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Biofeedback system enhances the time of balance and decreases the duration of pre-prosthetic training

*Silvia Porras-Rangel[1], Ana B. Aguilar-Valencia[1], Sandra E. Dau-Iñiguez[1], Abraham Zepeda-Moreno[2], Sylvia E. Totsuka-Sutto[3], Iván G. Andrade-Flores[1], Marisol Agredano-Jiménez[1] and Sergio Sánchez-Enriquez[4]**

[1]Centro de Rehabilitación Integral Sra. Olivia Miramontes Aguirre, Guadalajara, Jalisco, Mexico; [2]Instituto de Cáncer Infantil y de la Adolescencia; [3]Department of Physiology; [4]Biochemical Laboratory, Department of Biologic and Molecular Genomics. Centro Universitario de Ciencias de la Salud, Universidad de Guadalajara, Jalisco, Mexico

ABSTRACT

Background: Diabetes mellitus is the leading cause of non-traumatic lower limb amputations. The goal of rehabilitation in these patients is to enable them to appropriately handle a prosthesis so they can reintegrate into society. However, many patients do not achieve this goal because they fail to maintain the balance needed to control the prosthesis. **Objective:** To analyze the effectiveness of a biofeedback electronic system for balance training in patients with femoral amputations secondary to diabetic foot. **Methods:** A single-blinded, randomized clinical trial was conducted. Forty patients with femoral amputation secondary to diabetic foot were divided into two groups: (i) control (n = 20), with conventional pre-prosthetic training; and (ii) patients rehabilitated with a biofeedback electronic system (n = 20). For each patient, 10, 20, and 30 sessions were carried out and balance measurement (minimum and maximum time of balance) was performed using a digital chronometer at the end of each session. **Results:** Baseline clinical and demographic

RESUMEN

Antecedentes: La diabetes *mellitus* es la principal causa de amputaciones no traumáticas de miembro inferior. La meta de la rehabilitación en estos pacientes es permitirles el uso correcto de la prótesis para que sea posible su integración a la sociedad. Sin embargo, muchos pacientes no logran esta meta debido a que son incapaces de mantener el equilibrio necesario para controlar la prótesis. **Objetivo:** Analizar la efectividad de un sistema electrónico para el entrenamiento del equilibrio en pacientes con amputación secundaria a pie diabético. **Métodos:** Se realizó un ensayo clínico aleatorizado ciego simple en 40 pacientes con amputación femoral secundaria a pie diabético subdivididos en grupo control (N = 20 con entrenamiento preprotésico convencional), y grupo experimental (N = 20 con entrenamiento con el sistema electrónico de equilibrio). Se realizaron 30 sesiones de entrenamiento por paciente y se evaluaron los tiempos mínimo y máximo de equilibrio a las 10, 20 y 30 sesiones de entrenamiento. **Resultados:** No hubo diferencias significativas

Dirección para correspondencia:
*Sergio Sánchez-Enríquez
Departamento de Biología Molecular y Genómica
Centro Universitario de Ciencias de la Salud
Universidad de Guadalajara
Sierra Mojada, 950
Col. Independencia, C.P. 44340 Guadalajara, Jal., México
E-mail: serlucis@hotmail.com

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characteristics were similar between the two groups. Differences in the minimum time of balance were noted from the 20th session. Patients using biofeedback had a mean minimum time balance of 38.7 ± 41.0 seconds compared to 7.9 ± 3.3 seconds in those who did not ($p < 0.01$). This difference persisted into the 30th session (57.7 ± 36.8 vs. 16.6 ± 16.1 seconds; $p < 0.01$). Maximum time balance was also found to be longer in patients from group 1, both at the 20th (64.5 ± 69.2 vs. 11.2 ± 4.7 seconds; $p < 0.01$) and the 30th session (83.9 ± 50.7 vs. 36.4 ± 30.7 seconds; $p < 0.01$). **Conclusions:** The electronic balance system is a useful tool for pre-prosthetic training. (REV MEX ENDOCRINOL METAB NUTR. 2016;3:7-11)

Corresponding author: Sergio Sánchez-Enríquez, serlucis@hotmail.com

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entre grupos en sus características clínicas y demográficas. A partir de la sesión 20 se detectaron diferencias en el tiempo mínimo de equilibrio. Los pacientes que utilizaron el sistema electrónico tuvieron un promedio de tiempo mínimo de equilibrio de 38.7 ± 41.0 s, comparado a 7.9 ± 3.3 s en el grupo control ($p < 0.01$). Estas diferencias se mantuvieron hasta la sesión 30 (57.7 ± 36.8 s vs. 16.6 ± 16.1 s; $p < 0.01$). El tiempo máximo de equilibrio fue mayor para el grupo con el sistema electrónico tanto a la sesión 20 (64.5 ± 69.2 s vs. 11.2 ± 4.7 s; $p < 0.01$) como a la sesión 30 (83.9 ± 50.7 s vs. 36.4 ± 30.7 s; $p < 0.01$). **Conclusiones:** El sistema electrónico de equilibrio es una herramienta útil para el entrenamiento preprotésico.

Palabras clave: Biodex. Equilibrio. Balance. Entrenamiento preprotésico. Reintegración social. Amputación. Diabetes *mellitus*.

INTRODUCTION

Secondary complications of diabetes mellitus (DM) are the first cause of non-traumatic lower-limb amputation[1]. After an acute event of amputation, patients and physicians face several difficulties that need to be overcome in order to facilitate the reintegration of the patient into society[2,3]. Among these difficulties is a proprioceptive deficit that leads to balance abnormalities[2,3]. These balance abnormalities delay training and increase the risk of falls, making the goal of proper rehabilitation very difficult to achieve in many patients[4].

Biofeedback electronic training balance systems have been developed to aid in the neuromuscular evaluation, exercise, and gait training as well as in the management of range of motion abnormalities in patients suffering from cerebrovascular disease, Parkinson's disease, spinal cord injury, or brain trauma[5]; yet, they have not been tested in patients with femoral amputations. The system consists of a dynamic tilt platform that promotes neuromuscular, visual, and vestibular control through a feedback system, which is based in recording the individual patient progress.

In the present study we analyze the effectiveness of a biofeedback electronic system for balance training in patients with femoral amputations secondary to diabetic foot.

METHODS

This is a randomized, single-blinded clinical study conducted at the Centro de Rehabilitación Integral "Sra. Olivia Miramontes Aguirre" in Guadalajara, Mexico. The study was carried out in compliance with the Declaration of Helsinki and all participants signed an informed consent. Our local ethics and scientific committees approved the study protocol. Patients were recruited according to the following criteria: (i) patients with femoral amputation due to diabetic foot; (ii) age 35-75 years; (iii) residents of Guadalajara. Patients with visual disturbances, bilateral amputation, with a body mass index (BMI) > 30, or with balance or equilibrium abnormalities due to vestibular, cerebellar, or neurological problems were excluded from the study.

Participants were randomized to either of the two of the following groups: (i) conventional pre-prosthetic training (n = 20) or (ii) biofeedback training using a validated electronic system (Biodex™; Shirley, NY, USA) (n = 20). All patients were trained in stump care and hygiene, as well as in postural alignment by

Table 1. Sociodemographic and health factors in patients included in this study

Variable	Measurement unit	Biofeedback system (n = 20)	Conventional therapy (n = 20)	P value
Age χ ± SD	Years	59.15 ± 11.7	58.2 ± 11.4	0.8*
Gender (n, %)	Male	12 (60)	16 (80)	0.3†
	Female	8 (40)	4 (20)	
Occupation	Employed	4 (20)	3 (15)	0.6†
	Unemployed	7 (35)	10 (50)	
	Home	7 (35)	5 (25)	
	Retired	1 (5)	2 (10)	
	Independent	1 (5)	0 (0)	
Education	Basic school	10 (50)	10 (50)	0.3†
	Secondary school	4 (20)	4 (20)	
	High school	2 (10)	3 (15)	
	University	1 (5)	3 (15)	
	Illiterate	3 (15)	0 (0)	
Diseases	DM	12 (60)	10 (50)	0.7†
	DM + HT	6 (30)	9 (45)	
	DM + HT + hyperthyroidism	1 (5)	0 (0)	
	DM + HT + CRD	1 (5)	1 (5)	
BMI (χ ± SD)	kg/m^2	25.4 ± 3.73	26.14 ± 4.20	0.4*
Height (χ ± SD)	m	1.61 ± 0.11	1.67 ± 0.1	0.11*
Weight (χ ± SD)	kg	66.43 ± 12.83	72.97 ± 13.02	0.11*

*Mann-Whitney U test; †χ^2 test.
DM: diabetes mellitus; HT: hypertension; CRD: chronic renal disease.

assisted mobilization in all ranges of movement and subsequently by standing and mirror feedback. Patients in both groups were similarly trained in stump strengthening through exercises with progressive resistance using elastic bands and balloon for hip and knee muscle workout. They were all prescribed exercises to strengthen the healthy limb using a stationary bicycle with very low resistance for 10 minutes daily and a series of 10-repetition squats; abdominal and paravertebral muscle strengthening by means of William's exercises and abdominal workout; and strengthening of thoracic limbs with isotonic exercises and techniques for stump desensitization.

Patients in the conventional rehabilitation group underwent training using parallel bars and lateralization techniques, whereas those in the biofeedback group were subjected to 15-minute sessions on a stable tilt platform. For each patient, 10, 20, and 30 sessions were carried out, measuring minimal and maximal time of balance using a digital chronometer.

Statistical analysis

Descriptive statistics were used to depict basal demographic and clinical characteristics. Quantitative variables were analyzed by means of either the Student *t* test or the Mann Whitney U statistic, depending on the results of the Kolmogorov Smirnov test; χ^2 test was used to analyze qualitative variables. A $p > 0.05$ was considered as statistically significant. Statistical package consisted of SPPSS version 20.

RESULTS

Basal demographic and clinical features of patients from both groups were similar and are shown in table 1.

The mean minimum times for balance (MnTB) at the 10th, 20th, and 30th rehabilitation sessions are shown

Table 2. Minimum time for balance between patients using the biofeedback system and conventional therapy

MnTB	Biofeedback system (n = 20) $\chi \pm$ SD (min-max) seconds	Conventional therapy (n = 20) $\chi \pm$ SD (min-max) seconds	P value*
10 sessions	3.7 ± 2.6 (1.1-12.4)	3.8 ± 2.3 (1.7-10.5)	0.952
20 sessions	38.7 ± 41.0 (12.1-180.5)	7.9 ± 3.3 (2.4-13.1)	< 0.01
30 sessions	57.7 ± 36.8 (15.0-180.12)	16.6 ± 16.1 (4.5-60.1)	< 0.01

*Mann-Whitney U test.
MnTB: minimum time for balance.

Table 3. Maximum time for balance between patients using the biofeedback system and conventional therapy

MxTB	Biofeedback system (n = 20) $\chi \pm$ SD (min-max) seconds	Conventional therapy (n = 20) $\chi \pm$ SD (min-max) seconds	P value*
10 sessions	8.6 ± 8.1 (2.5-39.1)	6.3 ± 3 (1.7-10.5)	0.625
20 sessions	64.5 ± 69.2 (14.5-240.3)	11.2 ± 4.7 (2.4-13.1)	< 0.01
30 sessions	83.9 ± 50.7 (18-180)	36.4 ± 30.7 (14.3-120)	< 0.01

*Mann-Whitney U test.
MxTB: maximum time for balance.

Table 4. Patients achieving the goal of minimum balance of 20 seconds: Comparison between patients using the biofeedback system and conventional therapy

Goal of balance at least 20 seconds	Biofeedback system (n = 20) n (%)	Conventional therapy (n = 20) n (%)	P value*
20 sessions	17 (85)	1 (5)	< 0.000
30 sessions	18 (90)	11 (55)	< 0.015

*χ^2 test.

in table 2. Whereas at the 10th session the MnTB was similar in the two groups, at the end of the 20th and 30th sessions this measurement was significantly longer in patients undergoing biofeedback rehabilitation than in those subjected to conventional rehabilitation. Similarly, the maximum times for balance (MxTB) depicted in table 3 did not differ between groups at the end of the 10th session, but were significantly longer in subjects from the biofeedback group than in those in the conventional rehabilitation group at the end of the 20th and 30th sessions.

At the end of the 20th session, 85% of the patients in the biofeedback group had achieved the goal of ≥ 20 seconds, whereas this was the case in only 5% of the subjects in the conventional rehabilitation group ($p < 0.0001$). This therapeutic target was reached by 90 and 55% of the subjects in the biofeedback and conventional rehabilitation groups, respectively, by the end of the 30th session ($p < 0.015$) (Table 4).

DISCUSSION

Diabetes mellitus is the leading cause of non-traumatic lower limb amputation[1]. The goal of rehabilitation of these patients is to enable them to appropriately handle a prosthesis so they can return to live a productive and independent life and reintegrate into society. Unfortunately, factors such as the inherent proprioceptive deficiency in the amputated area due to diabetic neuropathy and other balance disorders may hamper the rehabilitation process and sometimes delay or even prevent the achievement of this goal[2,3].

In this study we have demonstrated that a rehabilitation process based on an electronic biofeedback system effectively improves both MnTB and MxTB in these patients. The differences between subjects using the biofeedback system and those undergoing conventional rehabilitation are apparent as early as the 10th session; however, they become statistically significant at the end of 20th session. Although biofeedback systems have been used before in balance training in patients with equilibrium disorders, there are no published studies evaluating their performance in subjects who have lost a limb.

It has been shown that unstable surfaces enhance activation of core muscles[6]. This effect is thought to be achieved through reeducation of stabilizer muscles and lower limbs proprioception, especially for knee and ankle[7]. Use of unstable surfaces improves static balance while training agonist-antagonist muscles for balance in the new context of amputation due to a reeducation of stabilizer muscles[8,9]. Core reeducation is very important since a defective training could increase the time of rehabilitation and impair support mechanics[9].

Achieving a minimum time for balance of at least 20 seconds is of paramount importance for prosthesis control during gait, and rehabilitation using the biofeedback system succeeded in achieving this goal in over 85% of the patients as early as the 20th session. In contrast, only 55% of subjects undergoing conventional rehabilitation reached this target at the end of the 30th session, which means that 45% of these patients will not be able to handle prostheses. As expected, failing to rehabilitate these patients inherently leads to an increase in costs of care, both for the patients and for the institutions.

DECLARATION OF INTEREST

The authors declare that they have no conflict of interest.

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