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Footwear for Diabetics – Structural and Material Elements for the Prevention and Alleviation of Foot Lessions

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Abstract
Diabetic foot syndrome is a syndrome of specific conditions affecting the foot. It is a complication of diabetes. It occurs in 12-25% of patients with diabetes. Untreated, it leads to irreversible deformities and necrosis of the foot, often resulting in amputation. In this study the statistics and consequences of diabetic foot syndrome are described. Patients with diabetes need to take care of their lower limbs. Proper footwear can prevent foot wounds. Available solutions for the prevention and treatment of diabetic foot syndrome are presented herein: footwear, insoles and requirements for footwear materials. Appropriate equipment for a person with diabetes, especially one who has been diagnosed with diabetic foot syndrome or is at risk of such a condition, includes footwear and replaceable insoles. The parameters of footwear, insoles and footwear materials that are most optimal for patients with diabetes and diabetic foot syndrome were defined. The effect of a pulsed electromagnetic field and pulsed ultrasound on diabetic foot problems was evaluated.

Keywords
diabetic foot syndrome, diabetic footwear, insoles, diabetes, footwear materials, pulsed ultrasound, pulsed electromagnetic field.

1. Diabetic foot syndrome – an introduction

The earliest known description of diabetes can be found in medical texts originating from ancient Egypt, dated to 552 BC. These texts are collectively known as the Ebers Papyrus [1,2]. The medical literature of ancient India and China contains accounts of both diabetes mellitus and methods of its treatment [1]. The term “diabetes” was first used by Aretaeus of Cappadocia (129–199 AD), a Greek physician. It is derived from the Greek word “siphon,” as Aretaeus observed that diabetes causes a constant flow of urine [2, 3]. Prior to the advent of insulin, the life expectancy of individuals diagnosed with diabetes mellitus was significantly reduced, and the prognosis was exceedingly poor. Fortunately, the situation changed significantly with the discovery of insulin.

On 11 January 1922, the first injection of insulin was administered to a patient [4, 5]. However, the resolution of one issue gave rise to the emergence of another. The introduction of new varieties of high-purity insulin continues to present a significant risk of various complications. The complications associated with diabetes can have a profound impact on an individual’s quality of life, due to the multitude of potential complications that may arise. The three most significant complications are retinopathy, nephropathy, and neuropathy. Of particular significance is the connection between these and the development of diabetic foot syndrome. As reported by the International Diabetes Federation (IDF) in 2021 [5], 537 million adults worldwide are affected by diabetes. It is projected that this number will increase to 643 million by 2030 and 783 million by 2045.

As indicated by data from the Polish Ministry of Health [6], it is estimated that over 2 million individuals in Poland are currently affected by diabetes, with approximately 25% of these cases being undiagnosed. The prevalence of diabetes is approximately 6.54% (5.81% in men and 7.25% in women). In individuals aged 18 and above, the prevalence is estimated at 8% (7.15% in men and 8.9% in women). Among children under 15 years of age, the estimated incidence of diabetes is 17.7 cases per 100,000 inhabitants. It is anticipated that the number of individuals diagnosed with diabetes in Poland will double over the next 15 to 20 years. A significant proportion of these individuals will experience diabetic foot syndrome. A definition is provided by the International Diabetic Foot Working Group, “It is an infection, ulceration, and/or destruction of deep tissues, associated with neurological disorders and peripheral vascular diseases, of varying degrees of advancement in the lower limbs (below the ankle) in patients with diabetes” [7]. The risk of developing diabetic foot syndrome affects 12 to 25% of individuals with diabetes [8]. The most conspicuous consequence of diabetic foot syndrome is the formation of ulcers. The lifetime risk of diabetic foot ulceration is estimated to be between 19% and 34% [9]. Relapses are common following initial healing. Approximately 40% of patients experience a relapse within one year of ulcer healing, 60% within three years, and 65% within five years. An extreme manifestation of diabetic foot syndrome is known as Charcot’s syndrome (alternatively termed Charcot’s foot). This condition is distinguished by

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the deterioration of bones and joints. The prevalence of Charcot's syndrome in individuals with diabetes mellitus ranges from 0.1% to 8%, as documented in the literature [9]. In the most severe instances of diabetic foot syndrome, amputation may be a potential outcome. The likelihood of amputation in patients with diabetes is 30–40 times that of individuals without diabetes [10, 11, 12]. A significant challenge in the field of diabetic foot syndrome research is understanding the underlying mechanisms that contribute to its development. It is widely accepted that neuropathy, or damage to peripheral nerves resulting from demyelination caused by hyperglycemia, is the primary factor contributing to the development of diabetic foot syndrome [10, 13]. The longest sections of nerves, specifically those leading to the feet, are the most susceptible to destructive factors. The impaired conduction of nerve impulses limits the ability to perceive touch in the feet, to sense the ground, and, in general, to perceive one's own body in space (proprioception). In this condition, the patient is unable to perceive excessive pressure and is unable to control the position of the foot, which results in the foot being subjected to excessive loads in various areas. In addition, an incorrect flow of nerve impulses causes inappropriate muscle tension, which further alters the distribution of pressure on the plantar surface of the foot. It is also important to consider the destructive effect of hyperglycemia on the blood supply to the foot. This results in the development of atherosclerotic changes in the vessels of the lower extremities, and the consequence of neuropathy is the disruption of the regulatory processes of subcutaneous blood vessels. Consequently, the overloading of various areas of the foot results in the formation of wounds and ulcers, which are challenging to heal due to the impaired functioning of the circulatory system. These changes occur gradually and over an extended period of time. The patient may be unaware of the loss of sensation and therefore unable to discern that the pressure on the foot exceeds the permissible values. It is frequently the case that the development of ulcers is the first indication of this phenomenon. It is therefore imperative to conduct regular examinations for the presence of neuropathy and to perform detailed assessments of the feet for any deformities. The prevention of complications associated with diabetic foot syndrome can be achieved at two levels. It is of the utmost importance to manage the patient in a manner that prevents the occurrence of abnormal glucose levels. This is an evident course of action that hinges on the implementation of suitable pharmacotherapy and patient care, encompassing an appropriate diet. If the patient is treated and disciplined in an appropriate manner, there is a high probability that abnormal glucose levels will not occur, and thus, complications associated with diabetes will be avoided. Nevertheless, irrespective of whether glucose levels are successfully managed, it is imperative to ensure optimal care and monitoring of the lower limbs. It should be noted that the level of control is dependent on a number of factors. The primary objective is to refrain from wearing footwear that may result in abrasions and discomfort.

2. Footwear and insoles – important equipment for diabetics diagnosed with diabetic foot syndrome or at risk of such a disease

Appropriate equipment for an individual with diabetes, particularly one who has been diagnosed with diabetic foot syndrome or is at risk of developing such a condition, includes footwear and replaceable insoles. The essential criteria to be followed are as follows:

– avoid any locations that may pose a risk of tissue damage,
– prevent the application of excessive pressure, which could potentially lead to the formation of wounds or ulcers,
– redistribute high-value pressures to other areas of the foot.

The design of the sole and insole is responsible for the reduction of high pressure on the plantar surface of the foot. In regard to insoles, reductions can be achieved in two ways:

– the molding of insoles should correspond to the structure of the foot, thereby providing the largest possible support surface and distributing pressure over the largest surface area. In practice, this signifies a redistribution of pressure from one area to another.
– the utilization of soft, elastic materials is a key aspect of this process. Typically, these materials are foams. An example of such materials are: polyethylene foams (such as plastazote foams), polyurethane (Poron), ethylene vinyl acetate (EVA), neoprene and latex. The effect of such materials is to extend the phase of contact between the foot and the ground, while simultaneously reducing point pressures. This is achieved by enabling the less-loaded or unloaded areas of the foot to participate in the transfer of pressure to a greater or lesser extent. Figures 1 and 2 illustrate the impact of employing an elastic material. The application of a single layer of latex, with a thickness of 2 mm, resulted in an increase in the support surface and a reduction in the maximum pressure.

In practice, both methods are employed, though in the case of individuals with diabetes, the use of soft materials is imperative and meticulous care should be exercised during the molding process. It should be noted that the aforementioned list of available and used materials is not exhaustive. The use of new materials and combinations of different materials is becoming increasingly common. In the case of insoles for individuals with diabetes, the use of hard materials (e.g., cork, hard rubber) is contraindicated. These insoles are not designed to correct the position of the heel; rather, they are intended to eliminate high-pressure points.

In the context of molding insoles for individuals with diabetes, three primary categories of molding elements are typically utilized:

– footbed,
– longitudinal arch support,
– metatarsal support.

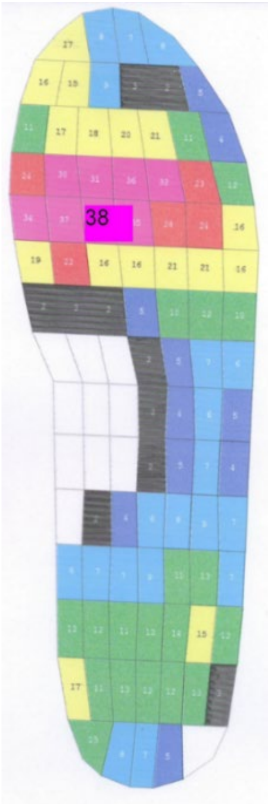

Fig. 1. Plantar pressure in footwear without any insole (source: own research)

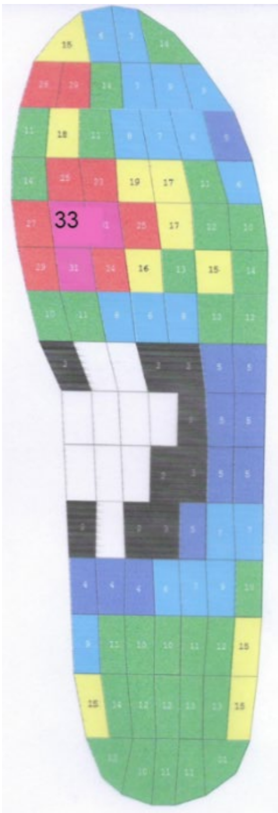

Fig. 2. Plantar pressure in shoes with an insole made of 2 mm thick latex. (source: own research)

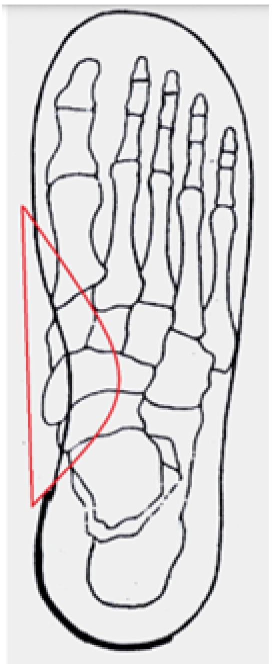

Fig. 3. Longitudinal arch support. Source: RAJCHEL-CHYLA, B., GAJEWSKI, R. Selected corrective elements and their use in making orthotics for children and adults (in polish) . Lecture at the Orthopaedic Footwear and Insoles Conference(in polish). Kraków, 2006.06.09. ISBN 83-922656-1-0. (with own modifications)

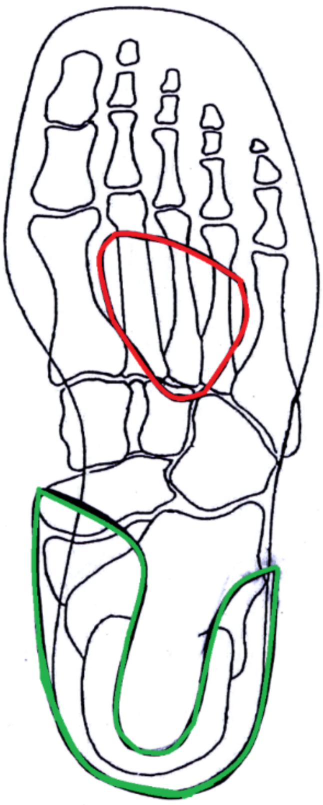

Fig. 4. Metatarsal support (red), footbed (green) – (source: own research)

At the current time, there are a number of methods that can be employed for the molding of insoles. This may be achieved through the use of milling to create a foam block, 3D printing, or molding in a thermoplastic material. This may also entail the use of the patient's own foot. In this instance, thermoplastic resins are employed, and the resulting process enables the attainment of an optimal fit. It should be noted, however, that the process is conducted under static conditions.

The use of molding alone to alleviate pressure in individuals with diabetes is not advised. It is important to note that even a highly effective custom-made insole is a passive element, while the foot undergoes a series of cyclical movements during the act of walking. [14, 15]. This can be incorporated into the design of the insole; however, it necessitates the use of highly delicate molding, which may not be as effective in transferring pressure as desired [16]. Therefore, in addition to molding, it is necessary to utilize foam materials in the case of diabetes, as they distribute peak pressures over a larger surface area and thereby reduce maximum pressure values [17].

In regard to the materials utilized, Poland has made significant strides over the past three decades. To provide a case example, we will present a profiled insole designed for a diabetic patient with foot complications in the 1990s. The insole comprises a steel plate that has been profiled in such a way that it contains a minimal heel bed, a metatarsal pad, and a longitudinal arch support. The entire structure is encased in natural leather.

It is additionally important to note that solutions in which the insole is replaceable are preferred. This is due to a number of factors:

- the material utilized for the insole may lose its elastic properties over time, necessitating the replacement of the insole with another,
- it is also important to note that the foot may become deformed over time, necessitating adjustments to the shoes. In practice, replacement of the insole is sufficient,

Fig. 5. Individually designed insole for diabetics made in 90-ies. (source: own research)

– maintaining hygiene in shoes is more straightforward when the insole can be removed and washed. This also allows for the inspection of the foot for any wounds.

It is therefore recommended that individuals with diabetes engage in comprehensive foot care, which encompasses the use of shoes that are properly fitted to accommodate replaceable insoles and the regular replacement of these insoles themselves.

The following section will present an overview of the available types of insoles and the various production options.

In the absence of deformity or symptoms of diabetic foot syndrome, it is feasible to utilize off-the-shelf insoles. The fabrication of these insoles may be accomplished through a variety of techniques. Typically, the insoles are constructed from prefabricated components that are joined through gluing and covered with padding. At this juncture, leather linings are frequently employed. Additionally, press forming and injection molding are frequently employed. In addition to the aforementioned methods, these techniques are also employed in the fabrication of bespoke insoles. It is also noteworthy that standard insoles are now available that have been adapted to meet the needs of individuals with deformities. In such instances, the insoles are constructed from multiple layers of foam materials, each with a distinct hardness. In cases of significant deformities, particularly those that pose a risk of ulceration, it is imperative to utilize insoles that are tailored to the specific needs of the patient. In such instances, a plethora of diagnostic, design, and manufacturing techniques are available for insoles. Both traditional and contemporary techniques are employed, including milling on computer numerical control (CNC) milling machines and three-dimensional (3D) printing.

The elements are constructed from cork or plastic foam of varying degrees of hardness. In large orthopedic companies, dies for individual elements

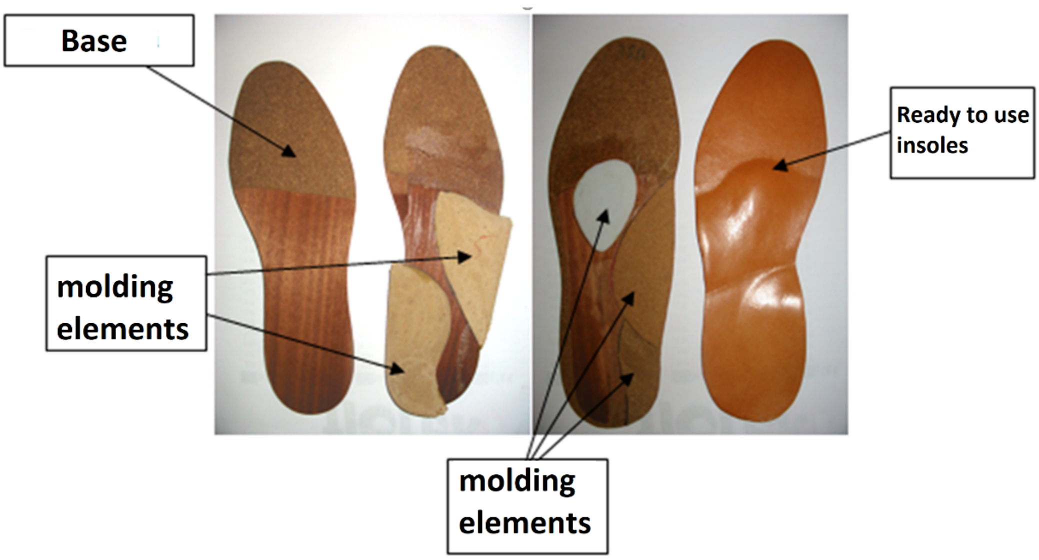

Fig. 6. Examples of insoles made using the traditional method (source: own research)

Fig. 7. Elements for the construction of individual insoles based on various prefabricated elements (source: own research)

are manufactured with the objective of facilitating and accelerating work processes. In the case of smaller offices, the elements are cut manually using templates that are appropriate for the task at hand. Presently, orthopedic companies provide pre-fabricated elements, either cast or handmade. For example, Flexor, a Spanish company, has proposed a comprehensive set for manufacturing insoles for adults, comprising bases and corrective components. The locations where the elements are to be affixed are delineated on the base (Figure 6).

Additionally, insoles can be manufactured using the thermoplastic method. This method employs the use of a thermoplastic resin as the base material, which is then molded to achieve the desired shape. In some instances, soft foam materials are adhered directly and molded as a single entity. Conversely, in other instances, the foam materials and/or various components are adhered subsequent to molding.

The thermoplastic method can be divided into two distinct forming methods. In the initial method, the base is constructed directly on the patient's or client's foot. In the subsequent method, an individual last is first created, and then the insole is formed on it.

All of these methods guarantee an optimal fit for the patient's foot. Additionally, various profiling elements may be employed. To illustrate, in the instance of direct molding of insoles on the foot via the Orthofeuille method, rigid elements are affixed within the mold in which the patient's foot is positioned, thereby shaping the base in an optimal manner. However, in the Sidas method, profiling is achieved by the appropriate shaping of the pneumatic cushions on which the patient's foot is placed.

In the case of indirect molding, a cast of the foot is initially created, upon which the last is subsequently formed. The

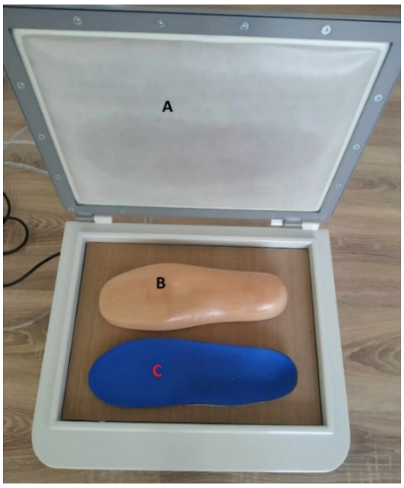

Fig. 8. System for making thermoplastic insoles. A- vacuum pump, B - last, C - ready insole. (source: own research)

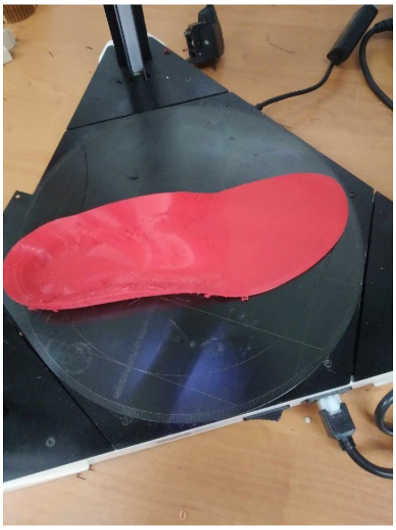

Fig. 9. Insole printed on a 3D printer (source: own research)

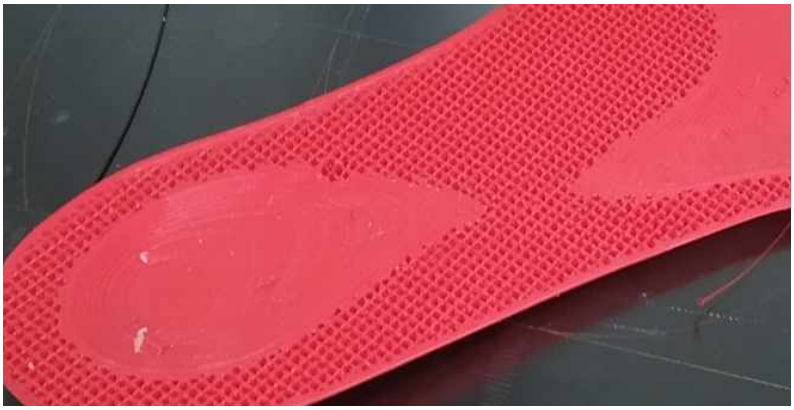

Fig. 10. Cross-section through an insole printed on a 3D printer. Visible internal openwork structure ensuring the softness of the insole. (source: own research)

Fig. 11. An insole individually adapted to a patient with a foot at risk of ulcer formation, made by gluing several layers of foam material together. A hole is provided in the area of high pressure (source: own research)

formation of the insole base is achieved through the use of a vacuum pump (Figure 8). In this instance, profiling elements are incorporated through the modification of the last and/or the addition of supplementary elements to the insole. It is noteworthy that this method is the preferred approach for the fabrication of insoles for severely deformed feet, such as those exhibiting Charcot-Pondé deformity. In the thermoplastic method, regardless of the principle according to which the insoles are manufactured, numerous layers of foam materials can be utilized, contingent on the necessities of the patient and the availability of space within the shoe, thus reducing pressure.

An alternative methodology is the fabrication of insoles through milling. This method employs the use of foam blocks, which are shaped into insoles through the use of a computer numerical control (CNC) milling machine. The effect of varying degrees of hardness in specific locations is achieved by selecting blocks comprising individual layers of varying hardness.

An alternative methodology for the fabrication of insoles is the utilisation of 3D printing technology (Figure 9). In this instance, the desired level of hardness is achieved by varying the amount of material used to fill the object (Figure 10).

In the case of ulcerated areas, thick, multi-layer insoles are the most common choice of footwear. These insoles feature depressions or holes in strategic locations where high pressure and the risk of ulceration are present. The objective of these modifications is to prevent direct contact between the foot and the ground in these vulnerable areas. It is imperative that the edges of the hole be crafted in a manner that does not create a sharp edge, as this is a necessary condition for the insole to be safe and effective. Figure 11 illustrates an example of an individually crafted insole, constructed using a combination of diverse materials.

It is important to note that in the case of individuals with diabetes, it is essential to ascertain whether the insole in question is capable of fulfilling its intended functions. Despite the most rigorous skills and knowledge, it is possible that the developed insole may prove ineffective and may even result in an overload of the foot in a specific area. In the case of insoles designed to provide complete relief (such as those shown in the photograph), research into the distribution of pressure on the plantar surface of the foot enabled us to ascertain the requisite thickness of the insoles.

To achieve complete relief for the feet in a specific area, standard insoles are also employed, which can be tailored to individual requirements by removing a section of the insole from the affected area.

It is important to note that while different methods have their respective advantages and disadvantages, the primary determining factor in the quality of the insole is the competence of the designer and contractor. Furthermore, the availability of diagnostic methods represents a significant factor, which is a topic warranting further discussion.

The insole is an integral component of footwear, and both the insole and the shoe should be selected with the intention of ensuring optimal functionality when worn together. In selecting footwear, it is essential to consider the various stages of foot deformation and the extent of diabetic foot syndrome.

In the absence of deformities and/or symptoms of diabetic foot disease, it is generally recommended that individuals with diabetes can wear any type of footwear, provided that it is properly constructed. The footwear must be devoid of any areas that could potentially cause injury to the foot, whether minor or major. Additionally, the use of replaceable insoles is recommended to facilitate a more thorough examination of the interior of the footwear. The absence of foot deformities does not negate the necessity for patients to conduct periodic examinations of their feet. At this juncture, it is possible to utilize standard footwear, including sports footwear [18]. The utilization of running shoes for the prevention of plantar diabetic ulcers, as well as footwear designed specifically for individuals with diabetes, is recommended, provided that they are indistinguishable from conventional footwear (Figures 12, 13, 14). Nevertheless, it is essential to ascertain whether a specific shoe model is appropriate for a particular patient. It would be beneficial to gain insight from competent orthopedic store staff and/or medical professionals in order to determine the optimal approach.

Fig. 12. Preventive footwear, made in series (own research)

This approach may be regarded as controversial, given that a considerable number of specialists maintain that individuals with diabetes should be provided with footwear that is specifically designed for their condition. However, the authors' experience, supported by a review of the literature, confirms that the use of specialized footwear for people with diabetes in the absence of clinical necessity is futile. In the case of therapeutic footwear, the requisite condition for its efficacy is its utilization, or, in other words, its acceptance. Diabetes frequently impacts professionally active individuals, including women, who are highly attuned to their appearance and are unlikely to tolerate footwear that is aesthetically unappealing [19].

It is therefore recommended that a compromise be reached. This is particularly relevant given the authors' experience that it is not possible to compel patients to use footwear they do not like. Doing so would result in a loss of control over the footwear and the types of footwear being used.

In cases where individuals have deformities or alterations related to diabetic foot conditions, it is imperative to utilize specialized footwear. At this juncture, the utilization of bespoke footwear may be justified. Nevertheless, it is possible to utilize standard footwear with specialized properties, provided that it has been subjected to a professional inspection. These include, above all, greater width in the forefoot area, a higher toe, and attachment to the foot (laces, Velcro) enabling the footwear to be adjusted to the width of the foot and to the changing width of the foot during the day. The general requirements for such footwear are as follows:

– footwear that extends by approximately 1 cm beyond the length of the foot,
– a broad and elevated toe section,
– secure and comfortable seams and joins, avoiding areas that might cause discomfort on the feet,
– interior dimensions of the footwear that accommodate the thickness of the insole.

In considering the issue of insoles, it is important to acknowledge the impact of insole' thickness. It is important to note that the use of replaceable insoles is a necessary component of this process. Given that diabetes typically results in increased pressure on the feet, it is essential to utilize insoles with a greater thickness than those designed for individuals with less severe foot complications. In the case of sandals (Figure 18), this necessitates the utilization of a structure that ensures the insoles are enveloped by the upper around the entire circumference.

In the context of home footwear, there is greater potential for utilizing designs that align with the specific needs of individuals with diabetes. This includes the incorporation of textile materials in the upper construction and the incorporation of fastening methods that facilitate adaptation to the unique shape of the patient's foot. An exemplar of such footwear is the Dr. Orto line, as offered by Befado.

It is similarly advised that roller and rocker soles be employed in such footwear. These are rigid soles that permit foot movement due to an optimal cradle profile. This structure results in immobilization of the metatarsophalangeal joints while simultaneously reducing pressure on the metatarsophalangeal joint line [20, 21].

Fig. 13. Orthopedic footwear manufactured in series - intended for people with diabetic foot syndrome (source: own research)

Fig. 14. Orthopedic footwear manufactured in series - intended for people with diabetic foot syndrome (source: own research)

In essence, the distinction between roller and rocker soles hinges on the profile utilized. In the case of the roller shoe, the outsole exhibits a constant curvature. In contrast, the rocker shoe features a discontinuous contour of the outsole. Nevertheless, at the present time, this differentiation is not rigorously observed, and these designations are used interchangeably.

It should be noted that the aforementioned types of footwear are only suitable for use in the absence of ulcers on the foot. In the event of foot wounds, more radical treatments are required, including hospitalization and immobilization of patients. However, footwear models have been developed that can be utilized in instances of wound or ulceration. These are shoes that utilize a vacuum to conform the footwear's shape to the foot while simultaneously alleviating ulcerated regions. A number of producers and distributors of this type of footwear are currently in operation, including MedReha and Oped Medical.

A particular category of footwear designed for individuals with diabetic foot ulcers encompasses shoes that provide comprehensive relief for the rearfoot or forefoot. These shoes are typically utilized following surgical procedures, facilitating ambulation within the domestic environment. This enables patients to engage in activities such as using the toilet without risking further injury to the affected foot. It is evident that such footwear is unsuitable for outdoor use.

In conclusion, individuals with diabetes may require the following types of footwear:

– preventive footwear, manufactured in series, intended for individuals with diabetes who do not have diabetic foot syndrome and do not suffer from major foot deformities,
– orthopedic footwear produced in series is intended for individuals with diabetic foot syndrome (ischemic, neuropathic, or mixed) and/or foot deformities, characterized by distortion and pain in the feet with high pressure on the metatarsal bones,
– custom-made orthopedic footwear is intended for individuals with significant foot deformities (e.g., Charcot foot in the context of diabetes),
– post-operative and therapeutic footwear is designed for individuals who have undergone foot surgery and/or have foot ulcers.

It is also essential to consider the selection of appropriate materials for footwear, ensuring that they meet the necessary hygiene and rheological requirements.

2.1. Footwear materials – an important aspect of the construction of diabetic footwear

In addition to the design, the materials used in the construction of diabetic footwear are of significant importance. The materials utilized in the fabrication of insoles for diabetic foot conditions encompass a range of options, including leather and synthetic alternatives such as polyurethane, ethylene vinyl acetate (EVA), microcellular rubber (MCR), and cork [22]. The use of therapeutic footwear has been demonstrated to be an effective method for reducing the incidence of new ulcers and the rate of amputation in individuals with diabetes. A multitude of footwear options for individuals with diabetes have been subjected to rigorous analysis and assessment, encompassing comfort, cushioning, materials, arch support, coverage, style, and size variations [23]. Footwear for the diabetic foot should be constructed with a well-cushioned, roomy, and protective design. The shoe's midsole, composed of EVA foam, provides an optimal equilibrium between support and softness. The outer shell, composed of 100% leather, offers a soft yet protective barrier against external contamination. The use of Velcro fastenings facilitates the process of donning and doffing the footwear. In the event of swelling feet throughout the day, a snug fit may be required; thus, Velcro is a popular choice. Furthermore, it is crucial to select a wide and extended nose pad to safeguard the toes from impact, with ample space for mobility. A lack of space in the toes can result in poor circulation and the formation of wounds on the feet. The products are manufactured using natural materials, including leather and knitted or crocheted fabrics. These shoes offer optimal protection for individuals with diabetes, providing essential support and reducing perspiration. The shoes should be constructed with a hard exterior and soft interior. A robust sole will provide protection for the foot from sharp objects. The design should be fully enclosed, with a covered foot that is safeguarded from sand, splinters, pebbles, loose nails, and other debris that can be challenging to detect for individuals with impaired sensation in their feet. The interior should be seamless and the insole soft. The heel and arches should be relatively low [24-30].

It is difficult to indicate which feature/ parameter is the most important. Basically, the design of proper footwear for people with diabetes should be approached holistically. For example: the correct shape is an important feature, but if the gauge is not appropriate, there will be a conflict between the shoes and the foot. If we meet both requirements, it will be lost if we use stiff, unhygienic materials. A springy sole will compensate for uneven terrain, but it will be insufficient if we do not provide a comfortable insole directly under the foot, tailored to the patient's needs.

The creation of footwear for individuals with diabetes has been enhanced by the advent of sophisticated techniques, particularly for those afflicted with diabetic foot syndrome. The application of reverse engineering (RE) methodologies facilitated the conversion of point clouds corresponding to scanned shoe footprints and diabetic foot data into stereoscopic lithography (STL) grids. A slicing algorithm was developed and employed to identify pertinent features of the diabetic foot circumference and shoe hooves. An artificial neural network, designated as a self-organizing map (SOM), was employed to categorize 60 sets of hoof data into analogous clusters. The foot shapes of three patients with mild diabetes were entered into the self-organizing map (SOM) for analysis. An expert questionnaire analysis of the circumference characteristic data was conducted using an analytic hierarchy process (AHP), which yielded the circumference weights. Subsequently, Gray's relational analysis (GRA) was employed to ascertain the correlation between foot circumference and the corresponding hoof range. The most appropriate hoof for each patient with mild diabetic foot syndrome can be determined by calculating the relative fitness function for each patient. By correlating the diabetic foot with suitable hooves, an effective strategy for designing shoes for patients with mild diabetes was demonstrated, which can then be manufactured according to individual requirements [31].

2.1.1. *Antibacterial footwear materials*

Foot ulcers, which are highly prevalent among individuals with diabetes, are particularly susceptible to the development of infections. Cutaneous injuries, such as wounds and burns, frequently become more severe as a result of colonization by *P. aeruginosa*, leading to infection. *P. aeruginosa* is responsible for over 50% of severe burn infections and is the second most commonly isolated organism from chronic wounds, including diabetic ulcers, pressure ulcers, and burn wounds [32]. In this context, the prevention of microbial colonization of the foot and wound site will facilitate faster healing and contribute to the prevention of infection. The addition of further functions (antibacterial, antifungal, or self-cleaning) to footwear materials is described in numerous reports in the literature. Such material properties have been demonstrated to prevent infections in diabetic lower extremities and facilitate the healing of preexisting wounds. Examples of such substances include:

1) antibacterial, antifungal, and antiviral effects:
- nanoparticles of silver, titanium, tin, gold, copper [33],
- nanofillers (silver, zinc, selenium, gold, oxides of copper, zinc and titanium, hexagonal boron nitride, graphene, graphene oxide, reduced graphene oxide, carbon nanotubes) in a variety of polymeric materials [34],
- nanoparticles of titanium dioxide (TiO_2) modified with noble metals, such as silver [35],
- natural active compounds including curcumin, plant extracts, essential oils, natural dyes, cyclodextrin and its derivatives [36],
- N-halamins [37],
- active polymers based on biguanides [38],
- compounds containing silicon and nitrogen [39].

2) self-cleaning effects:
- nanoparticles of titanium dioxide [40],
- nanoparticles of silicon dioxide (SiO_2) [41],
- polydimethylsiloxane (PDMS) and methods of combining it with titanium dioxide and silicon dioxide [42-43].

A research and development project is underway that is yielding antimicrobial properties in materials. These properties are obtained through a variety of methods. In the footwear industry antimicrobial coatings are deposited on leather used for insoles by direct current magnetron sputtering. An antimicrobial coating was developed for application to the surface of leather insoles via physical vapor deposition. The coating contained silver nanoparticles (NP) [44]. The application of silver nanoparticles to porcine leather resulted in a reduction in softness but also conferred beneficial antibacterial properties, which may prove effective in preventing bacterial foot infections. The use of leather coated with silver nanoparticles as a material to prevent foot infections and to provide added value for shoe manufacturing is a viable proposition [45].

It is frequently the case that antimicrobial substances, otherwise known as biocides, possess characteristics that preclude their direct application to materials. Such substances are, for example, sensitive to temperature, light, or moisture. Methods are being sought to prolong the action of the active substances, facilitate controlled release, and protect the sensitive substance from external factors. One such method is microencapsulation, in which the active ingredient is encased in a polymeric envelope [46]. The primary objectives of microencapsulation are as follows:

- protection of the active compound from environmental factors (light, temperature, moisture, unsuitable pH, etc.) that can affect the stability and efficacy of the active substance,
- controlled release of the active substance at a defined pH and temperature to ensure optimal activity at the intended site,
- the use of a polymeric matrix which facilitates the handling of the active substance, as the protective properties of the matrix mitigate any potential adverse effects associated with the substance,
- reduce or eliminate any unpleasant taste or odour of the active compound or any of the core materials,
- reduce the volatility of the active ingredient [47, 48, 49, 50].

The synthesis of microcapsules comprising the active ingredient (chlorhexidine digluconate) and their subsequent incorporation into the lining of diabetic footwear resulted in a sustained drug release, as evidenced by in vitro testing. This solution, comprising diabetic footwear with microcapsules, will serve as an adjuvant therapy to oral therapy, releasing the drug in the application area over an extended period of time [51]. Furthermore, diabetic footwear can be coated with materials that possess combined antibacterial and self-cleaning properties [52]. The combination of these properties may prove advantageous in preventing infection by inhibiting microbial growth and preventing wound contamination.

Furthermore, a methodology was established for the application of natural biocides to leather utilized in the production of footwear, including chitosan derived from raw shrimp shells. The leather surface was treated with a chitosan solution using a polyvinyl alcohol binder, which facilitated the formation of a thin, transparent film on the leather surface. Chitosan demonstrated robust antimicrobial efficacy against all the microbial strains tested, including *E. coli*, *S. aureus*, *B. subtilis*, *P. aeruginosa*, and *A. niger* [53]. Another natural biocide employed in the treatment of footwear materials is essential oils, including cinnamon [54, 55, 57, 59, 60], thyme [56, 57], clove [57], oregano [57], lavender [57, 58], and mint [58]. The microencapsulation of essential oils is a common practice, as it serves to prolong the effect of the oils by reducing their volatility.

A review of the literature reveals numerous solutions with additional antimicrobial properties; however, there is a paucity of studies examining the impact of such materials on the diabetic foot. The advancement of footwear innovations, encompassing all aspects (design, materials), is crucial for the protection of diabetic feet, the enhancement of user comfort, and the attainment of beneficial outcomes (e.g., enhanced blood circulation, cell regeneration) in affected foot regions.

3. Influence of electromagnetic fields and ultrasound on wound healing

An additional therapeutic option for patients with diabetic foot syndrome is the utilization of electromagnetic fields and ultrasound to stimulate cellular proliferation and tissue regeneration, thereby accelerating wound healing.

In addition to its established use in imaging, early studies demonstrated the efficacy of low-intensity ultrasound (LIU) in promoting bone mineralization in vitro through the production and secretion of prostaglandin E2 and its activation of EP2 and EP4 receptors [61]. Subsequent reports demonstrated that low-intensity ultrasound (LIU) and low-intensity pulsed ultrasound (LIPUS) can facilitate wound healing, enhance sciatic nerve axonal regeneration and myelination, and restore significant function after surgery in animals. This is achieved by improving nerve conduction and brain-derived neurotrophic factor (BDNF) release, at least temporarily [62-64]. The use of LIU/LIPUS provided relief to patients with carpal tunnel syndrome in several clinical trials [65].

Low-intensity pulsed ultrasound (LIPUS) was employed to reduce the time required for fracture healing and to prevent non-union by exerting micromechanical pressure on the bone, thereby stimulating bone healing [66]. This approach has been particularly beneficial for individuals with diabetes, who often experience delayed fracture healing, vasculopathy, and neuropathy [67, 68]. There have been numerous studies published on the impact of ultrasound (utilising different parameters) on wound healing in human diabetic foot ulcers [69]. The application of electromagnetic fields has also been demonstrated to have beneficial effects in the treatment of diabetic wounds, including ulcers [70, 71]. Pulsed electromagnetic fields and pulsed ultrasound were demonstrated to stimulate tissue healing, growth, and regeneration [72] in diabetic foot ulcers and wounds. The combined action of electromagnetic fields and ultrasound was employed in the treatment of osteoarthritis of the knee [73], and also demonstrated efficacy in the treatment of diabetic foot problems.

4. Summary

Diabetes is a disease of civilization, and the complications associated with it are a significant threat to health and life. One of the complications associated with diabetes is diabetic foot syndrome. This condition affects 12 to 25% of individuals with diabetes, and in severe cases, it can result in the amputation of the foot. The selection of appropriate footwear is an important factor in the prevention of foot lesions. Individuals with diabetes may require footwear from one of the following categories, depending on the stage of the disease and the presence of complications:

- prophylactic, mass-produced footwear – designed for individuals with diabetes who do not have diabetic foot syndrome and do not suffer from severe foot deformities,
- orthopedic footwear, mass-produced – intended for individuals with diabetic

foot syndrome (diabetic ischemic foot syndrome, diabetic neuropathic foot syndrome, mixed form of diabetic foot) and/or with foot deformities, characterized by deformities and foot pain with severe pressure on the heads of the metatarsal bones,
- bespoke orthopedic footwear – designed for individuals with severe foot deformities, including those with Charcot foot, a condition that affects the bones of the foot in individuals with diabetes,
- post-operative and therapeutic footwear – designed for individuals who have undergone foot surgery and/or who are experiencing foot ulcers.

Footwear for patients with diabetic foot should possess the following characteristics:
- materials: soft, high-quality, and meeting hygienic parameters,
- shape: appropriate for the patient's anatomy, taking into account any deformities,
- minimum number of stitches,
- a footwear gauge higher than standard footwear,
- springy sole,
- antibacterial properties,
- ergonomic insole.

Despite the abundance of biomechanical research on the design of insoles to reduce sole pressure, there are significant discrepancies in the type of material used, as well as in the shape, design, and properties of insoles and footwear. While the impact of insoles on sole pressure has been substantiated in numerous studies, there is still a dearth of evidence regarding the selection of optimal insole materials for alleviating sole pressure and modifying abnormal gait patterns [74]. The manufacturing process remains largely dependent on repeated trial and error, based on practitioner experience and material availability, rather than on the condition of the patient's feet and the effectiveness of pressure relief.

The combined action of electromagnetic fields and ultrasound has been demonstrated to be an effective treatment for diabetic foot problems.

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Declaration of Conflicting Interests

The authors declare there is no conflict of interest.

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