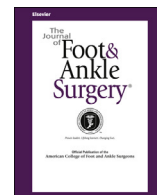




Contents lists available at ScienceDirect

## The Journal of Foot &amp; Ankle Surgery

journal homepage: [www.jfas.org](http://www.jfas.org)

## Does First Ray Amputation in Diabetic Patients Influence Gait and Quality of Life?



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### ARTICLE INFO

Level of Clinical Evidence: 4

#### Keywords:

biomechanics  
diabetes  
gait analysis  
hallux  
quality of life

### ABSTRACT

It has recently been suggested that first ray amputation in diabetic patients with serious foot complications can prolong bipedal ambulatory status, and reduce morbidity and mortality. However, no data are available on gait analysis and quality of life after this procedure. In the present case-control study (6 amputee and 6 nonamputee diabetics, 6 healthy non-diabetic), a sample of amputee diabetic patients were evaluated and compared with a sample of nonamputee diabetic patients and a group of age-matched healthy subjects. Gait biomechanics, quality of life, and pain were evaluated. Compared with the other 2 groups, amputee patients displayed a lower walking speed and greater variability and lower ankle, knee, and hip range of motion values. They also tended to have a more flexed hip profile. Pain and lower quality of life were related to worsening biomechanical data. Our study results have shown that gait biomechanics in diabetic patients with first ray amputation are abnormal, probably owing to the severity of diabetes and the absence of the push-off phase provided by the hallux. Tailored orthotics and rehabilitation programs and a specific pain management program should be considered to improve the gait and quality of life of diabetic patients with first ray amputation.

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Diabetes is one of the most common chronic diseases in the world. The incidence of diabetes has increased steadily in recent years (1). Type 2 diabetes mellitus has reached epidemic proportions, affecting 56 million people in Europe (i.e., 8.5% of the adult population) (2). Although the natural history of diabetic neuropathy remains unclear, the late sequelae of the disease include foot ulceration and, in the worst scenario, amputation (3). According to community-based studies from North America and European countries, the annual incidence of

diabetic foot ulcers ranges from 0.6% to 2.2% (4). It has been estimated that diabetes and its comorbidities account for 50% of the lower extremity amputations performed worldwide (5), and an estimated 85% of all diabetes-related amputations are preceded by a foot ulcer (6).

Neuropathy, foot ulceration and, in the worst cases, amputation, lead to limited joint mobility in 30% to 40% of diabetic patients, especially in the ankle joint and first metatarsophalangeal joint (7). Joint impairment can lead to functional gait variations, and their severity depends on the extent of the neuropathy, ulcers, and level of amputation (8–11).

Two reviews (12,13) of gait characteristics in diabetes reported (1) the presence of conservative strategies, including slower walking speeds, prolonged double support time, and a wider base of gait; and (2) the presence of greater step variability. All these factors lead to

**Financial Disclosure:** None reported.

**Conflict of Interest:** None reported.

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an increased risk of falls and a greater likelihood of developing a foot ulcer.

Regarding the biomechanical studies on kinematic gait changes in diabetic patients with neuropathy, contrasting results have been reported. A study conducted by Paul et al (14), in which diabetic patients with neuropathy were compared with those without neuropathy, detected differences in gait parameters (i.e., neuropathic subjects walked more slowly and took smaller steps). Similarly, longer double and single stance times, lower minimum vertical force, and lower growth rates were seen in the neuropathic patients compared with the diabetic and nondiabetic subjects (15). In contrast, Yavuzer et al (16) found slower gait, shorter steps, and limited knee and ankle mobility in patients without neuropathy, but not in those with neuropathy, compared with healthy subjects.

Some studies have investigated the kinematic gait changes in diabetic patients who have undergone amputation. Walking limitations depend on the level of the amputation. Major amputations will result in significant functional impairment associated with the increase in the physical effort required to maintain walking ability (14). Partial foot amputations, such as transmetatarsal amputations or forefoot amputations, have less effect on a patient's walking ability (15).

Few data are available on gait analysis in patients with forefoot amputations. Transmetatarsal amputation not only preserves ankle function and maintains a distal weightbearing surface but also ensures a more energy-efficient gait (17) compared with more proximal amputations. The latter result in compromised foot and ankle propulsive function and, consequently, in transfer of the primary role of power for walking from the ankle to the hip (5,17–19).

No studies have yet been conducted on the kinematic gait changes in patients who have undergone first ray amputation (FRA), defined as amputation of the phalanges and at least part of the metatarsus (20). This surgical technique was recently proposed as a procedure that can save the foot, prolong the patient's bipedal ambulatory status, and reduce the patient's morbidity and mortality (21).

Abnormal gait can negatively affect quality of life (QoL) and has been observed in a range of pathologies (22). A significant worsening occurs in the QoL of diabetic patients (23) in relation to peripheral nerve damage (24). However, no studies have yet investigated the relationship between quantitative gait parameters and QoL in diabetic patients.

The aim of the present study was to investigate whether diabetic patients with FRA adopt different walking strategies from either nonamputee diabetic patients or healthy subjects. Pain and QoL were evaluated to analyze possible differences between amputee and nonamputee diabetic patients and to evaluate any correlation between these patient-oriented subjective tools and the objective gait data.

## Patients and Methods

### Participants

Our study should be considered a pilot study conducted for exploratory data analysis purposes. We enrolled 6 male diabetic subjects with unilateral FRA, the amputee diabetic patient (ADP) group (mean age 75, range 60 to 90 years; disease duration since diagnosis, mean  $\pm$  standard deviation  $16 \pm 6.6$  years); 6 diabetic patients without FRA, the diabetic patient (DP) group (2 females, 4 males; mean age 68.16, range 65 to 73 years; disease duration since diagnosis, mean  $13 \pm 7.6$  years); and 6 healthy subjects, the healthy subject (HS) group (4 females, 2 males; mean age 67.5, range 64 to 73 years). The inclusion criteria were type 2 diabetes mellitus (with or without diabetic neuropathy) and the ability to walk independently without assistance or walking aids. The exclusion criteria were a history of previous amputation, cognitive or visual impairment, cardiac diseases (which could reduce safety when walking), and other diseases liable to cause motor gait impairment (e.g., radiculopathy and fractures). The diagnosis of peripheral neuropathy was defined as a neuropathy disability score  $>5$  (25) and pathologic nerve conduction velocity findings. Self-reported data (using QoL and pain standardized measures) were collected, and an objective gait evaluation was performed of all 18 subjects. All the participants gave written informed consent before

inclusion in the study, which complied with the Declaration of Helsinki. The ethics committee of the Don Carlo Gnocchi Onlus Foundation approved the experimental protocol, which was explained, together with the aims of the research, to the subjects involved in the study.

### QoL and Pain Assessment

The QoL assessment was performed using the Short-Form 36-item Health Survey (SF-36) and North American Spine Society (NASS) questionnaire. Pain was evaluated using the numeric rating scale (NRS), ID-Pain, and the Neuropathic Pain Symptom Inventory (NPSI). The official Italian version of the SF-36 (26) consists of 36 questions that cover the general health of patients. It contains 10 specific categories of physical and emotional domains. The scores for each category range from 0 to 100, with very low values corresponding to severe physical impairment or emotional discomfort. The NASS, which is used to analyze neurologic symptoms and lower limb function, yields 2 scores: lumbar spine pain/disability (NASS-P) and lumbar spine neurogenic symptoms (NASS-L). The score for each category ranges from 0 to 100, with higher scores indicating better health (27). The NRS (range 0 to 10) measures the intensity of pain, with the score ranging from 0 (no pain) to 10 (the worst imaginable pain) (28,29). ID-Pain is a 6-item self-administered questionnaire developed by Portenoy (30) to discriminate neuropathic from nociceptive pain. The NPSI is a self-administered questionnaire designed to evaluate various symptoms of neuropathic pain. Each item is quantified on a numeric scale (range 0 to 10). The final version of the NPSI contains 12 items: 10 that describe the different symptoms and 2 that assess the duration of spontaneous ongoing and paroxysmal pain. A total intensity score can be calculated by summing the scores of the 12 items (31).

### Gait Analysis

The gait analysis was performed using the Smart D500 stereophotogrammetric system (BTS Bioengineering, Milan, Italy). The system consists of 8 infrared cameras (sampling rate of 250 Hz) to acquire movement of the reflective spherical markers placed over anatomic landmarks. The subjects were equipped with 22 retroreflective markers, according to the Davis protocol (32). The markers were placed on the following anatomic landmarks: seventh cervical vertebra, right and left acromioclavicular joint, right and left anterior superior iliac spine, sacrum, right and left greater trochanter, right and left mid-thigh, right and left lateral femur condyle, right and left fibular head, right and left mid-shank, right and left lateral malleolus, right and left fifth metatarsal head, and right and left heel. Anthropometric data were collected for each subject (33). Before formal measurements were started, practice sessions were performed to familiarize the participants with the procedure. They were trained to walk barefoot (without shoes for nonamputee patients and without toe filler for amputee patients) straight ahead along a level surface that was approximately 6-m long. Both diabetic and healthy subjects were asked to walk at a comfortable self-selected speed. Ten linear walking trials were acquired for each subject. To avoid fatigue, groups of 5 trials were separated by a 1-minute rest.

### Data Analysis

Three-dimensional marker trajectories were tracked using a frame-by-frame tracking system (Smart Tracker-BTS, Milan, Italy). Data were processed using 3-dimensional reconstruction software (SMARTAnalyzer, BTS, Milan, Italy) and MATLAB, version 7.4.0, software (MathWorks, Natick, MA). The gait cycle duration was defined as the interval between 2 consecutive heel contacts of the same foot. The following spatiotemporal parameters were calculated: stance, percentage of duration of the swing and double support phases, cadence, step length, and step width. For all spatiotemporal parameters, the coefficient of variation was calculated as the ratio between the standard deviation and the mean value for each subject. To evaluate the asymmetry and bilateral coordination of gait, the spatial asymmetry index (SAI; Eq. 1) and temporal asymmetry index (TAI; Eq. 2) were calculated for the ADP group as follows (34):

$$SAI = 100 \times \left( 1 - \frac{\text{StepLength\_AmputeeSide}}{\text{StepLength\_NoAmputeeSide}} \right) \quad (1)$$

$$TAI = 100 \times \left( 1 - \frac{\text{SingleSupportTime\_AmputeeSide}}{\text{SingleSupportTime\_NoAmputeeSide}} \right) \quad (2)$$

For the DP and HS groups, the SAI and TAI were computed according to Hodt-Billington et al (35), using the lower and higher values of the step length and single support time, respectively. Higher absolute SAI and TAI values indicate greater asymmetry, and perfect symmetry in the spatiotemporal parameters corresponds to an SAI and a TAI of 0.

To assess the lower limb joint kinematics on the sagittal plane, we calculated the hip, knee, and ankle joint angular displacements and their range of motion (ROM). Specifically, we considered the amputated and nonamputated side for the ADP group

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