

## THE RELATIONSHIP BETWEEN HIGH PRESSURE AREAS AND DIABETIC FOOT ULCERATION-ORTHOTIC SOLUTIONS

Taina Elena AVRAMESCU<sup>1</sup>, Rucsandra Elena Dănciulescu MIULESCU<sup>2,3</sup>

1. University of Craiova, Department of Kinesiology and Sports Medicine

2. "Carol Davila" University of Medicine and Pharmacy, Bucharest

3. "N.C.Paulescu" National Institute of Diabetes, Nutrition and Metabolic Diseases Bucharest

**Corresponding author:** Rucsandra Elena Dănciulescu Miulescu, [rucsandra\\_m@yahoo.com](mailto:rucsandra_m@yahoo.com)

**Abstract:** *Diabetes mellitus is recognized as a major public health issue. The affection is associated with microvascular and macrovascular complications. The diabetic foot syndrome is a major complication of diabetes with a significant influence on quality of life due to the fact that can generate: lower mobility, higher dependence on others, higher risk of amputation, depression and is one of the most costly complications of diabetes. Diabetic foot ulcer is generated by a combination between neuropathy, peripheral vascular disease and high foot pressures. Alone high foot pressures is not a direct cause of ulceration but is an important factor in the occurrence of this pathology. The plantar pressure measurement is recognized by important entities from clinical practice and can be detected by platform systems and in-shoe systems. Determination may allow the creation of orthopedic footwear for high-risk diabetic patients. International guidelines suggest or recommend the use of therapeutic footwear in diabetic patients with high-risk.*

**Key words:** diabetes mellitus, high pressure areas, orthopaedic footwear

### Introduction.

Diabetes mellitus is recognized as a major public health issue. According to 8<sup>th</sup> edition of diabetes atlas published by the International Diabetes Federation in 2017 more than 425 million subjects are diagnosed with diabetes [1]. Diabetes is associated with microvascular and macrovascular complications. Diabetic foot is a major complication of diabetes, defined as "a group of syndromes in which neuropathy, ischemia and infection lead to tissue breakdown, resulting in morbidity and possible amputation" [2]. In 2017 Zhang P and collaborators have published a systematic review and meta-analysis about the global epidemiology of diabetic food ulceration. The authors have analyzed the result of the studies in the following databases: PubMed, EMBASE, ISI Web of science and Cochrane and concluded that the global diabetic food prevalence was 6.3% which was higher in males than in females and higher in type 2 diabetes patients than in type 1 diabetes patients [3]. The diabetic food syndrome has significant influence on quality of life due to the fact that it can generate: lower mobility, higher dependence on others, higher risk of amputation, depression and is one of the most costly complications of diabetes [4, 5, 6].

The management of diabetes consist of lifestyle modification (nutrition therapy, physical activity, smoking cessation, diabetes self-management education and support, psychosocial care) and pharmacologic therapy. In 2019, American Diabetes Association has published in Diabetes Care, the standards of medical care in diabetes. The association had the following recommendations in regards of foot care:

1. providing the information about the foot preventive self-care to all patients with diabetes mellitus;
2. the annual foot evaluation to identify risk factors for ulcer and amputations; for patients with evidence of diabetic peripheral neuropathy or prior ulceration or amputation, the foot examination it is required to be performed at every visit;
3. the use of therapeutic footwear for diabetic patients with high-risk (patients with severe neuropathy, history of amputation or foot deformities) [7].

### The role of high pressure areas in the occurrence of diabetic ulceration foot.

Diabetic foot ulcer is generated by a combination between neuropathy, peripheral vascular disease and high foot pressures. Alone high foot pressures is not a direct cause of ulceration but predispose diabetic patients with peripheral neuropathy to develop this

pathology [8, 9]. Stokers and collaborators led one of the first studies on plantar pressure in diabetic patients; they have reported that the highest maximum plantar pressure are present at the site of ulceration [10]. Stress RM *et al* in a study published in 1997 in Diabetes Care, in which were included 97 diabetic patients (34 patients without history of peripheral neuropathy and foot ulceration, 14 patients with neuropathy without history of foot ulceration and 49 patients with history of neuropathy and plantar ulceration) mention that "*neuropathic patients have an increase in dynamic plantar foot pressures placing them at risk for plantar ulceration*" [11]. A meta-analysis published in 2014 in PLoS One by Fernando ME *et al* were compared the plantar pressures in diabetic patients without peripheral neuropathy and patients with peripheral neuropathy and active or history of foot ulceration. They concluded that plantar pressures is significantly higher in patients with diabetic peripheral neuropathy with a history of foot ulceration compared to those with diabetic neuropathy without a history of ulceration [12].

The sites of maximum plantar pressure in diabetic patients have been investigated in several studies. Stress RM and collaborators in the previously mentioned study reported that in patients with history of neuropathy and plantar ulceration the highest pressure is present in the fourth and fifth metatarsal heads. [11]. Qiu X *et al* investigated the plantar pressure parameters from 10 foot regions in 65 patients with type 2 diabetes. The study revealed high plantar pressure levels in the metatarsal heads [13]. Payne C *et al* reported after analyzing the plantar pressure in 50 diabetic patients that neuropathy "*played a key role in plantar pressure levels in a diabetic foot, and especially in the hallux, in the first metatarsal head, and in the heel region*" [13, 14].

#### **Foot plantar pressure measurement**

The plantar pressure measurement is recognized by important entities from clinical practice and can be determined by platform systems or plantar sensors. Platform systems "*are constructed from a flat, rigid array of pressure sensing elements arranged in a*

*matrix configuration and embedded in the floor to allow normal gait*" [15]. They are used for static and dynamic studies and are restricted to research laboratories. Plantar sensors are included in the shoes and measure plantar pressure during activities and some systems provides information to the patient when above-threshold pressures occur [16]. The plantar pressure sensor requirement are: linearity, hysteresis, sensing area size pressure range and temperature sensitivity. There are currently several pressure sensors: the most common are capacitive, resistive, piezoelectric and piezo-resistive sensor [15]. Determination of the plantar pressure allow the creation of personalized orthopedic footwear for high-risk diabetic patients.

#### **Diabetic foot management**

Diabetic foot education include daily self-inspection, avoiding of trauma and contact the physician if any new abnormality appear. In some situations, diabetic patients fail to identify changes that cause delayed treatment [17]. Authors of the guide on the management and prevention of the diabetic foot 2011 mention that 5 elements are important in foot management: regular inspection and examination of the at risk foot, identification of the at risk foot, education of patient and family, appropriate footwear and treatment of nonulcerative pathology [18]. In 2015 the international working group on the diabetic foot recommends in order to prevent recurrent plantar foot ulcer in high-risk patient with diabetes the use of orthopedic footwear [19]. The clinical practice guide published by Society for Vascular Surgery in collaboration with American Podiatric Medical Association and the Society for Vascular Medicine, published in 2016 recommends using "*custom therapeutic footwear in high-risk diabetic patients, including those with significant neuropathy, foot deformities, or previous amputation. In patients with plantar diabetic foot ulcer (DFU), we recommend off-loading with a total contact cast or irremovable fixed ankle walking boot*" [20].

The results of the efficacy of custom diabetic footwear with respect to prevention of ulceration are controversial. In 2002 Reiber GE and coworkers published in JAMA the

results of a randomized controlled trial in which were enrolled 400 diabetic patients with history of foot ulcer that not require shoes for foot deformity. 121 patients received 3 pairs of therapeutic shoes and 3 pairs of customized medium-density cork insets with neoprene closed-cell cover, 119 patients received 3 pairs of therapeutic shoes and 3 pairs of prefabricated, tapered polyurethane insertions and 160 patients (control group) ordinary shoes. Two-year cumulative re-ulceration incidence across the three groups was low. The authors concluded that therapeutic or customized medium-density cork insets with neoprene shoes conferred no significant ulcer reduction compared with control footwear [21]. In contrast Uccoli L and collaborators evaluated the efficacy of manufactured shoes (specially designed for diabetic patients) to prevent relapses of foot ulceration in 69 diabetic patients: 33 patients received therapeutic shoes and 36 patients had usual footwear. The number of ulcer relapses after 1-year were significantly lower in patients that used therapeutic shoes compared to usual footwear [22]. A prospective cohort study by Busch K and Chantelau E published in 2003 reported the benefits of specialized footwear in decreasing the relapses of foot ulceration [23]. The clinical practice guide published by Society for Vascular Surgery in collaboration with American Podiatric Medical Association and the Society for Vascular Medicine suggest that the routine prescription of therapeutic footwear cannot be recommended over a preventive foot care program in low-risk diabetic patients but can be considered in diabetic patients with high-risk [20]. The Guidelines for the treatment of diabetic ulcers published in 2006, recommends: "*Protective footwear should be prescribed in any patient at risk for amputation (significant arterial insufficiency, significant neuropathy, previous amputation, previous ulcer formation, preulcerative callus, foot deformity, evidence of callus formation)*"[24].

### Conclusion.

Diabetic foot education is important to prevent ulcerations and amputations. High foot pressures do not a direct cause of

ulceration but predispose diabetic patients with high-risk to develop this pathology. Determination of the plantar pressure allow the cration of orthopaedic footwear. International guidelines suggests or recommends the use of therapeutic footwear in diabetic patients with high-risk.

### References

- [1]. International Diabetes Federation. IDF Atlas. 8th edition. Available from: <http://www.diabetesatlas.org>.
- [2]. Forlee M. (2010), What is the diabetic foot? The rising prevalence of diabetes worldwide will mean an increasing prevalence of complications such as those of the extremities. *Continuing Medical Education*, 28(4): 152–156,.
- [3]. Zhang P, Lu J, Jing Y, Tang S, Zhu D, Bi Y. (2017) Global epidemiology of diabetic foot ulceration: a systematic review and meta-analysis. *Ann Med*, 49(2): 106-116.
- [4]. Shearer A, Scuffham P, Gordois A, Oglesby A. (2003), Predicted costs and outcomes from reduced vibration detection in people with diabetes in the US. *Diabetes Care*, 26(8): 2305–2310,.
- [5]. Kerr M, Rayman G, Jeffcoate WJ. (2014). Cost of diabetic foot disease to the National Health Service in England. *Diabet Med*, 31(12): 1498–1504.
- [6]. Prompers L, Huijberts M, Schaper N, Apelqvist J, Bakker K, Edmonds M, Holstein P, Jude E Jirkovska A, Mauricio D, Piaggese A, Reike H, Spraul M, Van Acker K, Van Baal S, Van Merode F, Uccioli L, Urbancic V, Ragnarson Tennvall G. (2008), Resource utilisation and costs associated with the treatment of DFUs. Prospective data from the Eurodiale Study. *Diabetologia*, 51(10): 1826–1834,.
- [7]. American Diabetes Association. (2019), Standards of Medical Care in Diabetes. *Diabetes Care* (Supplement 1): S124-S138.
- [8]. Masson EA, Hay EM, Stockley I, Vevas A, Betts RP, Boulton AJ. (1989), Abnormal foot pressures alone may not cause ulceration. *Diabet Med*, 6(5): 426-428,.
- [9]. Vevas A, Murray HJ, Young MJ, Boulton AJ. (1992), The risk of foot ulceration in diabetic patients with high foot pressure: a prospective study. *Diabetologia*, 35(7): 660-663,.
- [10]. Stokes IAF, Faris IB, Hutton WC. (1975), The neuropathic ulcer and loads on the foot in diabetic patients. *Ada Orthop Scand*, 46(5): 839–847,
- [11]. Stress RM, Jensen SR, Mirmiran R. (1997), The role of dynamic plantar pressures in diabetic foot ulcers. *Diabetes Care*, 20(5) : 855-858,.
- [12]. Fernando ME, Crowther RG, Pappas E, Lazzarini PA, Cunningham M, Sangla KS, Buttner P, Golledge J. (2014), Plantar pressure in diabetic peripheral neuropathy patients with active foot ulceration, previous ulceration and no history of ulceration: a meta-analysis of observational studies. *PLoS One*, 9(6): e99050,.

- [13]. Qiu X, Tian DH, Han CL, Chen W, Wang ZJ, Mu ZY, Liu KZ. (2015), Plantar Pressure Changes and Correlating Risk Factors in Chinese Patients with Type 2 Diabetes: Preliminary 2-year Results of a Prospective Study. *Chin Med J (Engl)*, 128(24): 3283-3291.
- [14]. Payne C, Turner D, Miller K. (2002), Determinants of plantar pressures in the diabetic foot. *J Diabetes Complications*, 16(4): 277-283.
- [15]. RazaK AH, Zayegh A, Begg RK, Wahab Y. (2012), Foot plantar pressure measurement system: a review. *Sensors(Basel)*, 12(7): 9884-9912.
- [16]. Bus SA. (2016), Innovations in plantar pressure and foot temperature measurements in diabetes. *Diabetes Metab Res Rev*, 32(Suppl. 1): 221-226
- [17]. Howard IM. (2009), The Prevention of Foot Ulceration in Diabetic Patients. *Physical Medicine & Rehabilitation Clinics*, 20(4): 595-609
- [18]. Bakker K, Apelqvist J, Schaper NC, International Working Group on Diabetic Foot Editorial Board. (2012), Practical guidelines on the management and prevention of the diabetic foot 2011. *Diabetes Metab Res Rev*, 28(Suppl 1):225-231
- [19]. Bus SA, Armstrong DG, Van Deursen R, Lewis J, Caravaggi C, Cavanagh PR; International Working Group on the Diabetic Foot. (2016), IWGDF guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes. *Diabetes Metab Res Rev*, 32(Suppl 1): 25-36
- [20]. Hingorani A, LaMuraglia GM, Henke P, Meissner MH, Loretz L, Zinszer KM, Driver VR, Frykberg R, Carman TL, Marston W, Mills JL Sr, Murad MH. (2016), The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. *J Vasc Surg*, 63(2 Suppl): 3S-21S.
- [21]. Reiber GE, Smith DG, Wallance C, Sullivan K, Hayes S, Vath C, Maciejewski ML, Yu O, Heagerty PJ, LeMaster J. (2002), Effect of therapeutic footwear on foot reulceration in patients with diabetes: a randomized controlled trial. *JAMA*, 287(19):2552-2558
- [22]. Uccioli L, Faglia E, Monticone G, Favales F, Durola L, Aldeghi A, Quarantiello A, Calia P, Menzinger G. (1995), Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care*, 18(10): 1376-1378
- [23]. Busch K, Chantelau E. (2003), Effectiveness of a new brand of stock 'diabetic' shoes to protect against diabetic foot ulcer relapse. A prospective cohort study. *Diabet Med*, 20(8): 665-669
- [24]. Steed DL, Attinger C, Colaizzi T, Crossland M, Franz M, Harkless L, Jonson A, Moosa H, Robson M, Serena T, Sheehan P, Veves A, Wiersma-Bryant L. (2006), Guidelines for the treatment of diabetic ulcers. *Wound Repair Regen*, 14(6): 680-692