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RESEARCH OF MATERIALS AND DESIGN OF ORTHOPEDIC INSOLE

Abstract. The article is done to study the influence of orthopedic products based on composite materials on the comfort of shoes for diabetic patients. The purpose of the work is to identify certain preventive and therapeutic effects of orthopedic products for people with diabetes. The study focuses on various composite materials, predominantly silicone-based, the feet of diabetic patients, and the design of orthopedic products. To develop specialized insoles were utilized data derived from anthropometric investigations conducted on the feet of diabetic patients. Statistical parameters characterizing the feet were meticulously determined and subsequently employed in the design of insoles tailored for diabetic footwear. A comprehensive methodology was employed in the development of these specialized insoles, integrating a mathematical model and a computer program to simulate the insole, alongside an image analysis program that facilitated the extraction of anthropometric data. The resulting design of the insole for comfortable diabetic shoes encompasses three distinct layers: an upper layer, a lower layer, and an intermediate layer. The use of orthopedic insoles made of silicone composites allowed to reduce the pressure on the painful areas of the foot. The outcome of this study is the development of orthopedic products that not only contribute to the treatment and rehabilitation of diabetic patients but also enhance their overall quality of life. Furthermore, this research underscores the potential to elevate the level of social security for these individuals. As such, the significance of this study lies in its ability to address a pressing healthcare issue, ultimately improving the well-being of diabetic patients.

Keywords: footwear, diabetes, orthopedics, insole, insoles composite.

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Introduction. The review and analysis of information on the current situation in the field of diabetes mellitus confirm the need to activate work on the creation of comfortable shoes and materials. According to well-known doctors, it is crucial to ensure normal living conditions for patients with diabetes, diabetic foot syndrome (DFS) is given to comfortable diabetic shoes [1,2].

DFS is a complex pathological condition that manifests in individuals with diabetes mellitus. According to the World Health Organization's definition, DFS is characterized by the destruction of deep foot tissues accompanied by neurological and circulatory abnormalities in the lower extremities [3]. One of the primary contributors to foot damage in diabetic patients is ill-fitting footwear, as conventional shoes often lack the necessary structural adaptations and orthopedic features essential for promoting the normal functioning of diabetic feet [4,5].

The regions of the foot that endure the highest levels of pressure during walking and standing are particularly susceptible to damage, leading to structural changes and discomfort. Consequently, individuals with DFS often employ various orthopedic products, including insoles, to alleviate the stress on affected areas.

Insoles represent a critical component of footwear, influencing factors such as support, comfort, thermal insulation, hygiene, and the prevention of foot deformities and localized overloads. The integration of orthopedic orthoses has demonstrated its potential in preventing pathological changes associated with DFS [6-8].

Recent research efforts have introduced innovative polymeric biocomposite materials founded on regenerated cellulose. These materials exhibit promising bioactive properties and find applications in the shoe industry, particularly in the context of DFS management [9]. These advancements open new avenues for the treatment and prevention of DFS, highlighting the significance of ongoing research in the field of orthopedic materials and their potential to enhance the comfort and well-being of individuals living with diabetes.

The result [10,11] of the optimization method is a special insole design with continuously variable stiffness/shape within its area, which ensures smooth pressure distribution for patient comfort. The results showed a 40% reduction in maximum pressure on the foot.

The article [12, 13] reviews the findings presented in two key references, which investigate the impact of material hardness and support height in orthopedic insoles on ankle joint load. The central contention put forth by these studies is that material hardness does not appear to exert a significant influence on ankle joint load, in contrast to the pivotal role played by the height of insole support.

The paper [14] presents polymer composite for optimizing a new composition that can change the temperature of orthopedic insoles. In the following study [15] a mathematical model was created for the distribution of pressure in the sole which in turn contributed to obtaining normalized experimental results and the corresponding height values were calculated for the zones of the insole.

This article delves into the critical aspect of footwear quality, with a specific focus on comfort as a pivotal determinant. The comfort of footwear hinges upon the precise alignment between the foot's shape and size and the internal spatial dimensions of the shoe. The parameters governing the internal configuration of footwear are primarily contingent upon the shape and size of the last used in the manufacturing process. For diabetic footwear, it is imperative to employ lasts of medium, wide, and extra-wide fullness, allowing for additional space to accommodate footbeds and orthopedic elements.

The insole configuration comprises three distinct layers: the upper layer, crafted from lining leather treated with fungicides, the lower layer composed of cardboard, and the intermediate layer incorporating shock-absorbing composite material.

Conditions and methods of research. The research centered on the investigation of various composite materials derived from silicone, the feet of individuals diagnosed with diabetes, and the designs of removable orthopedic products.

To assess the mechanical properties of the composite materials based on silicone, two key instruments were employed:

- universal Testing Machine H25KT Tinius Olsen: This apparatus facilitated the evaluation of the mechanical behavior and tensile strength of the silicone-based composites. The tests were conducted under standard room temperature conditions following the guidelines outlined in the international standard ISO 20344.

- hardness Tester Shore Durometers HPSA-M: The hardness tester was instrumental in determining the hardness characteristics of silicone-based materials.

Anthropometric parameters of the feet were obtained using a specialized photoplantogram.

The photoplantogram (Fig. 1) consists of a set of mirrors, a camera, and lighting fixtures. It allows for determining and fixing the image of the plantar surface of the foot, for this reason, the foot of the subject is placed on a perforated support platform. Image clarity is achieved as a result of uniform illumination of the entire surface of the support and aperture of the camera lens.

Figure 1. Photoplantogram

The photoplantogram is a valuable tool utilized in this study to facilitate a comprehensive geometric analysis of the target object, enabling precise determination of its spatial positioning, shape, and dimensions. In this particular context, the photoplantogram is employed to capture and quantify the geometric characteristics of the plantar region of the feet in patients afflicted with Diabetic Foot Syndrome (DFS).

The subject is positioned with their right foot resting on a transparent perforated support platform, specially designed for this purpose.

Illumination is strategically arranged from three distinct sides, and an intricate system of mirrors, ingeniously situated beneath the support platform, is employed to capture the image of the plantar surface of the foot.

After printing the pictures from the photoplantogram, the longitude and latitude dimensions are taken in the characteristic areas of the foot (Fig.2).

In the pursuit of creating footbed tailored for diabetic patients, a foundation of anthropometric studies was established to inform the design and customization of these essential orthopedic components, including heel pads, toe pads, and insoles.

Parameters encompassed the following key dimensions of the feet: foot length, foot width along both the outer and inner arch, and the width of the heel.

This comprehensive dataset of anthropometric measurements, meticulously acquired through systematic research, has played a pivotal role in shaping the design and construction of the footbed.

Research results and discussion. A mathematical model and a computer program for insole modeling have been developed. Anchor points for the model are determined (Fig. 3).

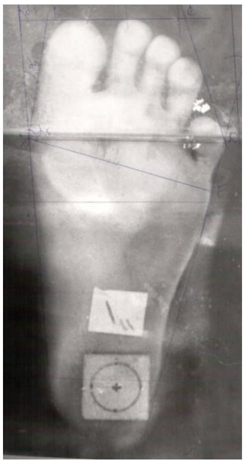

Figure 2. Photoplantogram

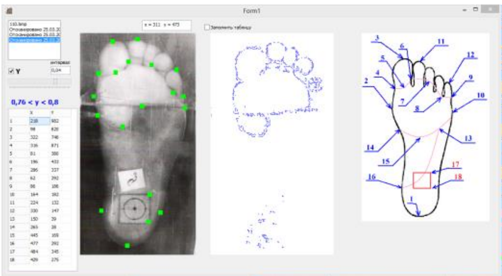

Figure 3. Program tabulagram

In this study, a specialized program has been meticulously developed for the purpose of analyzing photographs and extracting crucial anthropometric data, as depicted in Figure 3. This program serves as a valuable tool in streamlining the process of selecting anchor points necessary for the construction of a mathematical model. The selected anchor points are efficiently recorded in a structured table, and the entire dataset is systematically saved in a separate file for further analysis and reference. To enhance the versatility and functionality of the program, it incorporates an integrated brightness image analyzer, enabling the selection of user-defined sections of the spectrum in the YCbCr format. This feature provides valuable insights into areas of heightened pressure and zones with minimal load on the foot, offering an in-depth understanding of foot mechanics.

Moreover, in the determination of the shape of the massage arches, an interpolation polynomial has been effectively employed. The general arc is divided into two separate points. The following designations are introduced: points A and B are the centers of circles; points C, D, and E - are the edges of the massage arches; R1 and R2 are the radius of the circles (Figs.4 and 5).

In the context of this study, a pivotal aspect of the research involves the precise determination of the parameters, centers, and radii of arcs, as illustrated in Figure 6. This endeavor hinges upon knowledge of the coordinates of the three distinct points that define each arc.

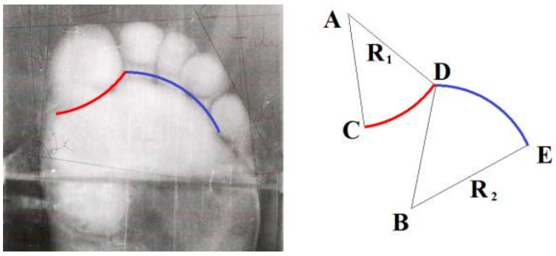

Figure 4. Forms of massage arches

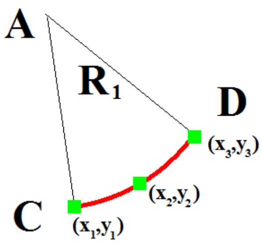

Figure 5. Arc point coordinates

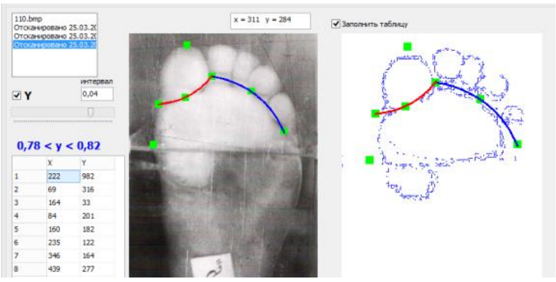

Figure 6. Massage arches

For methodological clarity and rigor, the system of equations underpinning this process is solved separately for each individual arc.

$$\begin{cases}(x_1-x)^2+(y_1-y)^2=R^2\\(x_2-x)^2+(y_2-y)^2=R^2\\(x_3-x)^2+(y_3-y)^2=R^2\end{cases} \tag{1}$$

In the Maple computer algebra environment, we obtain the following coordinates of the center of the circle:

$$x=\frac{1}{2}\frac{\left(x_1^2(y_2-y_3)+x_2^2(-y_1+y_3)+x_3^2(y_1-y_2)+y_1^2(y_2-y_3)+y_2^2(y_3-y_1)+y_3^2(y_1-y_2)\right)}{\left(x_1(y_2-y_3)+x_2(y_3-y_1)+x_3(y_1-y_2)\right)}, \tag{2}$$

$$y=-\frac{1}{2}\frac{\left(x_1^2(x_2-x_3)+x_2^2(-x_1+x_3)+x_3^2(x_1-x_2)+y_1^2(x_2-x_3)+y_2^2(x_3-x_1)+y_3^2(x_1-x_2)\right)}{\left(x_1(y_2-y_3)+x_2(y_3-y_1)+x_3(y_1-y_2)\right)}.$$

For the calculation, triples of numbers (4,5,6) and (6,7,8) were used. To find the radius, it is enough to find the distance from any of the three points to the center of the circle.

$$R = \sqrt{(x_1 - x)^2 + (y_1 - y)^2} \quad (3)$$

The design and composition of the intermediate layer of removable insoles, crafted from composite materials, are tailored to address the specific nature of the foot ailment in consideration. These insoles can be configured to include the intermediate layer under the heel, metatarsophalangeal region, or even extend across the entire plantar surface of the foot, as exemplified in Figure 7.

The intermediate layer, a pivotal component of the developed insole, is fabricated from silicone composites augmented with varying proportions of microcrystalline cellulose (MCC) to enhance its physical and mechanical properties. The incorporation of MCC offers a distinctive advantage, enabling the customization of mechanical attributes, hardness, and deformation characteristics, catering to the specific requirements dictated by the patient's foot ailment and body weight. This approach significantly augments the comfort and suitability of the footwear.

The fabrication of these orthopedic insoles employs a hot molding process conducted within a thermostat at a controlled temperature of 70°C for a duration of 15 minutes. This technique is instrumental in producing orthopedic elements tailored for a wide array of clinical needs, utilizing pre-designed molds. These molds have been meticulously developed, taking into account the results of anthropometric studies, to ensure a precise fit and optimal functionality in the management of diverse foot conditions.

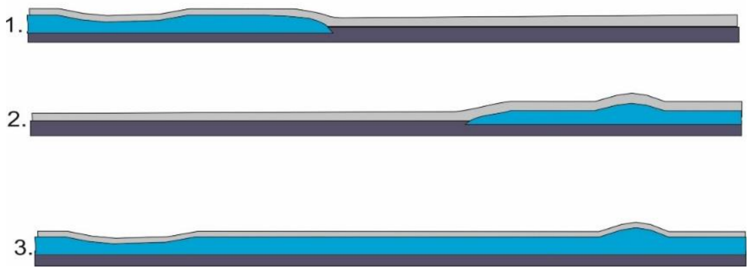

Figure 7. Orthopedic insoles designs

In the development of orthopedic insoles, three distinct designs have been devised to address specific aspects of foot comfort and health. In the first design, referred to as insole #1, a strategically positioned recess in the heel region is featured. In the second design, denoted as insole #2, a supportive roller is incorporated in the area of the phalanx of the toes. The third design, insole #3, combines both a roller in the phalanx area and a recess in the heel region. The roller component is engineered to provide cushioning and massage benefits for the toes, while the heel recess is designed to alleviate the load on the heel region of the foot.

Conclusion. The findings from the experimental implementation of shoes equipped with the proposed insole design over a one-month period, particularly among patients exhibiting statistical insufficiency of the feet, have demonstrated a notable preventive and therapeutic impact. This effect is characterized by the alleviation of painful sensations that were previously prevalent across the entire plantar surface of the feet.

The integration of this specific insole design holds significant promise for enhancing the overall comfort and hygiene of footwear designed for diabetic patients. It is evident that this innovation can offer substantial relief and potentially mitigate foot-related discomfort among this patient group.

The results of this study contribute to the ongoing efforts to address the unique needs of diabetic patients by providing orthopedic solutions that promote both comfort and health, thus advancing the quality of life for individuals dealing with diabetes and associated foot conditions.

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ОРТОПЕДИЯЛЫҚ ҰЛТАРАҚТЫҢ МАТЕРИАЛДАРЫ МЕН КОНСТРУКЦИЯСЫН ЗЕРТТЕУ

Аңдатпа. Мақала композитті материалдар негізіндегі ортопедиялық бұйымдардың диабетпен ауыратын науқастарға арналған аяқ киімнің жайлылығына әсерін зерттеуге арналған. Жұмыстың мақсаты қант диабетімен ауыратын адамдарға ортопедиялық бұйымдардың белгілі бір профилактикалық және емдік әсерін анықтау болып табылады. Зерттеу әртүрлі композициялық материалдарға, негізінен силиконға, диабеттік табандарға және ортопедиялық бұйым конструкциясына негізделген. Арнайы ұлтарақтарды әзірлеу үшін қант диабетімен ауыратын науқастардың табандарына жүргізілген антропометриялық зерттеулерден алынған деректер қолданылды. Табандарды сипаттайтын статистикалық параметрлер мұқият анықталып, кейіннен диабеттік аяқ киімге арналған ұлтарақтарды әзірлеуде қолданылды. Бұл мамандандырылған ұлтарақтарды әзірлеуде математикалық модельді және табанды модельдеу үшін компьютерлік бағдарламаны біріктіретін кешенді әдістеме, сондай-ақ антропометриялық деректерді алуды жеңілдететін кескінді талдау бағдарламасы қолданылды. Нәтижесінде, ыңғайлы диабеттік аяқ киімге арналған табан конструкциясы үш бөлек қабаттан тұрады: үстіңгі қабат, төменгі қабат және аралық қабат. Силиконды композиттерден жасалған ортопедиялық ұлтарақтарды қолдану аяқтың ауыратын жерлеріне қысымды азайтуға мүмкіндік берді. Бұл зерттеудің нәтижесі қант диабетімен ауыратын науқастарды емдеу мен оңалтуға ғана емес, сонымен қатар олардың жалпы өмір сүру сапасын жақсартуға ықпал ететін ортопедиялық бұйымдарды жасау болып табылады. Сонымен қатар, бұл зерттеу осы адамдарды әлеуметтік қамсыздандыруды жақсарту әлеуетін көрсетеді. Сондықтан бұл зерттеудің маңыздылығы денсаулықтың өзекті мәселесін шешу қабілетінде, сайып келгенде, қант диабетімен ауыратын науқастардың әл-ауқатын жақсартуда.

Тірек сөздер: аяқ киім, қант диабеті, ортопедия, ұлтарақ, композитті ұлтарақ.

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ИССЛЕДОВАНИЕ МАТЕРИАЛОВ И КОНСТРУКЦИИ ОРТОПЕДИЧЕСКОЙ СТЕЛЬКИ

Аннотация. Статья посвящена исследованию влияния ортопедических изделии на основе композитных материалов на комфортность обуви больных сахарным диабетом. Цель работы выявление определенных профилактических и лечебных эффектов ортопедических изделий для людей с сахарным диабетом. В исследовании основное внимание уделяется различным композиционным материалам, преимущественно на основе силикона, стопам больных сахарным диабетом и конструкции ортопедических изделий. Для разработки специализированных стелек были использованы данные, полученные в результате антропометрических исследований, проведенных на стопах пациентов с диабетом. Статистические параметры, характеризующие стопы, были тщательно определены и впоследствии использованы при разработке стелек, предназначенных для диабетической обуви. При разработке этих специализированных стелек была использована комплексная методология, объединяющая математическую модель и компьютерную программу для моделирования стельки, а также программу анализа изображений, которая облегчила извлечение антропометрических данных. В результате конструкция стельки для удобной диабетической обуви включает три отдельных слоя: верхний слой, нижний слой и промежуточный слой. Применение ортопедических вкладышей, изготовленных из силиконовых композитов позволил снизить давление на болезненные участки стопы. Результатом этого исследования является разработка ортопедических изделий, которые не только способствуют лечению и реабилитации пациентов с диабетом, но и улучшают общее качество их жизни. Кроме того, это исследование подчеркивает потенциал повышения уровня социального обеспечения этих людей. Таким образом, значимость этого исследования заключается в его способности решить насущную проблему здравоохранения, в конечном итоге улучшая самочувствие пациентов с диабетом.

Ключевые слова: обувь, диабет, ортопедия, стелька, стельки композитные.