23rd ABCM International Congress of Mechanical Engineering
December 6-11, 2015, Rio de Janeiro, RJ, Brazil

COMPARATIVE ANALYSIS OF THE USE OF NATURAL LATEX CUSTOM INSOLE IN DIABETIC FOOT TREATMENT THROUGH BIOMECHANICAL EVALUATION IN STATIC EXAMINATION

Gustavo Adolfo Marcelino de Almeida Nunes[1]
Suélia de Siqueira Rodrigues Fleury Rosa[1]
1-Laboratório de Engenharia e Biomaterial – BioEngLab®, Engenharia Biomédica, Faculdade Gama - Universidade de Brasília – UnB - FGA, Brasília, Brazil.
gusnunes@gmail.com; suelia@unb.br
Adson Ferreira da Rocha[2]
2- Engenharia Biomédica, Faculdade Gama - Universidade de Brasília – UnB - FGA, Brasília, Brazil.
adson@unb.br
Diego Colón[3]
3- Laboratório de Automação e Conrole (LAC), Escola Politécnica da Universidade de São Paulo, Departamento de Engenharia de Telecomunicações e Controle – Universidade de São Paulo – USP, São Paulo - SP, Brazil.
diego@lac.usp.br
José Manoel Balthazar[4]
4- Divisão de Mecânica Aeronáutica - Instituto Tecnológico da Aeronáutica – ITA, São José dos Campos - SP, Brazil.
jmbaltha@ita.br

Abstract. *The diabetic peripheral neuropathy (DPN) is considered a public health problem, due to the association of neural damage to vascular damage in the lower limbs, in which the feet are susceptible to abnormal weight discharge. The objective of this paper is to analyze the influence of the natural latex custom insole in the plantar pressure of a diabetic patient, through a biomechanical evaluation of performance in the static position. The plant load in the forefoot, with peak plantar pressure is described and correlated with the use of the insoles and its absence. Thus, a better evaluation of the association between the change in plantar pressure and the introduction of latex insole will be possible, as well as the distribution of plantar loads between right foot and left foot of the patients. The results will be compared, in order to discuss the techniques applied, considering the great diversity of equipment and methodologies used in the literature. A proposal to establish a pattern from this technique is formalized, considering our regional characteristics, which probably clearly define its benefits in the treatment and prevention of diabetic foot.*

Keywords: *diabetic foot, biomechanical evaluation, plantar pressure, latex insole, comparative analysis*

1. INTRODUCTION

Currently, more than 285 million adults worldwide are affected by diabetes. This number is expected to reach, approximately, 439 million people by 2030. A common complication among diabetes patients is diabetic peripheral neuropathy (DPN), which affects 30% to 50% of patients with diabetes and is, often, asymptomatic. Symptoms, however, when they appear, include numbness, weakness, tingling or pain. The DPN can progress to a painful change that affects approximately 16% to 33% of patients with diabetes and 50% of those with confirmed diabetic neuropathy (Huffman C., *et al.*, 2014).

The most common form of DPN is referred to as "diabetic sensorimotor polyneuropathy" (DSPN), and is predominantly characterized by sensory changes in the "glove-and-stocking" distribution, which essentially consists of the ends of the lower and upper limbs (Min Yoo, *et al.*, 2015; Morales-Vidal S., *et al.*, 2014). These symptoms may include significant deficits in tactile and pain sensibility, vibrating sensation, lower-limb proprioception and synesthesia, caused by neuronal apoptosis promotion and inhibition of nerve regeneration in diabetes, which can result in one of the most common and undesirable symptoms of neuropathy: the pain. This symptom, common in DPN, is called painful DPN (P-DPN), and has a significantly negative impact on anxiety and depression, gait variability, and overall life quality aspects (Yoo M, *et al.*, 2015), such as: the well-being, mood and basic functions present and performed in the daily lives of patients. Another factor that must be considered is the significant increase in medical care costs (Huffman C., *et al.*, 2014).

Most patients with painful DPN, often feel pain in their feet (96%) and / or toes (67%). The highest incidence occurs in the evening, with 57% of patients reporting substantial interference during their sleep. Another important consequence of painful DPN is that, in a subgroup of patients, pain affects the ability to walk and one-third of patients report having to use an accessory device, such as a cane, walker or wheelchair, as an aid for walking because of neuropathy. It is worth noticing that a high quality of life is directly linked to the ability to walk, because, once the patient has a reduction in such skill, consequently, there is a significant loss of autonomy and physical independence. The treatment of pain due to DPN remains being a major challenge for health professionals and patients, and, currently, the only available and effective treatments are the improvement in glucose control and pain management (Huffman C., *et al.*, 2014).

The diabetic foot syndrome is a serious and very complex disease, in which polyneuropathy, infection, peripheral vascular disease (PVD) and foot deformity were identified as key factors for diabetic foot ulceration (Martínez, *et al.*, 2014; Boulton A.J., *et al.*, 2004). The neuropathic diabetic (ND) is considered the main permissive factor for the development of foot ulcers on diabetic patients and is present in about 80 to 85% of the cases. The ND is defined as the presence of signs and symptoms of dysfunction of peripheral nerves, attributable exclusively to diabetes. Among the signs of ND are included reduced sensibility to pain, vibration and temperature, skeletal muscle atrophy of the small interosseous muscles (claw toes and hammer), anhidrosis and strain of feet dorsal veins (Reis, *et al.*, 2014; Frykberg, *et al.*, 1998).

The recurrence of ulcers in the lower limbs, especially in the feet of patients with diabetes mellitus is still a major challenge for health system. Although several therapies have been described and developed for the ulcers in diabetic foot, recidivism rates are still very high. Shoes and insoles have been recommended as effective therapies to prevent the development of new ulcers in patients with diabetes (Martínez, *et al.*, 2014).

The ulceration that occurs on the plantar surface of the foot, in people with diabetes continues to be common, debilitating, of difficult treatment, and expensive, both for the patient and for the Brazilian Unified Health System (SUS). In the absence of ischemia, neuropathy and subsequent loss of protective sensation have been presented as one of the major risk factors for developing a first ulcer, combined with repeated stress on areas around bone prominences, where the tissue protection have been displaced or have also their mechanical properties altered by the disease. There we have the ideal setting for the development of ulcers (Telfer, *et al*., 2014).

High dynamic plantar pressures significantly increase the risk of foot ulcers in patients with diabetes mellitus. Such ulcerations, resulting from complications of the disease, are associated with a significant burden on the daily life of the patient as well as to increased mortality. After the healing of a foot ulcer, many diabetic patients have recurrence of ulcers. Recent evidence suggests that high plantar pressures are also a significant determinant for recurrence of ulcers in the diabetic foot. Thus, it is recommended that interventions should routinely target the abnormal plantar pressures that may arise in the feet of patients (Barn R., *et al*., 2015).

Currently, there is a consolidated clinical tradition by the use of footwear, technical prevention and treatment load reduction in healing of plantar foot ulcers of patients with diabetes. However, the research literature in this area has been quite rooted in past experiences, where the doctor looks for solutions in classic practical situations, rather than seek new evidence and studies published in the most recent literature (Bus, *et al.*, 2004). Even though being able to be avoided, in most cases, most treatments of diabetic foot ulcers focuses on the acute phase, mainly seeking to solve peripheral vascular disease, infections and wound treatments. The evidence of these complications has increased in recent years, and the guidelines and international protocols have been widely published (Martínez, *et al*., 2014).

In the literature there are several studies investigating the pressure variation. According to Rao S., *et al*., 2010 and Stucke S., *et al.,* 2012, the pressure and shear stress variables applied to different points produce more pronounced effects in the front foot region (forefoot) than in the regions of the heel. In another study, the results show that the pressure peak does not occur at the same point of shear stress (Sawacha Z., *et al*., 2009). Some authors used transducer insoles to be an indicator and improver to carry out the distribution plant through adjustments in commercial shoes and insoles such as DH Pressure Relief Shoe™ and Insole of DH Pressure Relief Shoe™, with hexagonal shape and the possibility of removal of certain parts, to promote relief of plantar pressure in the region (Ribeiro and Rodrigues, 2013; Piaggesi A., *et al.*, 2007; Pai S., *et al.*, 2012).

2. THEORETICAL FOUNDATIONS AND MATERIALS

2.1. **Organic Control Theory**

Biological systems have, often, similar behaviors to dynamic systems, extensively studied in control engineering. In other words, a biological system may behave in an extremely complex manner, and may be influenced by external variables such as, several fluctuations, noise and sudden or unexpected changes. Nevertheless, as we observe in established dynamic systems, it is possible to mold a biological system in order to obtain a response to this system, being in accordance to the desirable specifications and standards, to achieve considerable patterns, with performance close to a considered normal or healthy functioning.

Through default behavior analysis, or established models of certain dynamical system, it is possible, applying techniques of classical control theory, combined with the use of devices and intelligent software, to control and / or mold characteristics of an existing system changed by external variables to an ideal behavior, previously known. This model should be designed so that the obtained response can be constantly monitored and changed by a feedback to the system itself, so that it can be corrected by acting on the system dynamics, whenever there are any major discrepancies compared to the result to be achieved.

The Organic Control Theory arises in this context and, through the study of biological systems from the perspective of biomedical engineering controls, aims to build architectures that can command complex dynamic behavior. The intervention of an organic controller aims to, not only have a standard performance, but to be a controller capable of generating an intelligent system interference, by means of its manufacturing material (natural latex) acting together with devices and software's sensoring. The importance of the concept of Organic Control is justified by the need for a new approach to biological control systems, which are usually complex systems with nonlinear dynamics and high dimension, since the traditional methods cannot be applied to control design (Ribeiro and Rodrigues, 2013).

Given the above, Organic Control Theory is defined, which basically consists in confectioning, by means of a biomaterial, a controller that can act on the dynamics of a biological system. The main objective of an organic controller is to obtain an output response, according to the performance specifications of an operating system within acceptable specifications and standards.

2.2. Biomaterials

It can be considered a biomaterial, any substance, synthetic or not, that can be used as a treatment to replace part of a living system or to act directly and in direct contact with living tissue. The biomaterials are designed to repair and / or reconstruct parts or functions of organs and tissues, so that they may serve as matrix, vehicle, carrier, or enhancer of new tissue formation and / or reconstitution (Ribeiro and Rodrigues, 2014).

Synthetic or natural materials have been compared or suggested for clinical and experimental use in several species. The substitute material, to be considered ideal, must have low cost production, be easy to handle, must promote tissue growth in the host, allowing scar tissue to have the strength similar to normal tissue infections, be resistant, not promote exacerbated inflammatory response, not form adhesions and fistulas, not have physical characteristics altered by liquid tissue, be flexible, inert, porous and resistant (Reis, 2014; Wang, 2008; Dallan, 2005).

When a foreign material comes into contact with biological fluids, protection responses are triggered and manifest themselves as inflammatory or immunological processes, aiming the elimination of the foreign body. Therefore, the good performance of a post-implant biomaterial is associated with a balance of biocompatibility and biofunctionality. Biocompatibility is the most important feature, because the biofunctionality of the material can only manifest itself through the good performance of a biomaterial (Reis, 2014; Ribeiro and Rodrigues, 2014).

2.3. Latex Insole (*Hevea brasiliensis*)

Natural latex is a milky liquid extracted from the rubber tree *Hevea brasiliensis*, which has satisfactory results, which motivates the conducting of further work in this area, and its experimental use in different tissues. In the reported usages, the one presented by (Brandão, *et al*., 2007) is a vascular micro-perforated prosthesis, made of tissue covered with a compound derived from natural latex and evaluated for its patency, thrombogenicity, biocompatibility and healing process, besides some mechanical properties. The microperforated latex tissue prosthesis, with characteristic of biomaterial, showed structural qualities as a vascular substitute, stimulated endothelial growth and presented adequate tissue integration when used in dogs. Pinho *et al.,* 2004 observed the effect of the latex membrane repair process of the ocular conjunctiva in rabbits, showing that the natural latex membrane seemed to benefit the conjunctiva scarring and neoangiogenesis (Ribeiro and Rodrigues, 2014).

Many research using this material as an implant in different tissues have shown satisfactory results, which motivate the performance of new work in this area, in different species. When dealing with diabetic patients with chronic leg ulcers, there are authors who handled diabetic skin ulcers with the use of biomaterials. In this case, it used the natural latex biomembrane, an alternative dressing for treating skin ulcers, effective, economical, easy to handle and with the ability to accelerate healing. In addition, it has a debriding and neoangiogenic potential, which make the healing process faster and dynamic, essential in the healing of ulcers in diabetic patients (Reis, 2014; Frade, *et al*., 2004).

2.4. Pressure signals acquiring platform

In this study, it was used the Novel's Emed® Pedography Platform, model n-050, which is an accurate electronic system for recording and evaluating pressure distribution under the foot in static and dynamic conditions. This platform has the following dimensions: 700 x 403 x 15, 5 mm. It has 6 sensors with a 475 x 320 (mm) area, with a resolution of 4 (sensors/cm^2). Other important platform data are: frequency 50 Hz; pressure range: 10-1.270 Kpa; pressure threshold 10 Kpa; accuracy: ± 5% ZAS; Hysteresis: < 3%; temperature range: 10-40 ºC; maximum total force: 193.000 N; cross talk: -40 dB and synchronization: sync-out pulse at start (Novel, 2015).

The plantar pressure data were obtained and processed by software Novel, allowing dynamic and / or static testing. The variables are: contact area, contact time, maximum force and peak pressure. Contact area refers to the amount of contact between the foot and the plantar surface of the sensor, measured in cm^2. The pressure peak is the highest pressure value recorded by each sensor over the entire support stage, it's unit of measurement is the kPa. The contact time is the period in which the surface maintains contact with the platform, and is expressed in ms. The maximum force is the sum of the measured force at each platform sensor. In other words, the maximum force obtained in the plant area during the time of contact with the surface, it is expressed in Newtons (Orlin M.N., *et al*., 2000).

Diabetic foot has kinematic and dynamic changes, such as: low range of motion, low movement speed, reduced torque, gait changes and output pulse changes which has as a response: a change in plantar pressure which can alter it and cause, thus, severe ulcerations in the plantar region of the foot. Analyzing the dynamics of this process, it is observed that the proposed controller operates in attenuating the plantar pressure signal, resulting in the stabilization of this dynamic, through the inclusion of individual buffers in the regions of critical incidence of customized insoles.

In this context, we can see that studies which aim to analyze the plantar pressure distribution have become the target of constant research in several areas, especially in the health sciences. Thus, studies involving the plantar pressure are highlighted in various aspects, such as studies that allow, in addition to plantar diseases and deformities research, checking the influence of certain treatments or surgeries, such as comparative assessments on the contribution of muscle dysfunction of the lower limbs in altering the plantar pressure distribution and consequent foot ulcers in diabetic patients. Such evaluations provide, as the present study proposes, when observing atypical plantar pressure, the development and analysis of solutions which enhance the plantar pressure distribution, in order to improve the patient's life quality, avoiding complications e discomfort from irregular plant pressure distribution on the feet.

The purpose of this study is, in addition to present the new conceptual tendency of the Organic Control Theory, to show its performance through plantar pressure monitoring through a platform (Novel's Emed® Pedography Platform - model n-050), promoting changes in the original mechanical system, through the intervention of a new controller: a custom made insole for diabetic foot, made of biomaterial derived from latex (*Hevea Brasiliens*). The sum of these resourses, called the Organic Control, will be employed on observation and possible correction of the physical phenomena (injuries and disabilities) listed above. The usage of latex as compatible biomaterial with the biological system of the human being is wide and can be used in many fields of health sciences.

3. METHODS

At a first, a survey was conducted among several diabetic patients with type I diabetes, in order to find an individual with representative and relevant characteristics to perform the test. The selected individual was a female adult, aged between 30 and 40 years. This patient was diagnosed with Type I diabetes for more than 20 years. Since then, performes periodical necessary care and has controlled diabetes, conducting daily and continuous glucose rate monitoring.

Chosen the patient, the next step was to construct the custom made latex insole. For this, it was first made a negative alginate mold, and subsequently, the positive pink plaster mold. Both materials are well known and widely used in dentistry, for the molding of the dental arch and for making dental prostheses or dental appliances. The alginate is a substance that when mixed with water becomes rapid drying bulk, which perfectly maintains the form of what is intended to shape. In the third stage, with the plaster mold ready, it goes to the latex insole molding. For this, we used the bi centrifuged and pre vulcanized latex, from Du Látex brand.

The research was conducted at the Strength Analysis Laboratory of the Physical Education Faculty at the Brasília University (FEF-UnB), under the supervision of Professor Suélia de Siqueira Rodrigues Fleury Rosa. Before starting the experiment, the patient was submitted to the measurement of the following parameters: heartbeats, registering 94 bpm; the oxygen concentration in the blood, registering 98% SPO_2% as well as glucose levels, registering 84 mg / dL. In the next step, the patient was placed standing barefoot and without latex insole under the Novel's Emed® Pedography Platform - model 050-n, where several measurements were made for both, the left and the right foot. Finally, the patient was asked to put on the latex custom-made insoles and the whole procedure was repeated. Plantar pressure measurements data, obtained with and without the use of the insole were recorded at Novel Software.

The variables obtained in the experiment were: Maximum strength (N), Pressure peak (N / cm^2), Contact time (p) (% ROP), and Contact area (cm^2). Each foot of the patient was sectioned into four monitoring regions, named: Hindfoot, Midfoot, Forefoot and Toes.

4. RESULTS

The most relevant results obtained for the bare feet tests were as follows: 1) Left Foot Barefoot: Maximum strength (N) – Hindfoot: 461,0±49,9, Midfoot: 192,2±39,7, Forefoot: 710,5±34,6, Toes: 123,0±6,2; Pressure peak (N / cm^2) - Hindfoot: 29,6±5,2, Midfoot: 15,3±2,0, Forefoot: 60,8±3,5, Toes: 60,5±8,5; Contact time (p) (% ROP) - Hindfoot: 56,0±3,3, Midfoot: 68,4±2,8, Forefoot: 84,4±1,9, Toes: 73,7±6,4; Contact area (cm^2) - Hindfoot: 35,45±0,68, Midfoot: 30,75±0,77 , Forefoot: 52,20±0,39, Toes: 9,25±0,54. 2) Right Foot Barefoot: Maximum strength (N) - Hindfoot: 465,0±28,4, Midfoot: 215,9±18,6, Forefoot: 682,1±14,5, Toes: 83,2±32,8; Pressure peak (N / cm^2) - Hindfoot: 30,9±2,3, Midfoot: 22,1±5,8, Forefoot: 65,8±18,7, Toes: 37,7±10,2; Contact time (p) (% ROP) - Hindfoot: 58,0±3,7, Midfoot: 69,6±2,6, Forefoot: 84,3±1,4, Toes: 58,9±4,1; Contact area (cm^2) - Hindfoot: 33,65±1,25, Midfoot: 29,15±0,40, Forefoot: 49,05±1,15, Toes: 9,80±1,86. Fig. 1 shows the test results for bare feet.

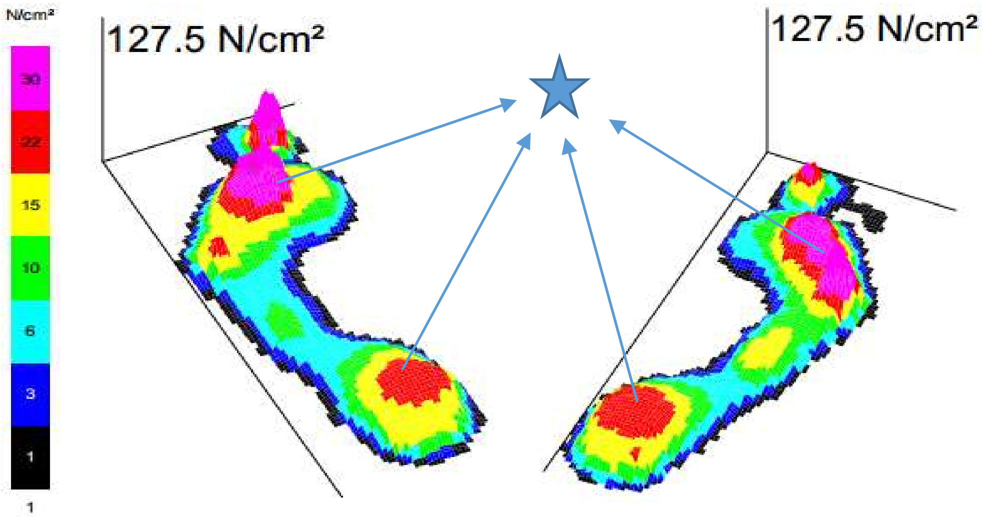

Figure 1. Pressure Distribution of Barefoot. The marked star shows de high plantar pressure areas – Novel Software Images

The total values obtained for the test with bare feet for the Left Foot were: Maximum strength 815,0±37,5 (N), Pressure peak 64,5±4,4 (N / cm^2), Contact time (p) 100,0±0,0 (% ROP), and Contact area 127,65±1,47 (cm^2). The total results obtained for the Upright were: Maximum strength 774,5±28,8 (N), Pressure peak 66,3±18,2 (N / cm^2), Contact time (p) 100,0±0,0 (% ROP), and Contact area 121,65±2,74 (cm^2).

The following results were obtained for the test using the latex custom insole: 3) Left Foot with Latex Custom made Insole: Maximum strength (N) - Hindfoot: 311,1, Midfoot: 167,3, Forefoot: 248,1, Toes: 152,3; Pressure peak (N / cm^2) - Hindfoot: 33,0, Midfoot: 15,0, Forefoot: 20,0, Toes: 50,0; Contact time (p) (% ROP) - Hindfoot: 100,0, Midfoot: 98,7, Forefoot: 100,0, Toes: 99,3; Contact area (cm^2) - Hindfoot: 29,25, Midfoot: 27,75, Forefoot: 44,75, Toes: 17,75 . 4) Right Foot with Latex Custom made Insole: Maximum strength (N) - Hindfoot: 235,1, Midfoot: 88,5, Forefoot: 237,1, Toes: 134,5; Pressure peak (N / cm^2) - Hindfoot: 14,0, Midfoot: 11,0, Forefoot: 12,5, Toes: 50,0; Contact time (p) (% ROP) - Hindfoot:

100,0, Midfoot: 99,3, Forefoot: 100,0, Toes: 98,7 and Contact area (cm^2) - 30,00, Midfoot: 20,00, Forefoot: 40,50, Toes: 18,75. The results are shown in Fig. 2, below.

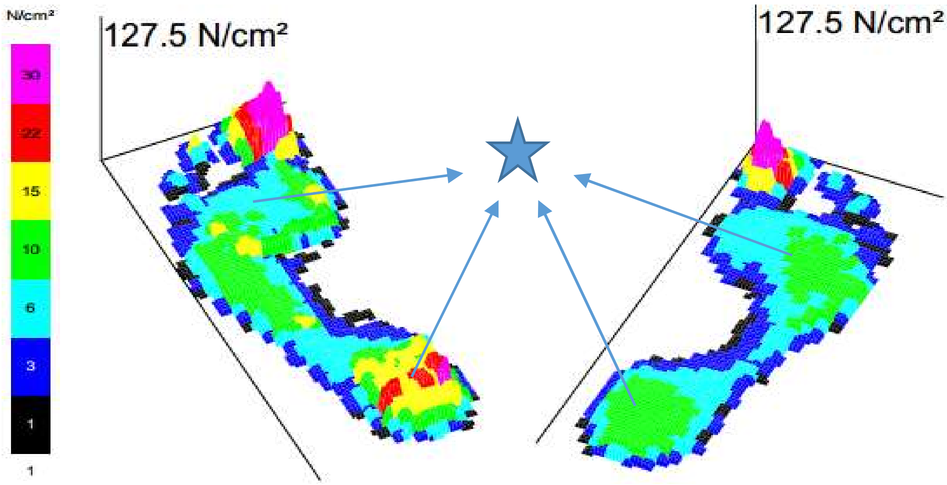

Figure 2. Foot Pressure Distribution with Custom Made Latex Insoles. The marked star shows the reduction of plantar pressure – Novel Software Images

The total values obtained for the test using the custom made latex insole were: Left Foot: Maximum strength 570,9 (N), Pressure peak 50,0 (N / cm^2), Contact time (p) 100,0 (% ROP), and Contact area 119,50 (cm^2). The overall results for the Right Foot were: Maximum strength 574,1 (N), Pressure peak 50,0 (N / cm^2), Contact time (p) 100,0 (% ROP), and Contact area 109,25 (cm^2).

5. DISCUSSION

As can be seen in several presented studies, the plantar pressure distribution changes in the diabetes mellitus individual's gait, may increase significantly the risk of foot ulceration. In addition, various studies point to the risk of recurrence of ulceration, which have significant higher rates when preventive and corrective measures are not adopted, for the treatment of DPN. Ulcerations, resulting from a significant clinical worsening, due to the disorder, contribute in a representative manner to a significant loss of life quality to the patients as well as to the risk of amputations of the lower limbs, and finally, the risk of death. The high plantar pressures are noteworthy for determining recurrence of ulcers in the diabetic foot.

Through the analysis of the obtained plantar pressure data during the research, it is observed that with the use of the proposed controller, it was possible to diminish significantly the plantar pressures in the patient's feet. The observed attenuation occurs both, in the total maximum force applied to the feet, dropping from 815.0 ± 37.5 (N) in bare left foot to 570.9 (N) in the left foot with the custom made insole latex, and from 774.5 ± 28.8 (N) on the bare right foot, to 574.1 (N) on the right foot with the custom made insole latex, as in the pressure peaks, where was observed a reduction of 64.5 ± 4.4 (N/cm^2) in bare left foot to 50.0 (N/cm^2) on the left foot with the custom made insole latex, and 66.3 ± 18.2 (N/cm^2) on the bare right foot to 50.0 (N/cm^2) on the right foot with the custom made insole latex.

The most significant reduction of the plantar pressure per region was observed in the forefoot region, where the peak pressure was attenuated, resulting in a decrease of 60.8 ± 3.5 (N/cm^2), in the left foot and 65.8 ± 18.7 (N/cm^2) on the right foot, without the use of the insole, to 20.0 (N/cm^2) on the left foot and 12.5 (N/cm^2) on the right foot, using the insole. Another important result was obtained in the midfoot region, where the maximum force was reduced from 192.2 ± 39.7 (N) on the left foot and 215.9 ± 18.6 (N) on right foot, without the use of the insole, to 167.3 (N), on the left foot and 88.5 (N) on the right foot, using the insole.

In this preliminary study, for the personalization and individualization of shock absorbers, in addition to the specifications mentioned above, are taken into consideration the rate of plantar pressure during walking and the distribution of this pressure, which affects consequently it's amount, location and size. Since the other insoles, from technical literature and the commercially available, in the production and placement of buffers, consider only one standard model, its dimensions are almost the same, regardless of location on the insole.

The fully individualized and personalized confection of this insole, following the anatomy and characteristics of the patient's feet, allow the positioning of customized shock absorbers, at the desired points, and necessary for a specific impact absorbing during walking and an accurate plantar pressure distribution. In addition, it accommodates perfectly some deformities of the feet (hollow or plane foot, bunions, claw toes, hammer, etc.), unlike the industrialized insoles with cushioning systems, which are not made in a personalized and individualized way. Regarding the size, shape and proportions of the feet, industrialized insoles consider only the standard model of shoe numbering system and, therefore, this makes it impossible to accommodate feet deformities, if there are any.

The goal of this insole is to redistribute the pressure across the plantar surface of the foot, specifically, the reduction of excessive pressure in regions that are under injury danger, and the transfer of this excess pressure to areas without risk. This custom insole is also indicated to prevent the appearance of lesions in the feet and also aid in wound healing in the final stage. Other features are related to the increase of the support surface to the soles of the feet and are also able to provide a personalized comfort, because it is completely made according to the anatomical shape of the foot, providing feeling of softness and well-being, as they allow the correct distribution of plantar support between the legs, improves support base and provides better stability between the legs. This study presents the use of a biocontroller that can help health professionals in the prevention and treatment of patients with diabetic foot, in addition to expand the related research horizons to a wider range of individuals and variables to be considered.

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7. RESPONSIBILITY NOTICE

The authors Gustavo Adolfo Marcelino de Almeida Nunes, Suélia de Siqueira Rodrigues Fleury Rosa, Adson Ferreira da Rocha, Diego Colón and José Manoel Balthazar are the only responsible for the printed material included in this paper.