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A REAL TIME PLANTAR PRESSURE FEEDBACK DEVICE FOR FOOT UNLOADING

The design and development of a plantar pressure control device, adapted to correct plantar pressure distribution patterns, is described. This device is based on the artificial return of information in real time to instantaneously reveal to subject certain events, of which he was unaware and which are difficult to quantify, such as the pressure variation generated by foot-ground contact. An acoustic alarm and visual signals, adjusted to a specific pressure load, alert the user in the case of excessive plantar pressure. So, our feedback device is designed to substitute for loss of feeling in patients who have peripheral neuropathy secondary to diabetes mellitus. The ultimate aim of this project is to prevent the development of neuropathic foot ulceration by providing both visual and auditory extrinsic sensory feedback to compensate for the malfunctioning peripheral nerves and to transmit information to the patient about dangerous conditions on the plantar surface of the feet. A trial of the device in a healthy subject is presented to evaluate whether a new gait pattern can emerge thanks to feedback from plantar pressure measurements.

1. INTRODUCTION

The biofeedback method is an old approach commonly used in patient's physical rehabilitation. The term "biofeedback" is derived from control system technology and from biological studies of self-regulatory mechanisms that make human functioning possible [1]. This method requires external feedback (usually visual and/or acoustic) brought transitorily by electronic equipment to detect, amplify and reveal instantaneously to patients internal biological processes and functions of which they are unaware [2]. The biofeedback method is particularly indicated in situations where the intrinsic and extrinsic sources of information are absent or insufficient, or more generally, when a self-regulating system is disturbed. Recent progress in measurement tools such as pressure transducers enable us to consider new devices for rehabilitation particularly in the rehabilitation of a pathological gait pattern.

Measurements of plantar pressure distribution play a crucial role in the assessment and the treatment of foot disorders or, more generally, in gait disturbances. They enable us to study and quantify the events at the "foot-ground" interface and could be used in the development of a biofeedback method. The aim of this work is to present a new plantar pressure control device able to restore visual and auditory signals in real time, in the case of excessive plantar pressure detection

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in relation to a specific pressure load. While the auditory feedback works on the all or nothing principle like previous devices, the visual feedback is modulated in proportion to pressure. Indeed, thanks to a colour scale that gives the precise pressure intensity, the subject can predict an increase in pressure and react accordingly. This device must improve the subject's awareness of the gait pattern in order to correct and optimise the load distribution patterns and to learn to use a new gait pattern.

2. INSTRUMENTATION

The sensors chosen for the plantar pressure feedback device was the Paromed hydrocells ™ (S-P by Kraemer, Paromed Medizintechnic GmbH, D-8201 Markt Neubeuern, Germany). Seven hydrocells are connected to a small waist-mounted data acquisition box comprising a conditioning unit, which produce the linearisation and amplification signals. A 10 m cable allows the connection to a PC computer for data acquisition, analysis and display. This system can collect pressure data from the seven sensors for 30 seconds with the sampling frequency set at 150Hz. Up to 8 differential analog inputs are able to convert data to a maximum throughput of 200 kHz. The digital data stored in the computer were then processed and analysed for relevant information. The locations of the hydrocells under the areas of maximum pressure were identify after a barefoot walking test on a Footscan® force-plate (RSscan International, Olen, Belgium). A 1/1 scale footprint picture was obtained. The Footscan software pinpointed landmarks of the same size as the hydrocells on the highest pressure areas. Thus, seven areas were identified under the lateral and medial heel (LH, MH), the fifth (M5), the third (M3) and the first (M1) metatarsal heads and the Hallux. These footprint locations were coloured in with black ink and then transferred and inserted in an insole.

3. METHODS

Five healthy volunteer subjects took part in this trial of the device. All the walking tests were performed on a motorized treadmill with the belt speed set at the subject's comfortable walking speed (3.5 $km.h^{-1}$). The subjects, equipped with the sensors insoles, performed a first walking test to record the peak plantar pressure distribution in normal conditions (PP_{NC}) during 27 consecutive steps. The critical peak plantar pressure threshold (PP_{CR}) was then defined as 5% below the PP_{NC}. Then, six walking tests (T1 to T6) were performed. The subjects were instructed to attempt to unload the first metatarsal head pressure site (M1). This area was chosen for the experimental trial because it is an at-risk area well known for the development of plantar ulceration in neuropathic diabetic subjects. The unload condition concerned the right foot only. The tests lasted 30 seconds and enabled us to record the plantar pressure of 27 consecutive steps. The auditory feedback functioned as an alarm and was fed back to the subject through two loudspeakers connected to the portable computer. Auditory feedback was triggered when the local pressure under the area concerned by the unload exceeded a previously determined threshold, the critical peak pressure (PP_{CR}). To limit the excessive unload shift, PP_{CR} minimal and maximal enclosed the PP_{CR} to ± 2,5%. Each channel had its own PP_{CR}, which was determined and adjusted by the physician

according to each patient's specificity. Furthermore, a switch activated or de-activated the warning signal for each channel so that the auditory feedback of a single sensor could be returned. Moreover, each pressure sensor had a different tone in the auditory feedback ranging from the lowest bass tones to the most high-pitched sounds. The visual feedback was returned to the subject through a control screen placed in front of him and consisted of a plantar footprint with visualization of the location of each sensor. To the right of the plantar footprint, a range of colours, from blue to red, marked the intensity of the pressure exerted under each location. The more the pressure was increased, redder the colour became. The visual feedback allowed the subject to control and modulate the load shift to remain in a colour range, from blue to green, considered as acceptable, i.e. not dangerous for the foot area. Each channel could be selected separately to order the unload precisely and return the feedback under the areas considered relevant. Thus, step by step, the subject enquired into dynamic events at the foot-ground interface and preserved overall foot awareness.

4. STATISTICAL ANALYSIS

We used Stastistica 6.0 software for all analyses. The normal Gaussian distribution of the data was verified with the Shapiro-Wilks test. When the normal distribution criterion was met ($p < .01$) a one-way ANOVA was used to compare standard condition test data (PP mean and PTI mean) with those of unloading tests (T1-T6) by differentiating each of the seven foot locations. All the steps recorded (N=27) were analysed. Compound symmetry, or sphericity was verified with the Mauchley test. A Neuwman-Keuls post-hoc test was used to identify significant differences ($P<0.01$) and thus to observe the influence of unloading on the parameters. When the normal distribution was not met, a Friedman ANOVA was used. In this case, post-hoc comparisons were made with the Wilcoxon matched pairs test.

5. RESULTS

Table 1 shows the results obtained under the first metatarsal head (M1) after the 6 tests corresponding to the 5% M1 unloading. Results differed according to whether unloading was successful or not. Indeed, if the peak pressure recorded under M1 during the unload condition was between the PP_{CR} minimal and maximal threshold, the step was considered as a success. Inversely, if the peak pressure recorded under M1 during the unload condition was superior to the PP_{CR} maximal or inferior to the PP_{CR} minimal threshold, the step was considered as a failure.

All results are expressed in percent and showed the differences observed between peaks of pressure recorded in normal condition and unload condition.

Table 1. Results obtained under the right corresponding to the 5% M1 unloading.

	Success steps $PP_{NC} = PP_{CR}$		Failure steps $PP_{NC}<PP_{CR}$		$PP_{NC}>PP_{CR}$	
	% success	% unloading	% failure	% unloading	% failure	% unloading
Subject 1	19	6,52	48	31,97	33	Overload 11,34%
Subject 2	14	6,17	48	28,46	38	Overload 17,02%
Subject 3	26	7,03	59	31,73	15	Overload 5,3%
Subject 4	23	7,17	42	32,40	35	Overload 9,85%
Subject 5	30	6,74	44	25,51	26	Overload 16,33%

6. DISCUSSION

To prevent gait pattern impairment, such as foot ulceration in diabetic patients with peripheral neuropathy, we have developed an augmented sensory feedback device from the plantar pressure measurement. An initial trial is presented to verify whether healthy subjects can easily and quickly learn to use the device. Moreover this trial explored how normal subjects responding to this system and taking feedback into account could correct the actual gait pattern or learn a new motor skill programmation. The study shows that it is possible to modify the plantar pressure distribution so as to unload M1 foot area considered at risk in the diabetic subjects. However, the results show the difficulty of subjects to overcome a fine and precise control of the foot unloading that was respected only in 25% of cases during the first attempts.

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