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**RESEARCH ARTICLE**

# Biofeedback can reduce foot pressure to a safe level and without causing new at-risk zones in patients with diabetes and peripheral neuropathy

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## Abstract

**Background** Plantar pressure reduction is mandatory for diabetic foot ulcer healing. Our aim was to evaluate the impact of a new walking strategy learned by biofeedback on plantar pressure distribution under both feet in patients with diabetic peripheral neuropathy.

**Methods** Terminally augmented biofeedback has been used for foot off-loading training in 21 patients with diabetic peripheral sensory neuropathy. The biofeedback technique was based on a subjective estimation of performance and objective visual feedback following walking sequences. The patient was considered to have learned a new walking strategy as soon as the peak plantar pressure (PPP) under the previously defined at-risk zone was within a range of 40–80% of baseline PPP in 70% of the totality of steps and during three consecutive walking sequences. The PPP was measured by a portable in-shoe foot pressure measurement system (PEDAR®) at baseline (T0), directly after learning (T1) and at 10-day retention test (T2).

**Results** The PPP under at-risk zones decreased significantly at T1 ($165 \pm 9$ kPa, $p < 0.0001$) and T2 ($167 \pm 11$, $p = 0.001$), as compared with T0 ($242 \pm 12$ kPa) without any increase of the PPP elsewhere.
At the contralateral foot (not concerned by off-loading), the PPP was slightly higher under the lateral midfoot at T1 ($68 \pm 8$ kPa, $p = 0.01$) and T2 ($65 \pm 8$ kPa, $p = 0.01$), as compared with T0 ($58 \pm 6$ kPa).

**Conclusions** The foot off-loading by biofeedback leads to a safe and regular plantar pressure distribution without inducing any new 'at-risk' area under both feet.

**Keywords** diabetic foot; foot off-loading; plantar pressure; biofeedback; patient education

**Abbreviations** PPP, peak plantar pressure

## Introduction

The elevated plantar pressure and the peripheral sensory-motor neuropathy with loss of protective pain sensation of the foot are the most relevant factors involved in diabetic foot ulceration [1,2], which, in turn, is the leading cause of lower extremity amputations [3]. The areas of high plantar pressure need to be off-loaded for successful ulcer healing and for prevention of foot ulcers. In the absence of adequate sensation due to neuropathy, the patient's feedback is not useful in judging whether pressure relief has been achieved [4].

A considerable effort has been done in the field of foot off-loading in patients with diabetes, and a variety of devices are available. Total contact casts and non-removable walkers have been shown to be extremely effective for ulcer treatment [5,6]. On the other hand, the risk of ulcer recurrence frequently under the same area of the foot is high [7,8], and therefore, a continuous off-loading could be suitable [9]. In fact, all available methods are effective for treating foot ulcers but are less effective in terms of secondary prevention. Altering walking habits may help reduce the incidence of ulcer formation in these patients.

Studies about walking pattern changes in order to reduce plantar pressure are available [10–14]. Biofeedback-based systems enable the subject to initiate new walking gait strategies using visual and/or auditory information [15,16]. However, very limited literature exists in the field of gait pattern changes induced by biofeedback in diabetic patients with peripheral neuropathy.

Recently, we have shown in a group of 13 patients with diabetic peripheral neuropathy of the lower limb that foot off-loading under the at-risk area is achievable by learning with terminally augmented visual biofeedback [14]. However, it is not known if the new gait pattern after the biofeedback intervention induces the development of new 'hot spots' with high plantar pressure under foot zones different from those before the intervention. The development of such in new at-risk area(s) of foot in a patient with diabetic peripheral neuropathy could be potentially harmful and may contribute to new foot ulcer formation.

Thus, the aim of the present study was to analyse the impact of the new walking strategy, learned by terminally augmented biofeedback technique, on plantar pressure distribution under both feet of patients with diabetes mellitus and peripheral sensory neuropathy.

## Materials and methods

### Study population

A total of 25 subjects with diabetes mellitus were recruited for the study from the Service of Therapeutic Education for Chronic Diseases, WHO Collaborating Centre, University Hospitals of Geneva, Switzerland. All participants gave their written informed consent to participate in this study, which was approved by the local ethics committees of the University Hospitals of Geneva.

The inclusion criterion was type 1 or type 2 diabetes mellitus with peripheral neuropathy at the lower limb. The peripheral neuropathy was defined by the absence of both patellar and ankle reflexes on clinical examination and evaluated by the vibration perception threshold (VPT) using a 128-Hz Rydel–Seiffer® (Arno Barthelmes, Tutlingen, Germany) tuning fork [17] at the great toe and internal malleolus of both feet. The patient was asked to respond if he could no longer feel the vibration. At this time, the vibration was determined on the nine-point grading scale (0/8–8/8) of the tuning fork. The patient was considered to have neuropathy if the VPT were inferior or equal to 4/8.

Patients with memory impairment as evaluated by the Mini-Mental Status Examination (MMSE $< 24$, [18]), history of rheumatoid arthritis, congenital defects and foot deformities (e.g. Charcot deformity, prominent metatarsal heads, pes cavus, clawing of the toes, hallux valgus, hallux rigidus) were excluded from the study.

### Plantar pressure measurement

We measured the plantar pressure by the validated PEDAR® device (Novel GmbH, Munich, Germany) [19,20]. This in-shoe mobile system consists in flexible and size adaptable insoles containing 99 capacitive sensors for dynamic plantar pressure measurement. An acquisition rate of 50 Hz has been used for data collecting.

After a careful clinical examination of both feet, followed by an initial measurement of plantar pressure distribution during walking by PEDAR® (four trials, 15 steps each), the zone of the highest plantar pressure under the left or right foot was determined by the physician. This zone was considered to be at risk for foot ulceration and was the target for off-loading during the learning session. The peak plantar pressure (PPP) at the level of the at-risk zone was measured by the Pedar-x/Expert® (Novel GmbH, Munich, Germany) software with mask option.

In addition to the PPP measured under the at-risk zone to be off-loaded, we also measured the plantar pressure distribution under the whole feet in order to check if, during the at-risk zone off-loading by biofeedback, a new high pressure zone had developed under other areas of the right or left foot. For that, the PEDAR® insole containing 99 sensors was divided into 11 areas (Figure 1). The PPP under the at-risk zone as well as the PPP under all other areas of both feet was measured at baseline (T0), at the end of the learning period (T1) and after the retention test at 10 days (T2). At different measurements, patients wore their own shoes that they wear in daily living activities on a regular basis.

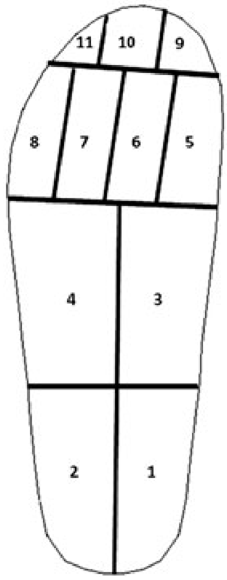

**Figure 1. Division of the insole into 11 zones**

## Biofeedback training procedure

A terminally augmented biofeedback technique, which we previously developed and described [14], was used for foot off-loading. The learning instructions, training and plantar pressure measurements were made by the same investigator for all subjects.

The functioning of the PEDAR® system and the feedback information (graphical representation of plantar pressure on a computer screen) was explained to the patient first. The biofeedback training consisted in walking sequences (10 steps), each followed by a subjective estimation of performance and objective visual feedback (graphical representation of plantar pressure) via PEDAR® system.

Before starting the training, every patient underwent a preliminary learning phase in order to understand the biofeedback information provided by the PEDAR® system. Patients were asked to walk as naturally as possible with PEDAR® insoles. After each walking sequence during this preliminary learning, they received information regarding the biofeedback related to the last 10 steps, and the target plantar pressure to be achieved was re-explained (i.e. the plantar pressure within the 'safe zone' for the majority of steps and in three consecutive walking sequences of 10 steps). When necessary, additional explanation was given to the patient for better understanding of the relationship between the local pressure under the at-risk zone, the information provided by biofeedback and the target pressure to be achieved.

Once the preliminary learning phase terminated and patients understood the learning instructions (the biofeedback provided by PEDAR®), the learning phase was started. Patients were asked to try a new walking strategy without any help or suggestion of the investigator while walking as naturally as possible and until the PPP under the previously defined at-risk zone was reduced to a safe level. At the end of each walking sequence of 10 steps, the patient was asked for his/her subjective estimation of performance as well as to check the PC screen (Hewlet Packard, colour LCD monitor 19-inch) showing the graphics corresponding to the plantar pressure under the at-risk zone at each step of the walking sequence. In this way, when 70% of the steps (e.g. seven steps from 10) and during three consecutive walking sequences had the PPP at the level of the at-risk zone within the range of 40–80% of the baseline PPP, the patient was considered to have learned and adopt his new walking strategy.

After the learning period, a retention test (T1, acquisition test directly after practice) consisting of three successive walking sequences without objective pressure feedback was recorded for each patient. Before this retention test, the following instruction was given to the patient: 'Please, walk as you have been doing during last walking sequence. This time, I will not show you the results and I will not ask you for your personal pressure estimation after walking'. After the training and the first retention test, an appointment was taken for patients 10 days later for a second retention test (T2). Before leaving the hospital, patients were asked to walk during their daily living activities next days as they did at the end of the training and during the retention test T1.

After 10 days, we performed a retention test (T2) similar to T1, consisting of three successive walking sequences without objective pressure feedback. At T2, the following instruction was given to the patient: 'Please, walk as you have been doing in your normal life this morning.'

As a primary outcome for each walking sequence during the retention tests, we measured the PPP under the at-risk zone of the foot. If the PPP was within the range of 40–80% of the baseline PPP, we considered it as the achieved target.

## Statistical analyses

The STATA 10.1 software package (StataCorp, College Station, Texas, USA) was used to perform statistical analyses. We used analysis of variance with Bonferroni post hoc testing to determine the differences between PPP at different phases of the learning procedure and retention tests. Results are expressed as mean ± SE. A $p$-value $<0.05$ was considered statistically significant.

# Results

Among the initially recruited subjects ($n = 25$), four subjects were excluded from the study: one because of language-related communication difficulties, two patients had a history of neurological disease and one patient has not achieved the target PPP during the learning procedure. Finally, 21 patients with diabetes (nine women, 12 men) were included in statistical analyses. The characteristics of the studied population are summarized in Table 1.

## The impact of biofeedback on peak plantar pressure under the at-risk area of the foot (Table 2)

In 14 patients, the at-risk area of the foot was located under the first and/or second metatarsal heads (zone 5 and/or 6, Figure 1), in three patients under the forth metatarsal head (zone 7) and in three patients under the lateral midfoot (zone 4). In one patient, the at-risk area was situated under the great toe (zone 9).

**Table 1. Characteristics of the studied population**

| | |
|---|---|
| *N* (type 1/type 2 diabetes) | 21 (6/15) |
| Women/men | 9/12 |
| Age (years) | 57.8 ± 2.9 |
| Body weight (kg) | 85.8 ± 3.6 |
| Body mass index (kg/m$^2$) | 29.5 ± 1.2 |
| Duration of diabetes mellitus (years) | 17.3 ± 2.1 |
| Vibration perception threshold (right/left foot) | 2.4 ± 0.25/2.4 ± 0.25 |

Results are expressed as mean ± SE.

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**Table 2. Evolution of the peak plantar pressure under the at-risk area of the foot over time**

| | Peak plantar pressure (kPa) | $p$-value * |
|---|---|---|
| T0, baseline (before learning) | 242 ± 12 | — |
| T1, end of learning | 165 ± 9 | <0.0001 |
| T2, retention test (10 days) | 167 ± 11 | 0.001 |

Results are expressed as mean ± SE.
*As compared with T0.

In all patients, the PPP under the at-risk area was significantly reduced at the end of the learning period (T1, 165 ± 9 kPa, $p < 0.0001$), as compared with baseline T0 (242 ± 12 kPa). At the 10-day retention test (T2), the PPP persisted to be significantly lower (167 ± 11 kPa, $p = 0.001$) than the baseline PPP and comparable with the PPP at the end of the learning period ($p = 0.70$).

## The impact of biofeedback on plantar pressure distribution under the whole foot (Table 3)

The PPP has been assessed under all of the 11 foot zones (Figure 1) separately for the foot being 'at-risk' (concerned by off-loading) and for the contralateral foot.

*Foot considered being 'at-risk'*
The PPP under the second and third metatarsal heads (zone 6) decreased significantly at T1 (158 ± 11 kPa, $p = 0.002$) and T2 (163 ± 12, $p = 0.03$), as compared with at T0 (183 ± 9 kPa). Similar results were found under the toes (zones 9, 10 and 11).

Under the great toe (zone 9), the PPP decreased significantly at T1 (79 ± 10 kPa, $p = 0.0006$) and T2 (104 ± 13, $p = 0.03$), as compared with T0 (145 ± 17 kPa).

Under the second to fourth toes (zone 10), the PPP decreased significantly at T1 (54 ± 6 kPa, $p = 0.004$) and T2 (63 ± 6, $p = 0.03$), as compared with T0 (78 ± 9 kPa).

Under the fifth toe (zone 11), the PPP decreased significantly at T1 (27 ± 6 kPa, $p = 0.0001$) and T2 (26 ± 5, $p = 0.0009$), as compared with T0 (44 ± 7 kPa).

The PPP under the first metatarsal head (zone 5) decreased significantly at T1 (134 ± 15 kPa, $p = 0.03$) but not at T2 (147 ± 16), as compared with T0 (162 ± 11 kPa).

The lateral midfoot (zone 4) showed a higher PPP at the end of learning (T1, 70 ± 6 kPa, $p = 0.02$) as compared with baseline T0 (54 ± 5 kPa), but this difference was no more statistically significant at the 10-day retention test (T2, 64 ± 7 kPa, $p = 0.10$).

The PPP under the fourth and fifth metatarsal heads (zones 7 and 8), heel (zones 1 and 2) and median midfoot (zone 3) did not show any differences at T1 and T2 as compared with baseline T0.

*Contralateral foot*
When analysing the contralateral foot (not requiring the off-loading), the only difference we observed was in the lateral midfoot (zone 4). In this zone, the PPP was significantly higher at T1 (68 ± 8 kPa, $p = 0.01$) and T2

**Table 3. Peak plantar pressure distribution under different foot zones after biofeedback learning as compared with baseline**

| | At-risk foot | | | Contralateral foot | | |
|---|---|---|---|---|---|---|
| | Baseline | End of learning | 10-day retention | Baseline | End of learning | 10-day retention |
| Foot zone | (T0) | (T1) | (T2) | (T0) | (T1) | (T2) |
| Zone 1 (Heel) | 130 ± 6 | 121 ± 10 | 128 ± 11 | 122 ± 6 | 124 ± 8 | 131 ± 10 |
| Zone 2 (Heel) | 135 ± 7 | 134 ± 11 | 140 ± 11 | 114 ± 7 | 116 ± 8 | 117 ± 9 |
| Zone 3 (Median midfoot) | 35 ± 3 | 30 ± 3* | 32 ± 3 | 21 ± 4 | 20 ± 4 | 21 ± 5 |
| Zone 4 (Lateral midfoot) | 54 ± 5 | 70 ± 6* | 64 ± 7 | 58 ± 6 | 68 ± 8* | 65 ± 8* |
| Zone 5 (First MTS) | 162 ± 11 | 134 ± 15* | 147 ± 16 | 140 ± 7 | 135 ± 8 | 136 ± 7 |
| Zone 6 (Second to third MTS) | 183 ± 9 | 158 ± 11** | 163 ± 12* | 185 ± 10 | 179 ± 9 | 178 ± 11 |
| Zone 7 (Fourth MTS) | 130 ± 9 | 134 ± 12 | 131 ± 11 | 140 ± 9 | 144 ± 10 | 136 ± 11 |
| Zone 8 (Fifth MTS) | 62 ± 5 | 65 ± 7 | 62 ± 5 | 63 ± 6 | 65 ± 6 | 60 ± 5 |
| Zone 9 (Great toe) | 145 ± 17 | 79 ± 10*** | 104 ± 13* | 142 ± 13 | 133 ± 14 | 134 ± 14 |
| Zone 10 (Second to fourth toes) | 78 ± 9 | 54 ± 6** | 63 ± 6* | 81 ± 9 | 74 ± 7 | 81 ± 9 |
| Zone 11 (Fifth toe) | 44 ± 7 | 27 ± 6*** | 26 ± 5*** | 53 ± 7 | 46 ± 6 | 45 ± 7 |

Results are expressed as mean ± SE.
MTS, metatarsals.
As compared with baseline (T0):
*$p < 0.05$.
**$p < 0.01$.
***$p < 0.001$.

(65 ± 8 kPa, $p = 0.01$), as compared with T0 (58 ± 6 kPa). The PPP at the level of the other 10 zones was not different at T1 or T2, when compared with baseline.

## Discussion

The aim of the present study was to determine, in diabetic patients with peripheral sensory neuropathy of the lower limb, whether the off-loading of an at-risk area of foot by biofeedback induces a homogeneous and regular pressure distribution under both feet. After previously developing a biofeedback technique [14], we now evaluate the impact of the at-risk area off-loading on plantar pressure distribution in a cohort of patients with diabetes different from our previously published study [14].

The present study confirms our previous results indicating that patients with peripheral neuropathy are able to change their walking pattern in absence of adequate sensation [14]. The foot off-loading persists over 10 days without inducing a new 'at-risk' area of foot with high plantar pressure.

The original aspect of the present study is the demonstration that after learning by biofeedback, the plantar pressure was regularly distributed under both at-risk and contralateral foot. Thus, the foot off-loading by biofeedback leads to a safe and regular plantar pressure distribution without inducing any new 'at-risk' area under both feet. When analysing the pressure distribution, there was a significant decrease of PPP under the forefoot of the at-risk foot, while on the contralateral foot, the PPP was significantly increased under the lateral midfoot. This could suggest that patients achieve the foot off-loading by redistributing the plantar pressure homogenously from the at-risk area to the whole foot (i.e. concerned by off-loading) and by shifting the pressure on the lateral side of the contralateral foot (not concerned by off-loading). This new walking pattern does not lead to increase of plantar pressure at any other areas of the feet.

Existing off-loading devices (e.g. total contact casts, removable walkers, therapeutic footwear), when adequately used, are extremely effective for ulcer healing. On the other hand, the recurrence rates of neuropathic ulcers remain high [8,21,22], and, in the same patients, ulcers may occur frequently under the same area of the same foot [7]. Cavanagh and Bus suggested that there could be a need for continuous off-loading in these patients [9]. Even if the existing off-loading devices are effective in acute phases, it seems not realistic to propose these tools for secondary prevention and for a long-term period.

Owings *et al.* [7] measured in-shoe plantar pressures in a group of patients with diabetic neuropathy who had prior foot ulcers that had remained healed. After a median of 3 years since healing, many of these patients had extremely high pressures at prior ulcer sites. As measured by the same instrumentation as in our study, an in-shoe pressure goal of <200 kPa has been proposed by the authors. Other studies have shown that in-shoe pressure can be systematically reduced to the 200 kPa range [23,24]. In our study, the mean in-shoe PPP under the at-risk area was 165 ± 9 kPa at the end of learning and remained stable in the 10-day retention test (167 ± 11 kPa), suggesting that foot off-loading by a biofeedback approach could be a valuable method for a safe plantar pressure reduction.

To our knowledge, this is the first attempt to demonstrate that patients with diabetic peripheral neuropathy and loss of protective pain sensation are able to off-load the at-risk area of foot by biofeedback without developing any new 'hot spot' potentially at-risk for ulceration. The biofeedback technique, as used in the present study, could be an additional and valuable tool to the existing devices (e.g. therapeutic footwear and insoles) for treatment and prevention of diabetic foot ulcers on the long term. When considering that the recurrence rates of neuropathic foot ulcers are high, it seems reasonable to suggest new techniques or devices that may help these patients to modify their walking pattern, which should persist on the long term.

It has been shown for many years that the majority of lower extremity complications are preventable through different educational programmmes for patients and health care providers [25–27]. Experience has shown that patient education itself is not sufficient on the long term. Multiple approaches combining education and new techniques based on instrumentation could be more effective in terms of primary and secondary prevention of lower extremity amputations.

Some limitations to this study should be discussed. First, the sample size is small. It should be mentioned, however, that the existing literature in the field of biofeedback used for foot off-loading is limited; studies mostly present results of healthy volunteers or in particularly small sample sizes. To our knowledge, no study evaluating the potential 'side' effects of biofeedback in patients with insensate feet is available.

Second, the effect of biofeedback was evaluated in subjects without foot deformities. Diabetic patients with advanced stages of neuropathy could present Charcot deformity, prominent metatarsal heads or other deformities. In the present study, the objective was to test if, in the presence of sensory loss, learning by biofeedback induces the development of any new areas of high plantar pressure. We excluded all confounding factors potentially having impact on gait pattern. However, our results should be confirmed in diabetic patients with both sensory and motor neuropathy.

Third, we used the 128-Hz Rydel–Seiffer® tuning fork and not a neurothesiometer for peripheral neuropathy testing. However, it has been shown that the tuning fork reliably detects lower limb neuropathy in comparison with the neurothesiometer and that the tuning fork is a useful screening test for diabetic neuropathy [28].

Finally, our study is of short duration. The persistence of the new walking strategy induced by biofeedback learning should be confirmed on a longer follow-up period (e.g. weeks or months).

In summary, the terminally augmented visual biofeedback helps reduce plantar pressure in diabetic patients with peripheral neuropathy without foot deformity to a safe level and without increasing the pressure at any other areas of both feet. This is particularly important for avoiding new foot ulcer formation due to the newly adopted walking pattern following the biofeedback intervention. Additional research is now needed to evaluate the long-term outcomes of patients with diabetes presenting plantar ulcers when trained by biofeedback.

## Conflict of interest

Nothing to declare.

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