The Correlation Between Biomechanical Parameters of Lower Limb and Overall Risk for Diabetic Foot Ulcer

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Abstract

Background/Aim: Preventing lower limb diabetic complications begins with identifying those at risk for diabetic foot ulceration (DFU). DFU development is related to abnormal pattern of plantar pressure distribution caused by alterations in foot rollover process due to loss of foot-ankle muscular strength, impaired range of motion (ROM) and nervous function, as their integrity is needed to enable proper load absorption on plantar surface. Objective of study was to determine correlation between biomechanical parameters of lower limb: ankle and foot muscle strength, ROM at ankle joint (AJ), subtalar joint (SJ) and first metatarsophalangeal joint (I MTP) and overall risk for DFU assessed by IWGDF 2019 Guidance risk stratification system.

Methods: A cross-sectional study included 100 diabetic patients, both types. Patients were classified into 4 DFU risk categories applying IWGDF Guidelines 2019 stratification risk system. Function of ten foot and ankle muscles was evaluated by manual muscle testing applying Michigan Diabetic Neuropathy Score system and was expressed by muscle score (MS) on dominant leg. ROM at AJ, SJ and I MTP was measured with a goniometer on dominant leg and was expressed by degree (°).

Results: Average MS in specified categories were as follows: Category 0: 9.2; Category 1: 13.9; Category 2: 13.3; Category 3: 15.2 and they were significantly different. Average ROM at AJ in specified categories were as follows: Category 0: 49.3°; Category 1: 48.8°; Category 2: 45.5°; Category 3: 44.6° and they were not significantly different. Average ROM at SJ in specified categories were as follows: Category 0: 37.8°; Category 1: 31.3°; Category 2: 35.0°; Category 3: 28.7° and they were significantly different. Average ROM at I MTP in specified categories were as follows: Category 0: 78.6°; Category 1: 74.4°; Category 2: 65.5°; Category 3: 57.9° and they were significantly different.

Conclusions: Risk for DFU ulcer significantly correlates with decreased ankle and foot muscle strength and ROM at SJ and I MTP but does not correlate with ROM at AJ.

Key words: Diabetes; Diabetic foot ulcer; Muscle strength; Muscle weakness; Range of motion.

Introduction

Worldwide 463 million people are living with diabetes mellitus (DM) and this number is expected to rise to 700 million by 2045.1 Diabetic foot ulcer (DFU), as one of the most severe diabetic complications of the lower extremities, will be developed in up to 34 % of persons with diabetes during their lifetime.2 Amputation, as the most serious complication of diabetes in the lower extremities, takes place every 20 seconds somewhere in the world.3 In the United States, health
care costs for people with diagnosed diabetes accounts for one-quarter of the total health care costs and more than half of that is directly related to diabetes.\textsuperscript{4} More than a third of the cost of diabetes treatment is lower-extremity-related.\textsuperscript{2} Although the data on the burden of diabetes foot disease are obvious, this complication is underestimated in scientific and clinical practice compared to other DM complications.\textsuperscript{5} DFU usually develops as a result of several risk factors present in people with diabetes, with diabetic peripheral neuropathy (DPN) and peripheral arterial disease (PAD) usually playing a central role in this process. DPN causes loss of protective sensation (LOPS), increases the skin susceptibility to cracking, can sometimes lead to deformities of the foot which often result in abnormal foot loading.\textsuperscript{6} Human gait is a result of integrated performances of the lower limb, requiring a healthy neuro-musculoskeletal system which can be affected by diabetes. DFU development is related to an abnormal pattern of plantar pressure distribution caused by alterations in the foot rollover process due to loss of foot-ankle muscular strength, impaired range of motion (ROM) and nervous function, as their integrity is needed to enable proper load absorption on the plantar surface.\textsuperscript{7-11} The ROM at joints is altered in diabetes\textsuperscript{12} and can result in abnormally high intrinsic plantar pressures and lead to plantar ulceration, but only as a contributor to other risk factors.\textsuperscript{13} There is evidence that hyperglycaemia accelerates the loss in muscle size and strength, especially in the distal muscles of the lower leg.\textsuperscript{14} Weakness evaluated by manual testing has been reported to be an independent risk factor for the development of DFU, probably because muscle weakness at the ankle and knee in DPN leads to the abnormal application of pressure at the sole during gait due to alterations of the biomechanics of the foot.\textsuperscript{15, 16}

Considering the above facts about the DFU burden, the health care profession's noble quote is worth stating: "prevention is better than cure".\textsuperscript{17} Unfortunately, prevention does not receive top priority when it comes to DFU. Two cornerstones of the preventative foot care are: 1) to implement knowledge in daily foot care and b) to improve treatment adherence.\textsuperscript{18} According to the recommendations outlined in the Guidelines on the prevention and management of diabetic foot disease published by the International Working Group on the Diabetic Foot (IWGDF), identifying patients who are at risk for ulceration is the first step in prevention.\textsuperscript{6} For at-risk patient identification, the IWGDF has established a stratification system that also directs care interventions. Key risk factors include LOPS, PAD and foot deformity, history of foot ulceration and any level of lower extremity amputations.\textsuperscript{19}

Relationship between the biomechanical parameters of the lower limb and the assessed DFU risk in diabetic patients has not yet been explored, however, it was assumed that the overall DFU risk is positively correlated with the decline of the lower extremity muscle performance. If there is a positive relationship between these variables, it might be possible to establish an additional set of preventative measures to decrease the complications of DM of the lower extremities by using an active rehabilitative approach with the goal of muscle strengthening and increasing the mobility at the joint.

The objective of the study was to determine the correlation between the biomechanical parameters of the lower limb: ankle and foot muscle strength, ROM at ankle, subtalar and first metatarsophalangeal joint and overall risk for diabetic foot ulceration assessed by IWGDF 2019 Guidance risk stratification system.

**Methods**

**Design and population**

Patients with both types of diabetes mellitus who were registered with primary health care physicians were the subject of this cross-sectional study. The sample of 100 adult patients who entered the study consisted of patients from ten primary health care clinics. The sample was selected in a way that patients who were seen for their insulin needs or for their oral hypoglycaemic medication management were invited to the study consecutively, without any specific criteria. The survey included medical records review, interview for the sake of detailed with the medical history, as well as measurement and testing of the patients. Medical records were the source of personal data, data on the type of DM, duration and management of the disease up to date and HbA\textsubscript{c} values not older than six months.\textsuperscript{20, 21} The clinical examinations were performed routinely by the same examiner. Data analysis was performed in 2020.
Diabetic foot risk assessment

Using the data obtained from comprehensive examinations and the history taking, the patients were classified into risk categories for DFU applying IWGDF Guidelines 2019 stratification risk system as follows: the risk Category 0 - patients with normal findings; the risk Category 1 (low risk) - patients with LOPS or PAD; the risk Category 2 (moderate risk) - patients with LOPS + PAD, or LOPS + foot deformity or PAD + foot deformity; the risk Category 3 (high risk) - patients who had LOPS or PAD and one or more of the following: history of a foot ulcer, lower-extremity amputation and end-stage renal disease.\textsuperscript{19} LOPS was assessed as follows: vibration testing using a 128-Hz tuning fork, tests of pinprick sensation on the dorsum of foot, tactile sensation test using cotton wool on the dorsum of foot and Achilles ankle reflex assessment.\textsuperscript{22, 23} Vibrationary sensation was tested over the tip of the great toe bilaterally. Abnormal vibratory sensation was defined as a situation when the patient loses vibratory sensation while the examiner still perceives it with a 128-Hz tuning fork on the tip of the toe. A disposable pin was applied just proximal to the toenail on the dorsal surface of the hallux, with just enough pressure to deform the skin. The inability to perceive pinprick over either hallux was an abnormal test result. Ankle reflexes were tested using the tendon hammer, with the patient kneeling on a chair. Absence of ankle reflex either at rest or upon the reinforcement, was regarded as an abnormal test result. One or more abnormal tests would suggest LOPS, while at least two regular tests and no abnormal test would rule out LOPS.\textsuperscript{22}

Vascular examination included palpation of the posterior tibial and dorsalis pedis pulses bilaterally, which was characterised as “present” or “absent”.\textsuperscript{24-26} The presence of two or less of the four pedal pulses indicated PAD.\textsuperscript{25}

Foot strength assessment

Foot and ankle muscle function were evaluated with manual muscle testing (MMT) on the dominant leg. The same scoring system, which is used in the Michigan Diabetic Neuropathy Score, was applied.\textsuperscript{10, 27, 28} MMT indicates the ability of the tested muscle to produce an active movement against the examiner’s resistance. Score 0 was for normal muscle strength, 1 for mild, 2 for severe muscle weakness and 3 for complete loss of muscle strength. As described, the muscle score (MS) was obtained for each set of muscles that were examined. The minimum score was 0 (normal strength in 10 muscles) and the maximum score was 30 (complete loss of strength in 10 muscles). Higher scores indicated increased muscle weakness.\textsuperscript{27, 29} In described testing positions, the manual clinical assessment\textsuperscript{30} was performed for the following muscles: triceps surae, tibialis anterior, interosseus, lumbrical, flexor hallucis brevis, extensor digitorum brevis, extensor digitorum longus, flexor digitorum brevis, extensors hallucis longus and extensor hallucis brevis.\textsuperscript{10}

Range of motion measurement

The joint mobility at the ankle joint (AJ), subtalar joint (SJ) and first metatarsophalangeal joint (I MTP) was determined using a goniometer on the dominant lower limb.\textsuperscript{31-33} ROM at the AJ was measured with the patient in a supine position. The passive maximum range of talor flexion and extension were measured and the sum of the two values was recorded as ROM at the AJ.\textsuperscript{32} The ROM at SJ was measured with the patient in a prone position. The maximum range of calcaneal inversion and eversion were measured and added up to indicate the ROM at the SJ. The range of passive extension to plantar flexion at the I MTP was measured with the patient supine and the ROM at the I MTP was recorded as the sum of those two values.\textsuperscript{32, 33}

Foot deformities assessment

The presence of deformities such as hammer toes, claw toes, prominent metatarsal heads and high medial arch were assessed using a foot deformity score. Hammer toes were defined as “a hyperextended metatarsophalangeal joint with a flexion deformity of the proximal interphalangeal joint and hyperextension of the distal interphalangeal joint”. Claw toes were defined as “hyperextension of the metatarsophalangeal joints and flexion of the proximal and distal interphalangeal joints”. Prominent metatarsal heads were defined as “any palpable plantar prominences of the metatarsal site of the foot”. Lastly, high medial arch was defined as “an abnormally high medial longitudinal arch”. A point was given for each deformity present to whatever degree, with a maximum score of 6 (3 for one leg) because subject could only score for one of the toe deformities. In patients with amputations, the result on the one leg
counted twice. Patient was defined as having a deformity if he/she had a score of 2 or more.

**Statistical analyses**
The statistical analyses were done using the software package IBM SPSS Statistics. For a statistical analysis continuous data were presented as means and standard deviations. To test the statistical significance between variables, the one-way ANOVA test were applied. The cut off for the significance of the results was \( p < 0.05 \).

**Results**

Demographics and diabetes characteristics are shown in Table 1. In the sample of the 100 patients, there were more women (53 %) than men (47 %). The average age of the group was 61.91 ± 10.74 years and the average diabetes duration was 12.25 ± 8.60 years. There were 96 patients with type 2 DM and 6 with type 1 DM and average HbA\(_1c\) value was 7.85 ± 1.73 %.

<table>
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<th>Patients' characteristics</th>
<th>IWGDF patients categories</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
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<td>1 (n = 16)</td>
</tr>
<tr>
<td>Males (n)</td>
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</tr>
<tr>
<td>Females (n)</td>
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<td>Age (years)</td>
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<tr>
<td>Diabetes type 2 (n)</td>
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</tr>
<tr>
<td>HbA(_1c) (%)</td>
<td>7.5 ± 1.4</td>
<td>8.8 ± 1.8</td>
</tr>
</tbody>
</table>

¹ p values for the ANOVA tests; * Statistically significant difference; IWGDF- International Working Group on the Diabetic Foot;

![Figure 1: Diabetes duration and risk for diabetic foot ulceration](image)

Diabetes duration in groups of patients classified into different diabetic foot ulcer risk categories significantly increases with risk progression; \( p < 0.05 \).
Score 0 was for normal muscle strength, 1 for mild, 2 for severe muscle weakness and 3 for complete muscle loss of strength. Minimum score was 0 (normal strength in 10 muscles) and maximum score was 30. Muscle strength in groups of patients classified into different diabetic foot ulcer risk categories significantly declines with risk progression; \( p < 0.05 \).

The average range of motion (ROM) at ankle joint (AJ) in groups of patients classified into different diabetic foot ulcer risk categories does not significantly differ; \( p > 0.05 \).

Based on the IWGDF Guidelines 2019 stratification risk system, patients were classified into one of the risk categories. The largest number (51\%) of patients were classified into risk Category 0. Sixteen percent of patients were classified into risk Category 1, 21\% into risk Category 2 and 12\% of patients were classified into risk Category 4. There was no significant difference in the average age, body mass index and HbA\(_1c\) values in patients classified into different risk categories, but diabetes duration differed significantly (Figure 1).

The average muscle strength in the patients who were classified into risk Category 0 was 9.2°, 13.9° for those in the risk Category 1, 13.3° in the...
The average range of motion (ROM) at the subtalar joint (SJ) in groups of patients classified into different diabetic foot ulcer risk categories significantly declines with risk progression; \( p < 0.05 \).

The average ROM at AJ in the group of patients classified into risk Category 0 was 49.3°, risk Category 1 was 48.8°, risk Category 2 was 45.5° and the risk Category 3 was 44.6°, as shown in Figure 3. The average ROM at AJ in the groups of patients classified into different risk categories was not significantly different (\( F = 0.988, p = 0.402 \)).
The average ROM at SJ in the group of patients classified into risk Category 0 was 78.6°, risk Category 1 was 74.4°, risk Category 2 was 65.5° and those classified into risk Category 3 was 57.9°. The average ROM at I MTP significantly declined with risk progression (F = 4.615, p = 0.005), as shown in Figure 4.

The average ROM at I MTP in the group of patients classified into risk Category 0 was 78.6°, risk Category 1 was 74.4°, risk Category 2 was 65.5° and those classified into risk Category 3 was 57.9°. The average ROM at I MTP significantly declined with risk progression (F = 4.615, p = 0.005) as shown at Figure 5.

**Discussion**

One hundred patients in the study group were classified into one of the risk categories based on the comprehensive foot examination and history taking. Most patients were classified into risk Category 0 (51 %) as determined by normal clinical findings, followed by those classified into risk Category 2 (21 %), as defined by the presence of LOPS + PAD, LOPS + foot deformity, or PAD + foot deformity, with or without the presence of deformity. Sixteen percent of the patients were classified into risk Category 1 as determined by the presence of the LOPS or PAD. The lowest number of patients were classified into risk Category 3 (12 %) as determined by the positive anamnestic data on the presence of an ulcer or amputation. So far, there are no published studies on the overall risk for developing DFU and ankle and foot muscle strength so far. The effects of the certain determining clinical elements for the risk categorisation are explained. Risk Category 0 determines the absence of positive clinical findings, so it is to be expected that patients classified into this category have greater muscle strength compared to those patients classified in the other risk categories with some complications. The presence of LOPS, PAD and foot deformity is the determining factors for classifying patients into risk categories 1 and 2. The presence of the LOPS is due to the presence of a certain degree of DPN and many studies proved a strong association between DPN and the loss of muscle strength. The muscle atrophy in diabetic patients is most pronounced in distal parts of the lower leg indicating a length-dependent neuroopathic process. The presence of PAD is also one of the determining factors for classifying patients into risk Category 1 and 2. Regenstein found the correlation between the PAD with chronic changes in affected muscle morphology and its function. Muscles in the region affected by PAD has demonstrated denervation and a reduction in the cross-sectional area of type II muscle fibres. In patients with PAD there is also a decrease in oxidative enzyme activities, more pronounced with increasing disease severity. McDermott also confirmed that the PAD affects muscle strength, especially the distal lower extremity muscles.

Some authors believe that there is a relationship between intrinsic foot muscle weakness caused by motor neuropathy and the development of foot deformities such as pes cavus, claw toe deformity, hammer toe deformity and hallux valgus, however, this relationship has not been sufficiently explored, especially regarding the muscle weakness level that affects the development of the deformities. Patients classified into risk Category 3 had ulcer or amputation in the history and the level of diabetes and poor glycaemic control is associated with increased production of glycosylation end products, metabolic derangements, endothelial injury and oxidative products that are pathophysiological base of those conditions.
lowest muscular strength compared to patients classified into lower risk categories. Ulcers are most commonly of the neuropathic or neuro-ischaemic origin which means that the loss of muscle strength in patients classified in this risk category is primarily influenced by a neuropathic and/or ischaemic process. The average ulcer healing time is 8 weeks to 78 days and in many cases the ulcer does not heal passing into chronic wounds, which affects the mobility, loss of muscle fibres and consequently loss of muscle strength. As 80% of the cases of amputations are preceded by an ulcer, the period of inactivity in patients with an amputation can be very prolonged and affects accelerated muscle loss, strength reduction and functional capacity.

The ROM values at AJ in patients classified into different risk categories are not statistically significant, but it is worth noting that the average value of the ROM at AJ has decreased from the lower to the higher risk category. The average value of ROM at SJ in patients classified into risk Category 0 is 37.8° and in patients classified into risk Category 3 is 28.75°. It has been proven that there is a statistically significant difference in the mean values of the ROM at SJ between risk categories. The average value of ROM at the I MTP joint in patients classified into risk Category 0 is 78.6° and in patients classified into risk Category 3 is the smallest and it is 57.92°. This study has found a strong relationship between the average values of ROM at I MTP joint in patients classified into different risk categories. There are no studies that explored the relationship between the values of ROM in different risk categories for development of DM complications at lower extremities.

The limited joint mobility (LJM) at AJ and I MTP joint have been identified as a causing factor of local pressure increase and ulcer formation in patients with DPN. LJM and reduction of the elasticity of the ankle in diabetic patients develop due to three mechanisms: (1) collagen glycosylation based on the hyperglycaemic state; (2) shortening of triceps fibres and (3) qualitative changes in connective tissue because of increasing in fibrous versus contractile tissue. Shorter ROM in patients classified into Category 2 compared to the patients classified into the risk Category 1 can be explained by the presence of additional qualitative changes in muscle tissue and formation of connective tissue due to ischaemia in patients with PAD. The lowest ROM in patients classified into Category 3 characterised by history of ulcer or amputation can be explained by adaptive changes in the tissues resulting from the long-term inactivity of patients during the ulcer healing process and more intensive tissue changes caused by hyperglycaemia which primarily led to the onset of ulceration or amputation in these patients.

The main goals of physical therapy interventions in DM patients are to prevent complications, to reduce the effects of immobilisation, to maintain functional capacity and to minimize the onset of complications. Presently, in most cases, physical therapies are applied when DFU and amputation have already occurred and only occasionally are used as preventative procedures. This research highlights the significance of the continued surveillance and screening, along with some elements of biomechanical assessment of the feet in a primary care setting, intending to identify factors that can be influenced by active measures aiming to reduce the incidence of diabetic complications on the lower extremities.

The limitation of this study is the fact that overall physical activity and fitness were not individually assessed as both parameters have impact on muscle strength. Assessment of the muscle strength is done using MMT which is a subjective evaluation method. This weak spot in measurement objectivation is alleviated by utilisation of a qualitative system used in Michigan Diabetic Neuropathy Score which offers four grades of strength and measuring by the same examiner. The range of motion measurement is also performed by an examiner; however, the human error was minimised through high-quality preparation, including drawing lines from joint centre using prongs. The use of subjective measure in the assessment of musculoskeletal system performance is justified when it is used meticulously and by a single examiner. Although many studies have shown a correlation between diabetes and some functions of the musculoskeletal system, there are no studies that evaluated the total risk for DFU development and lower limb biomechanical parameters, which presents another limitation in the methodology and the results analysis.
Conclusion

The risk for diabetic foot ulcer significantly correlates with diabetes duration, decreased ankle and foot muscle strength, as well as decreased range of motion at the subtalar joint and first metatarsophalangeal joint, but it does not correlate with the range of motion at the ankle. It is a huge scientific and professional challenge to explore if an active approach through targeted physical therapy and rehabilitation procedures improves the biomechanical parameters of the lower limb and thus slows down - or even stops progression of DM complications and reduces the risk of amputations. In conclusion, the simplicity and low cost of the assessment of the lower limb biomechanical parameters could be an additional developing DFU risk screening tool and its results could be the basis for another active preventative or rehabilitative approach.

Acknowledgement

The authors would like to thank and acknowledge all the study participants who gave up their time to take part in this study. Thank you also to the colleagues from the Primary Healthcare Centre Banja Luka and the Institute for Physical Medicine and Rehabilitation „Dr Miroslav Zotović“ Banja Luka for their assistance in carrying out the study.

Conflict of interest

None.

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