

Assistive products for people affected by diabetic foot

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Abstract: Diabetes mellitus (DM) requires a broad view of its complications, being a disease that affects an increasing number of people. As a result, complications occur in the lower limbs, such as the “diabetic foot”, and the consequences in some more advanced stages are amputations and deaths. Therefore, assistive technologies (AT) assist with equipment, strategies and services that promote functionality, related to the activity and participation of people with disabilities or reduced mobility, aiming at autonomy, independence and social inclusion, developing materials and products for routine tasks how to eat, cook, dress and perform personal needs. This study aimed to analyze and identify AT products aimed at people with diabetic foot that resulted in patent filings for shoes and insoles aimed at people with this complication. The National Industrial Property Institute, the World Intellectual Property Organization and the Espacenet and Latipat - European Patent Office were used as databases available on the internet, using keywords related to diabetes and diabetic foot, with a 10-year deposit periodicity. The results showed five national and 11 international patents for inventions. Most patents are related to the typical ulcerations of sick feet, highlighting behaviors that lead to these injuries, aiming to reduce their effects or even avoid them. The research identified little interest in national and international research in the development of products that face the vascular consequences of DM. It is hoped that the content of this research will stimulate the continuation of innovative research that benefits people with diabetic foot.

Keywords: assistive technologies, diabetic foot, diabetes mellitus, patents.

1. INTRODUCTION

Diabetes mellitus (DM) is a silent disease that affects 12 million Brazilians, taking Brazil to the 4th place in the ranking of countries with the highest number of patients with this pathology [1]. It refers to a metabolic disorder of heterogeneous etiologies, characterized by hyperglycemia and disturbances in the metabolism of carbohydrates, proteins and fats, resulting from defects in insulin secretion and/or action [2]. Diabetes is a complex chronic disease that requires regular medical monitoring and lifestyle changes (healthy eating, physical activity, quitting smoking, weight control), disease self-management (medication adherence, blood glucose self-monitoring) and prevention of complications (adherence to foot care and screening for visual and kidney problems). The lifestyle habits of modern society, characterized by the high consumption of unbalanced diets and reduced practice of physical exercises, have brought numerous implications for the health of the population, with an increase in the occurrence of chronic non-communicable diseases such as DM [3].

Caused by DM, peripheral vascular and neurological changes produce distortions in the normal physiology and anatomy of the feet. These changes cause the appearance of pressure points and skin dryness, which causes damage to local circulation, making healing more ineffective and slower [4], which can lead to the formation of skin lesions from repetitive trauma in a patient. fragile tissue and the process, in most situations, progresses to amputations and death [5].

The disease called “diabetic foot” is one of the most serious complications of diabetes, and in more advanced stages it generates high rates of amputations, premature deaths and health costs [6]. Infections in the feet of people with the disease are the main contributors to increased morbidity, mortality and decreased quality of life [7]. In the general population, these complications are caused by peripheral neuropathy, leading to foot deformities and 40% to 70% of all non-traumatic lower limb amputations [8]. Among the recommendations for the prevention of ulcerations in people with high-grade DM, one should avoid walking barefoot, not wearing shoes without socks or with thin-soled slippers, whether indoors or outdoors [9]. The various complications that can afflict the feet of diabetic patients always appear as hidden signs, making the initial diagnosis difficult, so it is of fundamental importance to carry out monitoring with medical teams so that in case of suspicion of wounds or ulcers, immediate intervention is carried out [10].

Once deformities are identified in the assessment of the feet of people with DM, the main pillars for the prevention of amputations of the feet are used, such as prescription and choice of resources that mitigate the overload, such as: therapeutic shoes, protectors and insoles and orthotics [11]. Therefore, it is extremely

important to develop technologies that aim to remove some of the barriers to full participation and practicality for people with some type of disability and impaired mobility, such as those that DM causes to people over time.

From this perspective, Assistive Technologies (AT) enter as an area of understanding, with multidisciplinary aspects, which aims to improve autonomy and quality of life for those who are affected by different limitations [12]. For the World Health Organization (WHO) AT is considered a subset of health technologies, being the application of organized skills and knowledge to assistive products, systems and services [13].

Also according to this organization, assistive products, also used to prevent disability and secondary health conditions, are external products such as devices, equipment, instruments or software, which aim to maintain or improve the functionality and independence of the elderly, people with disabilities, people with noncommunicable diseases, people with mental health conditions including dementia and autism, and people with gradual functional decline.

Therapeutic or orthopedic footwear for users with neuropathic foot is considered essential and is part of the list of the 50 priority assistive products, defined by the WHO as highly necessary products to improve or maintain individual functionality [14]. In order to protect the diabetic feet of people with diabetes and/or insensitive people, the manufacture of therapeutic footwear and biomechanics must respect some basic principles of modeling, invention and manufacture, in accordance with ABNT standards established by the Brazilian Institute of Technology [15].

One of the effective ways to protect inventions is patent applications in assistive technology related to mobility, followed by the built environment, hearing and vision. A 'patent' is understood as a temporary property title over an invention or utility model, granted by the State to inventors or authors or other individuals or legal entities holding rights over the creation [16].

In a patent application, a search performed correctly can mean a high level of confidence that the invention meets the patentability requirements to be accepted by the National Institute of Industrial Property (INPI) that permeate between novelty, inventive step and industrial application [17]. The INPI is the only body at the national level responsible for registering patents for technological innovations.

Given the need to know and identify AT products aimed at the diabetic foot, the objective of this research was to prospect patents available in the market for shoes and insoles applied to patients with diabetic foot that can lead to an improvement in the life of the affected person.

2. MATERIAL AND METHODS

This is a study of an applied nature, exploratory objective, quantitative approach and bibliographic procedure, with patent research. The research was carried out at the Federal University of Mato Grosso do Sul (UFMS) – Faculty of Medicine (FAMED). Patent deposits for products for the diabetic foot were sought with a periodicity of 10 years, using specifications aimed at assistive technology and complications of diabetes such as wounds, ulcerations and amputations due to this pathology. To this end, there was active research using the authors' computers during the months of February and May 2021 on the sites of three databases seeking specific results between the years 2011 and 2021.

The following databases (table 1) used for research were chosen from the Simplified Guide for Searches in Free Patent Databases [18]:

Table 1: Free access digital databases used in research

DIGITAL LIBRARY	SITES
National Institute of Industrial Property (INPI - PATENTS)	https://busca.inpi.gov.br/pePI/jsp/patentes/PatenteSearchBasico.jsp
World Intellectual Property Organization (WIPO – PATENTSCOPE)	https://patentscope.wipo.int/search/en/search.jsf
Espacenet e Latipat - European Patent Office (EPO)	https://lp.espacenet.com/

Source: Authors.

As a criterion for inclusion of patents in the research, keywords in two languages were used for searches in the databases chosen for the study in order to filter requests for patent deposits with specifications, such as technologies used in the manufacture of shoes, insoles or foot orthotics diabetic at risk of ulceration: Portuguese language (key words: “technologyaid for diabetics”, “diabetes”, “diabetic foot”, “insole”, “insole for the footdiabetic”, “diabetic foot shoes”) and English language (keywords: “assistedtechnology for diabetics”, “diabetic”, “diabetic feet”, “insole”, “footwear for diabeticfeet”).

3. RESULTS AND DISCUSSION

3.1 Platform of the National Institute of Industrial Property (INPI)

On the INPI website, 527 patent deposits were found, in which none was totally focused on “AT for diabetics”. However, five were found patent filings that were in line with the research objective:

Patent 1 - BR1120190085742: under the title “Apparatus and method for evaluating tissue susceptibility to the formation of diabetic foot ulcer”, brings a device connected to insoles to detect a pre-ulcer condition that allows implementation of preventive techniques. The apparatus comprises a sensor fixed in flexible substrate, such as an insole, which assesses the susceptibility of tissue to ulcer formation in the diabetic foot, indicating subepidermal moisture value and the patient's skin temperature measurement.

Patent 2 - BR1120140138605: under the title “Insole to support the foot of a person”, brings an invention that provides an insole to support a person's foot diabetic, in which the insole serves as a support under the heel, under the medial process of the heel and under the lateral part of the heel, thus stabilizing those parts that functionally form supports for the arches of the foot. This invention relates to footwear to treat pronation (parts of the foot that tend to curve inwards and the arch of the foot flattens out) and when this process occurs, the soft tissues become stretched and the joint surfaces of the bones of the feet are placed at unnatural angles to each other.

Patent 3 - PI1103692-3: under the title “Cushioning insole for diabetic feet”, brings an invention that refers to an insole with a damping system to reduce excessive pressure in areas that are at risk of ulceration. This insole works by uniformly redistributing pressure on the entire plantar surface of the foot. Its function is to reduce excessive pressure in regions that are under the danger of injuries, and its functionality is to transfer this pressure in excess to non-hazardous areas.

Patent 4 - PI1103691-5: under the title “Sensorized insole for diabetic feet”, brings invention that refers to an insole with an electronic system for monitoring the plantar pressure control. The active element of this insole is the electronic circuit which will monitor the pressure applied by the feet with each step cycle (gait). the insole is able to calculate and record data on the pressure to which the feet of the patients in everyday situations, such as potholes and ramps, which can lead to morphological changes and this data can be passed on to your doctor.

Patent 5 - PI1103690-7: under the title “Healing insole for diabetic feet”, brings invention that relates to a healing insole for diabetics, with of tissue neof ormation. This insole promotes healing of ulcers and is useful for the treatment of diabetic foot in diabetic patients. The active element of this insole is an electronic tissue regeneration circuit, in which a cell is used signal radiator based on the principle of tissue regeneration using low-power laser type radiation that has an angiogenic action and may cause tissue neof ormation.

3.2 Plataforma do World Intellectual Property Organization (WIPO)

On the WIPO website, 1850 patent applications related to the diabetic patients, in which none were totally focused on “assistive technology”. However, 10 patent deposits were found that were in accordance with the research objective.

Patent 1 - WO/2018/098463: under the title “Double-layer insole for of diabetic foot injury” brings an invention that refers to an insole with a which has inside cavities configured to supply fluids that adapt to the internal pressures of the diabetic foot.

Patent 2 - WO/212228123: under the title “Device for detecting neuropathy of the diabetic foot” brings an invention that refers to a model that uses a detection of diabetic foot neuropathies, comprising a sensor in the insole of the shoe.

Patent 3 - WO/108308779: under the title “Shoe system for monitoring and decompression of plantar pressure in diabetic patients” brings an invention that refers to a system that reduces the pressure exerted by the body on the foot sole, through electrical sensors.

Patent 4 - WO/20190231578 and Patent 5 - WO/20180008000: under the title "Insole personalized bipartite for diabetic patients” and “Custom insoles for diabetics and pressure ulcers”, respectively, bring inventions that refer to to customizable insoles for each patient's foot and may include several parts of different softness, depending on his needs.

Patent 6 - WO/2019/076461: under the title “Insoles with sensors” brings insole capable of monitoring data received by a plurality of sensors. The sensors aim to obtain data related to the pressure exerted by the wearer when walking or running, relative humidity and temperature inside the shoe.

Patent 7 - WO/107242639: under the title “Protective footwear for patients diabetic” brings an invention specifying a suitable footwear for the foot of that person affected by DM, referring to the adaptability and comfort of the foot of the diabetic.

Patent 8 - WO/2017002122: under the title “Insole for protection of the diabetic foot” brings an invention with a silver nanoparticle coating on its surface. This surface offers antibacterial protection for diabetes from the presence of silver, allow the device to adhere to the limb, reduce shear and friction. At lower levels, its advantages are to dissipate pressures and normal voltages, control and direct the loads.

Patent 9 - WO/209489552: under the title “Shoe with foot prevention function diabetic” brings a utility model with a pair of shoes with the function of prevent diabetic feet with massage that penetrate the bottom surface of the shoe and sole.

Patent 10 - WO/2827485: under the title “Shoe to stimulate blood flow” brings an invention that relates to footwear for diabetics. the present invention seeks to provide footwear that stimulates blood flow, presenting benefits therapeutics for these patients with circulatory problems in the foot, helping in the healing of the wounds present there, aiming to assist in the arterial and venous flow of the member.

3.3 Plataforma do Espacenet e Latipat - European Patent Office (EPO)

On the EPO website, 140 patent applications related to the diabetic patients, in which none were totally focused on “assistive technology for diabetics”. Only one patent deposit was found in accordance with the purpose of this study.

Patent 1 - 20040103561: under the title “Footwear with orthopedic systems” brings a model that refers to a shoe for diabetics. Includes the insole and body of the footwear configured in expanded EVA material, weighing less than 120 grams and inner pad containing nanometric silver ions.

Based on patent searches performed less than 1% of patents surveyed at INPI met the research objective. Even smaller amount was found in WIPO and EPO, with, respectively, 0.54% and 0.71% patents deposited aimed at meeting the needs of the diabetic foot, where they can be grouped into four types (table 2).

Table 2 Total patents grouped by type of use.

Devices function			
Pressure surge reducer	Sensor of monitoring	Stabilization and comfort	Artifice regenerative
PI1103692-3	BR1120190085742	BR1120140138605	WO/2017002122
WO/2018/098463	PI1103691-5	WO/20190231578	WO/2827485
	WO/212228123	WO/20180008000	
	WO/108308779	WO/107242639	
	WO/2019/076461	WO/209489552	
	PI1103690-7	20040103561	
12,50%	37,50%	37,50%	12,50%

Source: Authors.

Studies show that the use of shoes for diabetics promotes a reduction in the average of the peaks of plantar pressure in the order of 22% to 31%, being that this effect may contribute to the prevention of injuries associated with diabetic foot¹⁹. The most appropriate shoes are those that support and protect the feet from trauma. mechanics, distributing pressure points, which have no seams and are in good condition [19].

Of the total number of registered patents, 12.5% are aimed at reducing peaks depression. Such deformities alter the pressure points in the plantar region leading to overload and skin reaction with local hyperkeratosis (callus) which, with continuous ambulation, progresses to ulceration [20]. Pressure ulcers in patients who have DM are the result of repetitive trauma or excessive pressure that act on extremities whose sensitivity may be reduced or absent.

Factors involved in the etiology of ulcers are related to the type of footwear, normally inadequate, trauma, walking barefoot, in addition to tortuosity of the feet and calluses that can trigger complications typical of diabetic people, like the diabetic foot [21]. The reduction of pressure peaks may favor stimulation blood and consequently promote a regenerative effect. In this regard 12.5% of the researched patents have some resource aimed at regeneration tissue with therapeutic benefits.

The pathophysiology of ulcers, common in the diabetic foot, has components neuropathic and vascular causes of injuries from the pressure that this foot type can suffer. The damage affects the function of the sweat glands and reduces the hydration capacity of the skin, leading to skin lesions, causing a greater damage associated with pressure (from footwear or the fingers themselves) and, finally, skin lesions [22].

Clinically, the relationship between plantar pressure and injury makes the reduction of pressure an important criterion for the development of therapeutic insoles [23]. It is important to remember that regions with high pressure can be an indication of callosity. Regarding inventions found in this research with active that reduces plantar pressure and has long-lasting antibiotic effects, in addition to promoting comfort and preventing infections proved to be viable and necessary for the reality in which the patient lives.

Another triggering factor for diabetic foot is the slight sweating of the feet that, most of the time, it will result in a thin and dry epidermis, which will facilitate the appearance of cracks, leading to a decrease or even loss of sensitivity and reduced muscle tone in the lower limbs. In this way, calluses appear, microfractures and, consequently, ulcers; these important parameters in the development of diabetic ulcers, therefore, the development of technologies assistive devices, such as some found in this research, that combat such processes negatives proves to be fundamental [25].

Sensory neuropathy makes it possible to subject the foot to extremes of stress with consequent painless fractures, these fractures that progress to serious injuries can lead to amputations. Therefore, inventions that seek to detect such neuropathies is important for the prevention of diabetic foot. Studies show that the footwear most suitable for people with DM is the one that will be characterized by the comfort, absence of seams and the correct number to avoid pinching the fingers and that doesn't get loose, being not recommended those with a pointed beak and flip-flops or sandals as they can cause pressure points on the limbs of these patients [26]. From this perspective, 37.5% of patents offer resources related to stabilization and comfort.

In the search for signs suggestive of the risk of injury, most part of the research focuses on investigating the presence of dehydration, fissures, cracks and interdigital spaces related to foot moisture. These are changes frequently found in the feet of people with diabetes and their presence, associated with loss of peripheral sensitivity, is often diabetic foot trigger [27].

More severe cases of diabetic foot lead to more severe situations, such as amputation. Early preventive measures, stimulation of blood circulation and the healing of diabetic ulcers has been reported as fundamental for amputation prevention [28]. Therefore, individuals with diabetes mellitus have a chronic health condition and care is needed so that there is a good quality of life [29]. In this sense, the monitoring resources by through sensors attached to the insoles, found in 37.5% of the patents, can help the user and his doctor to adopt the best decision making for mitigate the harmful effects of the diabetic foot.

Through this research, the presence of technologies idealized to this underserved public, where the objectivity of the research was achieved, even identifying a low number of patents. During the search for assistive products, it remained clear that the present scenario needs greater investment due to the low number of products found. The methodology employee was satisfactory, as it enabled expanded research in different countries, as well as it is important to point out that the largest holder of patents in the world is China, and it is also the country that appears as the greatest inventor of assistive products aimed at diabetic patients in general.

In view of the above, it was noticed that the bibliographies used in the construction of this research brought the problem experienced by people who are affected by the diabetic foot, exposing, as a difficulty faced by many, the risk of development of ulcers and the lack of assistance, pointing to a agreement between reality and science, clarifying the lack of Technologies Assistives for people with this type of dysfunction. Thus, the limited interest of companies that can design and manufacture products that bring improvement and quality of life of these people is evidenced and as a consequence we see the persistence of complications such as amputations and deaths.

Difficulties in accessing these products or the low options available in the market can be identified as a factor that hinders this assistance from subjects who need them, thus corroborating the results of research performed in this study, which indicated low patented products. In Brazil, the concern is even greater, since this

is the reality of millions of people who present the disease and do not have the conditions to acquire these articles, thus requiring public policies and investment in research.

Studies show that the likelihood of wound healing is significantly lower in the diabetic group when compared to the non-diabetic group. diabetics. Furthermore, the lowest rate of scarring occurs in groups of patients with venous ulcers compared to those without venous ulcers [30]. In this context, it is expected that this research will contribute to stimulate investment and the development of new shoes, insoles and orthotics in order to better meet the needs of needs of people who are harmed by this chronic disease that increases in statistics every year.

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