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DOES B.I.R.D FOOT CONTROL SUPPLY SENSITIVITY DISTURBANCE INDUCED BY EMLA CREAM ANAESTHESIA

SHORT NOTE

Numerous studies on the development of new biofeedback device conception have already been undertaken. Patients with loss of protective pain sensation are unable to modify their gait when abnormal and excessive plantar pressure occurs. For this reason, we have developed and tested a portable baropodometric biofeedback, on healthy subjects, to prevent injuries by informing the subject when local pressure exceeds a determined threshold. Anaesthesia cream enables us to determine the ability to use our device with a perturbation of the plantar sensory inputs. Results showed 58.2% of success steps in the EMLA condition while the placebo condition showed 57.5% of success steps.

1. INTRODUCTION

The gait analysis, in population suffering from perturbed plantar perception subsequent to metabolic diseases, infectious disorders or traumatic lesions, has been widely investigated [1]. Researches have focused their interest on the prevention of plantar ulceration development. The damaged physiological sensors of the foot can thus be augmented or replaced by external feedback system. In this way studies have develop biofeedback providing from the plantar pressure called Baro-Paedometric Biofeedback.. These systems provide visual and/or audio feedback in order to correct the plantar pressure distribution, when a local pressure exceeds the determined threshold [2].

The perturbation of the plantar sensory inputs of healthy subjects can be achieved using various techniques such as inducing ischaemia [3], local anaesthesia or by hypothermia [4]. Local anaesthetics using Eutectic Mixture of Local Anaesthetics (EMLA) has been preferred in this study.

The aim of this short communication was to determine 1) the ability of healthy subjects with a perturbation of the plantar sensory inputs to use our baro-paedometric biofeedback for foot unloading 2) to define the plantar pressure redistribution under both feet due to the unload

2. MATERIAL AND METHODS

2.1. POPULATION

Eighteen healthy subjects without foot or gait abnormalities took part in this trial, after providing written informed consent in accordance with a protocol approved by the Centre Hospitalier Régional Universitaire review board. Average mass, height and age were 70.2±10.4 kg, 1.78±0.05 m and 31.1±8.9 years.

2.2. INSTRUMENTATION SET

The whole biofeedback system is called B.I.R.D in which is short for Baropodometric Information Return Device. The B.I.R.D is composed of sensors, acquisition telemetry system and software to return the visual and auditory information.

The Paromed hydrocell [3] consists of an inbuilt Wheatstone bridge, inserted in a capsule filled-up with liquid silicon, incompressible fluid that produces a pressure map recorded on several carefully selected points on insoles. They represent the forces and stresses in anterio-posterior and medio-lateral foot areas (Fig 1).

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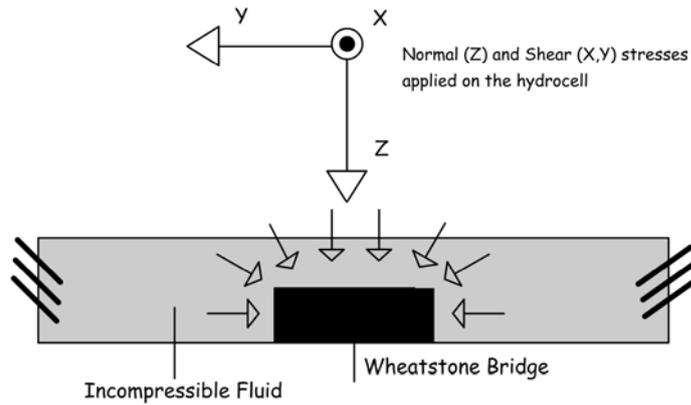
Fig 1. Hydrocell from paromed

Hence, in time of the foot - ground contact, the forces re-actions are recorded in form of the pressure, inside the hydro-cell.

After our calibration processes of the sensors, they enable us to verify sensitivity, linearity and hysteresis of the measurement system (table 1). The dynamic forces implementation unit enabled us to calibrate the sensors' set before the gait series are performed.

Peaks of pressure distinguished at the foot print; a RSScan (Olen, Belgium) pressure plate, was used for detection of the peak localisation and to determine the sensors distribution of the customized insole. Two insoles (right and left) were thus prepared comprising 6 Paromed hydro-cells, in each insole, distributed at:

- lateral heel (LH)
- medial heel (MH),
- metatarsal heads 5 (M5), 2 (M2), and 1 (M1),
- the Hallux.

The insoles were supplied by an amplifier and linked with Personal Computer via telemetrically joined data recorder. The metrological process and its experimental feedback (working in real-time mode) was organised for the bio-feedback customised software package, developed under the paper authors supervision.

Table 1. The Main characteristics of the Hydrocells Paromed (Gmbh. Germany)

Dimensions (mm)	
Diameter	22
Active sensing diameter	18
Thickness	3
Measurement range	0 to 625 kPa
Uncertainty	$\pm 1\%$
Stability	$\pm 2\%$ (at 400 kPa. deviation ± 2.5 kPa)
Hysteresis	0.1 kPa
Sampling Frequency for each channel	150 HZ

2.3. FEEDBACK FACILITIES

The visual feedback, which was returned to the subject through two control screens and by video projection, consists of plantar footprint visualisation scenes that correspond with localisation of the insole sensor set (Fig. 2).

The right of the plantar footprint is provided by a scale of colours, from blue, green to red; illustrating intensity of the pressure, at each of the sensors localisation point. A "scorer" was placed on the left side of the foot print, informing the user about the considered performances.

The plantar pressure distribution, in diagnostic trial was also performed in testing procedures over 100 consecutive steps, carried out in time of walking experiments. From this test the reference steps, reference steps EMLA and reference steps Placebo were defined. The peaks of pressure distribution were localised after series of experiments, as so called reference points finding. Each footprint was provided by this reference point then used for putting the diagnosis in relation to this point.

The peak plantar thresholds (PP_{CR}) were placed between 5% and 20% that brings us with: $PP_{CR} = PP_{NC}$ -5% and PP_{NC}-20%.

The reduction of 5% of the Peak pressure would be sufficient to reload the crucial point area, preventing the foot ulceration in its most affected area. This threshold level is considered as PP_{CRmax} value defined in work [2]. The reduction of 20% of the peak pressure, considered as PP_{CRmin}, enables us to limit excessive relief that result is implemented, in dangerous plantar pressure redistribution [2].

If the peak pressure is recorded under M1, for the unload conditions fulfilment (between the minimum 20% and the maximum 5% threshold settings) the step performances were considered as success step.

The audio feedback was also implemented as an alarm trigger, combined with the visual feedback. It indicates the local pressure over-load, at the selected area where the PP_{CRmax} was noticed. On the contrary, only the visual feedback informs the subject when the excessive relief occurs.
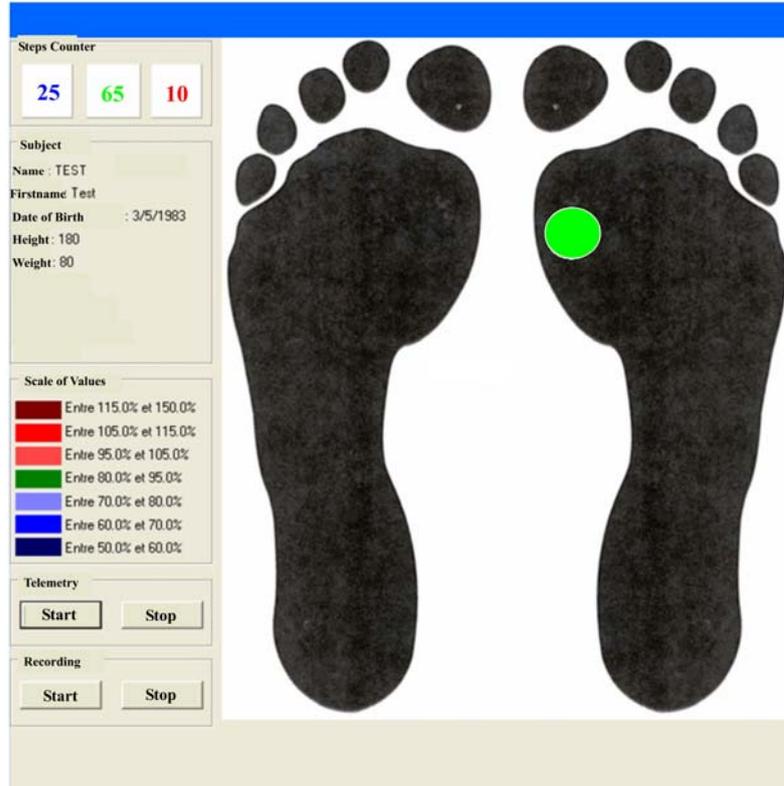
Fig 2. The biofeedback software interface

Each channel could be selected separately to unload the indicated area precisely, returning the feedback under the relevant area. Thus step-to-step, the investigated subject was informed of dynamic events at the foot-ground interface and the remained aware of the overall foot condition.

2.4. WALKING TEST

The walking tests were performed on a 20 m walkway with possibility of the most suitable walking speed finding (figure 3). Subjects were equipped with two customised insoles and with a belt with telemetric transmission system.

1: Walkway

2: Wall of projection

3: Projection screen

4: Photoelectri cells

5: Video projector

6: Loudspeaker

7: Computer

8: Telemetry receptor

9: Neopren shoes

10: Custumized insoles

11: acquisition belt
    a: Amplificator
    b: Logger
    c: Telemetry emettor
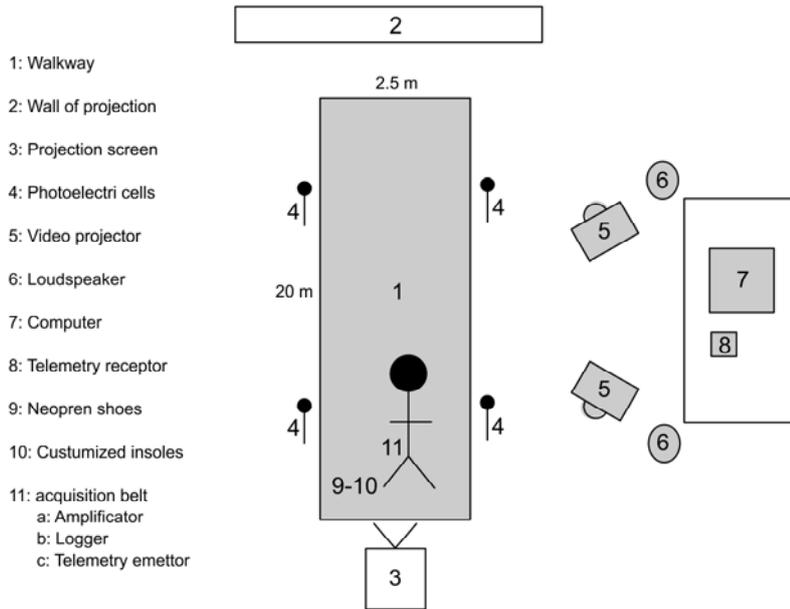
Fig. 3. Instrumentation for the walking test

The walking tests were divided in two sessions: Placebo Condition and EMLA condition were depending on a random selection. The figure 3 illustrated the trials organization.

Then a placebo cream (Vitamin E cream) or EMLA cream were applied during 60 minutes to the entire soles of the feet. Vitamin E cream was selected as the control because it has a colour and consistency similar to that of EMLA and has no anaesthetic effect.

Before and after the cream's application, subjects were instructed to identify pin-prick on the heel, the metatarsal heads and the Hallux.

Then subjects were obliged to relief the first metatarsal region (M1) over 100 consecutive steps, under the visual and acoustic biofeedback signals analysis. The unload conditions were applied to the right foot.
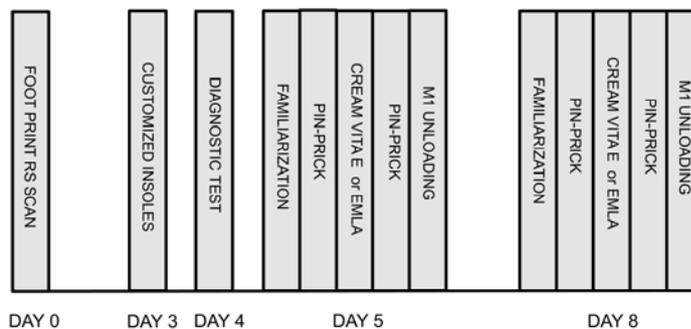
Fig. 3. organization of the walking test

2.5. STATISTICAL ANALYSIS

A repeated measured analysis of variance was used to compare the reference test and the EMLA and Placebo conditions. 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.

3. SOME RESULTS ANALYSIS

The descriptive results showed that subjects performed 57.5% of success steps under the Placebo condition and 58.2% under the EMLA condition.

Results showed no significant peak plantar pressure difference between the two conditions (ie. Reference steps and unload test)

Figure 4 represents the pressure to time integral distribution and redistribution. The diagnostic trial showed significant differences between the EMLA condition and the reference steps and between the EMLA condition and the Placebo condition

under the TM, M5 and Hallux. On the opposite, in unloading condition no significant differences appeared between the reference steps, the EMLA condition and the Placebo condition.
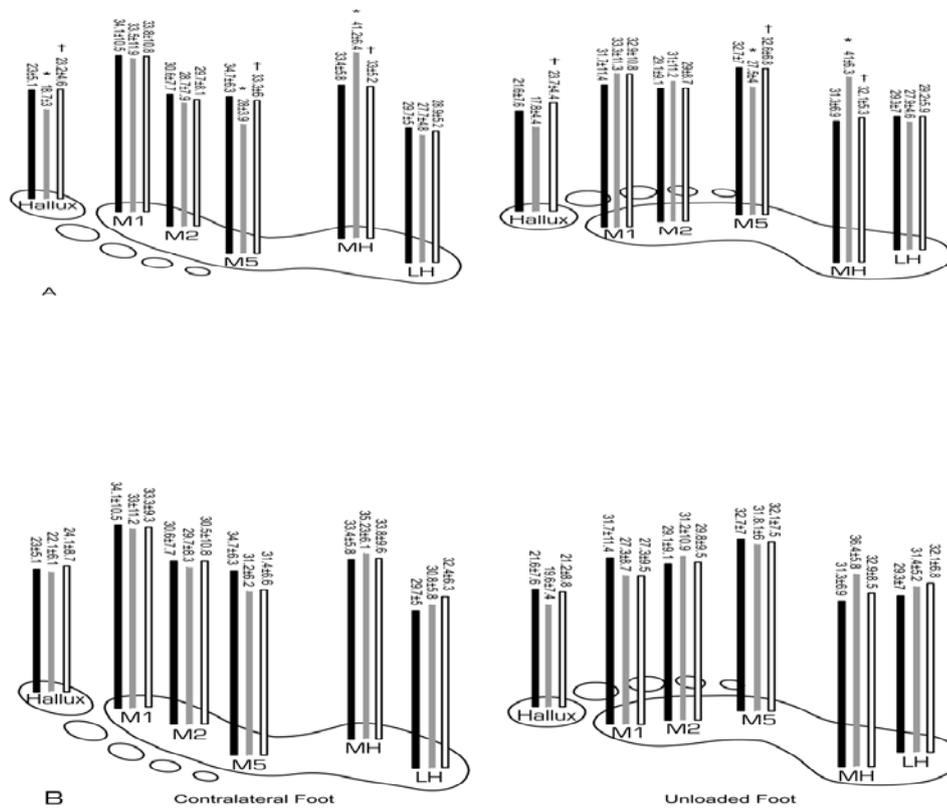
Fig. 4. PTI distribution in diagnostic trial (a) and PTI redistribution in unloading condition (b).

4. CONCLUSION

The plantar perturbation may be responsible for the distribution and altered duration of loading. The subject adopted a more conservative, less destabilising gait, with increased duration at heel level [4]. Our device enables subjects to be aware about their foot problems. Subjects become actors of their own re-education. The attentional focus and motivational aspect due to the unload task and BIRD interface might limit the effect of the EMLA on the plantar pressure redistribution. The limitation of the study protocol was the difficulty to induce severe plantar foot insensitivity. However no studies have presented a non-invasive method with a severe and long term insensitivity effect. Future investigation in people with diabetic peripheral neuropathy appeared necessary.

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