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Baropodometric information return device for foot unloading

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1. Introduction

The term biofeedback refers to the use of an external device to increase an individual's awareness of sensory events that accompany performance [1].

The biofeedback device can be considered as an interesting therapeutic method when a self-regulated system is disturbed [2]. This technique reveals visual, auditory or electrotactile information to the subject concerning physiological events [3–5]. Electromyographic biofeedback refers to the internal physiological process and has mostly been used to correct simple skills [6]. Tasks will be judged as simple if they have only one degree of freedom (the number of different ways of moving for a muscle joint system), can be mastered in a single practice session [6,7]. However biofeedback methods are applicable to correct complex activities, mobilizing several degrees of freedom and tend to be ecologically valid, if the feedback is based on a mechanical resultant of the movement, such as the external force [7,8]. Recent progress has been achieved for the development of measuring device conception, using force and pressure recording sensors, providing the user with new biofeedback interfaces [9–13]. These systems enable the subject to initiate new walking gait strategies using visual and/or auditory information [14–16]. As an example, Femery and colleagues have developed a system for continuous measurement of plantar pressure and feed-

ABSTRACT

Numerous studies on the development of new biofeedback device conception have already been undertaken. The devices are used for some methods of compensation for the data loss on sensors set. Patients with loss of protective pain sensation are unable to modify their gait when abnormal and excessive plantar pressure occurs. Repeated pressure can result in ulcer formation at specific points. For this reason, we have developed a baropodometric biofeedback to prevent injuries by informing the subject when local pressure exceeds a determined threshold. The case study of our visual and auditory biofeedback is encouraging. The system provides a warning system that may play a valuable role in preventing injuries or ulceration by changing the walking pattern without generating dangerous redistribution.

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back alarm. In a case study, a healthy subject on a treadmill was able to modify his gait in response to the auditory and visual signals. Such systems use different sensors, as well as different acquisition systems, from the in-shoe plantar pressure measurement system we have developed. These devices use a signal-warning system that may be particularly appropriate to the patient's disease, when suffering from lost nociceptive perception subsequent to metabolic diseases, infectious disorders or traumatic lesions. These patients are unable to detect changes in the environment and the footground interface which cause biomechanical mal-adaptation such as local excessive plantar pressure; thus, they are unable to modify their gait patterns in response to these mal-adaptations and reduce the biomechanical stressors [17]. The complete biofeedback system is called B.I.R.D for Baropodometric Information Return Device.

The aim of the present technical note was (1) to present a new biofeedback device for foot unloading (2) to determine the ability of a non-disabled adult to initiate a new gait strategy using our device when walking along a walkway.

2. Methods

2.1. Instrumentation

2.1.1. The pressure sensors

The hydrocell from Paromed (Gmbh, Germany) consists of an inbuilt Wheatstone bridge, inserted in a capsule filled with incompressible fluid, which results in a pressure from the different components of the ground reaction force (Fig. 1). This implies that the cells are sensitive to total mechanical stress which has three components: pressure acting normally (*z*) on the surface

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Fig. 1. Hydrocell from Paromed.

Table 1

The main characteristics of the hydrocell from Paromed (Gmbh. Germany).

Dimensions (mm)	
Diameter	22
Active sensing diameter	18
Thickness	3
Measurement range	$0 - 625$ kPa
Uncertainty	$+1%$
Stability	$\pm 2\%$ (at 400 kPa, deviation ± 2.5 kPa)
Hysteresis	01 kPa
Sampling frequency for each channel	150 HZ

and antero-posterior (*y*) and medio-lateral (*x*) shear stress acting tangential to the surface. The cells revealed realistic measures of pressure acting under the foot because they are sensitive to normal and shear stress. The Hydrocell is calibrated by the manufacturer and a calibration file is provided for each sensor. An individual calibration for each sensor was performed to ensure that statements of the absolute pressure at different regions of the foot could be substantiated. Our bench testing results of the sensors confirm previous data [15,18–20] (Table 1).

2.1.2. Insole development

To locate the areas of maximum pressure and place the hydrocell under these areas, the subject walked barefoot 3 times on a Footscan plate.1 The Footscan software enable us to pinpoint 5 landmarks of the same size as the hydrocell at the highest pressure areas that were identified under the lateral heel (LH) and medial heel (MH), metatarsal heads 5 (M5), 2 (M2), and 1 (M1), and the Hallux. A 1:1 scale footprint picture was obtained. The footprint locations were colored with black ink and were then transferred within individualized insoles. The hydrocells were thus inserted at these locations and the customized insoles were put in neoprene shoes matching the insole shape (Fig. 2). Compared to the previous study in which sensors were attached under the subject's foot, our solution appeared the most efficient to prevent damaged sensors and sensor migration due to shear stress [11,14,15].

2.1.3. Data acquisition chain

Each Hydrocell was connected by a flexible wiring (length: 125 cm, diameter: 1 mm) to a logger belt (Fig. 2). Flexible wiring was strapped on the subject's legs with adhesive tape. The logger belt (mass: 0.7 kg) consists of an amplifier box (XP24-00034²), a telemetry data logger (XAP-00221²) and a remote transceiver (XAP- $00219²$). Amplifier box can accommodate 16 sensors and amplifies their signals output. The telemetry data logger consists of a micro-

processor with an 8-bits analog-to-digital converter. The logger box is powered by 7 AA batteries and has a total capacity in use of 5 h. Then, the remote transceiver transmits the digital data to a PC transceiver (XAP-00220 2). The specificities of the telemetry system are a range of 250 m, a baud rate transmission of 57,600 bits/s and a frequency acquisition of 100 Hz. Pressure data can be viewed online during collection using our personal PC (Toshiba, Pentium 4, CPU 2.66 GHz, RAM 1 Go) and biofeedback software package.³ The investigator can make the decision whether or not to save the data to a file (coma separated values: CSV) during the biofeedback process. The digital data stored in the computer are then analyzed for relevant information.

2.1.4. Visual and auditory feedback

The feedback from this device is intended to cue the subjects to initiate a new gait strategy. The auditory signal was feedback to the subject through 2 loudspeakers connected to the PC. The auditory feedback was under the control of the investigator. First, the physician determined the investigating area and thus selected the type of sound (no sound, alarm and positive sound) and the quantity of different sounds (1, 2 or 3). Different types of sound enable us to inform subjects about their success (positive sound) or to indicate a failure (alarm). The auditory signal can be triggered in different ways according to the patient's plantar pressure pattern. (1) The alarm was triggered when the local pressure under the selected area exceeded a previously determined threshold, the critical peak pressure maximal (PPCR_{MAX}). (2) Previous baropodometric biofeedback devices did not take into account the excessive foot relief in their development. However, studies have shown that excessive overload may significantly overload other areas of the foot (*P* < 0.05) [15,20]. Thus, the auditory feedback could be triggered when the local pressure under the selected area was below a previously determined threshold, the critical peak pressure minimum ($PPCR_{MIN}$). Finally, the auditory feedback could be triggered when the local pressure under the selected area was between the PPCR $_{\text{MIN}}$ and the PPCR $_{\text{MAX}}$. These different ways to trigger the auditory feedback may be used independently or together.

The visual feedback was given to the subject by the use of two control screens placed at both ends of the walkway, using video projection in order to receive constant feedback. This visual feedback consists of plantar footprint visualization scenes corresponding with localizations of the insole sensor setting (Fig. 3). On the left of the plantar footprint there is a scale of colours, from blue, green to red; illustrating pressure intensity at each of the sensor localization points. The greater the pressure, the closer to red the color became. Visual feedback allowed the subject to control and modulate the load shift to remain within a color range [15]. A step counter was placed on the left side of the foot print, informing the user about the performances considered.

Each channel could be selected separately to unload precisely and return the feedback (auditory and visual) under the areas considered relevant. Thus step-by-step, the subject was informed of dynamic events at the foot-ground interface, and remained aware of the overall foot condition.

3. Illustrative case report

3.1. Participant

A healthy volunteer subject, randomly selected from among the college university lecturers, took part in this trial after providing written informed consent in accordance with a protocol approved by the Centre Hospitalier Régional Universitaire de Lille 2 review

Fig. 2. B.I.R.D system ((1) hydrocell and neoprene shoes, (2) amplifier, (3) logger box, (4) remoter transceiver, (5) transceiver for PC, (6) personal computer).

Fig. 3. Interface of the B.I.R.D system.

Fig. 4. Visual and auditory feedback.

board. The subject was 23 years-old, weighed 80 kg and was 176 cm in height.

3.2. Walking test

For the walking test the subject moved back and forth on a 25 m walkway. This enabled us to record the peak plantar pressure under all the footprint locations and both feet during consecutive steps. In both conditions (diagnostic and unload) the turn steps and the two steps before and after the turn were not included in the analysis.

After a brief explanation of the device, the subject performed the diagnostic walking test at his self-selected walking speed (1.20 m/s). The speed was then verified to ensure that the subject performed the same walking throughout the trials.

The peak plantar pressures of more than 100 consecutive steps (50 right and 50 left steps) were recorded (PPdt), and served as the reference level. The PPCR $_{MAX}$ was defined as 5% below the PPdt, that is $PPCR_{MAX} = PPdt-5%$. From the study by De Vita and Bates, a peak plantar pressure reduction of 5% under a specific foot area results in meaningful biomechanical impact beyond 25 steps [23]. The PPCR $_{MIN}$ was defined as 20% below the PPdt, that is $PPCR_{MIN} = PPdt-20\%$. Then the subject was told to relieve the first metatarsal region (M1) of the right foot only, within the PPCR $_{MAX}$ and PPCR_{MIN}, during 100 other steps performed using the B.I.R.D system. The M1 area was chosen for the trial because it is a wellknown at-risk area for the development of plantar ulceration in neuropathic diabetic subjects [24]. The auditory and visual feedbacks were returned as follows: the alarm was triggered and the M1 location colored in red (indicating a failure step) when the M1 peak plantar pressure (PP) was excessive (PP > $PPCR_{MAX}$). The positive sound was triggered and the M1 location colored in green (indicating a success step) when PP was between the two thresholds (PPCR_{MIN} < PP < PPCR_{MAX}). When the subject did not receive any sound and the M1 location was colored in blue (indicating an acceptable step), this means that the unloading was excessive but effective (PP < PPCR_{MIN}) (Fig. 4).

3.3. Experimental parameters

From the recordings, we computed peak plantar pressure (PP) and the pressure–time integral (PTI) at each of the 6-sensor locations for both feet. Mueller et al. defined PP and PTI as indices of potential trauma to skin and established that the PP indicates the highest magnitude of the stress and the PTI reflects the magnitude of the stress at a specific location over time [25]. The mean value and standard deviation (SD) were calculated over 50 steps for each foot.

3.4. Statistical analysis

We used Statistica software, version 6.0, for all analyses. The normal Gaussian distribution of the data was verified with the Shapiro-Wilks test (*P* < 0.01). We used a 2 way ANOVA (Repeated factor: Diagnostic, Success steps, Acceptable steps and Faulty steps) and feet (Unloaded and contralateral foot) to discern the effects of the unloading on both feet and across the experimental conditions. This was repeated for all the footprint areas. A post hoc "*t*" test was used to refine the analysis. Mean and standard deviation were then calculated using standard statistical methods. For all tests, *P* value was set at 0.05.

4. Results

Table 2 contains the results recorded during the diagnostic walking and the unloading processes over 50 right steps. Results from the peak plantar pressure and pressure-to-time integral redistribution are presented in Figs. 5 and 6 respectively. These data were collected to verify that a low PP decrease under M1 did not entail an increase in loading under other areas.

*4.1. *Peak plantar pressure redistribution*

A 5% to 20% PP reduction under M1 resulted in a significant PP mean decrease (12.9%) under the Hallux compared to the diagnostic condition (*P* < 0.05). An excessive unload resulted in a 23.3% significant PP increase under M5 compared to the diagnostic condition (*P* < 0.05). Moreover, a significant decrease appeared under M2 (9.7%) and under the hallux (contralateral and unload foot, 8.9% and 19.7% respectively) compared to the diagnostics steps (*P* < 0.05). Faulty steps resulted in a 9.2% significant PP decrease under M2

Table 2

Peak pressure values measured under M1 during the normal and the unloading condition.

	Diagnostic condition M1 Unloading				
		Success steps $20\% < PP < 5\%$ PP > 20%	Acceptable steps	Failure steps PP < 5%	
% of step		65	25	10	
PP mean	117	103	76	125	
SD	22	10	8	6	
PP min	86	95	63	116	
PP max	177	110	87	133	

Values are in kilopascals.

PP min: minimum peak pressure. PP max: maximum peak pressure.

Fig. 5. PP distribution during after foot unloading. (A) contralateral foot, (B) unload foot. Mean (SD), values are in kilopascal *: significant differences with the diagnostic steps (*P* < 0.05).

Fig. 6. PTI distribution after foot unloading. (A) contralateral foot, (B) unloaded foot. Mean (SD), values are in kilopascal, *: significant differences with the diagnostic steps $(P < 0.05)$.

(contralateral foot) and 9.5% significant PP increase under LH (contralateral foot) compared to the diagnostic condition (*P* < 0.05).

*4.2. *Pressure–time integral redistribution*

An excessive unload resulted in a 12.5% significant PTI increase under M5 compared to the diagnostic condition (*P* < 0.05). Faulty steps resulted in a 30.4% significant increase under TL (contralateral foot) compared to the diagnostic condition (*P* < 0.05).

5. Discussion

Recent technologies have enabled us to improve existing biofeedback systems in order to develop some additional diagnostic devices and/or to develop new rehabilitation methods based on "real-time" detection of abnormal walking parameter values.

In the present study, the aim was to optimize a baropodometric biofeedback device and to determine the ability of healthy subjects to initiate a new walking gait using it. In this way, modifications in pressure sensors, data chain acquisition and biofeedback software have been made.

Previous in-shoe plantar pressure measurement systems used pressure sensors called *Force sensing resistors* (FSR) [9,10,14,15]. However, the characteristics of the FSR seemed insufficient for further clinical applications, such as to prevent foot ulceration. Indeed, FSR detects normal stress acting on the surface and thus defines a very simplified action of the foot on the sensor area whereas plantar ulcers are linked to normal and shear stress [26]. Moreover, Maalej et al. have estimated the non-repeatability of the sensors at 15%. This low reliability of the FSR may limit accurate pressure analyses [27].

Conversely, the hydrocell from Paromed seemed more appropriate for clinical setting. In the study by Maluf et al., the Paromed sensors were integrated in a portable electronic device to monitor changes in plantar pressure, temperature and humidity that occur within a shoe during prolonged activity [11]. The Authors reported a high durability of the sensors. In effect, the Paromed sensors are equipped with connections that can be attached at a site external to the shoe, thereby reducing stress on sensor connections. Moreover, they concluded that the data from the Paromed sensor indicated good long-term reliability of pressure measurement [11]. However, this remains to be seen with long-term continuous use by patients in a home or work environment.

Our second goal was to develop an imbedded biofeedback device to perform foot unloading during ground contact. In a similar study, a subject was told to relieve M1 by 30% on a treadmill. The results reported that 84% of the steps (68 steps on 81) were unloaded over the threshold. However, the antero-posterior impulse of the ground reaction force was simulated by the treadmill [15,16]. In our study, the subject had to create the antero-posterior positive impulse to keep a constant walking speed and conversely at the same time to relieve the forefoot location. In this context, we modified the data acquisition chain by integrating a telemetry system, which did not appear to negate the foot unloading. The B.I.R.D device enabled the subject to relieve the first metatarsal head with satisfactory results in 90% of the cases (success + acceptable steps).

Plantar pressure relief is directly associated to load redistribution [28]. To prevent foot lesions, the main goal of the device was to reduce the plantar pressure under M1. Previous studies showed the feasibility for healthy and pathological subjects to unload the first metatarsal head. However, it seems important to verify that gait modification did not increase loading parameters under the other footprint locations (unloaded foot and contralateral foot). To detect the consequence of the M1 unloading under the other foot location and under the contralateral foot, we compared the plantar pressure between unloaded steps and diagnostic steps. Our results showed

that an excessive unload (more than 20%) resulted in significant PP and PTI increase under M5, which are other at-risk areas in the diabetic foot [24] (*P* < 0.05). Our findings supported previous investigation. Results from the study of Femery et al. reported that a 30% reduction of peak plantar pressures under M1 induced significant peak plantar increase under M5 (*P* < 0.05) [15]. In this context, the new software could be of interest to limit excessive weight shifting under other key areas. The acoustic and visual signal associated to PPCR_{MAX} and PPCR_{MIN} could be perceived as having diagnostic value in determining the true pressure [15]. Compared to previous studies we reinforced the success through positive sound. Betker et al. have already suggested that positive reinforcement is important to improve the motivational aspect and thus, enhance performance [29].

Results demonstrated the possibility of a moderate unload of M1 (5–20%) with the ability to unload 65% of success steps on the walkway and with maintenance of walking speed. However, its remains to be demonstrated whether or not such alterations are sufficient to reduce tissue loading at these sites below the threshold for injury [27].

A limitation of the device must be recognized. The device cannot be referred to as a portable feedback system. The actual B.I.R.D is an imbedded device and remains connected to a computer during telemetric data collection. Future development of the device should plan the autonomy of the device and may consider other biofeedback means (tactile, vibrator ...).

Another limitation concerned the connection between the sensors and the logger belt. The flexible wiring strapped on the leg may disturb the subject in his walking test. To improve the system, the logger box should be lighter and a wireless transmission of the data between the sensor and the logger should be considered.

The final limitation concerned the population of the study. Our ethics review board did not allow testing patients with sensory loss before proving the efficiency of the device on healthy subjects and the feasibility of relieving key areas, on a walkway, with maintenance of the walking speed. The results are encouraging and now lead to an application of the methodology for persons suffering from lost nociceptive perception.

6. Conclusion

The purpose of the B.I.R.D is to prevent the development of foot ulcerations by providing extrinsic sensory feedback to compensate for intrinsic mechanisms damaged due to disease or injury. The present study represents the initial phase of our visual and auditory feedback system. The results have indicated the feasibility of relieving the foot during locomotion on a walkway with maintenance of the walking speed. In addition, the system takes into account the redistribution of plantar pressure under other footprint locations and the contralateral foot. The next step is to transform the embedded system into a portable system supplying sensory input for foot disorders during daily life activities. Another avenue of investigation might determine the capacity of subjects to learn a new gait pattern using our system during a training program.

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Conflict of interest

The authors have no conflict of interest to declare.

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