

## Segmental lower limb mobility, muscle activity and plantar pressure analysis in individuals living with diabetic peripheral neuropathy: a systematic review and meta-analysis.

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### Citation

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### Review question

What are the effects of DPN on lower limb kinetics, kinematics, muscle activity, spatiotemporal parameters and plantar pressure distributions in type 2 diabetes?

### Searches

- MEDLINE OVID, Elsevier, PROSPERO, Cochrane Library, PubMed and CINAHL
- Publication dates: 2000 - 2020
- Language: Written in the English language only

### Types of study to be included

All types of quantitative, non-experimental, observational, prospective, comparative studies will be included in this review.

### Condition or domain being studied

Diabetic peripheral neuropathy (DPN) is the most common complication of diabetes, affecting up to 50% of individuals and their quality of life. DPN is characterised by the progressive loss of proprioception, somatosensory sensitivity and intrinsic distal muscle function. Musculoskeletal complications may cause bony deformities, such as clawing of digits and prominence of metatarsophalangeal joints and increase plantar pressures resulting in skin breakdown and ulceration.

Since the repetitive action of mechanical stress during gait in the presence of DPN may lead to ulcer development, better understanding of the mechanism and biomechanical components of ulcer development is of vital importance.

Literature shows that DFU are found on high plantar pressure areas, however, in the absence of neuropathy, high pressure areas alone do not lead to ulceration. This systematic review and meta-analysis aims to provide a comprehensive understanding of lower limb joint and muscle function and plantar pressures during gait in the presence of DPN. This, may provide evidence for the design of more efficient and specific treatment options of healing in order to prevent risk of amputation and reulceration. Reducing the mechanical loading on the ulcerated foot during gait may influence the healing of DFU and provide preventative mechanisms of ulceration.

## Participants/population

### Inclusion Criteria:

Studies published between 2000 and 2020

Studies written in the English language

Studies in the adult population ( $\geq 18$  years of age)

Studies investigating barefoot walking

Gait data acquisition done using 3D gait analysis systems

Studies investigating at least one outcome measure listed below

### Exclusion Criteria:

Studies published before the year 2000

Studies not written in the English language

Studies not in the adult population ( $< 18$  years of age)

Studies investigating gait whilst shod and/or with orthotic devices

Studies investigating treadmill walking

Studies not investigating at least one outcome measure listed below

Studies including lower limb active ulceration, amputation or Charcot deformity

Studies not providing datasets which are comparable (mean and standard deviation, SD)

## Intervention(s), exposure(s)

Studies investigating barefoot walking (not treadmill walking or shod) using 3D gait analysis systems will be included in this review.

## Comparator(s)/control

Studies having participants living with type II diabetes acting as the control groups will be included in this review.

## Main outcome(s)

At least one of these outcome measures should be measured for studies to fit in the inclusion criteria of this review:

1. Joint kinematics - reporting range of motion (ROM) findings for at least one lower limb joint (hip, knee ankle or any foot segment joint)
2. Joint kinetics - reporting findings on joint moments (hip, knee ankle or foot segment joints) and/or reporting vertical ground reaction forces (GRFs) at initial contact and/or toe-off
3. Spatiotemporal - reporting findings on gait velocity (m/s), stride length (m) and/or stride time (s)

4. Electromyography (EMG) - reporting findings on lower limb muscle activation peak (mV) and/or temporal pattern (% support)

5. Plantar pressure - reporting findings on peak plantar pressure (kPa) and/or pressure-time integral (PTI) (kPa.s) in the rearfoot, midfoot, forefoot, lateral heel, medial heel, lateral forefoot, medial forefoot and/or hallux

All of these outcome measures will be analysed qualitatively and quantitatively separately, in order to evaluate whether individuals living with diabetic peripheral neuropathy are affected by any of them.

#### Measures of effect

Only observational studies will be included in this review so data from studies will only be non-experimental.

#### Additional outcome(s)

None

#### Measures of effect

None

#### Data extraction (selection and coding)

The process of data extraction will be performed by the first author with the aid of the other authors for reviewing. Studies that reported at least one of the outcome measures were included for statistical analysis. The authors of studies having unreported or missing data will be contacted, and studies will be omitted from this review if there is no reply.

Descriptive statistics of participants from the included studies will be recorded in three tables:

- The first table will include the participants' age, body mass index (BMI), duration of diabetes and site of recruitment.
- The second table will illustrate the mode of DPN diagnosis and the exclusion criteria used in each included study.
- Data from all included studies of the outcome measures analysed in this review will be illustrated in separate tables including; the spatiotemporal parameters, lower limb joint kinematics, foot joint kinematics, lower limb joint kinetics, vertical GRFs (first and second peak), muscle activity (peak activation and temporal patterns), peak plantar pressure and pressure-time integral.

#### Risk of bias (quality) assessment

The quality of included studies will be independently evaluated by the first and last author using the Downs and Black quality assessment tool (Downs & Black, 1998). This 28-item checklist is the only tool which can be used in evaluating prospective, comparative, non-experimental quantitative studies and is divided into five main domains as follows;

- Item 1-11: analyses whether any of the included studies had issues with reporting bias.
- Item 12-14: deals with external validity, including participant recruitment and establishments or facilities where data was acquired.
- Item 15-21: investigates internal validity, including blinding of participants and investigators, compliance of participants during testing, accuracy of statistical tests and main outcome measures.
- Item 22-27: explores internal validity with respect to any selection bias present in the included studies
- Item 28: inspects whether the studies were sufficiently powered to detect clinically important effects where probability value for a difference due to chance was less than 5%

## Strategy for data synthesis

For ease of comparison and statistical analysis, data from the outcome measures of interest will be transformed into standardised units. Meta-analyses will be carried out on three or more studies reporting comparable data on any of the outcome measures analysed in this review using RefWorks.

Cohen's d will be used to compute the effect size, where the difference in mean values is divided by pooled SD. Moreover, the heterogeneity of the included studies will be calculated using the Q,  $I^2$  and  $\tau^2$  statistics. Finally, the results will be reported as standardised mean differences with 95% confidence intervals and p-values, in which forest plots will also be provided. According to Cohen (1988), a Cohen's d scores are interpreted as 0 (no difference in effect), 0-0.2 (small effect), 0.2-0.5 (medium effect) and  $\geq 0.8$  (large effect).

It is aimed that through these analyses, a clear evaluation of which outcome measures assessed in this review are affected by diabetic peripheral neuropathy is found in order to be able to provide better treatment options for ulcer prevention.

## Analysis of subgroups or subsets

Each outcome measure will be divided into the following subgroups where analysis would have been done on all participants in the included studies.

- Spatiotemporal parameters: gait velocity, stride length, stride time
- Joint kinematics: hip, knee, ankle, foot joint segment range of motion
- Joint kinetics: hip, knee, ankle foot joint segment moments and ground reaction forces (first and second peak)
- Muscle activity: lower limb muscle activation peak, temporal pattern
- Plantar pressure: peak plantar pressure and pressure-time integral in the rearfoot, midfoot, forefoot, lateral heel, medial heel, lateral forefoot, medial forefoot and/or hallux

## Contact details for further information

Erica Bartolo

[erica.bartolo.08@um.edu.mt](mailto:erica.bartolo.08@um.edu.mt)

## Organisational affiliation of the review

University of Malta

[www.um.edu.mt](http://www.um.edu.mt)

## Review team members and their organisational affiliations

Ms Erica Bartolo. University of Malta

Professor Claudia Giacomozzi. Italian National Institute of Health

Dr David Coppini. Mater Dei Hospital

Dr Alfred Gatt. University of Malta

## Type and method of review

Diagnostic, Meta-analysis, Prevention, Systematic review

### Anticipated or actual start date

29 May 2020

### Anticipated completion date [1 change]

08 February 2021

### Funding sources/sponsors

No funding or sponsoring was provided.

### Conflicts of interest

None known

### Language

English

### Country

Malta

### Stage of review [1 change]

Review Completed not published

### Subject index terms status

Subject indexing assigned by CRD

### Subject index terms

Diabetes Mellitus; Diabetic Foot; Diabetic Neuropathies; Foot; Humans; Muscles

### Date of registration in PROSPERO

16 October 2020

### Date of first submission

15 September 2020

### Stage of review at time of this submission [1 change]

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes

*The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.*

*The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.*

## Versions

16 October 2020

08 February 2021