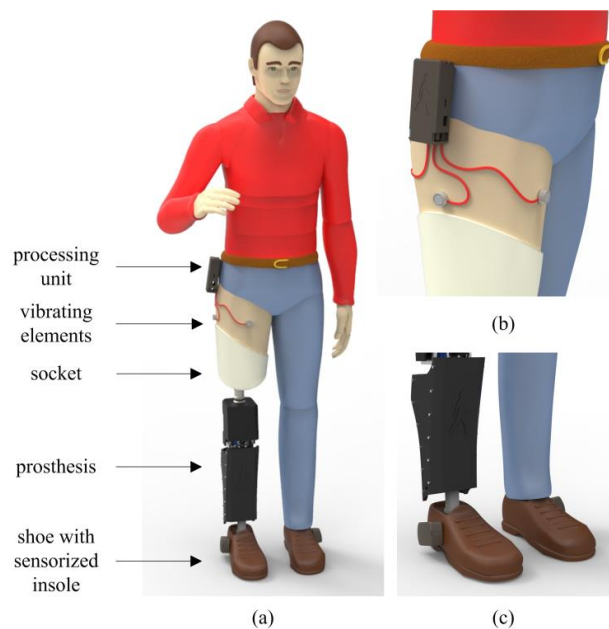


Fig. 1. Concept of the wearable feedback system. (a) Overview of the system. Data acquired from the pressure-sensitive insole are coded into time-discrete stimulations by means of vibrating elements placed on the stump. (b) Miniaturized vibrating elements are placed on the thigh inside the socket and driven by an electronic board attached to the belt. The board also runs the processing unit which records insole data and runs the algorithm for gait-segmentation and initiate the feedback events. (c) Shoe equipped with the pressure-sensitive insole. The electronic board housed in the plastic box outside the shoe communicates wirelessly with the processing unit.

pressure-sensitive elements. Each sensor of the array includes a light-emitting diode (LED) facing a photodiode as light receiver. These optoelectronic components were covered by a square-based pyramidal-frustum shell, made of opaque silicone, which deforms under the effect of a compressive force and, by means of an internal curtain, reduces the amount of light transmitted from the emitter to the receiver. This sensor showed high sensitivity to vertical loads, while low sensitivity to tangential loads. A detailed description of this technology was given in [43].

The array of sensors was connected to a custom electronic board, engineered by Robotech (Peccioli, Italy), and devoted to sampling (frequency 1.2 kHz), low-pass filtering (cut-off 40 Hz), de-sampling (ratio 12:1) and transmitting data over a Bluetooth connection to a remote processing unit, i.e., the above mentioned remote desktop PC equipped with Bluetooth receivers. The electronic board, Bluetooth communication module and battery of the pressure-sensitive insole were housed in a plastic case outside the shoe in order to avoid any discomfort or gait alterations. The total weight of each insole and its plastic box with electronics and battery was 162 g.

B. Processing of pressure-sensitive insole data

The 64 voltage signals from the pressure-sensitive insole were collected and real-time processed by means of a custom Labview routine (NI, Austin, TX, USA), that computed the values of the vertical ground reaction force ($vGRF$) and the x and y coordinates of the center of pressure (CoP_x, CoP_y). The x and y axes identify respectively the medial-lateral and antero-posterior foot sole directions; the y coordinate spanned

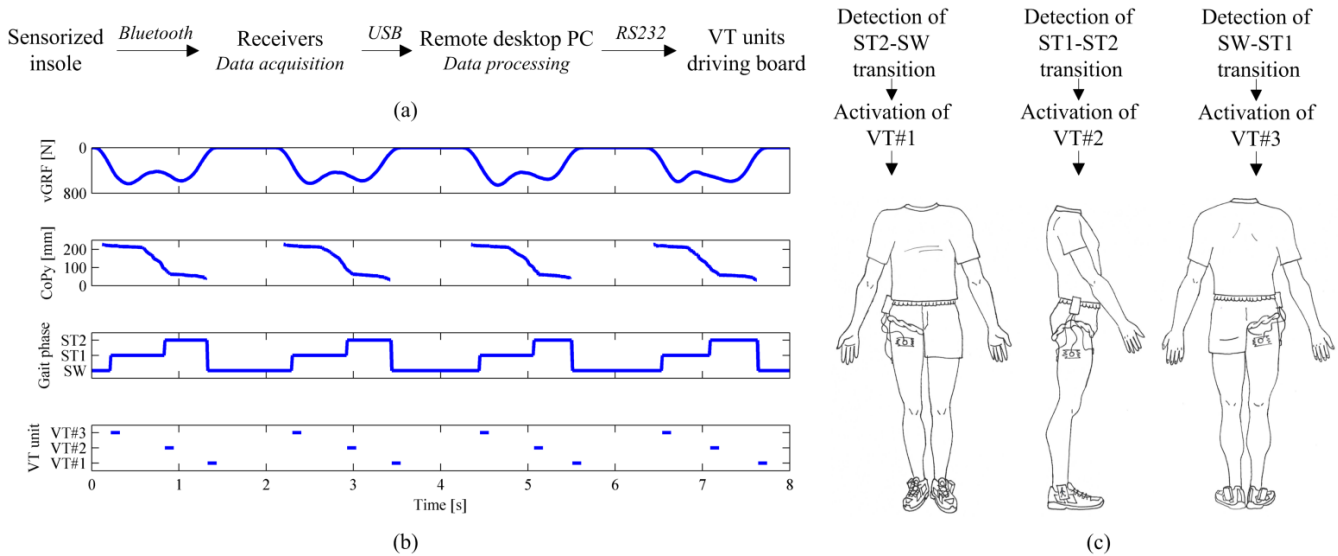


Fig. 2. Feedback strategy. (a) Data flow diagram. Data from the pressure-sensitive insole are sent through Bluetooth connection to the receivers. The remote desktop PC acquires data through a serial port and when detecting a phase transition commands the vibrator board to activate a specific VT element. (b) Gait segmentation running on the desktop PC. At gait-phase transitions (3rd panel from top) the host sends the commands to the corresponding VT element (bottom panel). (c) VT elements placement. VT#1 was placed on the rectus femoris belly and activated at ST2-SW transitions; VT#2 was placed on the vastus lateralis belly and activated at ST1-ST2 transitions; and VT#3 was placed on the biceps femoris belly and activated at SW-ST1 transitions.

0-250 mm corresponding to the toe and heel respectively.

Both $vGRF$ and CoP coordinates are biomechanical variables commonly used to segment the gait in phases [44]. We used them to segment the gait cycle into three phases [Fig. 2(b)], viz., ‘Stance 1’ (ST1), ‘Stance 2’ (ST2) and ‘Swing’ (SW), using the following criteria:

$$\begin{cases} CoP_x = CoP_y = NaN \rightarrow \text{phase: SW} \\ vGRF \geq 20 \text{ N and } CoP_y \geq 125 \text{ mm} \rightarrow \text{phase: ST1} \\ vGRF \geq 20 \text{ N and } CoP_y < 125 \text{ mm} \rightarrow \text{phase: ST2} \end{cases}$$

The proposed algorithm for gait-segmentation and command the vibrating elements is computationally efficient: 128 additions, 74 multiplications, 3 divisions and 4 numerical comparisons between double-precision floating-point numbers were used to calculate biomechanical variables and classify the gait phases while 2 additions and 2 multiplications were required to write the command to the serial port for driving the VT units. Accordingly, future implementations of the algorithm on a microcontroller will be easy, and the feedback system will be fully wearable.

C. Vibrotactile stimulation module

The three miniaturized VT units (Precision Microdrives, London, UK) each had a coin-like shape with 10-mm diameter, 10.2-mm height and weighed 3.6 grams. A custom electronic board controlled the vibrators to activate each VT unit independently. The electronic board was controlled from the desktop PC through a serial RS232 interface: given a command, VT units were activated within 2 milliseconds [45].

VT units were activated in a discrete manner in conjunction with the detection of gait-phase transitions, as shown in [Fig. 2(b)]. They produced vibrations at a frequency of 230 Hz, and were able to transfer a mechanical power of 600 mW to the thigh, with a peak force of ~ 1 N. They thus easily would activate Pacinian corpuscles [39], [40]. We confirmed in

pilot studies that healthy subjects indeed easily perceived the vibration during quite standing and that the selected stimulation amplitude, i.e., just above perception threshold, was never perceived as bothersome.

D. Experimental protocol

Ten able-bodied subjects (6 females) participated in the study: age 27 ± 1.8 ; weight: 64.5 ± 6.6 kg; height: $1.7.0 \pm 0.51$ m; foot size: 38–42 EU. They were asked to bring comfortable sportswear and athletic shoes. Both shoes were equipped with pressure-sensitive insoles [Fig. 3(a-b)] and they wore a belt housing the electronic board [Fig. 3(d)] for the control of the VT units [Fig. 3(e)], which were placed on the upper part of the right thigh [Fig. 3(c)]. Only signals from right insole [Fig. 3(c)] were processed online to detect gait events and deliver VT stimulations; the left insole served only for offline analysis of gait parameters.

Fig. 3(a) shows an overview of the feedback system worn by one subject during the experimental trials. VT units were secured to the thigh by means of silk seal tape. The entire equipment worn by the subjects neither hindered their movement, nor resulted in any discomfort.

Three VT units (labelled ‘VT#1’, ‘VT#2’ and ‘VT#3’) were placed on the longitudinal axis of the belly of the *rectus femoris*, *vastus lateralis* and *biceps femoris*, respectively [Fig. 2(c)], and were activated synchronously with the gait-phase transitions ST2-to-SW (i.e., *toe-off*), ST1-to-ST2 (i.e., *flat foot*) and SW-to-ST1 (i.e., *heel strike*), respectively. The duration of each time-discrete VT stimulation was set to 100 ms, i.e., long enough to be securely perceived and short enough to prevent VT unit activations to overlap.

The experimental procedures had two specific objectives: First, to test if subjects were able to detect vibrations applied on the thigh during walking and to what extent detection thresholds changed with increasing loss of synchronicity

between the VT stimuli and specific gait-phase transitions. Second, to test if subjects learn to associate gait-phase transitions not only temporally but spatially, i.e., that specific VT units were associated with specific gait-phase transitions.

To achieve these objectives, subjects were instructed to walk on a treadmill at a speed of 2 km/h once they were equipped with the feedback apparatus. All subjects first completed a 6 minutes *Training (T)* session to familiarize them with the equipment and to allow them to learn the association between gait events and VT elements. The following 4 experimental sessions (6 min each) all included 'catch trials', i.e., trials during which the standard activation pattern of VT units were deliberately modified, and the subjects were asked to alert the experimenter whenever they detected such an event. The catch trials were defined by a custom Labview routine that before each session randomly selected 30 transitions among the 600 in 200 consecutive steps with the only constraint that there should be at least one full step (i.e., 3 gait-phase transitions) between catch trials. The order of the experimental sessions were randomized for each subject.

- *Missing stimulation (MS)*: during this session, subjects were instructed to alert the experimenter by saying "No" if they detected that a VT stimulation was missing;
- *Missing stimulation with 200-ms delay (MS_D200)*: as for MS but in all VT stimulations were delayed 200 ms with respect to gait-phase transitions;
- *Missing stimulation with 500-ms delay (MS_D500)*: as MS_D200 but with a 500 ms delay;
- *Wrong stimulation (WS)*: as for MS but instead of omitting VT activations, an 'incorrect' VT was activated in catch trials.

Between each experimental session there was a 1-minute 'wash-out' during which the subject walked while receiving VT stimulation without any delayed, missing or wrong stimulation.

After the experiment, subjects completed a short questionnaire to score (i) their *cognitive effort* in identifying missing and wrong stimulations (score 1-5 for 'none', 'little', 'moderate', 'high', and 'very high') and (ii) the *quality of perception* of the different VTs (score 1 to 5 for 'none', 'poor', 'fair', 'good' and 'very good').

E. Data analysis

To evaluate the capability of the subjects to identify missing stimulations, we calculated the subjects' true and false positive identifications of the catch trials.

By means of one-way repeated-measures ANOVAs we analyzed the effects of delayed VT activation (i.e., sessions MS, MS_D200 and MS_500) on the total true and false positive rates for each VT unit and across all units. Post-hoc analyses with Bonferroni correction were performed when significant main effects were found.

Finally, to assess possible changes in gait as a consequence of the applied vibrotactile feedback we also calculated some temporal gait parameters. In particular we used data recorded from both insoles to calculate, for each step, the stance and swing duration, and the step cadence. One-way repeated

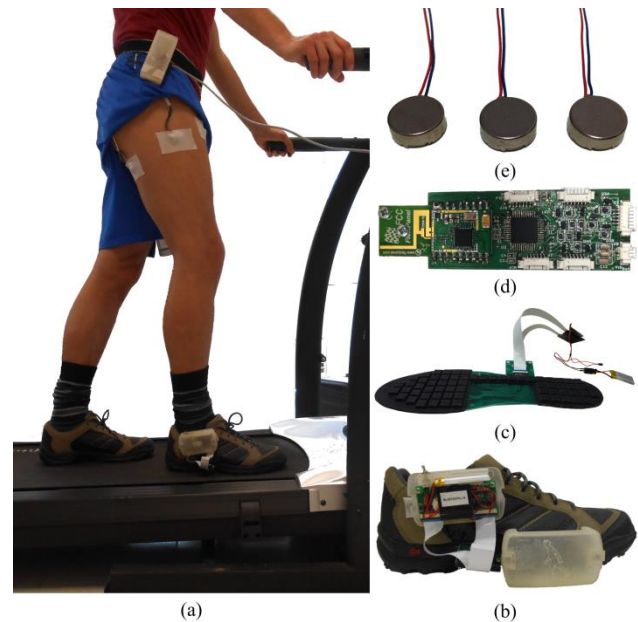


Fig. 3. Experimental set-up. (a) Overview of the experimental scenario. Subjects wore shoes, one equipped with two sensorized insoles, and a belt housing the electronic board which drive the vibrators, along with its battery pack. Vibrators were placed on the right thigh and fixed through silk seal tape. Subjects walked on the treadmill at 2 km/h. (b) Shoe instrumented with the pressure-sensitive insole. The box outside the shoe contains the electronic board which collect, pre-process and transmit wirelessly to the receiving unit the insole data; this box also contains the lithium polymer battery supplying the insole. (c) Overview of the pressure-sensitive insole. It is distinguishable the 64-element array. (d) The electronic board driving the vibrators. (e) Vibrating elements.

measures ANOVA with post-hoc paired t-test were used to test the statistical difference of gait parameters in the four experimental sessions.

$P < 0.05$ was considered statistically significant. All results are reported as mean \pm standard error of mean unless otherwise stated.

III. RESULTS

A. Recognition of missing stimulations

Results on the correctly-recognized missing stimulations were summarized in [Fig. 4]. The pattern in the aggregated data was identical in 7/10 subjects whereas 3 subjects showed the highest percentage of correctly recognized missing stimulations not in the MS session but in MS_D200; all subjects performed worse in the MS_D500 sessions.

There was a significant effect of delay on the percent total true positive responses ($P < 0.01$) with MS_D500 differing from both MS and MS_D200 ($P < 0.01$).

When considering individual VTs, the detection rates were for each VT significantly affected by the delay condition (MS, MS_D200 and MS_D500) but the patterns differed in a remarkable fashion [Fig. 4]. VT#1 and VT#2 showed similar trends, i.e., a monotonic decrease of the percent true positive with increased VT activation delays. In contrast, in all subjects, the highest detection rates of catch trials involving VT#3 was found in the MS_D500 sessions.

The false positive rate was very low in all conditions: 4.9 ± 4.3 , 5.6 ± 8.7 and 9 ± 7.9 for MS, MS_D200 and MS_D500,

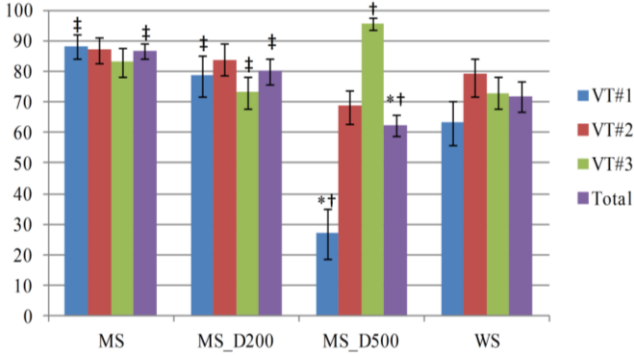


Fig. 4. Correct recognition of catch trials across the experimental conditions. Blue, red and green bars represent the average percentage of correctly recognized missing or wrong stimulations, respectively, of the VT#1, VT#2 and VT#3. 'Total' represents the percent correctly recognized catch trials across the three VT units. Standard error of mean is expressed through error bars.

*Significantly different from MS; † significantly different from MS_D200; ‡ significantly different from MS_D500.

respectively.

B. Recognition of wrong stimulations

The substantial true positive rate for detecting that VT units had been swapped was similar across VT units [Fig. 4], and the overall false-positive recognitions were across all VTs low, i.e., 1.5 ± 1.4 .

C. Gait patterns

Results on temporal gait parameters are shown in [Fig. 5]. Statistical results pointed out that in the four experimental conditions no change in temporal gait parameters occurred, neither for the right and left limb. In particular, for the right limb, one-way ANOVA revealed that stance duration (P-value=0.484), swing duration (P-value=0.329) and step cadence (P-value=0.662) did not change over the four conditions. Finally, from the comparison of gait parameters extracted from both left and right legs, there was no evidence of gait asymmetry.

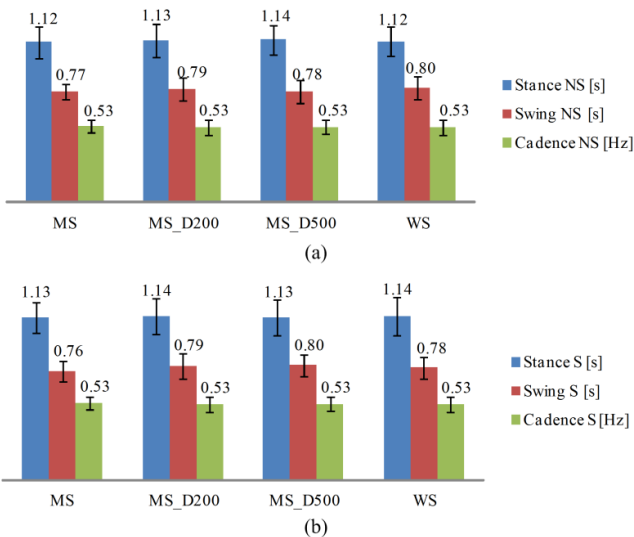


Fig. 5. Duration of the gait parameters in the four experimental conditions. (a) Temporal parameters calculated for the non-stimulated limb (NS). (b) Temporal parameters calculated for the stimulated limb. On top of the bars the average values of the stance duration, swing duration and step cadence are explicated. Vertical bars on top indicate the standard deviation.

D. Questionnaires

Table 1 presents the results of the questionnaires.

The self-assessed perception of each VT revealed that the VT#3 was the one better perceived by all of the subjects (4.2 ± 0.6).

IV. DISCUSSION

In this work we have presented a novel apparatus aiming at partially replacing somatosensory information useful for gait control in lower-limb amputees. Along with the description of the system working principle and implementation, we carried out experiments with healthy subjects from which we conclude that the system has excellent usability and that time-discrete low-intensity feedback is readily perceived by humans and potentially can assist control of gait kinematics.

A. Usability of the system apparatus

The proposed feedback system was designed with final application in mind, i.e., amputees. As such, we opted for a solution with very low encumbrance: the VT units can be easily inserted in the socket of transfemoral amputees and the pressure-sensitive insole under the prosthesis is transparent to the user. Moreover, providing low-intensity time-discrete stimulations minimize the risk of discomfort after extended usage. Indeed, the first outcome from the experimental activities is that all of the subjects could easily wear the apparatus and successfully walk: none of them reported any discomfort from wearing neither the belt equipped with the vibrators control box, nor the shoes with the pressure-sensitive insole, even after the execution of all the experimental trials.

Despite the wearability of the pressure-sensitive insole and vibrating units, the current implementation prevents amputees from using the system in activities of daily living given that data recording and processing were carried out by a PC. However, porting the gait segmentation algorithm to a micro-controller embeddable into the vibrators control box, will be a straightforward engineering task.

Finally, effectiveness and unobtrusiveness of the feedback strategy was also demonstrated by the results of the self-assessment questionnaires. All the VT stimulations were easily perceived and all tasks were judged as moderately demanding.

B. Synchronicity of the stimulation with relevant gait phase transitions affects perception

By designing the stimulation strategy of the feedback apparatus, we considered two main requirements for providing effective and unobtrusive stimulations.

First, we wanted to avoid the *adaptation phenomenon*, which usually results from prolonged mechanical stimulation of skin receptors [46]. For this reason, the time-discrete

Table 1. Self-assessment questionnaire.

Questions	Answer
Perceived effort in MS trial	3.2 ± 1.0
Perceived effort in WS trial	3.5 ± 1.1
Perceived increase in effort in MS_D200 & MS_D500 compared to MS	3.3 ± 1.3
Perception saliency of VT#1	3.0 ± 0.7
—" VT#2	3.4 ± 0.8
—" VT#3	4.2 ± 0.6

stimulation strategy was deemed appropriate to ensure the perception of stimulations without excessive excitement of the skin surface.

Second, vibrations of muscles can lead to excitation of muscle spindle afferents, and thereby alter proprioception and change gait biomechanics [47], and we therefore constructed a system delivering *low-intensity* vibrations.

However, the choice of using low-intensity vibrations, slightly above the perception threshold, was not risk free. First, it is well known that perception thresholds of mechanical stimulations on the skin changes from static to dynamic conditions [48]. Movement-induced decrease in sensitivity to cutaneous stimulation has been demonstrated repeatedly, for instance with respect to skin stimulation of both the hand [49], and the foot in dynamic conditions (e.g. during standing, walking and running [50]). Second, the threshold to detect task-irrelevant stimuli has been reported to vary dynamically during the step cycle [51]. To address these issues, we had to assess that the vibratory stimuli were actually perceived in dynamic conditions, i.e., during walking, and not 'filtered' away as task-irrelevant. The results from MS, provide strong evidence that even with low intensity stimuli healthy subjects after just a few minutes of training (i.e. around 6 minutes), readily perceived the stimulations and, importantly, readily detected when expected stimuli were not delivered (notice that the false-positive responses was on average 5/600, i.e., the subjects readily recognized the presence of practically every single VT activation). We also had to assess the perception of stimuli when vibrations were delivered at various moments during the step cycle, i.e., with delays with respect to the gait-phase transition in the MS sessions (i.e. 200 or 500 ms). Long latencies can under some conditions be expected with Bluetooth devices. Low-power Bluetooth devices for example, usually have latency time around 20 ms [52] with peaks up to 150-200 ms [53], [54]; moreover, when those kind of systems interfere with other wireless networks (e.g. WLAN networks) they can be affected by additional communication problems and consequently delays. Although wireless systems are rarely affected by communication delays longer than 200 ms, we investigated the worst possible scenarios, i.e. 200 and 500 ms. In addition, poor synchronicity between the actual gait events and the delivered feedback may, of course, be confusing to an end-user (visuo-tactile inputs are behaviorally 'synchronous' in multisensory integration tasks if the delay between them is <300 ms, [55]).

When the feedback was delayed 500 ms with respect to the corresponding gait-phase transitions, subject made more mistakes except for the catch trials involving VT#3 (Fig. 4). Interestingly, the three skin nerves stimulated by the three different VT units, respectively, have been reported to be subjected to different gating mechanisms during step cycles [51]. Given a gait cadence of about 0.5 Hz and a stance time of more than 1 s (Fig. 5), a 500-ms delay cause VT#1 and VT#2 to vibrate during either the initial or mid part of the swing phase, and VT#3 in the mid-stance phase, the latter being a phase in which somatosensory inputs from the standing limb are less affected by any masking effect deriving from concomitant afferent signals from the contralateral limb.

In short, the proposed feedback system can deliver information about the timing of gait-phase transitions in a reliable and effective manner and appears to be able to achieve this also in the presence of significant communication delays (≤ 200 ms).

C. Different gait-phase transitions were mapped on vibrating elements placed on different thigh sites in order to enrich the information conveyed to the subject

The effectiveness of a feedback system aimed at conveying information related to both the timing and the occurrence of a specific gait-phase transition relies on the capability of the subjects to identify the spatial location of the stimulation. To address this we conceived the experimental condition WS during which the timing of each stimulation was still correct and synchronous with each gait-phase transition while the correspondence between VTs and gait-phase transitions was purposively and randomly changed. Again, despite being exposed to the VT stimulation for only a short while, subjects successfully recognized more than 70% of wrong stimulation sequences with a negligible number of false-positive recognitions. The WS task is obviously more demanding than MS task and this may explain the higher variability across subjects. However, we claim that we have provided evidence that healthy humans quickly learn to spatially and temporally associate VT elements placed around the thigh and each associated with specific gait-phase transitions.

D. Low-intense discrete vibrations do not affect gait biomechanics

As already mentioned, application of vibrations on muscles (or tendons) modifies the proprioceptive information from muscles and thus may alter the gait biomechanics and posture [46]. For instance, when standing, muscle vibration can cause body tilting or the illusion of ego- or exo-motion, depending on the conditions of the stimulation [56]. Furthermore, the delivery of vibrations onto thigh and shank muscles during walking has effects on the posture (subjects tend to move forward) and on the walking speed (the gait cadence tends to increase) [57]. The vibrations provided by the VT units – lasting ~100 ms and transducing <1 W– were not intended to stimulate muscle receptors and cause undesired changes of the subject's gait biomechanics, and indeed, we found no such effects with the proposed system.

E. Limitations of this study and future experiments

Having healthy individuals as subjects does not, of course, allow any simple extrapolation to unilateral transfemoral amputees. Not only may their stump skin show higher sensory thresholds than in healthy subjects but there is a risk that VT units placed in a socket may be damped by the stump liner; these technological problems seem solvable. While the present results show that human readily learn the spatial and temporal relationship between time-discrete feedback delivered by vibrotactile units and specific gait-phase transitions, the main future challenge is to demonstrate that a system providing such feedback actually promotes physiological gait patterns. Finally, the subjective psychological acceptability of the

system will be object of future analyses.

ACKNOWLEDGMENT

The authors would like to thank Prof. B. B. Edin for helping in editing the manuscript and Eng. M. Moisé for helping with artwork in [Fig. 1].

REFERENCES

- [1] P. M. Kennedy, and J. T. Inglis, "Distribution and behaviour of glabrous cutaneous receptors in the human foot sole," *The Journal of physiology*, vol. 538, no. 3, pp. 995-1002, Feb. 2002.
- [2] R. Fitzpatrick, D. K. Rogers, and D. I. McCloskey, "Stable human standing with lower-limb muscle afferents providing the only sensory input," *The Journal of physiology*, vol. 480, part 2, pp. 395-403, Oct. 1994.
- [3] C. J. C. Lamoth, E. Ainsworth, W. Polomski, and H. Houdijk, "Variability and stability analysis of walking of transfemoral amputees," *Medical engineering and physics*, vol. 32, no. 9, pp. 1009-1014, Nov. 2010.
- [4] L. Nolan, A. Wit, K. Dudziński, A. Lees, M. Lake, and M. Wychowański, "Adjustments in gait symmetry with walking speed in trans-femoral and trans-tibial amputees," *Gait & posture*, vol. 17, no. 2, pp. 142-151, Apr. 2003.
- [5] W. C. Miller, M. Speechley, and A. B. Deathe, "Balance confidence among people with lower-limb amputations," *Physical Therapy*, vol. 82, no. 9, pp. 856-865, 2002.
- [6] M. A. Nurse, and B.M. Nigg, "The effect of changes in foot sensation on plantar pressure and muscle activity", *Clinical Biomechanics*, vol. 16, no. 9, pp. 719-727, 2001.
- [7] A. L. Hof, R. M. Van Bockel, T. Schoppen, and K. Postema, "Control of lateral balance in walking. Experimental findings in normal subjects and above-knee amputees," *Gait & posture*, vol. 25, no. 2, pp. 250-258, Feb. 2007.
- [8] A. H. Vrieling, H. G. Van Keeken, T. Schoppen, E. Otten, J. P. K. Halbertsma, a L. Hof, and K. Postema, "Gait initiation in lower limb amputees," *Gait & posture*, vol. 27, no. 3, pp. 423-430, Apr. 2008.
- [9] A. H. Vrieling, H. G. Van Keeken, T. Schoppen, E. Otten, J. P. K. Halbertsma, a L. Hof, and K. Postema, "Gait termination in lower limb amputees," *Gait & posture*, vol. 27, no. 1, pp. 82-90, Jan. 2008.
- [10] M. J. Burke, V. Roman, and V. Wright, "Bone and joint changes in lower limb amputees," *Annals of the rheumatic diseases*, vol. 37, no. 3, pp. 252-254, Jun. 1978.
- [11] B. W. Heller, D. Datta, and J. Howitt, "A pilot study comparing the cognitive demand of walking for transfemoral amputees using the Intelligent Prosthesis with that using conventionally damped knees," *Clinical Rehabilitation*, vol. 14, no. 5, pp. 518-522, Oct. 2000.
- [12] G. M. Williamson, R. Schulz, M. W. Bridges, and A. M. Behan, "Social and psychological factors in adjustment to limb amputation," *Journal of Social Behavior & Personality*, vol. 9, no. 5, pp. 249-268, 1994.
- [13] P. Langhorne, J. Bernhardt, and G. Kwakkel, "Stroke rehabilitation," *The Lancet*, vol. 377, no. 9778, pp. 1693-1702, May 2011.
- [14] K. A. Kaczmarek, J. G. Webster, P. Bach-y-Rita, and W. J. Tompkins, "Electrotactile and vibrotactile displays for sensory substitution systems," *Biomedical Engineering, IEEE Transactions on*, vol. 38, no. 1, pp. 1-16, Jan. 1991.
- [15] M. E. Rentschler, J. Dumpert, S. R. Platt, S. I. Ahmed, S. M. Farritor, and D. Oleynikov, "Mobile in vivo camera robots provide sole visual feedback for abdominal exploration and cholecystectomy," *Surgical endoscopy*, vol. 20, no. 1, pp. 135-138, Jan. 2006.
- [16] M. Benali-Khoudja, M. Hafez, J. M. Alexandre, and A. Kheddar, "Tactile interfaces: a state-of-the-art survey," In *Int. Symposium on Robotics*, vol. 31, Mar. 2004.
- [17] D. J. Di Lorenzo, D. J. Edell, M. J. Koris, and R. R. Riso, "Chronic intraneural electrical stimulation for prosthetic sensory feedback," In *Neural Engineering, 2003. Conference Proceedings. First International IEEE EMBS Conference on*, pp. 116-119, Mar. 2003.
- [18] V. G. Femery, P. G. Moretto, J. M. G. Hespel, A. Thévenon, and G. Lensel, "A real-time plantar pressure feedback device for foot unloading," *Archives of Physical Medicine and Rehabilitation*, vol. 85, no. 10, pp. 1724-1728, Oct. 2004.
- [19] R. Barclay-Goddard, T. Stevenson, W. Poluha, M. E. Moffatt, and S. P. Taback, "Force platform feedback for standing balance training after stroke," *Stroke*, vol. 36, no. 2, pp. 412-413, Feb. 2005.
- [20] C. B. Redd, and S. J. M. Bamberg, "A wireless sensory feedback device for real-time gait feedback and training," *Mechatronics, IEEE/ASME Transactions on*, vol. 17, no. 3, pp. 425-433, Jun. 2012.
- [21] L. Yang, P. S. Dyer, R. J. Carson, J. B. Webster, K. Bo Foreman, and S. J. M. Bamberg, "Utilization of a lower extremity ambulatory feedback system to reduce gait asymmetry in transtibial amputation gait," *Gait & posture*, vol. 36, no. 3, pp. 631-634, Jul. 2012.
- [22] A. Tino, M. Carvalho, N. F. Preto, and K. M. V. McConville, "Wireless vibrotactile feedback system for postural response improvement," In *Engineering in Medicine and Biology Society, EMBC, 2011 Annual International Conference of the IEEE*, pp. 5203-5206. IEEE. Aug. 2011.
- [23] D. H. Chow, and C. T. Cheng, "Quantitative analysis of the effects of audio biofeedback on weight-bearing characteristics of persons with transtibial amputation during early prosthetic ambulation," *Journal of Rehabilitation Research & Development*, vol. 37, no. 3, May 2000.
- [24] M. Y. Lee, C. F. Lin, and K. S. Soon, "Balance control enhancement using sub-sensory stimulation and visual-auditory biofeedback strategies for amputee subjects," *Prosthetics and orthotics international*, vol. 31, no. 4, pp. 342-352, Dec. 2007.
- [25] S. W. Wu, R. E. Fan, C. R. Wottawa, E. G. Fowler, J. W. Bisley, W. S. Grundfest, and M. O. Culjat, "Torso-based tactile feedback system for patients with balance disorders," In *Haptics Symposium, 2010 IEEE*, pp. 359-362. IEEE, Mar. 2010.
- [26] J. A. Sabolich, and G. M. Ortega, "Sense of feel for lower-limb amputees: a phase-one study," *Journal of Prosthetics and Orthotics*, vol. 6, no. 2, pp. 36-41, Spring 1994.
- [27] R. E. Fan, M. O. Culjat, C. H. King, M. L. Franco, R. Boryk, J. W. Bisley, E. Dutson, and W. S. Grundfest, "A haptic feedback system for lower-limb prostheses," *Neural Systems and Rehabilitation Engineering, IEEE Transactions on*, vol. 16, no. 3, pp. 270-277, Jun. 2008.
- [28] R. E. Fan, C. Wottawa, A. Mulgaonkar, R. J. Boryk, T. C. Sander, M. P. Wyatt, and M. O. Culjat, "Pilot testing of a haptic feedback rehabilitation system on a lower-limb amputee," In *Complex Medical Engineering, 2009. CME. ICME International Conference on*, pp. 476-479, Apr. 2009.
- [29] Peripheral sensory and supersensory replacement system. US Publication #20120109013. PCT WO/2012/055029
- [30] S. Crea, N. Vitiello, S. M. M. De Rossi, T. Lenzi, M. Donati, C. Cipriani, and M. C. Carrozza, "Development of an Experimental Set-Up for Providing Lower-Limb Amputees with an Augmenting Feedback," In *Converging Clinical and Engineering Research on Neurorehabilitation*, vol. 1, pp. 321-325, 2013.
- [31] C. Antfolk, M. D'Alonzo, M. Controzzi, G. Lundborg, B. Rosen, F. Sebelius, and C. Cipriani, "Artificial Redirection of Sensation From Prosthetic Fingers to the Phantom Hand Map on Transradial Amputees: Vibrotactile vs. Mechanotactile Sensory Feedback," *Neural Systems and Rehabilitation Engineering, IEEE Trans. on*, vol. 21, no. 1, pp. 112-120, Jan. 2013.
- [32] C. Cipriani, J. L. Segil, F. Clemente, and B. Edin, "Humans can integrate feedback of discrete events in their sensorimotor control of a robotic hand," *Experimental brain research*, pp.1-9, 2014.
- [33] M. D'Alonzo, and C. Cipriani, "Vibrotactile sensory substitution elicits feeling of ownership of an alien hand," *PLoS one*, vol. 7, no. 11, e50756, Nov. 2012.
- [34] U. Berglund, and B. Berglund, "Adaptation and recovery in vibrotactile perception," *Perceptual and Motor Skills*, vol. 30, no. 3, pp. 843-853, 1970.
- [35] R. S. Johansson, and B. B. Edin, "Predictive feed-forward sensory control during grasping and manipulation in man", *Biomedical Research - Tokyo*, vol. 14, pp. 95-95, 1993.
- [36] B. B. Edin, L. Ascari, L. Beccai, S. Roccella, J. J. Cabibihan, and M. C. Carrozza, "Bio-inspired sensorization of a biomechatronic robot hand for the grasp-and-lift task," *Brain research bulletin*, vol. 75, no. 6, pp. 785-795, Apr. 2008.
- [37] M. Roerdink, C. J. Lamoth, G. Kwakkel, P. C. Van Wieringen, and P.J. Beek, "Gait coordination after stroke: benefits of acoustically paced treadmill walking," *Physical Therapy*, vol. 87, no. 8, pp. 1009-1022, 2007.
- [38] S. Weinstein, "Intensive and extensive aspects of tactile sensitivity as a function of body part, sex, and laterality," In *The First Int'l symp. on the Skin Senses*, 1968.
- [39] R.W. Cholewiak, "The perception of tactile distance: Influences of body site, space and time," *Perception*, vol. 28, pp. 851-875, 1999.

- [40] E. C. Wentink, A. Mulder, J. S. Rietman, and P. H. Veltink, "Vibrotactile stimulation of the upper leg: Effects of location, stimulation method and habituation," In *Proc. of the IEEE International Conference of the IEEE Engineering in Medicine and Biology Society*, pp. 1668-1671, Aug. 2011.
- [41] S. Crea, M. Donati, S. M. M. De Rossi, C. M. Oddo, and N. Vitiello, "A Wireless Flexible Sensorized Insole for Gait Analysis," *Sensors*, vol. 14, no. 1, pp. 1073-1093, Jan. 2014.
- [42] S. Crea, S. M. M. De Rossi, M. Donati, P. Rebers ek, D. Novak, N. Vitiello, T. Lenzi, J. Podobnik, M. Munih, M. C. Carrozza, "Development of gait segmentation methods for wearable foot pressure sensors," in *Proc. of the IEEE International Conference of the IEEE Engineering in Medicine and Biology Society*, pp. 5018-5021, 2012.
- [43] M. Donati, N. Vitiello, S. M. M. De Rossi, T. Lenzi, S. Crea, A. Persichetti, and M. C. Carrozza, "A Flexible Sensor Technology for the Distributed Measurement of Interaction Pressure," *Sensors*, vol. 13, no. 1, pp. 1021-1045, Jan. 2013.
- [44] J. Perry, and J. R. Davids, "Gait analysis: normal and pathological function," *Journal of Pediatric Orthopaedics*, vol. 12, no. 6, pp. 815, 1992.
- [45] C. Cipriani, M. D'Alonzo, and M. C. Carrozza, "A miniature vibrotactile sensory substitution device for multifingered hand prosthetics," *Biomedical Engineering, IEEE Transactions on*, vol. 59, no. 2, pp. 400-408, Feb. 2012.
- [46] T. J. Moore, "A Survey of the Mechanical Characteristics of Skin and Tissue in Response to Vibratory Stimulation," *IEEE Transactions on Man-Machine Systems*, vol. 11, no. 1, pp. 79-84, Mar. 1970.
- [47] G. W. Hiebert, P. J. Whelan, A. Prochazka, and K. G. Pearson, "Contribution of hind limb flexor muscle afferents to the timing of phase transitions in the cat step cycle," *Journal of Neurophysiology*, vol. 75, no. 3, pp. 1126-1137, Mar. 1996.
- [48] C. E. Chapman, M. C. Bushnell, D. Miron, G. H. Duncan, and J. P. Lund, "Sensory perception during movement in man," *Experimental Brain Research*, vol. 68, no. 3, pp. 516-524, Jun. 1987.
- [49] R. J. Milne, A. M. Aniss, N. E. Kay, and S. C. Gandevia, "Reduction in perceived intensity of cutaneous stimuli during movement: a quantitative study," *Experimental Brain Research*, vol. 70, no. 3, pp. 569-576, Nov. 1988.
- [50] J. Duysens, A. A. M. Tax, S. Nawijn, W. Berger, T. Prokop, and E. Altenm uller, "Gating of sensation and evoked potentials following foot stimulation during human gait," *Experimental brain research*, vol. 105, no. 3, pp. 423-431, Mar. 1990.
- [51] E. P. Zehr, T. Komiyama, and R. B. Stein, "Cutaneous reflexes during human gait: electromyographic and kinematic responses to electrical stimulation," *Journal of neurophysiology*, vol. 77, no. 6, pp. 3311-3325, 1997.
- [52] M. J., Moron, R., Luque, E., Casilari, and A., Diaz-Estrella, "Minimum delay bound in Bluetooth transmissions with serial port profile," *Electronics Letters*, vol. 44, no. 18, pp. 1099-1100, Aug. 2008.
- [53] www.diffen.com/difference/Bluetooth_vs_Wifi.
- [54] T. Y. Chui, F. Thaler, and W. G. Scanlon, "A novel channel modeling technique for performance analysis of Bluetooth baseband packets," In *Proc. of the IEEE International Conference in Communications*, vol. 1, pp. 308-312, 2002.
- [55] S. Shimada, K. Fukuda, and K. Hiraki, "Rubber hand illusion under delayed visual feedback," *PloS one*, vol. 4, no. 7, e6185, Jul. 2009.
- [56] J. R. Lackner, and M. S. Levine, "Changes in apparent body orientation and sensory localization induced by vibration of postural muscles: vibratory myesthetic illusions," *Aviation, space, and environmental medicine*, vol. 50, pp. 346-354, Apr. 1979.
- [57] Y. P. Ivanenko, R. Grasso, and F. Lacquaniti, "Influence of leg muscle vibration on human walking," *Journal of Neurophysiology*, vol. 84, no. 4, pp. 1737-1747, Oct. 2000.