

APPLICATION OF FUNCTIONAL TEXTILES IN HEALTHCARE AREA DEVELOPMENT OF THERAPEUTIC SOCKS FOR DIABETIC FOOT: A CLINICAL STUDY

Paulo Rodrigues^{1,2}, Fernando Ferreira¹

¹ 2C2T-Centre of Textile Science and Technology, University of Minho

² Fiorima, SA

ABSTRACT

The use of multifunctional textile materials for health applications are showing a great development, namely in pathologies associated with the skin.

The development of new textile products combining adequate structures and finishing treatments, using the technology of micro encapsulation to promote gradual release from the clothing to the skin of active principals, presents a great potential.

Considering this purpose, socks has a great potential, as they guarantee a continuous and uniform contact with skin.

In this work, Diabetic Foot pathology will be characterized, a functionalized textile product will be described and the impact of a clinical test will be presented.

Key Words: *Functionalized Socks; Diabetic Foot; Pressure ulcer prevention; Foot ulcers*

1. INTRODUCTION

In Portugal it is estimated that there is one million persons with diabetes, accounting for 11% of its population, of which 5.4% is unaware of their diagnosis [1].

In the early stages, in general, the diabetic person is asymptomatic, increasing the risk of vascular and neuropathic chronic complications, in which stand out coronary heart disease, stroke and peripheral vascular disease, leading to an increased probability of developing hypertension, dyslipidemia and obesity [2,3].

The diabetic foot is a multifaceted pathophysiological condition, characterized by the appearance of trophic lesions, which occurs as a result in most cases of diabetic neuropathy [4]. Amputation is often the culmination of this disease state, initiated by single or repeated trauma, which become more serious with the start of gangrene or infection, caused by the failure in the healing process [5].

Studies show that the skin of a diabetic patient suffers deep and several changes associated with the advance of disease and age, particularly with the development of microangiopathy and neuropathy essentially the autonomic type [6]. Among the physiological changes of the coetaneous tissue causing a higher or lower capacity of the skin to act as a barrier against external factors, a decrease in thermal capacity adjustment in response to heat due to a reduction in the number of sebaceous glands results in a lower production of oil, a minor sensory stimulus, loss of elasticity, sagging, decrease in cellular immune response and a decrease in the thickness of the dermis and epidermis [7]. On the other hand, is more difficult to realize aggressive and traumatic stimuli, due to a decreased ability of sensory receptors [6].

Maintaining the integrity of the skin surface is essential for the body to defend against several changes, including the mechanical, thermal and chemical trauma or other possible situations to which the patient is exposed to throughout life [7].

After a few years, a patient suffering of diabetes patients will develop diabetic neuropathy and angiopathy the integrity of the skin can be damaged, due to external factors, as contact with chemicals, moisture, mechanical factors (eg, increased pressure and friction forces) and medication and internal factors such as altered metabolic state, bony prominences, changes in plantar support, immune deficit, development factors, altered sensitivity, altered nutritional

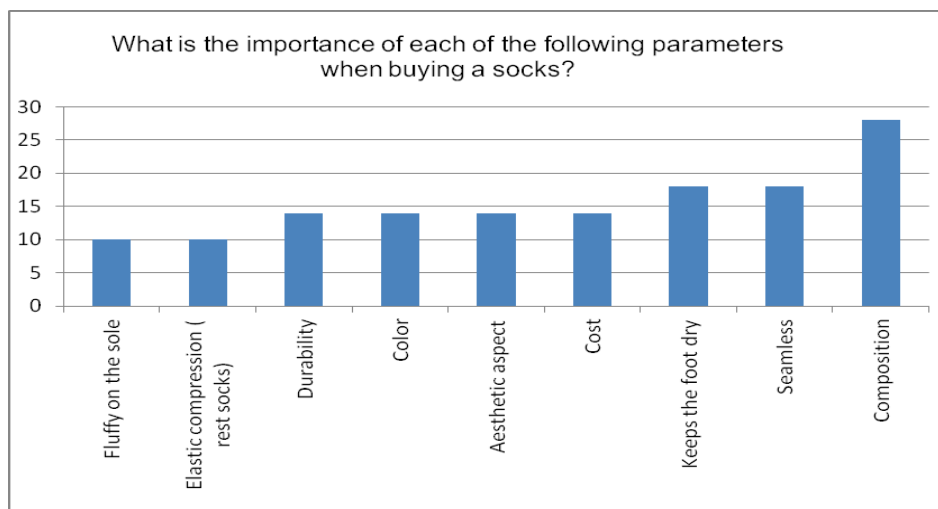
status, elasticity changes, among others [7]. This study aims to evaluate the effect of the use of socks in decreasing medically plantar pressures and improving the physical and chemical properties of the skin of diabetic patients.

2. EXPERIMENTAL

An experimental study of the type 2 diabetic population with a diagnosis made over 10 years ago was carried out. The 14 participants in the study were patients aged less than 35 years, diagnosed with diabetes for at least 10 years and with at least 2 clinical signs of diabetic neuropathy, such as skin dryness and digital hypoesthesia, measured with monofilament 10gr [8-9], and attended by Podiatry Consultation. The study excluded patients with marked ischemia, showing a lower pressure gradient than 0.75 mm / hg, patients with central or peripheral neurological disorders and patients with consequent changes in foot morphology of injuries or amputations feet.

The data collection tools was defined taking into account the literature review, being made the registration of socio-demographic variables, medical history and disease characteristics. Interview procedures were performed and clinical examination, which included the analysis and the measurement of plantar pressures and the physical and chemical properties of the skin.

In the begin of the study an interview was made to quantify the degree of importance of different characteristics of the socks, namely "absence of seams", "ability to keep the foot dry", "elastic compression", "cost", "aesthetic aspect", "composition", "color", "durability", and "plush on the base". The parameters "no seams", "durability" and "composition" have been considered the most important parameters and "elastic compression" was the least important (Graphic 1).



Graphic 1

Socks composition is 56% cotton + 28% polyamide + 14% Crabyon 2% elastane, thereby associating the usual components to Crabyon, which is a composite mixture obtained from the uniform mixture of cotton and chitosan, which is a biodegradable product obtained from the shells of crustaceans with anticoagulants, antibacterial, antifungal and hypo-allergenic properties.

In the design of the sock the total absence of seams and compression at the ankle and fingers was taken into account. Plush areas were strategically placed in the points of higher pressure and, therefore, more susceptible to ulceration, namely the dorsal area of the toes, the plantar region of the heel and metatarsal heads, as the figure shows (Figure 1).

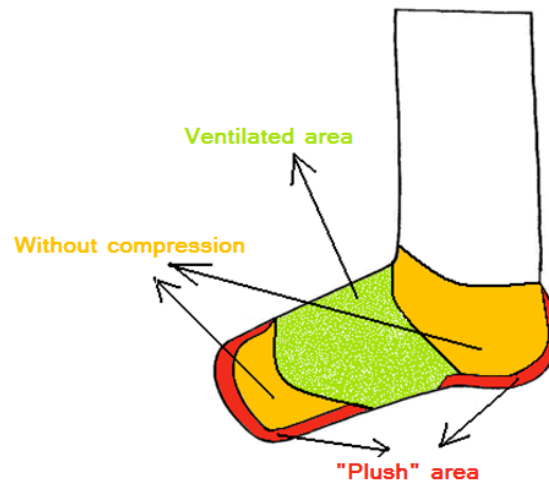


Figure 1: Graphical representation of the diabetic sock

In the textile structure, materials with moisturizing action ((DEVAN) Skin-Care microcapsules based on Aloe Vera and refreshing (R-eSCENTial)) were incorporated in one of the socks, in order to decrease the skin dryness resulting from neuropathy and to give the comfort feeling of freshness. Each of the alleged therapeutic effects of socks was tested through rigorous methodological protocol.

For the evaluation of plantar pressure was used WalkinSense, a system of insoles pressure transducers. This combines two important and complementary analyzes for evaluation of lower limbs: a dynamic plantar pressure (the weight distribution on the sole during walking) and the measurement of the activity (the distance traveled by patients, gait speed, the number of steps and the average stride length).

In the present study, 7 sensors were placed on the sole on selected positions. These sensors were associated with an insole base, adjusted to the patient's foot size and placed inside the shoe (Figure 2). The module set was placed in the anterior face of the leg, just above the ankle.

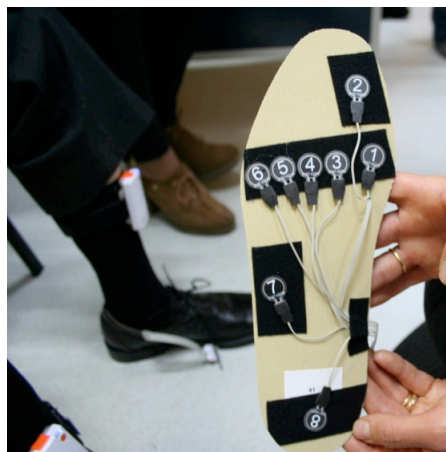


Figure 2: Image of the base insole with 8 sensors recording a valuation point to one of the patients in the sample

Each participant was instructed to wear the shoes initially without socks and put themselves in static standing position for 6 seconds (Figure 3).



Figure 3: Image taken from a time point assessed plantar pressures without socks

The information retrieved on the right and left foot, captured by the sensors, was sent via Bluetooth module to the computer (Figure 4).



Figure 4: Graphic image, transmitted by computer monitor, representative of plantar pressures in strategically selected locations in advance through the "WalkinSense" system

After this it was asked the patient to wear the socks, the same procedure was repeated and the information of each sensor was recorded. To evaluate the physical and chemical properties of the skin, particularly its elasticity, pH, temperature and humidity, a Cutometer® MPA device was used (Figure 5).



Figure 5: Cutometer MPA 580 used for evaluating the physical and chemical properties of the skin.

The assessments of physical and chemical properties of the skin surface were performed on both feet, on the plantar and upper foot area (Figure 6). For each patient, measurements were made in two different periods: T0 – Initial Time: before using therapeutic socks and TF – Final time: after 15 days of use of therapeutic socks

After the first evaluation 15 pairs of socks were provided to the patients in order to use the socks for the next 15 consecutive days.



Figure 6: Image taken during the moment of the evaluation of the physical and chemical properties of the skin, dorsal and plantar, of one of the patients of the sample

3. RESULTS AND DISCUSSION

As observed in Table 1, the population observed presented an average of 67.21 years old, with a larger number of male (78.6%) and with a BMI of 28.2 kg/m². The progression of the disease presents the range of 10 to 15 years with the highest number of cases, optimizing our sample as was wanted patients who manifest moderate neuropathy and uninvolved manifest ischemia [10].

Table 1 - Socio-demographic and clinical characteristics of participants

Variables		Mean (%)
Gender	Male	78,6
	Female	21,4
Age		67,21
Weight (Kg)		75,5
High (Cm)		163
Body Mass Index - BMI		28,2
Evolution in Years of DM	>10<15 Years	50
	>15<20 Years	14,3
	>20 Years	35,7

Table 2 shows a characterization of the pulses of the participants and it is possible to see that 50% of patients had normal foot pulse and 57.1% had a normal pulse upon palpation of the posterior tibial artery. These results confirm the absence of ischemia, criteria that allow the inclusion of these patients in the sample.

During the evaluation of cutaneous sensibility of the foot with 10g monofilament, it was detected the presence of neuropathic component on 51.4% of the patients with

hypoesthesia in the plantar surface of the hallux in both feet and 42.9% of hypoesthesia on the skin of the head of the 1st and 5th metatarsal (Table 3). The damage of autonomic fibers reduces or removes the sweat on the feet, increasing skin dryness, predisposing the appearance of cracks [3].

Table 2 - pulse rating of

Pulses		Right Foot (%)	Left Foot (%)
Foot Pulse	+	21,4	21,4
	++	50	50
	+++	28,6	28,6
Posterior Tibial Pulse	+	14,3	14,3
	++	57,1	57,1
	+++	28,6	28,6

Table 3 - Sensory evaluation with monofilament 10g

Sensory tests	Right Foot (%)			Left Foot (%)		
	A	H	N	A	H	N
Sup. Plantar Hallux	7,1	71,4	21,4	7,1	71,4	21,4
1 ^a Head MTT	-	42,9	57,1	-	42,9	57,1
5 ^a Head MTT	-	42,9	57,1	-	42,9	57,1
ALI	-	7,1	92,9	-	7,1	92,9
Heel	-	14,3	85,7	-	14,3	85,7
Instep	-	14,3	85,7	-	14,3	85,7

The evaluation with a 128 Hz diapason shows, in most cases, vibrating sensation for a period between 7 and 9 seconds in the bones surfaces in the 1st articulation MTF and the internal malleolus IM with percentage values of 71.4 and 78.6, respectively (Table 4). The evaluation of the physical and chemical properties of the skin took place under a temperature of 21.7 °C for T0 and 21.4 °C for TF and atmospheric moisture values of 49.08 in T0 and 45.62 in TF. In both moments, the values of variables are the reference values used for the optimal use of the measuring apparatus. The measurement of skin temperature of the foot was made using Skin-Thermometer ST probe 500 and were recorded values of 27.63 °C and 27.18 °C at T0 and 28.63 °C and 28.82 °C at T1, for the right foot and left, respectively.

Table 4 - Evaluation with 128 Hz tuning fork

Vibration time sense (s)	Right Foot (%)		Left Foot (%)	
	MTF	IM	MTF	IM
4	7,1	-	7,1	-
6	7,1	-	7,1	-
7	21,4	14,3	21,4	14,3
8	21,4	35,7	21,4	35,7
9	28,6	28,6	28,6	28,6
10	14,3	21,4	14,3	21,4

The variable of foot skin moisture, measured with Corneometer, presented values of 28.58 and 28.75 in T0, and 31.61 and 28.75 in T1, to the right and left foot, respectively. Although, with no differences statistically significant, we found that the decline values between T0 and T1, to the left foot, was higher. The incorporation of substances with moisturizing action (DEVAN) in Skin-Care microcapsules based on Aloe Vera and refreshing (R-eSCENTial), in left foot sock can explain these results.

The pH of the skin, measured with pH probe Skin-Meter, presented values of 5.26, 5.03 in T0 and 5.22 and 4.98 at T1, to the right and left foot, respectively. A decrease in values was observed when evaluating the two evaluation times, but with no statistical significance. However, the results deserve consideration, since maintenance of a low pH on the skin surface creates an unfavorable environment for the propagation of microorganisms, lowering the susceptibility of the skin to possible infection.

The elasticity of the foot skin was measured also at two different periods.

The R2 parameter is considered one of the main parameters to determine the elasticity of the skin. The measurement Cutometer recorded high significantly values, in statistical terms, of R2 at TF for the left foot (T0: 0.75 and TF: 0.86, with $p = 0.02$).

The measurement of plantar pressure with the "WalkinSense" showed decreasing values on the area of the foot, namely the plantar surface of the head of the 5th metatarsal (0.438 without sock and 0.358 with sock, with $p = 0.034$), in the rearfoot area (0.586 without sock and 0.513 with sock, with $p = 0.287$) and on the sole, the average value obtained by all the sensors (0,460 without sock and 0.362 with sock, with $p = 0.099$). Although there is a decrease registered by all the sensors, the differences presented in the forefoot area and on the plantar surface, have statistical significance (Figures 14, 15 and 16).

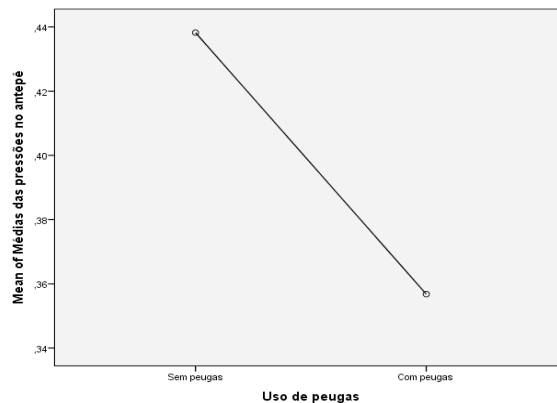


Figure 14: Graph representing the variation of the average pressure in the forefoot, without and with socks

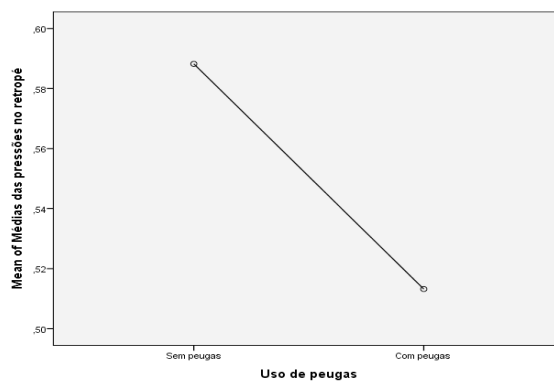


Figure 15: Representative graph of the variation in average pressures in the rearfoot, without and with socks

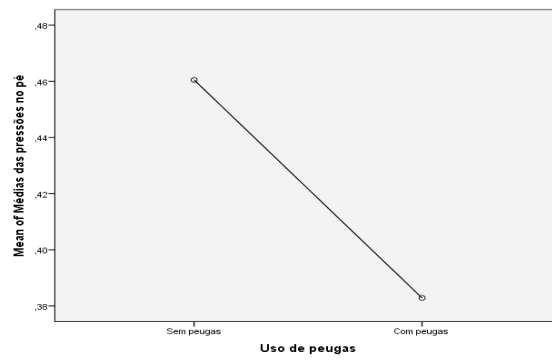


Figure 16: Representative graph of the mean variation of pressure in the foot, without and with socks

4. CONCLUSIONS

The clinical study developed lead to the characterization of some foot pathologies, namely Diabetic Foot, Tinea Pedis and Venous Insufficiency, the specific needs of each one in order to prevent or heal them and how to transfer this information to the development of textile products, namely socks, the most appropriate textile mean to actuate on this field.

The main results of this study related to the pathology diabetic foot were presented, namely the structure of the sock, the materials used and its impact in terms of clinical evolution.

The results suggest that the use of a sock with plush (textile mesh with rings), placed at strategic locations, decreases pressure per cm².

Also, the foot with the functionalized sock show differences in the assessment of physical and chemical properties of the skin, suggesting effectiveness in achieving the goals initially proposed:

- Reduction of plantar pressures;
- Improvement of the physical and chemical properties of the skin.

5. REFERENCES

- [1] **Relatório anual da Diabetes**. Direção Geral de Saúde. Fevereiro 2012.
- [2] **Mendonça, S. S.; Morais, J. S. e Gadelha de Moura, M. C. G.** "Proposal of a Protocol physiotherapeutic assessment for diabetics feet.", *Fisioter. Mov.*, 2011, Vol. 24, n. 2, pp. 285-298.
- [3] **Sacco, I.C.N; Sartor, C.D.; Gomes, A.A.; João, S.M.A. e Cronfli, R.** "Avaliação das perdas sensório-motoras do pé e tornozelo decorrentes da neuropatia diabética." *Revista Brasileira de Fisioterapia*, São Carlos, 2007, Vol. 11, n. 1, pp. 27-33.
- [4] **Ochoa-Vigo, K.; Torquato, M. T.C. G.; Silvério, I.A.S.; Queiroz, F.A.; De-La-Torre-Ugarte-Guanilo, M.C.; Pace, A.E.** "Caracterização de pessoas com diabetes em unidades de atenção primária e secundária em relação a fatores desencadeantes do pé diabético." *Acta Paul Enferm*, 2006; Vol. 19, n. 3, pp. 296-303.
- [5] **Reiber, G.E.; Lipsky, B.A. e Gibbons, G.W.** "The Burden of Diabetic Foot Ulcers" *Am J Surg*. 1998; Vol. 176, n. 2A, pp. 5S-10S.
- [6] **Schmid, H.; Neumann, C.; Brugnara, L.** "O diabetes melito e a deservação dos membros inferiores: a visão do diabetólogo." *J Vasc Br*, 2003; Vol. 2, n. 1, pp. 37-48.
- [7] **Resende, D.M.; Bachion, M.M.; Araújo, L.A.O.** "Integridade da pele prejudicada em idosos: estudo de ocorrência numa comunidade atendida pelo Programa Saúde da Família." *Acta Paul Enferm*, 2006; Vol. 19, n. 2, pp.168-73.
- [8] **Revilla, G.P.; Brito de Sá, A.; Carlos, J.S.** "O pé dos diabéticos." *Rev. Port Clín Geral*, 2007; Vol. 23, pp. 615-26.

- [9] Chacon, D.A.; Chaves, A. D. S. M.; Duarte, R. A.; Garcia, C. A. A.; Medeiros, A. C. Achados da fundoscopia e alterações do pé diabético em pacientes do Hospital Universitário Onofre Lopes/UFRN."Acta Cirúrgica Brasileira, 2005, Vol. 20, n. 1, pp. 3-7.
- [10] Frykberg R. G.; Zgonis T.; Armstrong D. G.; Driver, V. R.; Giurini J. M.; Kravitz S.R.; Landsman, A.S.; Lavery L.A.; Moore J.C.; Schuberth J.M.; Wukich D.K.; Andersen C.; Vanore J.V. "DIABETIC FOOT DISORDERS: A CLINICAL PRACTICE GUIDELINE", The journal of Foot and Ankle Surgery, 2006, pp. S2-S12.

ACKNOWLEDGMENTS

This work is supported by Portuguese National Funding, through FCT - Fundação para a Ciência e a Tecnologia, on the framework of project UID/CTM/00264/2013.



Corresponding author:

Paulo RODRIGUES
Fiorima, SA
Rua Quinta da Goja, 75
4700-155 Braga – Portugal
E-mail: paulo.rodrigues@fiorima.com

2C2T-Centre of Textile Science and Technology
University of Minho, Azurém
4800-058 Guimarães – Portugal

Co-author(s):

Fernando FERREIRA
2C2T-Centre of Textile Science and Technology,
University of Minho, Azurém
4800-058 Guimarães – Portugal
E-mail: fnunes@2c2t.uminho.pt