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Peak pressure data and pressure-time integral in the contralateral limb in patients with diabetes and a *trans*-tibial prosthesis

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ABSTRACT

Background: Clinicians currently rely on observational clinical data pertaining to the biomechanics of the diabetic foot. However, advances in technology can objectively describe this. A thorough understanding of the functional and mechanical consequences following *trans*-tibial amputations is lacking.
Research question: Does a *trans*-tibial prostheses significantly increase peak plantar pressures and pressure time integrals in the intact foot of patients with type-2 diabetes and neuropathy?
Methods: A prospective quantitative matched-subject design was employed. Twenty participants living with diabetes and peripheral sensory neuropathy were recruited. Ten participants presented with a *trans*-tibial amputation and 10 had intact feet. Participants were matched for gender, age, foot type and BMI. Peak plantar pressure and pressure time integral data were recorded using the Tekscan HR™ pressure mat system, using the two-step gait protocol. The Shapiro-Wilk test was used to determine normality of data. The Independent Samples *t*-test and the Mann Whitney *U* test were carried out to reject the null hypothesis.
Results: Although no significant differences ($p < 0.05$) in mean peak plantar pressures were observed in all the foot masks analysed between the amputee and the control group, a significant difference ($p = 0.002$) in mean pressure time integrals was recorded with highest pressure time integral (PTI) values under the 2nd–4th metatarsophalangeal joint (MTP joint) for the *trans*-tibial amputee group.
Significance: Cumulative exposure of both pressure and time can lead to tissue damage. PTI could be considered as an important contributory factor in determining ulcer formation. Elevated PTI under the 2nd–4th MTP joints sustained in the intact contralateral limb in patients using below knee prosthesis could possibly be due to gait alterations in this population. The preservation of the contralateral limb is of great concern and importance as this might impact patient's mobility and quality of life.

1. Introduction

According to the National Amputee Statistical Database [1], a *trans*-tibial or also referred to as a below-knee amputation is one of the most common lower limb amputations. Unilateral lower-limb amputees exhibit asymmetry in many gait features, such as ground force, step time, step length, and joint mechanics [2]. In a study by Bassett et al. [3], on average an adult makes approximately 5117 steps daily. Gait asymmetry has been reported to be of major concern in unilateral lower limb amputees since gait needs to be efficient and symmetrical in order to avoid excretion of excessive load on the intact limb and to avoid further complications [4,5]. Uneven or inefficient gait could increase plantar pressures, thus leading to soft tissue damage. Studies have been conducted to evaluate plantar pressure changes in patients with a unilateral *trans*-tibial amputation in patients living with diabetes, however, findings have been controversial about the kinetic and kinematic differences between both limbs [5]. We currently lack a thorough understanding of the functional consequences following amputation and in view of this, the authors advocate for a scientific justification to better understand and encourage a more symmetrical walking pattern in this specific population [5].

Clinicians usually rely on observation and descriptive data pertaining to the biomechanics of the diabetic foot, however, in recent years, new technologies in the field of clinical biomechanics have been introduced to aid clinicians to objectively assess the diabetic foot. Dynamic, segmental, gait analysis in conjunction with peak plantar pressure measurements have provided valuable insight [6]. Two measures of vertical plantar pressure are most commonly assessed. Peak plantar pressure (PPP) represents the maximum amount of pressure during stance and the pressure time integral (PTI) represents the amount of time over which maximum pressure is applied [7]. Research regarding the relationship between plantar pressures, pressure time

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integral and ulcerations has been thoroughly investigated [8] however research regarding changes in plantar pressure patterns in the contralateral limb following a *trans*-tibial amputation is scarce.

The preservation of the contralateral limb is of extreme importance since it has a great impact on the patient's quality of life and mobility [9]. It is evident that there is a gap in the literature related to this field, thus more research is required to facilitate treatment plans aimed at preserving the integrity of the contralateral intact limb. Thus the objectives of this study were to evaluate differences in mean peak plantar pressure distribution and mean pressure time integral of the contralateral foot in patients living with type 2 diabetes and a *trans*-tibial amputation when compared to non-amputees during ambulation.

The research question posed for this study included '*Does a trans-tibial prosthesis significantly increase peak plantar pressures and pressure time integrals in the intact foot of patients with type-2 diabetes mellitus and neuropathy?'* 'The null hypothesis postulated for this study specifies that transtibial prosthesis do not significantly affect peak planter pressures and pressure time integrals ($p > 0.05$) in the neuropathic population with type-2 diabetes indicating a 5% risk of concluding that a difference exists when this is no actual difference.

2. Methods

2.1. Methodological rigor

To test our hypothesis, a prospective non-experimental case-control matched subject design was conducted. The clinical tools used during this research were based on validated and previously published methods following a thorough review of the literature on international guidelines and recommendations. A database was constructed to record all the information.

2.2. Subject selection

This study was approved by the University Research Ethics Committee and all participants provided informed consent. All investigations were carried out in accordance with the principles of the Declaration of Helsinki as revised in 2017 [10].

Ten type 2 unilateral *trans*-tibial amputee participants using a below knew prosthesis (group 1) for at least one year, to ensure acclimatization with their prosthesis and 10 type 2 non-amputee, controls (group 2), all diagnosed with peripheral sensory neuropathy, participated in the study. The reason for the amputation was due to complications arising from neuropathic ulcerations. Participants were matched for gender, foot type and joint mobility at the ankle using precision matching. Precision matching is defined as creating pairs of participants who have identical scores on the matching variable. Whilst age and body mass index (BMI) were matched using frequency distribution matching. This type of matching is based on an average of each extrinsic characteristic. Foot posture was assessed and classified according to the Foot Posture Index (FPI-6). Joint mobility at the ankle was determined using a goniometer in order to exclude any participants presenting with ankle equines.

Exclusion criteria included all subject with active ulceration or minor amputations, such as digital and *trans*-metatarsal amputations in the contralateral limb as these might alter gait and pressure distributions. Major deformities such as Charcot Arthropathy was also excluded together with any participants who were either making use walking aids of wheelchair dependent. Participants who were either unable to participate in the study due to cognitive impairments or showed unwillingness to participate and follow study protocol were also excluded. The amputee participants all used their own prosthesis during the trial and a registered prosthesist verified the alignment and fit of prosthesis prior to testing.

2.3. Pressure mapping protocol

Peak plantar pressures and pressure time integrals beneath the foot were recorded using a pressure platform (HR Mat™,Tekscan, Boston, USA). Initially the participants were asked to stand on the mat to calibrate the system according to their body mass as per manufacturer instructions. The study protocol was discussed with the participants prior to data collection. A period of acclimatization was included for the participants to understand the 2-step walking protocol which was adopted. This protocol has been reported to be reliable and not very time consuming to implement [11], requiring the participants to make contact with the platform on the second step [12]. Each participant was instructed to stand on both feet exactly two steps prior to stepping on the pressure platform. The participants started walking by stepping first with one foot on the ground and the next step on the platform and continued walking for the next three steps [13]. Several practice trials were performed so as to familiarize the participants with the procedure and encourage natural gait, avoiding targeting. When the participants felt confident with their natural cadence walking, the dynamic plantar pressures under each foot were recorded. Since this study investigated dynamic plantar pressures of the contralateral foot in below knee amputees only pressures of one foot of each participant was recorded. The chosen foot in the control group, was matched according to the contralateral foot of each amputee participant.

This procedure was repeated five times and an average reading was calculated with regards to peak plantar pressures and pressure time integrals at the areas of interest, which included the hallux, 1st metatarsophalangeal joint (MTP joint), 2–4th MTP joints, 5th MTP joint and heel for both groups. These areas of interest were manually segmented by an expert who analysed carefully each recorded trial. Each trial produced five stance phases. The first and last stance phases of each trial were discarded, thus the mean value of the three remaining stance phases for each foot were used for evaluation.

The Shapiro-Wilk test was used to determine normality of data. The statistical tests used to analyse the differences in peak plantar pressures and pressure time integrals between the two groups included the Independent Samples *T*-test and the Mann Whitney *U* test. Statistical analyses were carried using the Statistical Package for the Social Sciences version 20.

3. Results

A total of 20 participants, including 14 males and 6 females were included in this study. The mean age for Group 1 was 65.6 years and 66.8 years for Group 2. The mean BMI for Group 1 was 30.72 kg/m^2 and the mean BMI for Group 2 was 31.3 kg/m^2.

Mean peak plantar pressures in the 1st MTP joint (6.02 kg/cm^2) and 2nd–4th MTP joints (4.6 kg/cm^2), were found to be higher for Group 1 when compared to the control group (1st MTP joint – 4.53 kg/cm^2; 2–4th MTP joints – 4.23 kg/cm^2). Conversely mean peak plantar pressures in the hallux (4.48 kg/cm^2), 5th MTP joint (3.37 kg/cm^2) and heel (4.26 kg/cm^2), were higher for the control group (Group 2) when compared to Group 1 (hallux (3.43 kg/cm^2), 5th MPJ (2.64 kg/cm^2) and heel (3.56 kg/cm^2). No significant differences in mean peak plantar pressures were observed in all the above foot masks analysed between the amputee and the control group (Tables 1 and 2).

The study also investigated whether there was a difference in pressure time integrals (PTI) amongst below knee amputees and their controls. Mean pressure time integrals in the 1st MTP joint (12.77 $Kg/cm^2/s$), 2nd – 4th MTP joints (23.27 $Kg/cm^2/s$), 5th MTP joint (4.28 $Kg/cm^2/s$) were found to be higher for Group 1 when compared to the control group 1st MTP joint (9.06 $Kg/cm^2/s$), 2nd - 4th MTP joints (15.48 $Kg/cm^2/s$), 5th MTP joint (3.76 $Kg/cm^2/s$). Conversely mean pressures time integral in the hallux (3.92 $Kg/cm^2/s$) and heel (25.83 $Kg/cm^2/s$), were higher for the control group (Group 2) compared to Group 1 hallux (2.39 $Kg/cm^2/s$) and heel (20.62 $Kg/cm^2/s$). A