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EXPERIMENTAL STUDY ON THE EFFECTS OF BASKETBALL ON PLANTAR PRESSURE DISTRIBUTION OF JUVENILES

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EXPERIMENTAL STUDY ON THE EFFECTS OF BASKETBALL ON PLANTAR PRESSURE DISTRIBUTION OF JUVENILES

ABSTRACT. With professional basketball games sweeping around the world, basketball is becoming more and more popular among juveniles. Therefore, it is of great significance to study the biomechanical effects of basketball on foot pressure and evaluate the impacts of basketball on the foot health development of juveniles in a scientific and objective manner. In this paper, by setting up an experimental group and a control group and using the RS-footscan force-measuring system, we attempt to test and analyze the planta support period, peak plantar pressure intensity, plantar impulse and foot axis angle of juveniles. The experimental results show that long-term basketball sports has a positive effect on the foot health development of juveniles. This study is very helpful to promoting basketball sports and preventing basketball injuries.

KEY WORDS: basketball, experimental verification, experimental group, control group, plantar pressure.

STUDIU EXPERIMENTAL PRIVIND INFLUENŢA PRACTICĂRII BASCHETULUI ASUPRA DISTRIBUŢIEI PRESIUNII PLANTARE LA TINERI

REZUMAT. Având în vedere amploarea jocurilor profesioniste de baschet la nivel mondial, baschetul devine din ce în ce mai popular printre tineri. Prin urmare, este foarte important să se studieze efectele biomecanice ale practicării baschetului asupra presiunii piciorului şi să se evalueze impactul acestuia asupra dezvoltării sănătăţii piciorului la tineri într-o manieră ştiinţifică şi obiectivă. În această lucrare, prin înfiinţarea unui grup experimental şi a unui grup martor şi prin utilizarea sistemului de măsurare a forţei RS-footscan, sunt testate şi analizate perioada de susţinere a boltei plantare, intensitatea presiunii plantare maxime, impulsul plantar şi unghiul axei piciorului la tineri. Rezultatele experimentale arată că practicarea baschetului pe termen lung are un efect pozitiv asupra dezvoltării sănătăţii piciorului la tineri. Acest studiu este foarte util pentru promovarea baschetului şi prevenirea rănilor apărute în timpul practicării acestui sport.

CUVINTE CHEIE: baschet, verificare experimentală, grup experimental, grup martor, presiune plantară.

ETUDE EXPÉRIMENTALE SUR LES EFFETS DU BASKET-BALL SUR LA DISTRIBUTION DE LA PRESSION PLANTAIRE CHEZ LES JEUNES

RÉSUMÉ. Compte tenu de l'importance des jeux de basket-ball professionnels dans le monde, le basket-ball est de plus en plus populaire auprès des jeunes. Il est donc très important d'étudier les effets biomécaniques du basket-ball sur la pression du pied et d'évaluer son impact sur le développement de la santé des pieds chez les jeunes d'une manière scientifique et objective. Dans cet article, par la création d'un groupe expérimental et d'un groupe de contrôle et à l'aide du système de mesure de la force RS-footscan, la période d'entretien de l'installation, l'intensité du maximum de pression plantaire, l'impulsion plantaire et l'angle de l'axe du pied sont testés et analysés chez les jeunes. Les résultats expérimentaux montrent que la pratique du basket-ball à long terme a un effet positif sur le développement de la santé des pieds chez les jeunes. Cette étude est très utile pour promouvoir le basketball et prévenir les blessures survenant lors de la pratique de ce sport.

MOTS CLÉS: basketball, vérification expérimentale, groupe expérimental, groupe de contrôle, pression plantaire.

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INTRODUCTION

Plantar pressure refers to the interaction force between the planta and the support surface. Plantar pressure distribution has something to do with contact area, moving posture, weight and other factors. In recent years, studies have been more intensive on foot pressure because it not only reflects foot functions, but also shows how body postures are controlled during different sports [1]. Currently, plantar pressure research has gone further into the footwear industry, medical orthotics, medical rehabilitation, sports biomechanics and other fields. Analyzing competitive sports based on plantar pressure is also a hot subject at present.

As an increasingly popular sport among juveniles, basketball has a lot of requirements for the human foot. Many basketball movements rely on feet, such as sudden stop, turn, side sliding and jump shot. Foot movements are the basis for completing a series of basketball movements [2]. Studying the dynamic features of foot movements in basketball games and understanding features like plantar impulse and plantar pressure can, on one hand, help protect feet and prolong their sport life span, and on the other hand, effectively verify the positive role that basketball is playing in promoting the foot health development of juveniles [3].

In this paper, through experimental study, we test the plantar pressure distribution of basketball players and ordinary juveniles using the RS-footscan force-measuring system. By setting up an experimental group and a control group, we measure, compare and analyze the planta support period, peak plantar pressure intensity, plantar impulse and foot axis angle. The experimental results indicate that playing basketball on a long-term basis can help juveniles build up physical endurance of their feet and improve their forefoot strength and foot stability.

METHODS

Physiological Mechanical Analysis of Foot

The foot is a complex structure of 26 bones, 33 joints, 126 ligaments, muscles and nerves arranged in a network-like form [4]. Its basic functions are to support the weight of the human body, act as a buffer to absorb impacts, propel the leg forward and help maintain balance. In addition to absorbing the ground reaction forces and supporting the body weight, as an "all-round" bone union, another important function of foot is to transform the force of the muscular tissues from the thigh to the shank to effective displacement to complete a variety of movements [5].

Basketball can be classified into ball-holding and non-ball-holding sports. In basketball games, the foot acts as a buffer to adjust the impacts of gravity center shifts on the body and provides power and buffer forces when a player makes a turn, stop, jump or other movement. Through long-term foot exercise, theoretically speaking, basketball players should have better physiological quality than ordinary people.

Descriptions of Foot Pressure Test Regions

There are a total of 10 test regions in the planta, namely T1, T2-T5, M1~M5, MF and HM. T1 refers to the hallux, T2~T5 refer to the 2nd~5th toes, and M1~M5 refer to the 1st~5th metatarsals. MF (Mid Foot) stands for the mid foot [6]; HM (Heel Medial) stands for medial side of the heel; and HL (Heel Lateral) stands for the lateral side of the heel, as shown in Figure 1.

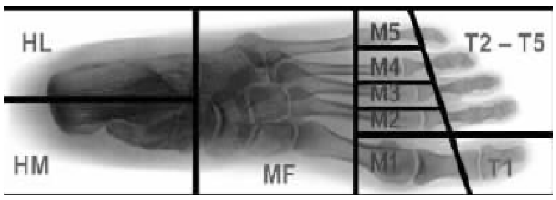

Figure 1. Foot pressure test area division map

In this paper, we test the following four groups of parameters of juvenile basketball players and ordinary juveniles: (1) initial contact phase, forefoot contact phase, foot flat phase and forefoot push off phase in a normal gait during the planta support period; (2) plantar pressure intensity, i.e. the pressure on the foot per unit of area (N/CM) [7]; (3) plantar impulse, i.e., the product of plantar pressure multiplied by action time (NS); (4) foot axis angle, i.e. the angle between the vertical axis of the foot and the walking direction (°).

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Plantar Pressure Distribution Test

Test Subjects

40 juvenile testees are involved in the foot pressure test, none of whom has any foot disease or injury. The testees are divided into an experimental group and a control group. The experimental group consists of 20 juvenile basketball players, all of whom are national Level 2 basketball players. The control group consists of 20 ordinary juveniles, none of whom has had any basketball training before. The basic information on the juveniles tested is listed in Table 1.

Table 1: The basic situation of the measured adolescents

Group	Gender	Weight (kg)	Age	Foot size	Sports level
Test group	Male	63.2±10.2	18.2±0.9	41±2.2	National second-level athlete
Control group	Male	62.2±8.6	19.2±0.96	41±2.5	None

Test Equipment

We adopt the RSscan footscan force-measuring system produced by a Belgian company [8] and use the Footscangaitscientific 7.97 software to store, analyze and extract the test data [9].

Test Requirements

1. In order to avoid the impacts of different shoe types and different individuals' fitness to shoe types on the test results, the juveniles are all barefoot during the test.

2. Considering the differences in the weights of the juveniles tested, in order to avoid the impacts of different weights on plantar pressure distribution, we carry out a pressure/weight standardization process to make sure the objectivity of the test data – recording the pressure value as a multiple of the weight.

RESULTS AND DISCUSSION

Test Results

Time Phase Distribution of the Planta Support Period

During a normal gait, when the right and left feet are contacting the ground, there are four time phases - initial contact phase, forefoot contact phase, foot flat phase and forefoot push off phase [10]. Table 2 shows the statistics of the foot-ground contact time percentage in each phase.

Table 2: Comparison of the proportion of each phase value between test group and control group in different periods

Phase	Left foot		Right foot	
	Test group	Control group	Test group	Control group
Landing stage	4.27±2.32	3.47±1.46	4.37±1.56	3.51±1.75
Forefoot contact	10.08±4.94	7.56±5.63	8.24±4.38	6.24±5.79
Full contact	38.04±7.62	40.52±10.72	32.38±8.92	40.72±11.18
Off the ground	53.61±6.03*	48.45±8.59	55.01±8.21Δ	49.53±9.37
Total	100	100	100	100

From the table, we can see that there is a significant difference between the times phases of the right and left feet in the push-off phase (*P<0.05, ΔP<0.05). Statistically speaking, the difference is very significant [11].

Figure 2 shows that the time phase distribution of the right and left feet contacting the ground during four time phases.

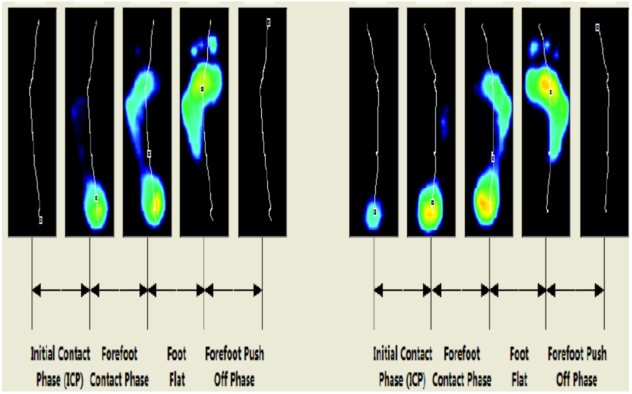

Figure 2. Time phase distribution of the foot support period

Peak Plantar Pressure

The foot can be divided into forefoot region, arch region and heel region. According to the regions shown in Figure 1, we compare the pressure values of the right and left feet [12]. The test results are shown in Table 3.

Table 3: Comparison of pressure peak/body weight between the test group and the control group (N/Kg)

Phase	Left foot		Right foot	
	Test group	Control group	Test group	Control group
T1	1.12±0.27	0.98±0.16	1.47±0.36	1.16±0.22
T2-5	0.23±0.14	0.19±0.08	0.25±0.12	0.21±0.11
M1	3.27±0.63	3.31±0.35	3.42±0.58	3.18±0.77*
M2	3.08±0.72	3.04±0.61	3.67±0.96*	3.08±0.23
M3	0.92±0.14	0.58±0.15	0.76±0.19	0.53±0.13
M4	3.11±0.58	2.79±0.41	3.14±0.47	2.85±0.36
M5	1.79±0.47	1.53±0.21	1.74±0.36	1.36±0.22
MF	2.96±0.43	3.04±0.36	2.77±0.34	2.91±0.28
HM	2.83±0.31	2.11±0.23	1.95±0.29	2.116±0.37
HL	0.61±0.17	0.74±0.11	0.55±0.13	0.63±0.25

From the table, we can see that the peak pressure in the forefoot region in the experimental group is greater than that in the control group, while the peak pressure in the arch and heel regions is smaller than that in the control group [13]. The maximum peak pressure in the experimental group appears in the M2 region while that in the control group appears in the M1 region [14], indicating that the foot power of juveniles trained in basketball sports is significantly greater than that of the control group. The two has a statistic difference (*P<0.05).

Peak Plantar Pressure Intensity

In the plantar pressure intensity test, the distribution of plantar pressure intensity is as follows: forefoot region>heel region>arch region. The test result shows that the overall pressure intensity of the experimental group is greater than that of the control group [15]. Details of test data are shown in Table 4.

Table 4: Pressure intensity peak distribution of the test group and the control group (N/cm^2)

Phase	Left foot		Right foot	
	Test group	Control group	Test group	Control group
T1	9.22±0.67	7.81±0.74	4.68±0.47	4.12±0.86
T2-5	1.23±0.16	1.12±0.28	2.85±0.17	1.91±0.14

M1	6.91±1.72	5.72±2.21	12.76±1.84	11.87±1.42*
M2	23.26±2.75Δ	19.89±1.86	20.21±2.44*	17.61±2.37
M3	10.65±2.47	8.02±1.96	18.97±2.03	15.54±1.89
M4	2.36±0.52	2.16±0.66	6.82±1.12	4.95±0.82
M5	2.18±0.37	1.81±0.24	1.86±0.41	1.74±0.36
MF	1.64±0.26	1.43±0.31	1.22±0.27	1.39±0.22
HM	6.88±1.16	6.04±0.96	7.53±0.83	6.74±0.56
HL	8.38±1.27	7.78±1.39	9.82±1.57	7.89±1.28

From the table, we can see that the maximum peak pressure intensity of the right and left feet appears in the M2 region (2nd metatarsal). Statistically speaking [16], there is a statistic difference between the experimental group and the control group (*P<0.05, ΔP<0.05).

Plantar Impulse

Similar to the distribution of plantar pressure intensity, the distribution of plantar impulse is also as follows: forefoot region>heel region>arch region. And the test result shows that the plantar impulse of the experimental group is smaller than that of the control group [17]. Details of test data are shown in Table 5.

Table 5: Impulse distribution of the test group and the control group (NS)

Phase	Left foot		Right foot	
	Test group	Control group	Test group	Control group
T1	18.23±5.74	21.62±6.43	25.88±4.61	29.17±5.33
T2-5	3.61±1.27	4.28±1.88	6.45±1.28	8.84±2.16
M1	16.85±4.92	19.65±6.32	35.76±5.61	38.92±6.61
M2	35.83±4.77	39.68±6.37	53.74±7.86*	57.71±8.09
M3	43.52±5.82Δ	46.28±6.29	48.91±7.93	52.26±7.97
M4	32.96±5.61	36.11±6.75	34.83±6.62	37.35±748
M5	21.73±6.44	23.67±7.85	12.64±4.73	16.69±5.22
MF	23.28±4.63	26.92±5.94	15.11±6.17	19.13±6.59
HM	41.84±3.02	45.96±4.87	51.83±4.64	56.81±6.04
HL	35.57±4.82	38.31±6.06	44.21±5.23	50.86±4.63

The maximum impulse of the left foot appears in the M3 region (2nd metatarsal) and that of the right foot appears in the M2 region (3rd metatarsal). The two have a statistic difference (*P<0.05, ΔP<0.05).

Foot Axis Angle

During normal gaits, vertically, the foot axis angle shows the changes in the foot stability while horizontally it can be used to compare the differences in the foot stability features. From Table 6, it can be seen that the foot axis angles of the right and left feet in the experimental group are all greater than those in the control group.

Table 6: Foot axis angles of the right and left feet in the experimental group

Group	Left foot	Right foot
Test group	10.2±1.7*	11.3±2.6Δ
Control group	7.8±2.2	8.9±1.5

Figure 3 shows the distribution of foot axis angles of the testees in the experimental group. The dotted lines in the figure are the vertical axes, and the angles between the red solid lines and the vertical axes are the foot axis angles. The colors which change from dark to light represent the plantar pressure distribution.

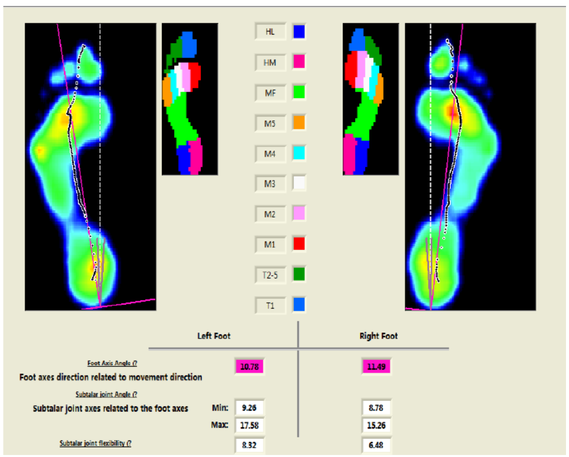

Figure 3. The foot angle distribution diagram of test group

Analysis of Test Results

Time Phase Analysis of the Support Period

In terms of the time phase of the push off stage, there is a significant difference between the experimental group and the control group, indicating that playing basketball on a long-term basis has an effect on the foot power in normal gaits. In normal gaits, the forefoot region is subject to prolonged pressure, so pressure is concentrated in the center. This shows that through long-time high-intensity basketball training and exercise, the foot power against the ground is more persistent. This indicates that after basketball training, players should pay attention to the rehabilitation of their feet and carry out mild exercise, to avoid fasciitis, Achilles tendinitis and other inflammations in their feet and muscle joints.

By conducting time phase analysis of the experimental group and the control group during the support period, we will understand how to make reasonable teaching plans and determine a scientific load training intensity for basketball sports.

Feature Analysis of Foot Power

Based on the test results of plantar pressure distribution and plantar pressure intensity distribution, we can analyze the foot power features. The feature of plantar pressure distribution is that forefoot region>arch region>heel region. The peak forefoot pressure and pressure intensity of the testees in the experimental group are all greater than those in the control group, indicating that in normal gaits, the power generated by the basketball players in the experimental group are greater than that by the ordinary juveniles in the control group and further showing that basketball can help increase foot power. In the arch and heel regions, the peak pressure intensity of the testees in the experimental group is less than that in the control group, indicating that the basketball players have better shock absorbing and buffering abilities, which can effectively mitigate impact injuries.

Effect Analysis of Plantar Buffering Capacity

Plantar impulse is an indicator of how well a foot can absorb the impacts and act as a buffer and is the accumulation of power and action time. The test results show that the impulses in the forefoot, arch and heel regions in the experimental group are smaller than those in the control group, indicating that through exercise, basketball players have better foot buffering capacity and can better absorb ground impacts. A good foot impulse buffering is of great significance to the protection of foot and knee joints, and is also helpful to improving the body's control and balance. This shows that basketball can help improve the overall motor function of juveniles and thus juveniles should be encouraged to participate in basketball training.

Foot Stability Impact Analysis

Foot axis angle refers to the angle between the longitudinal axis of the foot and the direction of walking. Medically speaking, when a foot axis angle is greater than 15°, the foot is abnormal. From the test data, it can be seen that the foot axis angles in the experimental group and the control group are in the normal range. The foot axis angles in the experimental group are greater than those in the control group, indicating that the experimental group have better abilities to control foot gaits. The increase of the foot eversion angle within a certain range can improve the contact area between the foot and the ground and increase the stability of the foot. Test results indicate that long-term participation in basketball sports can improve the foot stability, balance ability and coordination capacity of a juvenile.

CONCLUSIONS

Foot movements are one of the most critical part in basketball sports. Analyzing the effects of basketball on the foot support period, pressure, pressure intensity, foot impulse and foot axis angle is of great significance to scientifically guiding foot protection and evaluating the effects of basketball on foot movement abilities of juveniles. In this paper, through an experiment, we compare the experimental group and the control group and use the RS-footscan force-measuring system to measure and analyze various parameters and indicators. The conclusions and guiding significance of this paper are as follows:

(1) Basketball prolongs the time during which the feet of juveniles are off the ground, so

their foot buffering capacity and forefoot power are increased, and their foot stability is improved. Proper basketball exercise can help promote the foot health development of juveniles.

(2) Due to long-term training, pressure is relatively concentrated in the forefeet of the basketball players in the experimental group; therefore, players should relieve their foot pressure and reduce foot injuries by physical therapy and massage.

(3) Studying the foot dynamics with modern measurement methods can provide more scientific and objective data support, and thus it should be promoted more in the actual application.

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ASSESSMENT OF INFLUENTIAL FACTORS FOR PURCHASING GENT'S SHOES - UNDERSTANDING THE BASIC COMFORT PROPERTIES

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ASSESSMENT OF INFLUENTIAL FACTORS FOR PURCHASING GENT'S SHOES - UNDERSTANDING THE BASIC COMFORT PROPERTIES

ABSTRACT. There are many factors that have a great influence over customer's decision in case of choosing gent's shoes and also several features are related to comfort properties of shoes. The aim of the study was to identify the most influential purchase factors of gent's shoes along with disclosing frequently considered comfort factors through target sample population and experts. Two questionnaire experiments were performed among selected respondents and four experts' opinions were observed. The number of total interviewees who provided their preference of choosing factors during shoe purchase was 72 and the interviewees gave their feedbacks especially on basic comfort properties after wearing three pairs of sample shoes for a period of two months. Bar chart, pie chart, Pareto analysis and average weighted method were followed for assessing data. Style, comfort, price and colour were the top four factors that were suggested by the respondents respectively and style, comfort, color and price were considered by the experts at the time of purchasing new shoes, respectively. On the other hand, breathability, proper size and fit, light weight, flexibility and appearance were selected as the most considered factors regarding shoe comfort, whereas experts suggested size and fit, cushioning, flexibility, light weight, breathability, arch support and toe profile shape, respectively. Those who wore sample shoes made of synthetic upper materials and narrow fitted in the forefoot region during the experimental period, tended to perceive them as very uncomfortable.
KEY WORDS: comfort, preference, shoe, style

EVALUAREA FACTORILOR CE INFLUENŢEAZĂ ACHIZIŢIONAREA ÎNCĂLŢĂMINTEI PENTRU BĂRBAŢI - ÎNŢELEGEREA PROPRIETĂŢILOR DE BAZĂ CE ŢIN DE CONFORT

REZUMAT. Există mulţi factori care au o mare influenţă asupra deciziei clientului în cazul alegerii încălţămintei pentru bărbaţi şi multe caracteristici sunt legate de proprietăţile de confort ale încălţămintei. Scopul acestui studiu a fost de a identifica cei mai influenţi factori în achiziţionarea unei perechi de pantofi pentru bărbaţi, dezvăluind totodată factorii legaţi de confort cel mai des luaţi în considerare de un eşantion ţintă al populaţiei şi de experţi. S-au efectuat două experimente cu chestionare adresate respondenţilor selectaţi şi s-au luat în considerare opiniile a patru experţi. Numărul total de persoane intervievate care şi-au expus preferinţele privind factorii de decizie în procesul achiziţionării pantofilor a fost de 72, iar persoanele intervievate au oferit feedback în special cu privire la proprietăţile de bază ce ţin de confort, după ce au purtat trei perechi de pantofi de probă timp de două luni. Metodele utilizate pentru evaluarea datelor au fost diagrama cu bare, diagrama cu structură radială, analiza Pareto şi media ponderată. Stilul, confortul, preţul şi culoarea au fost primii patru factori indicaţi de respondenţi, iar stilul, confortul, culoarea şi preţul au fost considerate de experţi la momentul achiziţionării unor pantofi noi. Pe de altă parte, permeabilitatea vaporilor de apă, dimensiunea corespunzătoare şi potrivirea, greutatea redusă, flexibilitatea şi aspectul au reprezentat cei mai apreciaţi factori în ceea ce priveşte confortul pantofilor, iar experţii au luat în considerare dimensiunea şi potrivirea, capacitatea de amortizare a şocurilor, flexibilitatea, greutatea redusă, permeabilitatea la vapori de apă, suportul plantar şi forma profilului. Pantofii de probă cu feţe din materiale sintetice şi strâmţi în regiunea antepiciorului purtaţi în perioada experimentală au fost percepuţi ca fiind foarte incomozi.
CUVINTE CHEIE: confort, preferinţă, încălţăminte, stil

L'ÉVALUATION DES FACTEURS QUI INFLUENCENT L'ACHAT DES CHAUSSURES POUR HOMME - COMPRENDRE LES PROPRIÉTÉS DE CONFORT DE BASE

RÉSUMÉ. Il y a beaucoup de facteurs qui ont une grande influence sur la décision du client dans le cas de choisir des chaussures pour homme et également plusieurs caractéristiques sont liées aux propriétés de confort des chaussures. Le but de cette étude a été d'identifier les facteurs les plus influents dans l'achat d'une paire de chaussures pour hommes, tout en révélant les facteurs de confort le plus souvent pris en compte par un échantillon cible de la population et par des experts. On a mené deux expériences à partir d'un questionnaire avec la participation des répondants sélectionnés et les opinions de quatre experts ont été prises en compte. Le nombre total de personnes interviewées sur leur préférences des facteurs de choix lors de l'achat de chaussures a été 72 et les personnes interviewées ont donné leur avis sur les propriétés de confort de base après avoir porté trois paires d'échantillons de chaussures pendant deux mois. Les méthodes utilisées pour évaluer les données ont été le diagramme à barres, le diagramme à secteurs, l'analyse de Pareto et la moyenne pondérée. Le style, le confort, le prix et la couleur ont été les quatre principaux facteurs suggérés par les répondants tandis que le style, le confort, la couleur et le prix ont été pris en compte par les experts lors de l'achat de nouvelles chaussures. D'autre part, la respirabilité, la taille et l'ajustement appropriés, le poids léger, la flexibilité et l'apparence ont été les facteurs les plus appréciés pour le confort des chaussures, tandis que les experts ont suggéré la taille et l'ajustement, la capacité d'absorption des chocs , la flexibilité, la légèreté, la respirabilité, le support plantaire et la forme de profil. Ceux qui ont porté des échantillons de chaussures au tiges en matériaux synthétiques et étroits dans la région de l'avant-pied pendant la période expérimentale, les ont perçu comme très inconfortables.
MOTS CLÉS: confort, préférence, chaussure, style

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INTRODUCTION

Nowadays, a pair of shoes is not only used for its functional value but also for its fashion attributes. Since the foot has the most functional movement among our body organs, it should be protected in a hygienic way, for which appropriate footwear is needed. Well fitting, fit for purpose, supportive shoes which allow normal foot function, stable heel height of approximately 25 mm, adequate width and depth, outsole grip, flexible uppers and inshoe climate are the most considered factors for appropriate footwear [1]. Though footwear is a consumable good, it has no proper labeling on it which is generally used for many consumable goods to prescribe the quality information and constituents of particular goods in Bangladesh. That is why it makes a great puzzle for footwear customers of Bangladesh what they are buying, what the quality they are absorbing, as many artificial and synthetic leathers as well as fibers are now inundated in the footwear market for its low price. According to EU Directive No.94/11/EC [2], shoe materials information such as natural leather, natural leather with covering, artificial leather, textile material or synthetic material on the labeling of the product should be transcribed which is followed in the EU member states. Moreover, it is very essential to provide adequate information to the customers about the product features that will help them in purchasing their intended shoes. Customers usually consider different factors for choosing new shoes during purchase. They are intentionally or unintentionally influenced by these factors during the selection of a new shoe. At present, comfort features are widely searched for footwear, garments and apparel but what should be actually delved into the footwear for comfort features are mostly obscure to the general customers. For this reason, it was the part of this research to disclose the comfort features perceived by the customers along with experts' review in order to get reliable information. Through this study, footwear purchasing decision factors and comfort features considered by the respondents will be revealed and also experts' opinions will be extracted regarding these issues. Customers will be aware of the factors which should be considered as priority basis and gathered initial knowledge about the essential properties of comfort shoes which will make them able to differentiate between the basic comfort and discomfort properties of shoes that should be considered at the time of purchasing new shoes. Along with these, shoe manufacturers would find the customers' opinions as well as experts' suggestions with respect to various factors of shoe and their intended comfort features which will help them to develop new shoes successfully. There are different factors that may play a pivotal role in case of purchasing shoes; such as comfort, style, price, color, brand, outlook, upper material, weight, safety, heel height, don on & off and outsole material etc. Comfort properties are all about sensation, which can vary from person to person. Comfort can be prescribed as a feeling of relaxation and well-being [3]. Goonetilleke addressed comfort with respect to positive sensation [4]. Footwear comfort feature depends on many factors comprising material properties of shoe [5], shoe style, shoe fit [6, 7] and psychological factors, all of which have significant importance towards imparting sensation. At present, there are many synthetic materials being used in footwear industries along with leather. Being a natural material, leather has porous structure which makes it convenient for breathability and for this reason leather shoe has a great preference over synthetic shoe in case of comfort features. Casual and Moccasin shoes are more popular among the young users and these shoes are unlaced with more opening area and also considered as more comfortable shoes than that of any other styles. The core focus of this study was to unveil the factors that influence the decision of a customer during shoe purchase, to investigate the aspects that make shoe comfortable along with experts' investigations.

Literature Review

The decision of purchasing new shoes and comfort features can vary from one's to other's choice according to their needs, ages, health conditions, life styles, regions and living weather conditions. Particular style may affect the customers such as if one wants to buy running or dress shoes, so there will be some difference of intended comfort features and purchasing decision factors. Product consumption and purchasing decisions are

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influenced by the benefits that is found from the quality of goods [8]. Four factors are found such as comfort, aesthetics, perspiration and belief as the general criteria related to buying decision, and tactile (size, texture, feeling inside the shoe, and inside shoe climate), auditory (sound produced) and olfactory (unpleasant odors) senses are the main differences between comfortable and uncomfortable shoes [9]. In another study, style pattern, color of footwear, material used, brand and comfort by product used, durability of product, service and warranty given were identified as the influencing factors for purchasing shoes [10]. A survey conducted at Karachi revealed that price and quality are the most influential factors on consumer preference and purchasing intention [11]. Five key characteristics such as minimal heel to toe drop, neutral (shoes do not contain stability or motion control elements that interfere with normal foot motion), relatively light weight, wide toe box and optimum cushioning are the most considered features for running shoes [12]. Arch type compatibility with shoe design is also among the most considered factors for running shoes [13]. On the other hand, many people affected with stroke and Parkinson's were found to be comfortable with slippers indoors, whereas excessive heel height, reduced friction on the soles of footwear, walking barefoot, wearing socks or footwear with a flimsy sole were found as the most injurious factors for older people [14]. Therefore, it is very clear that comfort features and purchasing decision can vary from one customer to another. Environmental conditions and individual characteristics of the consumer are closely related with the feeling of comfort and discomfort [15, 16]. Comfort, fit, support, heel height, don on/off and weight are the most frequent considered factors for choosing shoes and heel rigidity and sole hardness are the poor characteristics for any kind of footwear [17]. Consumers' subjective feelings, ambient factors (temperature, humidity etc), hygiene properties (hygroscopicity, moisture return, wetting, capillarity and breathability) are the crucial factors for comfortable and uncomfortable shoes [18]. Pressure distribution is another considered factor for shoe comfort, peak pressure and perceived comfort has a negative correlation across the entire surface of the foot [19]. Several studies were conducted in order to know the purchasing factors and comfort features through survey study and wearing sample shoes but there is lack of experts' opinions in these studies and no preference ranking was established. An interactive survey study, feedbacks from respondents after wearing sample shoes and experts' opinions were conducted in this study in order to get a better result which will fill up the gap of the previous studies. Moreover, since purchasing factors and comfort features may vary from one country to another and there was no research about finding these factors in Bangladesh, this research will contribute a significant role to know about customers' behavior and customers will be able to know the important factors related shoe comfort and what they should search for purchasing shoes, from the experts' perspective. On the contrary, manufacturers will get a comprehensive guide line for producing comfort shoes and they will know more about how to satisfy customers' demand.

MATERIALS AND METHOD

The followed method of this research can be subdivided into two categories; such as interactive survey for finding purchasing factors as well as comfort features wearing sample shoes by the participants and experts' review about these factors to find a preferred ranking of these factors. The first experiment was carried out in the Dhaka city of Bangladesh among 72 male sample population who had at least 3 pairs of shoes. The sample population was selected equally from students and professional persons whose age range was 24 to 32 years and mean age was 27.4 years. All of the participants were related with footwear professions or leather/ footwear backgrounder students. The sample population was targeted considering the highest volume of youth against the total population of the country who used to prefer wearing casual and/or moccasin shoes. The sample shoes had been worn alternatively by the participants during an experimental period of two months from 20th April to 18th June, 2017 and feedbacks were collected after the experimental period. Then two academic and two industrial experts were requested for their reviews on shoe purchasing decision factors and comfort features in order to get most frequent perceived factors.

Two experiments had been done based on the specific questionnaires in the written form as quantitative analysis and verbal data analysis respectively by oral interviews. First experiment was conducted among 72 respondents in order to know the factors in case of purchasing gent's casual and/or moccasin shoes with preferred four factors and in the second experiment, feedbacks were taken from the participants after wearing sample shoes by them for the specified period of time span to evaluate the basic comfort properties of that categories of shoes. Data were collected through the answer of the prescribed fourteen multiple choice questions (M.C.Q) and in depth oral interview of the selected participants. Additional comments apart from the prescribed M.C.Q's were also accepted and considered. The survey questionnaires were prepared representing all the possible choosing factors and comfort properties of the casual and/or moccasin shoes to bring to light the real information what actually people thought before purchasing a pair of shoe. The sample questionnaires were categorized into three groups such as close-ended, preference and open-ended questions where most of the questions were open-ended. A preference ranking was established among the top four considered factors using participants' responses and represented graphically. Among the top four factors, frequency of the first preferred one was not counted during selecting the second preference and consequently the same process was followed for third and fourth preference, for example, when style was selected as first preference among the first four factors, it was omitted for second preference consideration but frequency of remaining three factors in case of first preference and second preference, were considered for selecting second preference and the same process was followed for third preference. The feedbacks from the sample population about comfort features were then analyzed through Pareto diagram in order to get most frequent factors. In the second part of this experiment, the aim of this research work was translated to four experts and feedbacks from respondents were shared through an open discussion session. A prescribed form with detail instructions was supplied to the experts for inputting their considered features regarding shoe purchasing decision factors and comfort features in a preferred way. Then in the second phase, only the factors which were considered by at least two experts were provided to make scoring again in order to attain frequently considered factors. An average weighted method was followed to bring out the most frequent factors and then analyzed the result with respondent's feedbacks.

RESULTS AND DISCUSSION

Choice Factors Analysis

The feedbacks from the survey regarding the choosing factors during purchasing shoes are depicted in Fig.1. Style was considered as the first priority factor at the time of purchasing shoes by the maximum participants and that was 91%. The second highest factor, i.e., comfort was chosen by 90% of the sample population. Price was another criteria that was considered by 83% of the participants as third factor for choosing shoes at the time of purchasing. Color, outlook, brand, leather upper, durability, weight, matching, safety, outsole features, heel height and synthetic upper were rest of the factors to be considered during shoe purchase and these were recommended by 79%, 66%, 65%, 64%, 61%, 55%, 45%, 41%, 29%, 23% and 13% of the experimental sample population respectively. The least number of participants, only 13% respondents considered synthetic upper materials as a comfort feature of shoe.

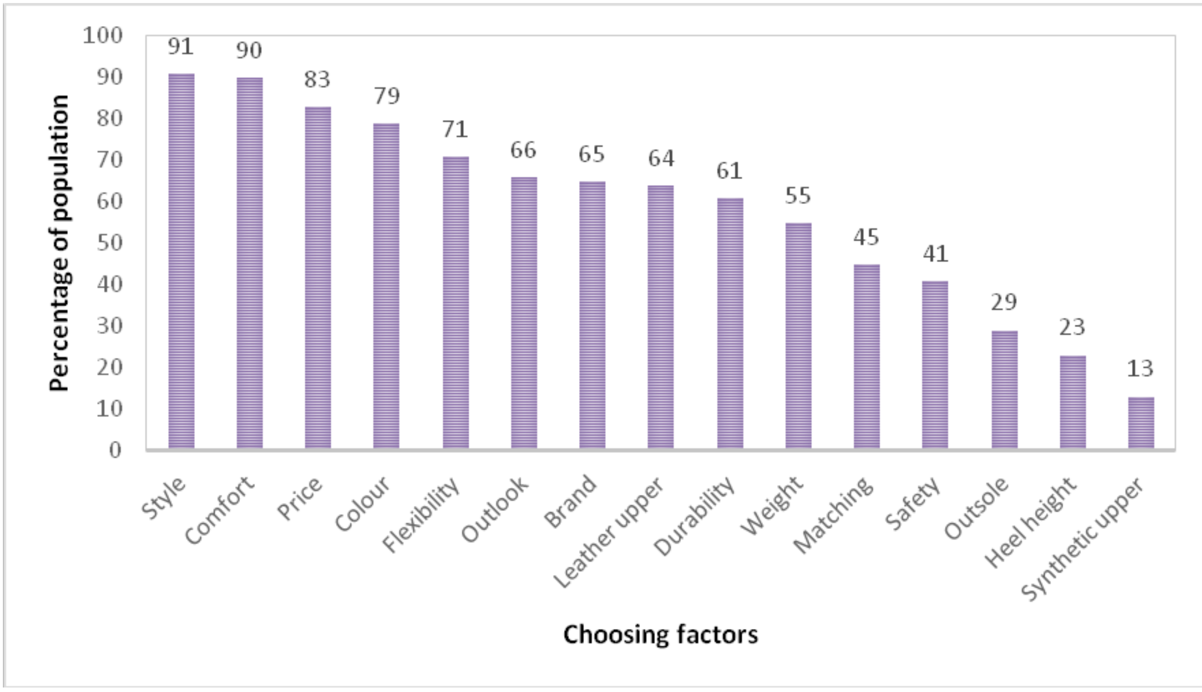

Figure 1. Percentage of choice factors during new shoe purchase

From the above analysis it can be observed that customers are fascinated at first by shoe's style rather than other important comfort features. After the style, they look for other properties of the shoes such as comfort, price, color, outlook, brand, leather upper, durability, weight, matching, safety, outsole, heel height and synthetic upper.

The other part of the first experiment was to prioritize the top four factors chosen by the participants from Fig.1, these factors are style, comfort, price and color accordingly.

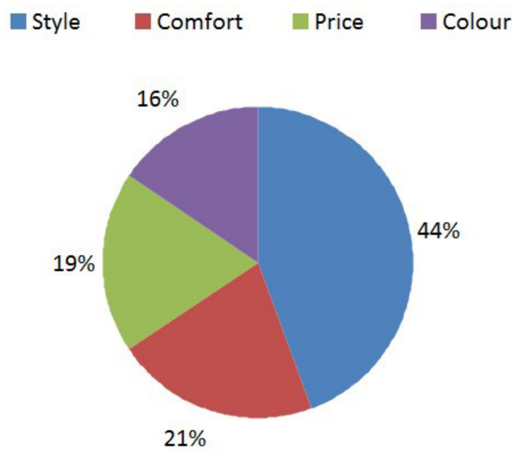

Figure 2. Style as first preference

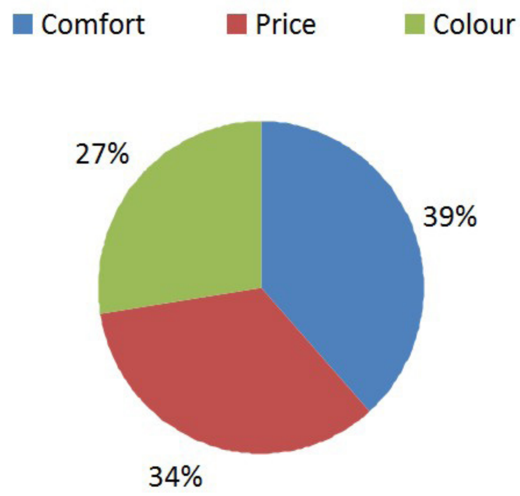

Figure 3. Comfort as second preference

From Fig.2, it is seen that the highest number of participants (44%) selected style as the first option according to their preference of choices. Comfort, price and color were chosen as first preference by 21%, 19% and 16% of the respondents particularly. Fig.3 indicates that comfort property was chosen as a second priority factor by 38% frequency of the sample population whereas price and color were preferred as second priority factors by 34% and 28% of frequency proportionally.

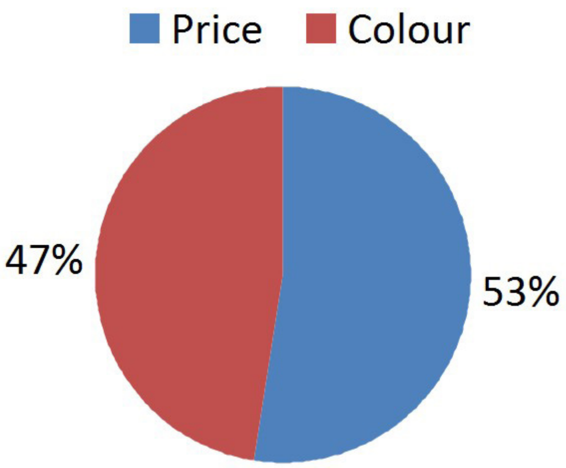

Figure 4. Price as third preference

After finding the first two preferred factors such as style and comfort, all frequency for the remaining two factors i.e., price and color from first to third preference were calculated to find the third preferred factor. In the Fig.4, the frequency for price (53%) was found slightly higher than that for color (47%). Since style, comfort and price were already observed as first, second, and third preferred factors respectively and therefore, the remaining factor color will be placed in fourth preference. From the above analysis, it can be summarized that customers considered shoe style firstly then comfort, price and finally color in case of choosing a pair of new shoe. The preference ranking can be depicted as style > comfort > price > color.

Verbal Data Analysis

According to the participants' feedbacks, statements were interpreted at the same level of detail and these were analyzed where 72 respondents provided 252 comments regarding comfort properties of shoe and total number of comments under each factor were presented in Fig. 5.

In Figure 5 English capital letters from A

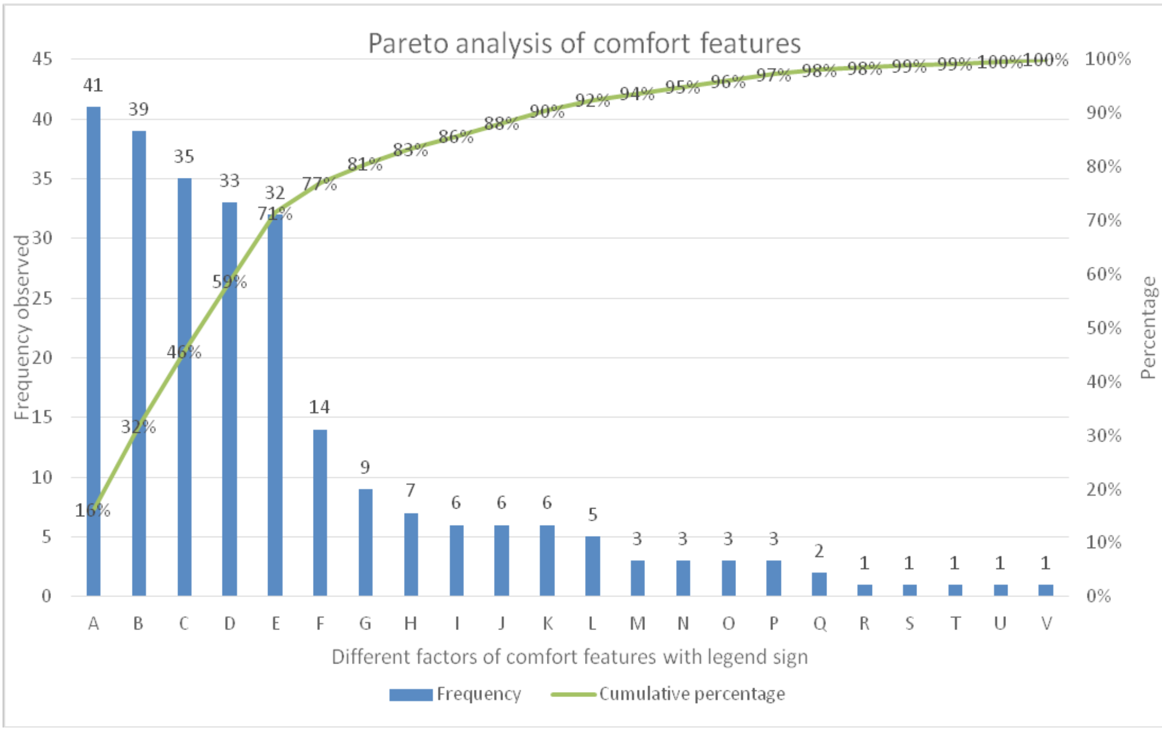

Figure 5. Pareto diagram for identified several comfort features by the respondents

to V were used as legend in order to represent twenty two features such as breathability of upper and lining material (A), proper size and fit (B), light weight of the shoe (C), cushioning ability of insole (D), flexible upper material (E), good appearance of the shoe (F), avoidance of extra heel height (G), leather upper and lining material (H), avoiding internal friction inside the shoe (I), flexible outsole (J), durability of shoe (K), enough toe space (L), slip resistance of outsole (M), padded top line (N), water resistance of upper material (O), softy upper and lining material (P), well-balanced toe spring and heel height (Q), proper arch support (R), softy Outsole (S), enough protection of shoe (T), shock absorptivity of insock (U) and air trapping quality in winter season (V).

After analyzing these comments by Pareto diagram, generally known as 80/20 principle whereas 20% of total factors are responsible for greater impact of the output and remaining 80% has the least influence over the result, it was observed that first six factors such as breathability (A), proper shoe size & fit (B), light weight (C), cushioning ability (D), flexible upper materials (E), and good appearance of the shoe (F), were mostly preferred to the experimental population. On the other hand, the rest of sixteen factors from G to V got less priority.

Breathability of upper and lining materials was considered by the highest number of participants (41) as the most important factor which makes the foot dry and prevents bad odor and bacterial growth inside the shoe. 39 of the participants mentioned proper size and fit as another comfort feature that ensures better fitting of the shoe and protects the foot from different foot ailments and injuries. The shoe should be light weight for more comfort and easy walking and this was also mentioned by the good number of experimental population. The cushioning ability and flexibility of shoe materials and whole shoe were addressed by the participants significantly whereas the appearance of the shoe was also considered among first six factors. Avoiding extra heel height, upper and lining material impact, avoiding internal friction, flexible outsole, durability, enough toe space, slip resistance, padded topline, water resistance, soft upper and lining, toe spring and heel height, arch support and other factors were considered by the least number of participants which signifies that most of the people have less perception on these factors before purchasing new shoes.

On the contrary, the participants who wore shoes made of synthetic upper material felt a high discomfort since this caused excessive perspiration and these shoes were less durable than leather shoes. Besides, participants who used pointed toe shoes, felt narrow fitting at the forepart region which caused extra pressure on the toes resulting blisters and pain in this area. Heavy weight of the shoe made the foot more tired at the time of walking, slow stepping and imparting muscles tension in the feet. Paying indispensability to the comfort factors of shoe, it can be summarized from this study that breathability of upper and lining material, flexibility of shoe, proper size and fit, light weight, enough shock absorption ability and optimum heel height of the shoe are the major comfort features according to participants' comments for any kind of shoe to be addressed before purchasing a pair of new shoe.

Analysis of Experts' Data

An average weighted method was conducted to get preferred purchasing factors and comfort features followed by four experts. A corresponding score for each factor was pursued

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by Table 1 and weight for particular factor was given by the experts' feedback. Then the average weighted method was resulted for disclosing the sequence of the factors for purchasing shoes and also for comfort features; depicted individually in Fig 6 and Fig 7.

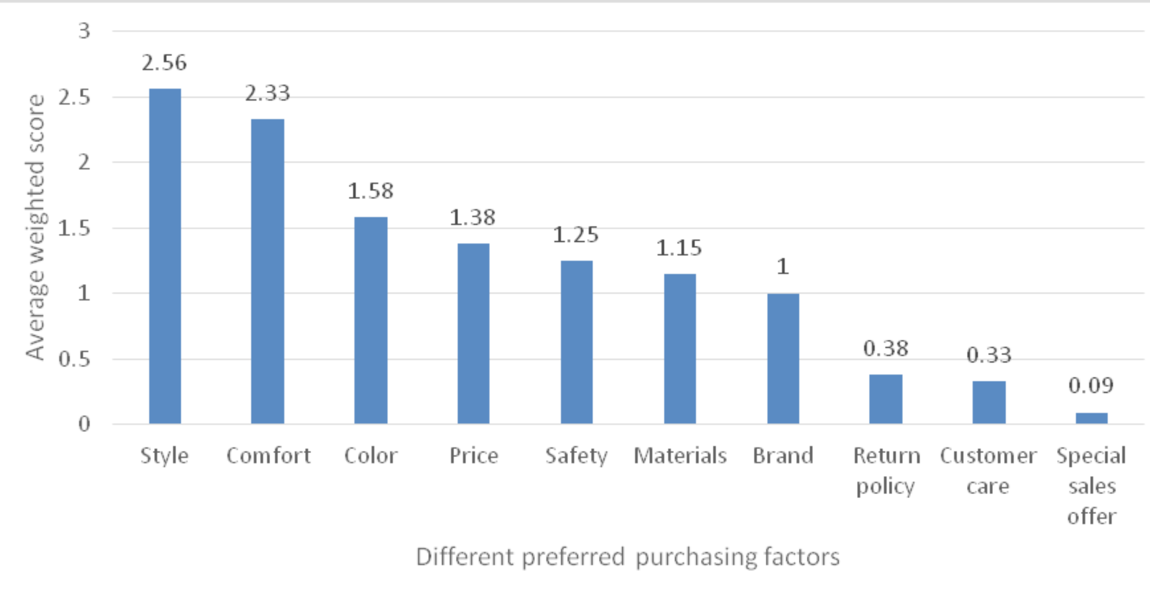

Figure 6. Different preferred purchasing factors suggested by four experts followed by average weighted method

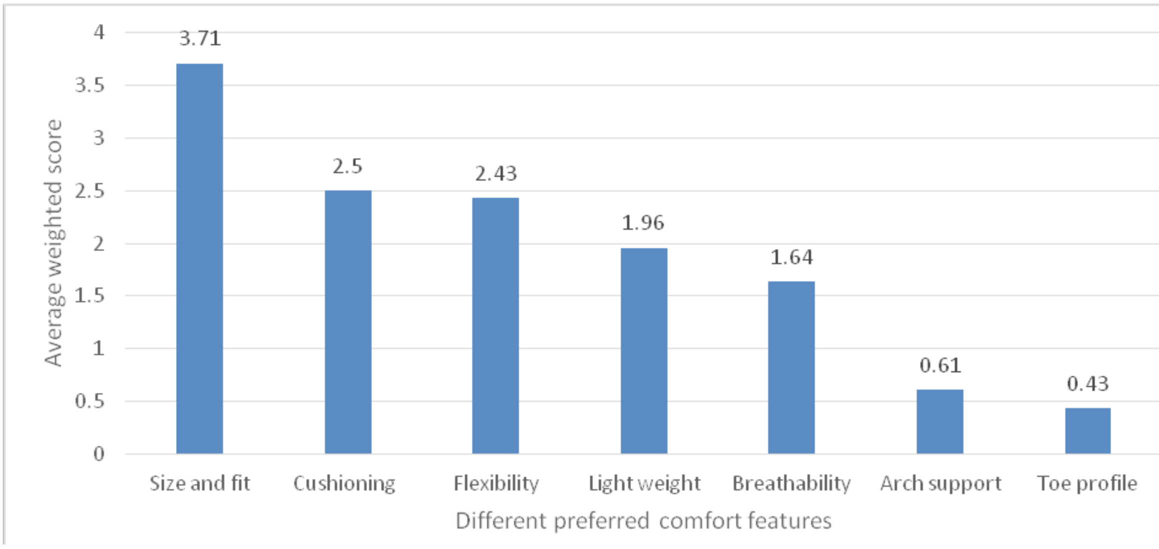

Figure 7. Frequently preferred comfort factors suggested by four experts followed by average weighted method

Table 1: Linguistic terms for rating criteria

Linguistic terms	Corresponding score
Very high influence	4
High influence	3
Medium influence	2
Low influence	1
No influence	0

Experts also have given priority to style and comfort that matches with the participants' choice. After comfort, experts preferred color, and then price whereas participants preferred price first and then color. Safety features, materials characteristics, brand value, goods return policy, customer care and special sales offer were then considered by them. The factors such as return policy, customer care and special sales offer were not identified in any previous literature but these have an indirect effect on shoe purchase.

In the second part of the experts' feedbacks, frequently comfort features were identified such as proper size and fit, cushioning ability of materials, flexibility of materials, light weight of the shoe, breathability of upper and lining materials, arch support and finally shape of the toe region of the shoe. Experts firstly consider proper size & fit and breathability as fifth factor whereas participants suggested breathability first.

Frequently Considered Common Comfort Features and their Implications

Size and Fit

The inner length of a shoe which is dictated by the corresponding standard last (a mould on which the shoe is made) length is termed as shoe size while fit is the ability to conform to the size, width, shape and proportions of the foot. There are different sizing systems; such as UK system, Paris point, US system and Mondo Point. Loose fitting of shoe may cause inconvenient in walking and will not be comfortable. On the other hand, narrow fit in the forefoot region can engender foot deformations; such as blister, hallux valgus, hammer toe, bunions and other vulnerable problems [20-22].

Cushioning Ability

Cushioning ability can be defined as the capacity of a material to absorb shock and dispersed the shock along its area properly. The use of resilient materials, particularly as an insole or midsole which absorbs step shock and provides a comfort zone between the sole of the foot and the ground, is essential for cushioning features [23]. During walking, the back part of the foot known as heel area which strikes the ground first and thus it faces opposite force according to the Newton's third law. If the material of a shoe can absorb this shock and distribute it uniformly to its area, it will provide more comfort to the wearers.

Flexibility of Materials

As our foot flexes during walking in the forepart region at the joint of metatarsal heads, upper materials and sole should be compatible with this flexing and also materials should endure this flexing without any damages. Leather has strong tensile and tear strength which make it comfortable as suitable flexible material with high degree of endurance.

Light-weightiness

The more the weight of the shoe, it will hinder the movements of foot and causes tiredness to the feet. The lesser the weight, the more comfort will be found in walking. It is roughly recommended that a pair of shoe should not weigh more than 500 gm.

Breathability

Breathability is the ability of a material to permit vapor and air from inside the shoe to outer environment produced by sweat glands and inner frictions between foot and shoe. It is defined as the volume of permitting water vapor in unit time and unit area. This property is generally considered as the most important characteristic for comfort features of shoe which prevents the foot from getting wet and excessive perspiration. In the absence of this property; the feet produce bad odor which may cause skin irritation, skin-allergy and favorable conditions for bacterial growth.

Arch Support

Arch support can be defined as a rigid support placed inside a shoe so that its moulded form fits the inner longitudinal arch (the inside curvature of foot) which relieves strain on the muscles of the foot while walking, standing or any kind of movement. Support is provided through the design of the shank (a metal bar used between insole and sole), an orthotic insole (the bottom of shoe in which sole is attached), an arch cushion, or padding [23]. Shoes with good arch support ensure proper control of the foot and extra support for fascia ligament of the foot from being distorted.

Toe Room Allowance

In order to ensure proper fitting of a shoe toe room allowance is an important feature that will provide the space for the free movement of toes that is required for comfort of the shoe during wearing. Toe room allowance is generally considered 3/8 inch to 1/8 inch, from longest toe to the end of each shoe (source: The National Shoe Retailers Association, Pedorthic Footwear Association and American Foot and Ankle Society). If sufficient toe room allowance is not ensured, the foot will be in a compact position that will affect proper size & fit and also cause narrow fitting that will cause severe discomfort.

CONCLUSION

This study has unveiled the most considered factors at the time of purchasing new shoes and also essential comfort features of gent's casual and/or moccasin shoes. Among many factors for choosing a pair of shoes, style has come out as the first priority factor that means customers are very fashionable and trendy. Comfort was the second factor that prevents our foot from different types of ailments and provides ease in walking; this factor signifies that customers always want comfort shoes. Though price is considered after style and comfort but it has a great influence over them. Retailers can focus on customer care, goods return policy and special sales offer which will influence the customers indirectly for purchasing shoes. On the other hand, customers should find proper size & fit, cushioning, flexibility, light weight, breathability, arch support and toe room allowance for ensuring better comfort before purchasing shoes. Since leather has its unique porous structure, it is considered as high breathable natural material which was suggested as preferred material for shoe manufacturing. The upper part of shoes should be made of flexible light material to match the shape of one's foot and also for compatibility with different movements of feet. Materials of insole and sole should have enough cushioning ability that will provide shock absorbing property to the shoe which is a necessary feature for comfort shoes. Shoe manufacturers should pay proper focus on these customers' requirements and satisfy the preferred comfort features at optimum price point.

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STATISTICAL-MATHEMATICAL PROCESSING OF ANTHROPOMETRIC FOOT PARAMETERS AND ESTABLISHING SIMPLE AND MULTIPLE CORRELATIONS. PART 2: CORRELATIONS AMONG ANTHROPOMETRIC PARAMETERS OF THE FOOT

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STATISTICAL-MATHEMATICAL PROCESSING OF ANTHROPOMETRIC FOOT PARAMETERS AND ESTABLISHING SIMPLE AND MULTIPLE CORRELATIONS. PART 2: CORRELATIONS AMONG ANTHROPOMETRIC PARAMETERS OF THE FOOT

ABSTRACT. Footwear manufacturing based on suitable lasts and appropriate sizes is possible, using the results obtained from anthropometric measurements. The construction of the last, the establishment of dimensions required to meet the comfort requirements of a larger proportion of consumers, must be based on the knowledge and the most accurate characterization of the anatomical-morphological differences of the types of foot encountered within that population of consumers as well as the frequency of these types within the population. For this purpose, it is periodically necessary to perform anthropometric studies on the population differentiated according to certain criteria (gender, age, geographical region, etc.) in order to obtain information about the dimensional particularities of the average representative foot for that population, the anthropometric parameters distribution laws that characterize the representative average foot of the country's population in terms of size. In order to define the characteristic dimensions of the foot, one- and two-dimensional distributions of anthropometric parameters were used as well as a series of correlations that model the interdependence among the various parameters, with direct applicability in designing the last. Linear regression equations can be used in last design to determine the dependences between the geometric parameters of the last in close connection with the laws of variation of the anthropometric parameters of the foot. Multiple linear correlations have been established demonstrating that there are very high correlations between certain variables.

KEY WORDS: anthropometric parameters, foot, correlation

PRELUCRAREA STATISTICO-MATEMATICĂ A PARAMETRILOR ANTROPOMETRICI AI PICIORULUI ŞI STABILIREA CORELAŢIILOR SIMPLE ŞI MULTIPLE. PARTEA 2: CORELAŢII ÎNTRE PARAMETRII ANTROPOMETRICI AI PICIORULUI

REZUMAT. Realizarea de încălţăminte pe calapoade adecvate, într-un pontaj corespunzător, este posibilă, prin utilizarea rezultatelor obţinute prin măsurători antropometrice. Construcţia calapodului, stabilirea tipodimensiunilor necesare satisfacerii cerinţelor de confort a unei ponderi cât mai mari de consumatori, trebuie să aibă la bază cunoaşterea şi caracterizarea cât mai exactă a diferenţelor de ordin anatomo-morfologic a tipurilor de picior care se întâlnesc în cadrul acelei populaţii de consumatori precum şi a frecvenţei acestor tipuri în cadrul populaţiei. În acest scop, periodic, este necesară efectuarea unor studii antropometrice asupra populaţiei diferenţiate după anumite criterii (sex, vârstă, regiune geografică etc.) în scopul obţinerii unor informaţii privind particularităţile dimensionale ale piciorului mediu reprezentativ pentru acea populaţie, legile de distribuţie a parametrilor antropometrici ce caracterizează sub raport dimensional piciorul mediu reprezentativ al populaţiei ţării respective. În vederea definirii tipodimensiunilor caracteristice ale piciorului, s-au utilizat distribuţii uni şi bidimensionale ale parametrilor antropometrici precum şi o serie de corelaţii ce modelează interdependenţa dintre diverşi parametri, având aplicabilitate directă în proiectarea calapodului. Ecuaţiile de regresie de tip liniar pot fi folosite la proiectarea calapoadelor pentru stabilirea dependenţelor dintre parametrii geometrici ai calapodului în strânsă legătură cu legile de variaţie a parametrilor antropometrici ai piciorului. S-au stabilit corelaţii multiple de tip liniar care demonstrează că există corelaţii foarte ridicate între anumite variabile.

CUVINTE CHEIE: parametri antropometrici, picior, corelaţie

LE TRAITEMENT STATISTIQUE-MATHÉMATIQUE DES PARAMÈTRES ANTROPOMÉTRIQUES DU PIED ET LA DÉTERMINATION DES CORRÉLATIONS SIMPLES ET MULTIPLES. DEUXIÈME PARTIE: DES CORRÉLATIONS ENTRE LES PARAMÈTRES ANTROPOMÉTRIQUES DU PIED

RÉSUMÉ. La fabrication des chaussures à partir d'une forme et des dimensions appropriées est possible en utilisant les résultats obtenus par des mesures anthropométriques. La construction de la forme, l'établissement des tailles standard pour satisfaire les exigences de confort pour la majorité des consommateurs, doivent être fondés sur la connaissance et la caractérisation plus exacte des différences anatomiques et morphologiques des types du pied rencontrés chez cette population des consommateurs, ainsi que la fréquence de ces types au sein de la population. A cet effet, périodiquement, il est nécessaire de mener des études anthropométriques sur la population différenciée selon certains critères (sexe, âge, région géographique, etc.) afin d'obtenir des informations sur les particularités dimensionnelles du pied représentatif pour la population, les lois de distribution des paramètres anthropométriques qui caractérisent le pied moyen représentatif de la population du pays. Pour définir les tailles standard caractéristiques du pied, on a utilisé des distributions uni- et bidimensionnelles des paramètres anthropométriques ainsi qu'un certain nombre de corrélations qui déterminent l'interdépendance entre les différents paramètres, avec application directe dans la conception de la forme. Les équations de régression linéaire peuvent être utilisées pour concevoir les formes de chaussures et pour définir les dépendances entre les paramètres géométriques de la forme en étroite collaboration avec les lois de variation des paramètres anthropométriques du pied. Des corrélations multiples ont été établies, démontrant qu'il existe des corrélations très élevées entre certaines variables.

MOTS CLÉS : paramètres anthropométriques, pied, corrélation

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INTRODUCTION

It is periodically necessary to perform anthropometric studies on the population differentiated according to certain criteria (sex, age, geographical region, etc.) in order to obtain information about the dimensional particularities of the average representative foot for that population, the laws of distribution of anthropometric parameters that characterize the representative average foot of the population of the respective country. In order to define characteristic dimensions of the foot, one- and two-dimensional distributions of anthropometric parameters as well as a series of correlations that model the interdependence among various parameters, with direct applicability in designing the last. The correlation between two or more anthropometric parameters is the statistical interdependence between them. The correlation involves establishing a real connection between the studied parameters, connection that may be analyzed in terms of its direction, form and intensity. Correlations among the studied anthropometric parameters are useful in the design of lasts and footwear.

EXPERIMENTAL

Materials and Methods

Using the INFOOT USB system, made up of the 3D scanner and the dedicated MEASURE 2.8 software, as a result of foot shape scanning and placement of anatomical points on the surface of the scanned foot shape, values for a set of 20 anthropometric parameters, lengths, widths, girths and angles were determined (Table 1) [1].

Table 1: Anthropometric parameters of the foot

1.	Foot length	Lp	(mm)
2.	Ball girth circumference	Pd	(mm)
3.	Foot breadth	Id	(mm)
4.	Instep circumference	Pr	(mm)
5.	Heel breadth	Ic	(mm)
6.	Instep length	Lr	(mm)
7.	Toe height	Hd	(mm)
8.	Instep height	Hr	(mm)
9.	Toe 1 angle	Ud1	(°)
10.	Toe 5 angle	Ud5	(°)
11.	Toe 1 height	Hd1	(mm)
12.	Toe 5 height	Hd5	(mm)
13.	Height of navicular	Hn	(mm)
14.	Height of Sphyrion fibulare	Hsf	(mm)
15.	Height of Sphyrion	Hs	(mm)
16.	Height of the most lateral point of lateral malleolus	Hme	(mm)
17.	Height of the most medial point of medial malleolus	Hmi	(mm)
18.	Heel angle	Uc	(°)
19.	Heel girth	Pc	(mm)
20.	Ankle girth	Pg	(mm)

Anthropometric footprints obtained using the INFOOT USB system were statistically analyzed using the SPSS software package, which is a package dedicated to statistical data processing, making it easy to obtain the desired results quickly. Anthropometric data collected by 3D scanning of the left and right foot were grouped into four samples (South, East, Centre-West and Total) and then statistical indicators of characterization (arithmetic mean and standard deviation) and statistical indicators of variation (minimum and maximum value, amplitude and coefficient of variation) were calculated for each variational sequence of the 20 anthropometric parameters studied. Regressions and correlations were established between parameters of the analyzed samples: statistical dependencies, simple linear correlations, simple non-linear correlations, multiple linear correlations.

Subjects

Anthropometric studies were conducted on a sample of 300 male subjects from three geographic regions of Romania: Dobrogea, Oltenia and Muntenia - South (100 subjects), Moldavia and Bucovina - East (100 subjects) and Transylvania and Banat - Centre and West (100 subjects). Subjects with particular anthropometric features, including deformities and structural abnormalities of the foot, were excluded.

RESULTS AND DISCUSSIONS

Simple Correlations (between Two Variables) to Characterize the Interdependence of Anthropometric Parameters

The intensity of dependence between two random variables, namely the analyzed anthropometric parameters, is quantitatively expressed by the coefficient of correlation, r_{xy} [2, 3]:

$$r_{yx} = \frac{\sum_{i=1}^{n}(x_i - \bar{x})(y_i - \bar{y})}{n S_x S_y} \qquad (1)$$

where:

$(x_i - \bar{x})$ si $(y_i - \bar{y})$ - deviations of particular values of variables from the average;

$S_x S_y$ - mean squared deviations of variables;

n – selection volume.

Values of coefficients of correlation between the studied anthropometric parameters are presented in Table 2. Coefficient of variation r_{yx} varies in the range between -1 and +1 (Figure 1). If r_{yx} is in the range (0,1) then dependence between variables is direct and if r_{yx} is in the range (-1,0) then the connection between variables is reversed.

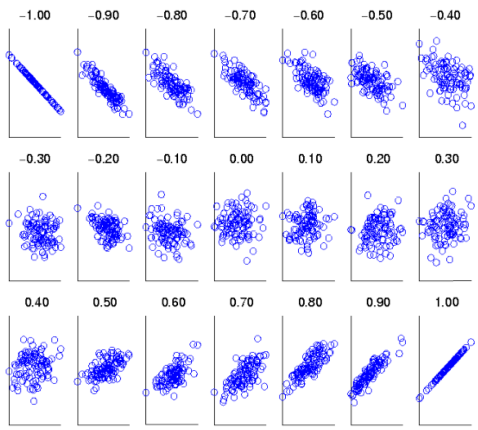

Figure 1. Graphic representation of correlations for r_{yx} from -1 to +1

Table 2: Matrix of values of coefficients of correlations between anthropometric parameters

	Lp	Pd	ld	Pr	lc	Lr	Hd	Hr	Ud1	Ud5	Hd1	Hd5	Hn	Hsf	Hs	Hme	Hmi	Uc	Pc	Pg
Lp	1.000																			
Pd	0.762	1.000																		
ld	0.651	0.966	1.000																	
Pr	0.529	0.827	0.745	1.000																
lc	0.506	0.622	0.608	0.590	1.000															
Lr	0.939	0.625	0.638	0.468	0.445	1.000														
Hd	0.866	0.507	0.492	0.455	0.454	0.813	1.000													
Hr	0.254	0.609	0.414	0.701	0.450	0.136	0.222	1.000												
Ud1	0.003	0.070	0.160	-0.033	0.017	0.023	-0.108	-0.168	1.000											
Ud5	0.009	0.297	0.329	0.266	0.089	-0.069	0.051	0.176	-0.061	1.000										
Hd1	0.254	0.440	0.315	0.493	0.462	0.203	0.280	0.633	-0.117	0.008	1.000									
Hd5	0.266	0.453	0.443	0.405	0.442	0.229	0.236	0.352	0.219	0.147	0.479	1.000								
Hn	-0.066	0.107	0.025	0.175	0.130	-0.141	0.048	0.431	-0.022	0.078	0.385	0.212	1.000							
Hsf	0.373	0.388	0.302	0.386	0.159	0.381	0.378	0.427	-0.154	0.088	0.310	0.062	0.303	1.000						
Hs	0.419	0.405	0.325	0.318	0.159	0.419	0.429	0.380	-0.152	0.042	0.203	-0.072	0.278	0.824	1.000					
Hme	0.458	0.438	0.358	0.403	0.210	0.453	0.445	0.426	-0.120	0.072	0.297	0.040	0.292	0.954	0.839	1.000				
Hmi	0.481	0.458	0.380	0.366	0.193	0.466	0.476	0.402	-0.140	0.077	0.209	-0.051	0.237	0.826	0.973	0.870	1.000			
Uc	0.124	0.041	0.091	0.023	-0.111	0.123	-0.070	-0.208	0.040	0.031	-0.193	-0.082	-0.184	0.128	0.006	0.111	0.028	1.000		
Pc	0.775	0.767	0.696	0.760	0.753	0.699	0.744	0.628	0.000	0.113	0.493	0.455	0.206	0.401	0.401	0.463	0.453	-0.137	1.000	
Pg	0.693	0.658	0.581	0.703	0.587	0.616	0.671	0.592	0.050	0.090	0.474	0.400	0.227	0.323	0.319	0.391	0.381	-0.172	0.897	1.000

Interpretation of coefficients of correlations:

r_{xy}=0.2-0.4 – Very low correlation - Orange

r_{xy}=0.4-0.7 – Low correlation - Green

r_{xy}=0.7-0.9 – High correlation - Blue

r_{xy}=0.9-1 – Very high correlation - Yellow

Linear correlations are described by the following regression equation [3-5]:

$$y=b0+b1*x \qquad (2)$$

Where:

x – independent variable;

y – value of the dependent variable calculated by means of reaction equation;

b_1, b_0 – coefficients of the regression equation.

Simple linear regression equations were determined for the pairs of anthropometric parameters characterized by the coefficients of correlation higher than 0.7 (strong and very strong correlation) and are presented in Table 3, and for exemplification, the graphic form of these equations is represented in Figures 2-15.

Table 3: Linear regression equations

No.	Correlated variables y=f(x)	R^2	Coefficients of equation b_0	b_1
1.	Id=f(Pd)	0.934	-1.864	0.416
2.	Id=f(Pr)	0.555	32	0.284
3.	Lr=f(Lp)	0.882	0.446	0.715
4.	Pd= f(Lp)	0.437	82.25	0.668
5.	Pc=f(Lp)	0.600	91.06	0.957
6.	Hd=f(Lp)	0.749	20.09	0.556
7.	Pr=f(Pd)	0.683	19.51	0.933
8.	Pc=f(Pd)	0.587	102.5	0.936
9.	Hr=f(Pr)	0.491	2.343	0.166
10.	Pc=f(Pr)	0.577	130.6	0.822
11.	Ic=f(Pc)	0.567	6.148	0.183
12.	Hd=f(Pc)	0.553	34.45	0.387
13.	Pg=f(Pr)	0.494	90.80	0.710
14.	Pg=f(Pc)	0.804	-12.6	0.836

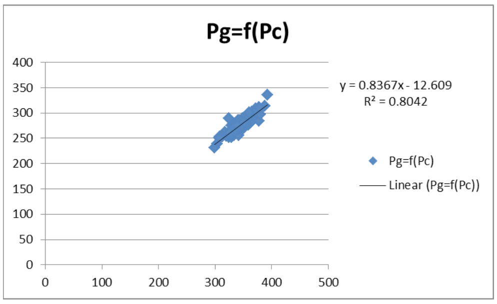

Figure 2. Graphic representation of the simple linear regression equation for correlated variables Pg and Pc

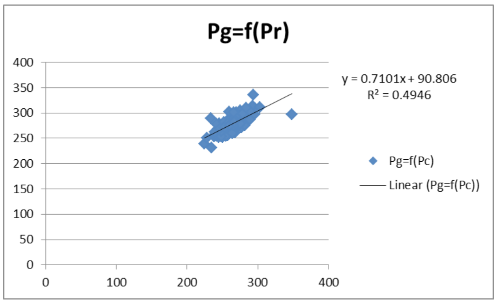

Figure 3. Graphic representation of the simple linear regression equation for correlated variables Pg and Pr

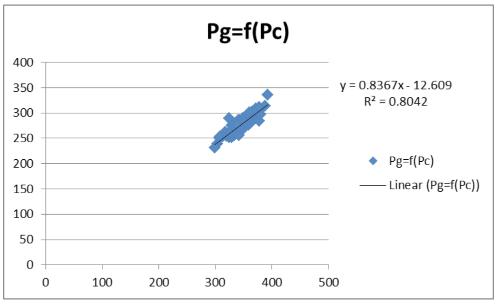

Figure 4. Graphic representation of the simple linear regression equation for correlated variables Hd and Pc

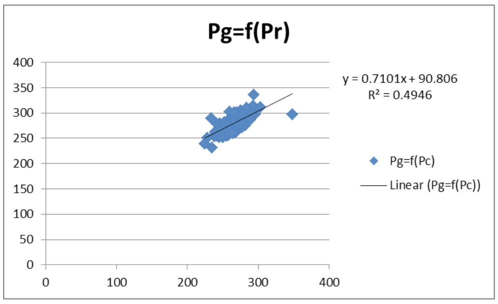

Figure 5. Graphic representation of the simple linear regression equation for correlated variables lc and Pc

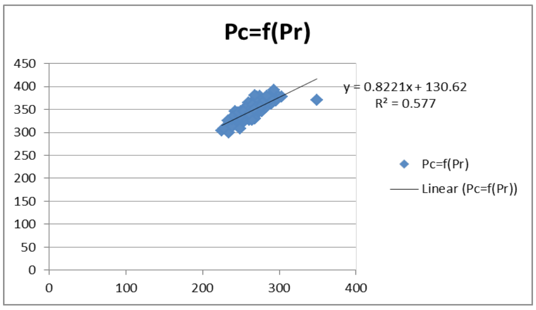

Figure 6. Graphic representation of the simple linear regression equation for correlated variables Pc and Pr

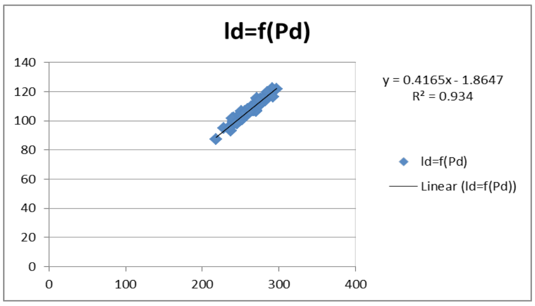

Figure 7. Graphic representation of the simple linear regression equation for correlated variables ld and Pd

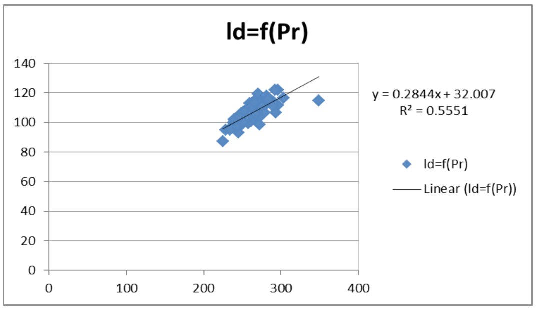

Figure 8. Graphic representation of the simple linear regression equation for correlated variables ld and Pr

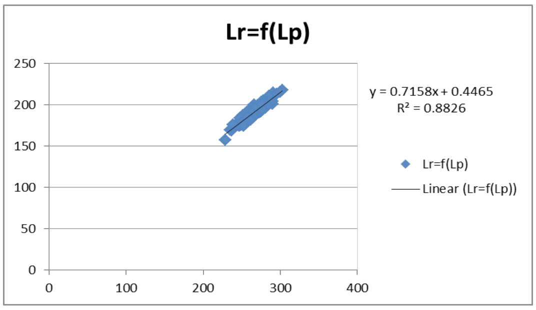

Figure 9. Graphic representation of the simple linear regression equation for correlated variables Lr and Lp

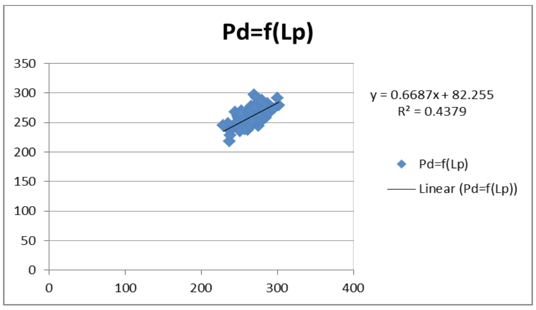

Figure 10. Graphic representation of the simple linear regression equation for correlated variables Pd and Lp

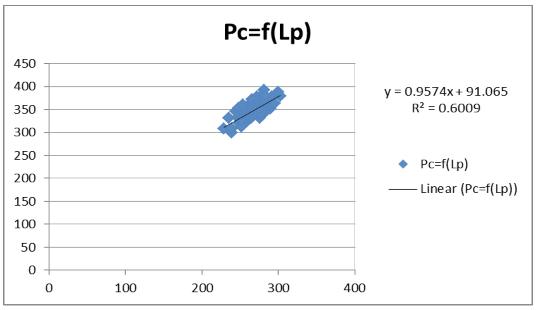

Figure 11. Graphic representation of the simple linear regression equation for correlated variables Pc and Lp

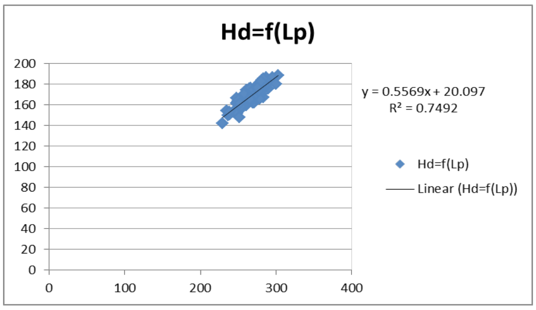

Figure 12. Graphic representation of the simple linear regression equation for correlated variables Hd and Lp

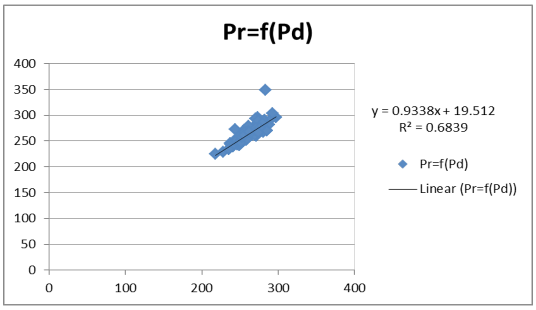

Figure 13. Graphic representation of the simple linear regression equation for correlated variables Pr and Pd

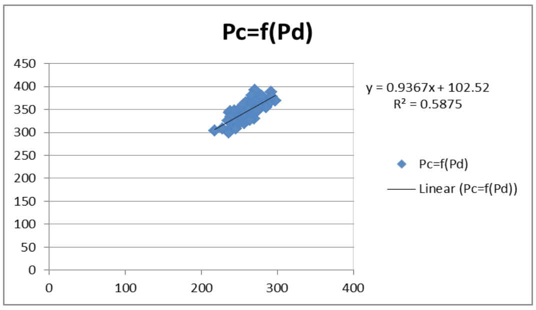

Figure 14. Graphic representation of the simple linear regression equation for correlated variables Pc and Pd

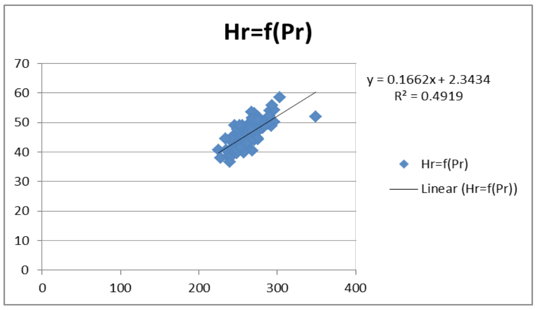

Figure 15. Graphic representation of the simple linear regression equation for correlated variables Hr and Pr

Multiple Correlations (among Three Variables) to Characterize the Interdependence of Anthropometric Parameters

Intensity of correlation among three variables is represented by the coefficient of multiple correlation R_{yx1x2} [2-4]:

$$R_{yx1x2} = \sqrt{\frac{r_{yx1}^2 + r_{yx2}^2 - 2r_{yx1}r_{yx2}r_{x1x2}}{1 - r_{x1x2}^2}} \quad (3)$$

Table 4 exemplifies the intensity among the following anthropometric parameters: Pr with Lp and Pd, ld with Lp and Pd, lc with Lp and Pd. There is a very high correlation of the ld variable with Lp and Pd, represented by the value of the coefficient of correlation R_{yx1x2}>0.9. In the case of the Pr variable depening on Lp and Pd and lc variable depending on Lp with Pd, correlations are high, 0.7<R_{yx1x2}<0.9.

Table 4: Values of simple and multiple coefficients of correlation

Anthropometric parameter	r_{yx1} Lp=x_1	r_{yx2} Pd=x_2	R_{yx1x2}
Pr= f(Lp, Pd)	0.602	0.765	0.832
ld=f(Lp, Pd)	0.545	0.928	0.915
lc= f(Lp, Pd)	0.654	0.755	0.789

CONCLUSIONS

- In order to characterize the dependence between two pairs of anthropometric parameters, the simple and multiple linear correlation was verified. For the simple correlation, coefficients of correlation r_{xy} were calculated, and the resulting values were compared with the values presented in the literature to characterize the type of correlation, namely:
  - r_{xy}=0.2-0.4 – Very low correlation
  - r_{xy}=0.4-0.7 – Low correlation
  - r_{xy}=0.7-0.9 – High correlation
  - r_{xy}=0.9-1 – Very high correlation

This analysis proved the existence of high and very high correlations, as follows:

- **Very high** correlations are obtained for the following groups of parameters: ld and Pd (r_{xy}=0.966), Lr and Lp (r_{xy}=0.939), Hme and Hsf (r_{xy}=0.954), Hmi and Hs (r_{xy}=0.973)
- **High** correlations are obtained for Lp and Pd (r_{xy}=0.762), Pr and Pd (r_{xy}=0.827), Pr and ld (r_{xy}=0.745), Hd and Lp (r_{xy}=0.866), Hr and Pr (r_{xy}=0.701), Pc and Lp (r_{xy}=0.775), Pc and Pd (r_{xy}=0.767), Pc and Pr (r_{xy}=0.760), Pc and lc (r_{xy}=0.753), Pc and Hd (r_{xy}=0.744), Pg and Pr (r_{xy}=0.703), Pg and Pc (r_{xy}=0.897).

- Simple linear regression equations were determined for the pairs of anthropometric parameters characterized by coefficients of correlation higher than 0.7 (strong and very strong correlations). Of all pairs tested, very strong linear dependences are found, described by the following relationships: ld=f(Pd), ld=f(Pr), Lr=f(Lp), Pd=f(Lp), Pc=f(Lp), Hd=f(Lp), Pr=f(Pd), Pc=f(Pd), Hr=f(Pr), Pc=f(Pr), lc=f(Pc), Hd=f(Pc), Pg=f(Pr). Linear regression equations (Y=f(x), Y=b0+b1*X) may be used in designing lasts to establish dependences among geometric parameters of the last in close connection with the laws of variation of anthropometric parameters of the foot.

- Establishing multiple linear correlations proved that there is a very high correlation of the ld variable (foot breadth) with Lp (foot length) and Pd (ball girth circumference) (ld=f(Lp, Pd), represented by the value of the coefficient of correlation R_{yx}1x2>0.9. In the case of variable Pr (instep circumference) depending on Lp (foot length) and Pd (ball girth circumference) (Pr=f(Lp, Pd) and lc variable (heel breadth) depending on Lp (foot length) and Pd (ball girth circumference) (lc=f(Lp, Pd)), correlations are high, 0.7<R_{yx}1x2<0.9.

Acknowledgements

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STUDY ON THE EFFECT OF RUBBER SOLE ON PRESSURE CHANGE OF FOOT MOVEMENT

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STUDY ON THE EFFECT OF RUBBER SOLE ON PRESSURE CHANGE OF FOOT MOVEMENT

ABSTRACT. With the progress of the times, more and more people are participating in sports to keep fit, which increased the demand and requirement on sport shoes, especially on their protection performance and shock absorption performance. The material and distribution of the rubber sole of sneakers often determine their quality and performance. This paper aims to analyze the performance of rubber sole and the pressure change of foot movement so as to provide reference for the design of sports shoes with excellent shock absorbing performance.
KEY WORDS: rubber sole, foot movement, pressure, change

STUDIU PRIVIND INFLUENȚA TĂLPILOR DIN CAUCIUC ASUPRA MODIFICĂRII PRESIUNII LA MIȘCAREA PICIORULUI

REZUMAT. Odată cu trecerea timpului, tot mai mulți oameni fac sport pentru a se menține în formă, ceea ce a dus la creșterea cererii de încălțăminte sport, precum și la exigența cerințelor, în special în ceea ce privește gradul de protecție conferit și capacitatea de absorbție a șocurilor. Materialul și distribuția tălpilor de cauciuc al încălțămintei sport determină adesea calitatea și performanța acesteia. Lucrarea urmărește să analizeze performanța tălpilor din cauciuc și modificarea presiunii la mișcarea piciorului astfel încât să ofere o referință pentru proiectarea încălțămintei sport cu performanțe excelente în absorbția șocurilor.
CUVINTE CHEIE: talpă din cauciuc, mișcarea piciorului, presiune, modificare

ÉTUDE SUR L’EFFET DE LA SEMELLE EN CAOUTCHOUC SUR LE CHANGEMENT DE PRESSION AU MOUVEMENT DU PIED

RÉSUMÉ. Au fil du temps, de plus en plus de personnes font du sport pour rester en forme, ce qui a entraîné une demande accrue de chaussures de sport et des exigences élevées, notamment en ce qui concerne le degré de protection et la capacité d’absorption des chocs. Le matériau et la distribution des semelles en caoutchouc déterminent souvent la qualité et la performance des chaussures. Cet article vise à analyser la performance des semelles en caoutchouc et le changement de la pression au mouvement du pied afin de fournir une référence pour la conception de la chaussure sport avec une excellente performance d’absorption des chocs.
MOTS CLÉS: semelle en caoutchouc, mouvement du pied, pression, changement

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INTRODUCTION

With the progress of science and technology, shoe-making technology has been greatly improved and people have put more emphasis on the performance of sports shoes. How to design sports shoes which can improve foot movement efficiency has become one of the key points in the research of the sports shoe manufacturing industry. By analyzing the foot pressure characteristics of the athletes in the walking race, Chinese scholar K.K. Wang found that functional insoles could reduce the risk of injury [1]. Chinese scholar W.J. Fu *et al*. discovered that there was little difference between the tibial acceleration peak value and the maximum pressure distribution in cement and grassland [2]. By measuring the pressure distribution and slippage of the shoe sole, Y. Yoshioka *et al*. [3] revealed the behavior of the sole during walking. Foreign scholar F.T. Tang *et al*. concluded that TCIFMP insoles were an effective corrective device that could be used for hind limb motion control, plantar stress relief and redistribution of elastic flat foot patients [4]. In this paper, sports foot sole pressure tests were carried out on both EVA rubber material soles and latex rubber material soles. By analyzing the stress condition of the two materials, the cushioning effect of the rubber soles was proved, which provided reference for the design of rubber sole shoes.

Rubber Material for Shoes

As China's natural rubber yield is small, synthetic rubber raw material [5] is often used to produce shoes, which has developed rapidly in recent years, with high level and large production scale. The successful application of synthetic rubber in the footwear industry makes up for the problem of China's lack of natural rubber production and broadens the application of rubber footwear. Synthetic resins including polystyrene (HS), ethylene/vinyl acetate (EVA) and thermoplastic elastomer (SBS) have also been widely used in rubber shoes [6], which further improved the performance and process adaptability of rubber shoes. Table 1 shows the applications and functions of synthetic rubber and resin main material.

Table 1: Applications and functions of synthetic rubber and resin main material

Material category	Material name	Application	Function
Synthetic rubber	SBR latex	Used with natural latex	Improve the stickiness of uppers of shoes
	Isoprene rubber	Used for the production of transparent soles	Match with high-end fashion shoes
	Methylpolybutadiene	With good slip resistance performance, suitable for use in rain shoes.	Improve the skid resistance performance
Synthetic resin	High styrene	Used in the glue or latex of rubber shoes	Used in primer or mortar, to improve the stickiness of shoes
	EVA	Largely used in midsoles	Used as the outsoles of rubber sandals and USB sports shoes

As rubber materials are increasingly applied in the shoemaking industry, the requirements on the performance of rubber materials are becoming more and more specific. The new development direction of rubber materials covers the following aspects: firstly, the weight of rubber materials should be reduced to make shoes lighter. The human engineering study [7] showed that every 1 gram increase in shoe weight can result in 6 gram load on the human foot. Secondly, the density of rubber materials should be decreased to lower the material hardness and increase flexibility so that shoe soles can better stand the bending force during movement and breakage can be avoided [8]. Thirdly, the rubber materials should have high plasticity, stretchability and abrasion resistance performance. Fourthly, the rubber materials should have artistic, anti-bacterial and durable characteristics. In the future, the shoemaking industry will have higher requirements on the performance of rubber materials [9]. Besides, composite rubber and related ancillary additive research will be accelerated.

MATERIALS - PREPARATION OF RUBBER MATERIAL SOLES

Main Raw Materials

Raw material 1: natural rubber (NR), ethylene-vinyl acetate copolymer (EVA) (with 18% of VA content), tetramethylthiuram disulfide (accelerator), bis-benzenesulfide (blowing agent).

Raw material 2: natural rubber (NR), styrene-butadiene rubber (SBR), stearic acid, sulfur monobenzenesulfide.

The Main Equipment

The main equipment is as follows: two-roll mixer, curing device, open mill [10], flat vulcanizing machine.

Preparation Process

Preparation of EVA - Rubber Foam Materials

Firstly, thin-passing was performed six times on natural rubber and ethylene-vinyl acetate copolymer. Then, white carbon black was added for plastication and mixing, followed by the addition of tetramethylthiuram disulfide. After the mixing, zipper pulls and cutting were performed on an open mill and then moulding foaming was carried out on a flat vulcanizing apparatus [11] to obtain the final EVA-rubber foam materials.

Preparation of High Wear-Resistant Foam Rubber Materials

First of all, a certain proportion of natural rubber (NR), styrene-butadiene rubber (SBR), stearic acid, foaming agent and abrasion agent were selected. After the natural rubber was plasticated, it was mixed with butadiene styrene rubber to form the sizing material, which was then batched off and placed at room temperature for 24 hours. After the above steps, the sizing material was added into an internal mixer, added with stearic acid and urea. After the machine was rechecked, the sizing material was discharged and placed in the open mill for hot refining so as to be processed into the shape of the sports soles. Then, after natural cooling, rough selvedge was cut to obtain the high wear-resistant foam rubber materials.

METHODS - FOOT PRESSURE TEST ON THE RUBBER SHOES

Research Objects

In this study, ten male college students were selected as subjects, with the BMI index between the normal male range of 20-25 (age: 23 years old; height: 173-178 cm; weight: 68-73 kg). The inclusion criteria for the subjects are as follows: love sports, with no foot deformity or injuries. Besides, the subjects kept good body conditions within 24 hours before the test to ensure the normal activity of the foot joints.

Test Equipment

Table 2 shows the test equipment applied in this study.

Table 2: Test equipment

Equipment	Function
Foot gauge (Deji Shoe Material Company)	To measure the foot size of the subjects and set the size of the test shoes to be 42 yards
Thickness gauge (Hongmao Instrument Equipment Co., Ltd.)	To measure the thickness of the shoes
Hardmeter (Shanghai Caichen Precision Instrument Co., Ltd.)	To measure the hardness of the shoes
Flat-plate pressure test instrument (Beijing Dimei de'er Technology Co., Ltd.)	To measure the distribution of foot and ground pressure
Insole type foot pressure tester (Shenzhen Yijie Instrument Co., Ltd.)	To measure the distribution of foot and upper pressure

Four pairs of test shoes E, F, G, and H were made by a shoe factory, with soft soles made of EVA foam rubber material [12], hard soles made of EVA foam rubber material, soft soles made of high wear-resistant foam rubber material and hard soles made of high wear-resistant foam rubber material [13] respectively, which were similar in sole and upper structure and weight, thereby ensuring the accuracy of the test.

Foot Pressure Test

The test was completed in the Sports Biomechanics Laboratory, whose ground was decorated with tiles, which avoided the influence of ground deformation changes. Meanwhile, the lab temperature was controlled between 20-24°C, with the humidity kept at 20%-40%. Firstly the 10 subjects did warm up exercises before wearing the test equipment. After they wore the shoes, they walked, jogged and jumped with a constant speed. The walking speed was controlled at around 1 m/s while the jogging speed was kept around 1.5 m/s to ensure the validity of the experimental data. In addition, the height of the stool in the jumping test was unified to be 45 cm.

Purpose

In this study, the insole type foot pressure distribution measurement system was applied to measure the foot pressure of the subjects during walking, jogging and jumping. By comparing the parameters such as peak pressure and pressure-time product values, the cushioning effects of different rubber materials were compared.

Requirements

The subjects chose the 41 yard insoles and did some adaptive training before the test [14] while the test system was calibrated. After replacing the test shoes, the measurement system was cleared in time to ensure the accuracy of the data. Besides, the position of the insole in the sports shoe was fixed to avoid errors caused by insole sliding.

RESULTS AND DISCUSSION

With the insole type foot pressure distribution measurement system, the foot pressure peak values of the subjects during the three motion tests under bare feet conditions and wearing the test shoes were measured. By analyzing the average pressure of the left and right foot under the standing state, it was concluded that the pressure of the left foot was smaller than that of the right foot. Therefore, the data of the right foot was taken as the experimental data.

Analysis of Plantar Pressure

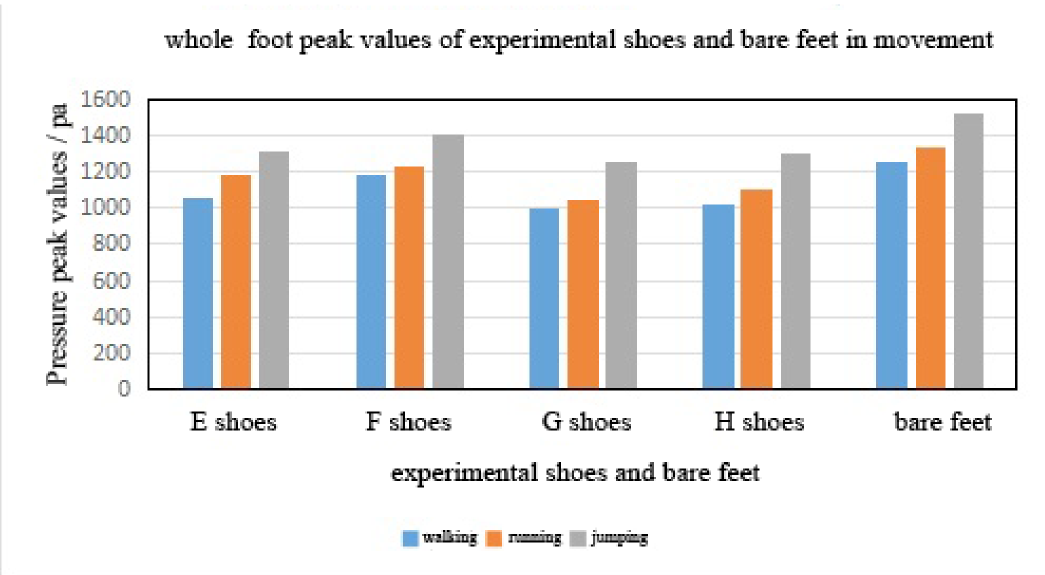

Figure 1. Whole foot peak values of experimental shoes and bare feet in movement

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As shown in figure 1, the pressure peak values wearing the test shoes were smaller than those in bare feet conditions, suggesting that the test shoes reduced the pressure on the subjects to some extent, playing a cushioning effect. The comprehensive foot pressure values of the four pairs of test shoes in walking, jogging and jumping were ranked as F>E>H>G. Suppose that the stress was the same, then smaller pressure peak values suggested greater action areas, i.e., the compactness between the feet and the shoes was high and stress distribution was dispersed, from which the cushioning effect of the shoes could be judged to be good. The ranking of the cushioning effect of the four pairs of test shoes was as follows: G>H>E>F.

Foot Pressure • Time Product Analysis

Figure 2 shows the product values of foot pressure peak values and time of the four pairs of test shoes during the three movements, which were calculated according to the following equation:

$$\text{Product value} = \text{pressure} \bullet \text{time} = \frac{F}{S}$$

(F: pressure; t: time; S: force area) (1)

The product values could reflect the size of the subject's work wearing the test shoes during movements, which were ranked as F>E>H>G, suggesting that G shoes were most helpful to the subjects, which improved the movement efficiency of the subjects, followed by E shoes and H shoes, while F shoes could cause injuries to the feet of the subjects.

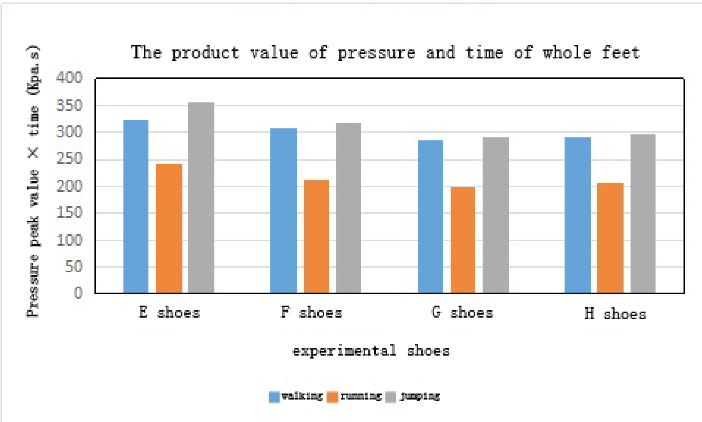

Figure 2. Product values of foot pressure peak values and time of the four pairs of test shoes during the three movements

Analysis of the Trajectory of the Sole Pressure Centre

While measuring the pressure peak values, the foot pressure measuring system also formed the foot pressure centre trajectory line, whose bending degree and length reflected the evenness of the force and the time of contact so as to reflect the stability of the shoe soles. As shown in figure 3, F shoes' pressure centre trajectory was the most bending and the shortest; the centre trajectories of G and H shoes were straight and long. Therefore, the stability ranking was as follows: G>H>E>F.

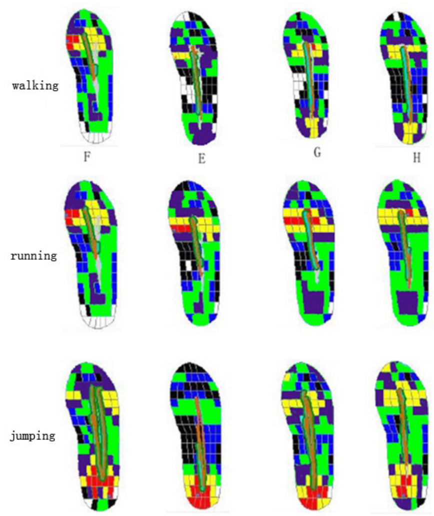

Figure 3. Test shoe foot pressure distribution centre trajectory line

CONCLUSION

Compared with EVA foam rubber soles, high wear-resistant foam rubber soles had more excellent performance and better cushioning effects, which were lighter and more flexible, with smaller density. Soft rubber was more suitable as a material for sports shoe soles because it had a good stretch capacity and could prevent the subjects from injuries during movement. In conclusion, rubber soles could ease the foot pressure to certain extent and the use of rubber material to produce sports soles was an appropriate choice. Nevertheless, since sole structure design, upper design and colour design are all important factors to improve the quality of sports shoes, they need to be further studied in the future.

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PRACTICAL ASPECTS OF IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR THE MEDICAL FOOTWEAR DESIGN

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PRACTICAL ASPECTS OF IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR THE MEDICAL FOOTWEAR DESIGN

ABSTRACT. A quality management system in place and functioning can be certified by a neutral body, third party, that certifies compliance of the design process of the medical footwear to the reference specifications in this field. In states where pedorthics is developed, professional associations provide an accreditation of facilities that are operating in the design and production of pedorthic devices. Another option for conformity certification in the field of medical devices consists in demonstrating that quality management system (QMS) of the organization complies with the requirements of the standard reference in the field, respectively SR EN ISO 13485: 2016 "Medical devices. Quality management systems. Requirements for regulatory purposes". Design work carried out according to the requirements of this standard contributes to the development of medical devices complying with the regulations in this field for the benefit of the patient. This paper aims to present practical aspects of implementing the quality management system requirements for the design of medical footwear, applicable to small and medium companies.

KEY WORDS: medical footwear design, conformity assessment, certification, quality management system

ASPECTE PRACTICE PRIVIND IMPLEMENTAREA CERINŢELOR SISTEMULUI DE MANAGEMENT AL CALITĂŢII ÎN PROIECTAREA ÎNCĂLŢĂMINTEI MEDICALE

REZUMAT. Un sistem de management al calităţii implementat și funcţional poate fi certificat de către un organism neutru, de terţă parte, care atestă conformitatea procesului de proiectare a încălţămintei medicale în raport cu specificaţiile de referinţă din acest domeniu. În statele în care pedorthica este dezvoltată, asociaţiile profesionale oferă un sistem de acreditare al facilităţilor în care se desfășoară activitatea de proiectare și producţie a dispozitivelor medicale specifice. O altă opţiune pentru certificarea conformităţii în domeniul dispozitivelor medicale constă în demonstrarea faptului că Sistemul de Management al Calităţii (SMC) al organizaţiei este conform cu cerinţele standardului de referinţă din domeniu, respectiv SR EN ISO 13485:2016 „Dispozitive medicale. Sisteme de management al calităţii. Cerinţe în scopuri de reglementare". Desfășurarea activităţii de proiectare în raport cu cerinţele acestui standard contribuie la dezvoltarea unor dispozitive medicale conforme cu reglementările din acest domeniu, în beneficiul pacientului. Lucrarea de faţă își propune să prezinte aspecte practice privind implementarea cerinţelor sistemului de management al calităţii în proiectarea încălţămintei medicale, aplicabile în cazul firmelor mici și mijlocii.

CUVINTE CHEIE: proiectarea încălţămintei medicale, evaluarea conformităţii, certificare, managementul calităţii

ASPECTS PRATIQUES DE LA MISE EN ŒUVRE DES EXIGENCES DU SYSTÈME DE GESTION DE LA QUALITÉ DANS LA CONCEPTION DE CHAUSSURES MÉDICALES

RÉSUMÉ. Un système de gestion de la qualité mis en œuvre et fonctionnel peut être certifié par un organisme tiers neutre qui certifie la conformité du processus de conception de chaussures médicales avec les spécifications de référence dans ce domaine. Dans les pays où le domaine de la pedorthics est développé, les associations professionnelles offrent un système d'accréditation des installations dans lesquelles la conception et la production de dispositifs médicaux spécifiques sont effectuées. Une autre option pour la certification de conformité dans le domaine des dispositifs médicaux est de démontrer que le système de gestion de la qualité (SMC) de l'organisation est conforme aux exigences de la norme de l'industrie, SR EN ISO 13485: 2016 "Dispositifs médicaux. Systèmes de gestion de la qualité. Exigences réglementaires". Le développement de l'activité de conception en relation avec les exigences de cette norme contribue au développement de dispositifs médicaux conformes à la réglementation dans ce domaine, au bénéfice du patient. Cet article vise à présenter des aspects pratiques concernant la mise en œuvre des exigences du système de gestion de la qualité dans la conception de chaussures médicales, applicables aux petites et moyennes entreprises.

MOTS-CLÉS: conception de chaussures médicales, évaluation de la conformité, certification, gestion de la qualité

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INTRODUCTION

Aspects of Conformity Assessment through Certification Practice

Certification is defined as third-party attestation, by an accredited neutral body, that a product, process or person conforms to the reference specifications, which can be a standard, a rule or a technical document, and so on [1]. Design work involves preparing a "technical project on a given topic, comprising technical and economic calculations, drawings, instructions, and so on, necessary for the execution of a building, a car, and so on" [2]. Thus, one of the activities of the design process is the "development of specifications" included in SR EN ISO 13485: 2016 "Medical devices. Quality management systems. Requirements for regulatory purposes" [3]. In conformity with SR EN ISO 9000:2015 "Quality management systems – Fundamentals and vocabulary", "design and development" is defined as "a set of processes that transform the requirements for an object into more detailed requirements for attaining that object" [4]. The requirements that form inputs can be expressed in a more general sense than requirements forming the output of the design and development process. Thus, for the process of designing medical footwear, prescription is constituted as an input. The prescription concept implies that the prescription form includes specific design features in accordance with the definition of medical custom-made devices but in reality this does not happen in current practice [5-7].

The solution proposed according to the medical literature was to develop prescription items in the following components:

- medical prescription containing medical objective and functional description,
- technical prescription containing specific design features of the medical device. These characteristics should allow the practical realization (manufacturing) of the medical device.

In this way, the responsibilities and competencies of the interdisciplinary team which should develop the conservative treatment of the foot mechanical pathologies with medical footwear can be defined more clearly.

In Romania the most common certification activity in the field of medical devices is the certification of the organization's quality management system (QMS) in accordance with the requirements of reference in the field, respectively SR EN ISO 13485: 2016 "Medical devices. Quality management systems. Requirements for regulatory purposes".

In states with tradition in designing medical footwear such as USA, the certification is done:

- both at individual level, the specialist being "Certified Pedorthist", who is working in health profession as a paramedical profession, being trained to apply a conservative treatment with medical footwear for a given patient,
- and at the company level, this being applied separately for companies that offer medical services to patients ("Patient Care"), or companies that offer medical devices design/ manufacturing services, or those providing clinical care services.

In these countries professional organizations play a key role in providing certification services. In this respect, the American Board for Certification in Orthotics, Prosthetics & Pedorthics (ABC) can be given as an example of the professional association that provides certification services [8, 9]. According to data published on the website of ABC Association, which is the national accreditation and certification centre in the orthotics, prosthetics and pedorthics field, it has conducted over 13,000 certifications of specialists and over 7,000 accreditations of companies in these sectors since 1948 [8].

A program dedicated to certification of the companies in the pedorthics field is developed by The College of Pedorthics of Canada [9, 10]. Belgium has developed a model of accreditation of care clinics dedicated to foot in which one of the criteria for recognition involves including a footwear technician in the treatment's multidisciplinary team [11]. Data collection and analysis and audits are conducted by an independent organization, Scientific Institute of Public Health (WIV-ISP) [11].

In the absence of specific medical footwear professional organizations, the base reference for certification of the design activities is the standard SR EN ISO 13485: 2016 "Medical devices. Quality management systems. Requirements for regulatory purposes". According to this standard the organization is expected:

- to identify its role in accordance with applicable regulatory requirements;

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- to identify the regulatory requirements that apply to its activities in these roles;

- to implement these applicable regulatory requirements to its quality management system.

Defining the role of the organization has an essential importance because its area of expertise is defined depending on the assumed role.

According to a study based on a "Questionnaire on activities related to prescribing, design and production of therapeutic and orthopedic footwear, and medical devices placed in shoes" [13], in Romania, companies operating in this market since 2001 have an average of 7 employees (a minimum of 2, maximum 17) involved in the design and execution activities of these types of medical devices. Share activities of these companies were as follows: 41.7% - footwear production; 48.8% - orthotic / prosthetic, 0% - recovery of health; 9.5% - other activities (e.g. commercial activities). All companies surveyed said they produce footwear, while 66.7% also conduct orthotic-prosthetic activities. It is noteworthy that in 2017 by accessing the websites of 15 companies producing orthopedic footwear in Romania which are in contractual relations with national insurance agency only two companies were identified that have posted on the website information on the implementation of QMS, one of which has posted online certificates for manufacture and service of custom-made medical devices (SR EN ISO 9001:2008 and SR EN ISO 13485:2012), while the other mentions only "ISO certification" without specifying the standard by which they achieved certification.

Viewed from the perspective of company size and qualification of specialized personnel, implementation of a quality management system can be seen as a time and resource consuming process. This paper presents a way to implement the requirements regarding the medical footwear design activities that can be useful in the management of small companies.

QMS REQUIREMENTS IMPLEMENTATION

The implementation of the quality management system procedures and forms can be made practical through a database that can be obtained in a simplified manner by using an accessible software solution such as Microsoft Excel. The database structure must meet all the requirements of SR EN ISO 13485. These requirements can be grouped into two categories depending on the connection they have with the central activity of custom-made medical devices design, namely:

- "general" requirements regarding the context of the organization, leadership, support, planning, and so on,

- "specialized" requirements that are crucial to the design process such as: operating, performance evaluation, improvement.

To do this, first the initial settings of the system and their way of relating have to be established. Figure 1 presents quality management system processes regarding the design process. This paper focuses on processes with an immediate key role to design processes, namely: the operation, performance assessment and activities improvement.

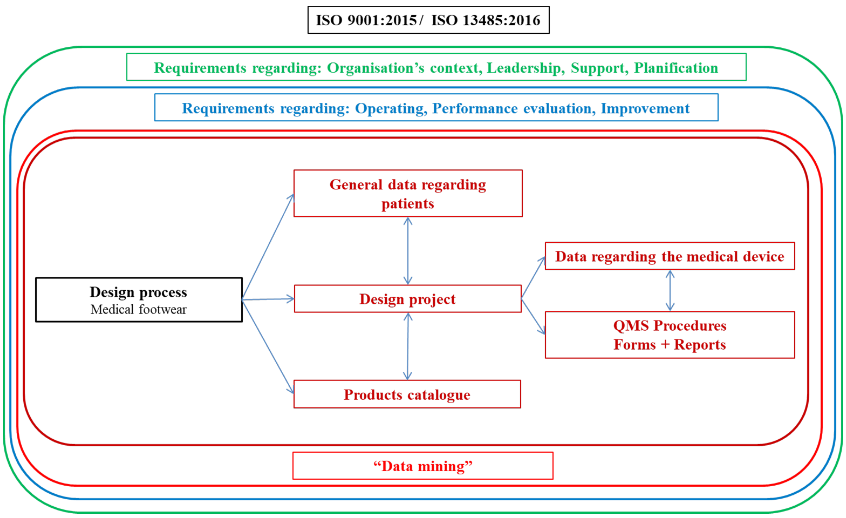

Figure 1. Processes of quality management system

Given the nature and scale of the medical footwear design activities, based on the requirements of ISO 13485: 2016 the following procedures and forms have been documented:

Procedures

1. "Design - development and risk management" procedure, code P-73, establishes the methods used by the function of design and development to ensure compliance to specific design characteristics contained in the medical prescription with the technical specifications of medical device design and risk management related to design.

2. "Storage and control of conformity design" procedure, code P-7511, describes the measures taken on how the design is carried out keeping compliance during internal processing and delivery to the recipient.

3. "Feedback and relationship with the customer" procedure, code P-72, describes the measures taken on how to carry out:

- identification and analysis of design requirements;
- effective communication with customers on information about the design, about the experience of post stage design, supply and demand, contracts and orders, complaints and reminders;
- QMS performance measurement on the customer's perception of the degree to which their requirements were satisfied and analysis of the experience in post design phase.

4. "Identification and traceability" procedure, code P 758-9. The purpose of this procedure is to describe methods and responsibilities that have been taken to identify the design throughout its manufacturing to ensure that the design project returned to the organization is identified and distinguishes from conforming design as well as to identify design progress in relation with requirements for measuring and monitoring. The procedure also describes how extensive traceability and design unique identification are ensured.

5. "Control of nonconforming design" procedure, code P-83, defines operational means and responsibilities provided for control of the design project that did not pass inspections and checks in accordance with the acceptance criteria set out or in case of complaint or requiring notification to third parties, the withdrawal of nonconforming designs. The designs are stored under control to avoid use and/or unintentional delivery.

6. "Corrective and preventive actions / learning from post-design experience" procedure, code P-85, describes the method of determining the real and potential causes of nonconformities, implementing corrective and preventive actions and learning from post-design experience. The procedure also describes the methods and responsibilities taken to determine and treat nonconformities of designs projects, services and to improve the system. The database also meets "Identification and traceability" procedural requirements.

Forms

- "Custom-made medical device design order form", code F1-F2, contains data on the beneficiary of design, the subject of the order and other terms such as design delivery together with the declaration of conformity,
- "Customer requirements data analysis form", code F2-72, determines whether an order is accepted or not based on analysis of requirements including standards and/or methods imposed by client, the existence of the necessary capability and financial conditions or delivery dates required to meet customer requirements,
- "Prescription", code PR. Prescription items were detailed in medical prescription and technical prescription,
- "Analysis and design validation", code F2-73, refers to the evaluation of the analysis, verification and validation processes of the design, specifying references, observations or changes where necessary,
- "Customer Satisfaction Questionnaire", code F3-72, for establishing a customer given rating based on various criteria such as design quality, quality-price ratio, relationship with organization employees, complaint resolution, organization flexibility regarding special customer requirements. Also through this questionnaire the customer is asked to indicate whether he will recommend services to other potential customers,
- "Nonconformity report and corrective/ preventive actions for the design", code F1-

85, contains data about designs relating to internal complaint or learning from post-design experience, the causes for the occurrence of nonconformities, directives issued to remedy the situation and reporting corrections or preventive actions. It determines both whether the design will be reviewed and the effectiveness of corrective and preventive action,

- "Nonconformity report and corrective/ preventive actions for the process", code F2-85, is similar with F1-85 form but refers to the QMS nonconformities.

The forms are annexes of the procedures, used for data collection and are listed in Table 1. All forms are constructed as Excel files so as to allow data analysis at any time. Database construction was based on an Excel file that contains three sheets named "Main", "Data Analysis" and "Menu". Database fields organised according to the procedures described above are:

- "Order" – according to form F1-72,
- "Prescription" – according to form P,
- "Design" – refers to medical device documents and virtual files,
- "Execution stage of design" – describes the execution stage of design,
- "Analysis, verification and validation of design" – according to form F2-73,
- "Customer satisfaction" – displays the rating given on the evaluation questionnaires according to form F3-72,
- "Control of nonconforming design" – according to form F1-85,
- "Nonconformity, corrective action, post-design experience", – according to form F2-85,
- "Virtual catalogue" – contains media of manufactured medical devices.

Table 1: Correspondence between database fields and QMS procedures and forms

No.	Field/ Form	Procedure	Form Code
1	Order	Feedback and customer relationship	F1-72 F2-72
2	General information on patients	Design and development and risk management	PR
3	Data on medical devices	Design and development and risk management	PR
4	Analysis, verification and validation of design	Design and development and risk management	F2-73
5	Customer satisfaction / Qualification	Feedback and customer relationship	F3-72
6	Control of nonconforming design	Control of nonconforming design	F1-85
7	Nonconformity, corrective action, post-design experience	Corrective and preventive actions / learning from post-design experience	F2-85

A record in the database corresponds to an order. Data entry was facilitated by using the so-called "drop-down list" which the operator uses to choose an option for a given cell from a list containing all the options defined for the field at a certain time. Thus, by selecting a cell in fields that have such a menu implemented, a specific message is displayed which indicates the action to be taken. For example, by selecting a cell in the "Execution stage of design", the "Choose the design stage" message will be displayed while by selecting the button opening the options list, the selection of design stage is achieved. All the positions corresponding to the above-mentioned fields are defined for a total of 25 records in the "Menu" sheet. Thus, for example, the list of diagnoses contained in the medical prescription can be updated at any time without requiring any changes except for updating the corresponding lists from "Menu" sheet. The "Data analysis" sheet shows the results of database queries made directly using the standard options of the application or by creating subroutines according to analyses that need to be made. This section provides data conforming on other QMS procedures specifications such as "Data Analysis" and "Management analysis" and "Storage and control of conformity design".

Benefits obtained from implementing such a quality management system for the design process through a database are numerous:

- database provides an overview of the inputs, processes and outputs that govern the design,
- allows maintaining system operation through warnings that occur when there is a

nonconformity, such as au unsatisfactory rating given by a patient,

- allows real-time analysis and correlations between the factors involved in the design: medical prescription, technical prescription, patient data, patient feedback, and so on,

- allows data mining and enhancing expertise by learning from post-design experience.

CONCLUSIONS

Implementation and certification of a quality management system in the design activity of custom-made medical devices is a voluntary choice that ensures and enhances the efficiency of the compliance activity of the medical footwear design. Application of standard SR EN ISO 13485: 2016 "Medical devices. Quality management systems. Requirements for regulatory purposes" in companies or departments of companies with a small staff number needs an adaptation of necessary procedures and forms so as to enable implementation of QMS not seen as time and resource consuming. The advantages of implementing such a quality management system justify the effort. Since the implementation of this system is voluntary, the decision on its implementation is essential and it is the responsibility of decision makers.

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COMPARISON OF SHOCK ABSORPTION PERFORMANCE OF BASKETBALL SHOE WITH DIFFERENT SOLE STRUCTURES

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COMPARISON OF SHOCK ABSORPTION PERFORMANCE OF BASKETBALL SHOE WITH DIFFERENT SOLE STRUCTURES

ABSTRACT. Basketball is a sport with high popularity, and it requires high on shoes. In violent experience, feet may be heavily impacted, which may cause damages to joints and nerves. Therefore, feet need the protection and shock absorption of basketball shoes. Today material science develops rapidly; the shock absorption system of basketball shoes is usually borne by the shock absorption property of shoe sole material. In recent years, the special design of basketball shoe sole structure has been a new approach to reduce shock. This study investigated the changes of impulse and pressure of sports shoes with different sole structures during sports through experiments, with the intention of providing a reference for the design and improvement of shock absorption sole of basketball shoes.

KEY WORDS: basketball shoes, sole structure, shock absorption, plantar pressure

COMPARAREA PERFORMANȚEI DE ABSORBȚIE A ȘOCURILOR A ÎNCĂLȚĂMINTEI PENTRU BASCHET CU DIFERITE STRUCTURI ALE TĂLPII

REZUMAT. Baschetul este un sport foarte popular, iar cerințele încălțămintei sunt exigente. În urma unei mișcări violente, picioarele pot fi puternic afectate, întâlnindu-se leziuni ale articulațiilor și nervilor. Prin urmare, picioarele au nevoie de protecția și absorbția șocurilor oferite de încălțămintea pentru baschet. Astăzi știința materialelor se dezvoltă rapid. Sistemul de absorbție a șocurilor din încălțămintea pentru baschet constă, de obicei, în proprietatea de absorbție a șocului a materialului din care este confecționată talpa încălțămintei. În ultimii ani, a existat o nouă abordare în designul încălțămintei pentru baschet pentru reducerea șocului. Acest studiu investighează modificările de impuls și presiune ale pantofilor sport cu diferite structuri ale tălpii, cu intenția de a oferi o referință pentru proiectarea pantofilor pentru baschet și îmbunătățirea absorbției șocurilor.

CUVINTE CHEIE: încălțăminte pentru baschet, structură talpă, absorbția șocurilor, presiune plantară

COMPARAISON DE LA PERFORMANCE D'ABSORPTION DES CHOCS DE LA CHAUSSURE DE BASKET-BALL AVEC DES SEMELLES AUX STRUCTURES DIFFÉRENTES

RÉSUMÉ. Le basket-ball est un sport très populaire, et les exigences de la chaussure sont élevées. Après un mouvement violent, les pieds peuvent être gravement atteints, avec des lésions au niveau des articulations et des nerves. Par conséquent, les pieds ont besoin de la protection et de l'absorption des chocs fournis par les chaussures de basket-ball. Aujourd'hui la science des matériaux se développe rapidement. Le système d'absorption des chocs des chaussures de basket-ball consiste en la propriété d'absorption des chocs du matériau à partir duquel la semelle de la chaussure est fabriquée. Ces dernières années, il y a eu une nouvelle approche de la conception de chaussures de basket-ball pour réduire le choc. Cette étude analyse les changements de pression et d'impulsion des chaussures de sport à semelles différentes, avec l'intention de fournir une référence pour la conception de chaussures de basket-ball et l'amélioration de l'absorption des chocs.

MOTS CLÉS: chaussures de basket-ball, structure de la semelle, absorption des chocs, pression plantaire

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INTRODUCTION

Basketball shoes usually have a protective effect. Shock absorption is a core part of the protective effect of basketball shoes. The shock absorption sole and structure of basketball shoes is always the key point in relevant studies of shoes manufacturing industry. Xu, W.Q. *et al*. [1] obtained the maximum deformation of the forefoot and heel of basketball shoes under load, which provided a reference for the shock absorption design of basketball shoes. Isobe, M. *et al*. [2] quantitatively investigated the effects of outer sole structure on mechanical property through controlling the design of running shoe sole by FEM computer simulation. Iwasa, Y. *et al*. [3] developed an evaluation method for shock attenuation of shoe sole during landing from a drop jump and found that the main area attenuating the landing force by its compressive deformation in drop jump was the rearfoot of shoe sole; however, the shock attenuation property could be affected by the hardness of the forefoot area if the mechanical conditions of the rear foot area were the same. This study analyzed the impulse and plantar pressure of two materials and verified the shock absorption effect of the soles of the three pairs of basketball shoes by performing plantar pressure test on ANTA core technology based basketball shoes, NIKE air cushion based basketball shoes and shock absorption sole technology based basketball shoes, which provided some suggestions for the manufacture of running shoe soles with shock absorption structure.

Structure of Basketball Shoe Sole

Basketball shoes are usually composed of upper and sole, and sole is an important part for shock absorption of basketball shoes [4]. Structural shock absorption which emerged in recent years is quite popular. The famous sole structural shock absorption technologies include Nike air cushion technology, ANTA core structure technology and Lining arc structure technology. Following was the introduction of the characteristics of ANTA core technology and Nike cushion technology.

ANTA A-shock core technology is shown in Figure 1. As shown in figure 1, it is the latest core technology of ANTA; a piece of highly elastic core material is placed at the heel of the basketball shoes to simulate trampoline to support feet.

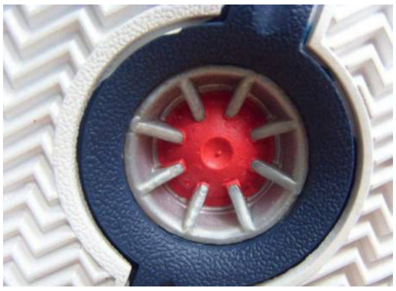

Figure 1. ANTA core technology

Nike air zoom [5] is shown in figure 2. Air zoom is a cushion with an air pressure of 20 PSI and a thickness of 4~8 mm. The air cushion has excellent rebound performance; hence it has excellent shock absorption and energy regeneration performance.

Figure 2. Nike air cushion technology

MATERIALS - PREPARATION OF SOLE WITH SUSPENDED SHOCK ABSORPTION STRUCTURE

Suspended Shock Absorption Structure

A suspended shock absorption sole was developed. Three layers of the sole was suspension layer, support layer and skid resistance layer from top to bottom.

The suspension layer was formed by injecting ordinary thermoplastic polyurethane (TPU) [6]. The central part was hollowed out, and then 16 cavities were dug and filled with elastic spheres. In addition, the support layer was mainly made from corn starch/ethylene-vinyl acetate (EVA) composite material. Sixteen spheres with good elasticity which were loosely jointed to be an integral whole penetrated the cavities in the suspension layer and closely adhered to the

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surface of the suspension layer; there was a 2-mm interspace. A shock absorption structure formed based on the rebound and recovery performance of the elastic sphere, which could effectively relieve the momentum and pressure of feet.

The skid resistance layer was mainly composed of natural rubber. It was connected to the distortion-proof layer on the lower surface of the suspension layer. X-shaped anti-skid slot was designed on the layer to increase skid resistance [7].

Manufacturing of Sole Material

Main Raw Materials and Instruments

The main raw materials included food-grade corn starch, talcum powder, EVA, ethyl acetoacetate (solubilizer), polyolefin elastomer (POE), urea (foaming agent) and dicumyl peroxide (DCP).

The main instruments included electronic balance, electronic thermal constant temperature blast drier, internal mixer, open type plastic purificating set, high-speed mixer [8] and plate vulkameter.

Preparation of Corn Starch/EVA Composite

Firstly EVA was divided into 100 parts by weight. Corn starch was divided into 40 parts. Four-factor and three-level orthogonal experiment was used. POE was represented by E, ethyl acetoacetate by F, and glycerol by H.

Firstly corn starch was dried at 75°C for 24 h using an electrothermal constant-temperature blast drier. After the corn starch was cooled to room temperature, it was mixed with propylene glycol by a high-speed mixer for 10 min. Finally the mixture was sealed and preserved for 45 h.

Smelting test was performed by matching POE, ethyl acetoacetate, talcum powder and glycerol according to Table 1.

Table 1: Different grades for factors

Grade	E/piece	F/piece	G/piece	H/piece
1	10	10	0	5
2	20	20	14	10
3	30	30	28	15

Composite material was prepared. Firstly EVA, POE, ethyl acetoacetate, talcum powder, glycerol, corn starch and other auxiliaries were weighed according to $L_9(3^4)$ orthogonal experiment table [9]. Then they were smelted using an internal mixer for 8 min. The mixed material was taken out when the temperature was between 95°C and 100°C. The mixed material was added into a plastic mixing mill along with DCP and urea for open mill. Foaming was performed when the temperature was between 170°C and 180°C. Finally corn starch/EVA composite was obtained.

The Optimum Performance of the Composite Material

The physical performance test was performed on the materials. The test indicators included hardness, proportion, tensile property, breaking elongation, tearing property and elasticity. The detection instruments included hardmeter, aerometer, resilience testing machine and electronic universal material testing machine.

Table 2: The detection results of physical properties of corn starch/EVA composite prepared by different formulas

Experiment	Formula	Hardness/%	Density/ $g \times m^{-3}$	Tensile strength / MPa	Breaking elongation /%	Tearing strength / kg·cm	Elasticity /%
1	$E_1F_1G_1H_1$	33	0.1023	1.18	233.16	6.94	42
2	$E_1F_2G_2H_2$	46	0.1089	1.25	192.57	10.92	47
3	$E_1F_3G_3H_3$	50	0.1323	1.43	183.49	9.76	45
4	$E_2F_1G_2H_3$	42	0.1125	1.72	224.31	9.11	48
5	$E_2F_2G_3H_1$	41	0.1097	1.51	193.46	8.49	46
6	$E_2F_3G_1H_2$	37	0.1064	2.36	272.13	9.42	53

7	$E_3F_1G_3H_2$	38	0.1148	1.43	176.81	8.02	48
8	$E_3F_2G_1H_3$	44	0.1139	2.55	291.76	9.89	59
9	$E_3F_3G_2H_1$	41	0.1002	1.94	277.36	12.21	51

The detection results of the performance are shown in Table 2. The composite prepared in experiment 8 had the best comprehensive mechanical performance and its tensile strength, breaking elongation and elasticity were 2.55 MPa, 291.76% and 59% respectively. It indicated that corn starch/EVA composite prepared in experiment 8 had the excellent plasticity and elasticity. Corn starch/EVA composite and suspension shock absorption structure were used in the manufacturing of sole of shoes A in the following test.

TEST SUBJECTS AND METHODS

Comparison Experiment on the Shock Absorption Performance of Basketball Shoes with Four Different Sole Structures

Research Subjects

Ten male university students who were willing to join the test were selected as the research subjects. They were all 23 years old, were 173 ~ 178 cm high, and weighed 68 ~ 73 kg. Their body mass index (BMI) [10] was between 20 and 25. The subjects had no clinical history, liked basketball, had no deformity or severe injury in feet, had obvious muscles, kept good physical condition within 24 h before test, had normal foot joint activities, and received professional basketball skilled action training previously.

Table 3 shows the basic condition of the four pairs of basketball shoes. Shoes A were manufactured by cooperating with a shoe factory and the other three pairs of shoes were purchased from department store. The components of the sole of the four pairs of shoes were similar and the thickness and hardness of the sole were basically the same.

Table 3: The basic conditions of four pairs of basketball shoes

Type	Technology used	Size (yard)	Weight of a single shoe (g)	Material of external sole
Shoes A	Suspension shock absorption sole technology	42	376.47	TPU/corn starch/EVA composite
Shoes B	Nike air Zoom	42	384.62	XDR rubber
Shoes C	ANTA A-shock core technology	42	368.53	Established EVA/rubber
Shoes D (control)	Ordinary structure	42	378.58	MD

Test Method

(1) Experimental instruments

A foot gauge (Deije shoetools) was used for measuring the size of the ten male university students, and the size of shoes was determined as 42 yard. A plate plantar pressure tester (Beijing Dimeideer Science and Technology Co., Ltd., China) was used for measuring the pressure distribution of feet and ground. An insole plantar pressure tester (Shenzhen Yijie Instrument Co., Ltd., China) was used for measuring the pressure distribution of feet and shoe upper.

(2) Details of test method

The plantar pressure distribution was measured using insole plantar pressure distribution measurement system when the subjects who wore the four pairs of shoes did actions of sudden stop and jump shot. The shock absorption condition of different shock absorption structures was compared in aspects of peak pressure and impulse.

The detailed requirements for the test were as follows.

The experiment was done in a sports biomechanics lab. Tile ground was used in the biomechanics lab to reduce the changes of ground to reduce ground deformation. The room temperature of the lab was kept between 20 and 24°C, and the humidity was kept between 26% and 40% [11].

Ten subjects warmed up firstly. Then the subjects who wore different test shoes did actions of sudden stop and jump shot. The forefoot, heel and mid-foot were taken as the main detection and analysis areas. All the subjects joined two tests. In one test, all the subjects were asked to take their shoes off; in the other test, they wore the test shoes. All the subjects should do standard actions of sudden stop and jump shot. The plantar pressure of two feet of the subjects was tested using the plate plantar pressure testing system.

Action of sudden stop [12]: each subject ran on a long runway when wearing no shoes and then stopped suddenly at the center of the pressure testing plate. Relevant parameters at the moment of sudden stop were recorded. After measurement in the barefoot condition, the subjects rested for a while and then started the other test. The pressure was measured for three times, and the average value was taken as the final result.

Action of jump shot: each subject did the action of jump shot when wearing no shoes and wearing four different pairs of basketball shoes. The subjects had a full rest every five minutes. Before test, they practiced the action [13]; after being familiar with the action, each subject took off from both feet and jumped to the same height. One foot landed at the center of the pressure test plate. Every foot was measured for three times. The average value was taken as the final result.

RESULTS AND DISCUSSION

Through analyzing the average pressure of the left and right foot in standing state, it was found that the pressure of the left foot was smaller than that of the right foot. Therefore the right foot was regarded as the powerful foot. The test data of the right foot were taken as the standard. The plantar pressure and peak plantar pressure were measured using the insole pressure testing system when the subjects wore no shoes and wore the test shoes.

Comparison of Impulse when the Subjects Were Barefoot and when they Wore the Four Pairs of Basketball Shoes

The computational formula of impulse was: impulse = F•s (F refers to acting force and s refers to the acting time of force) [14]. Average impulse could reflect the vibration of external force in a certain period. Larger impulse indicated poorer shock absorption performance of basketball shoes.

Finally the impulse during motion were obtained based on the measurement system data and excel, as shown in figures 3 and 4.

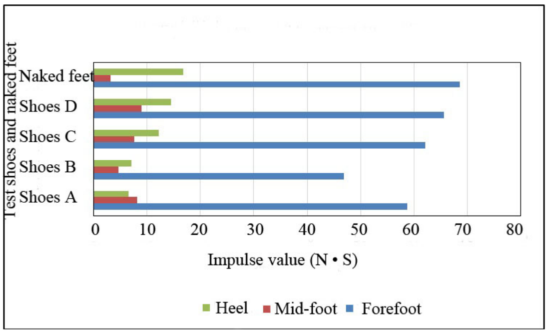

Figure 3. The impulse when the subjects did the action of sudden stop

Figure 3 demonstrated that the impulse of the forefoot was the largest when the subjects were barefoot, followed by shoes D, C, A and B; the impulse of the mid-foot was the largest when the subjects wore shoes D, followed by shoes C, A, B and barefoot; the impulse of the heel was the largest when the subjects were barefoot, followed by shoes D, C, B and A.

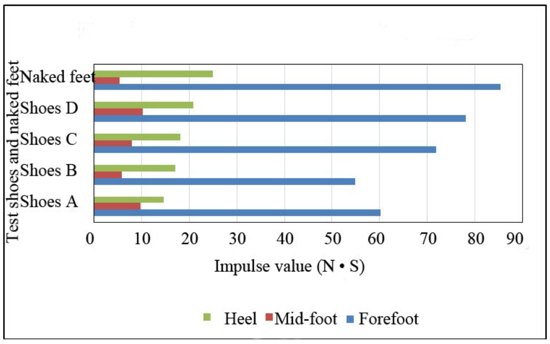

Figure 4. The impulse when the subjects did the action of jump shot

As shown in Figure 4, the impulse of the forefoot was the largest when the subjects did the action of sudden stop barefoot, followed by shoes D, C, A and B; as to the impulse of the mid-foot, shoes D was the largest, followed by shoes C, A, B and barefoot; as to the impulse of the heel, barefoot was the largest, followed by shoes D, C, B and A.

In conclusion, the impulse of the forefoot and heel when the subjects wore the four pairs of shoes was smaller than that when the subjects were barefoot, indicating the four pairs of test shoes had certain shock absorption effect; the shock absorption performance of the forefoot part of shoes B was the best, followed by shoes A, C and D; the shock absorption performance of the mid-foot of the four pairs of shoes was poor, and shoes B was a little better than the others; the shock absorption performance of the heel of shoes A was the best, followed by shoes B, C and D.

Comparison of Plantar Pressure when the Subjects Were Barefoot and when they Wore Four Pairs of Basketball Shoes

The computational formula of pressure was: pressure = acting force/acting area [15]; peak pressure refers to the largest pressure of an area. During human motion, larger peak pressure indicated larger counter force and severer plantar injury. From a different perspective, peak pressure could also reflect the shock absorption performance of a pair of shoes.

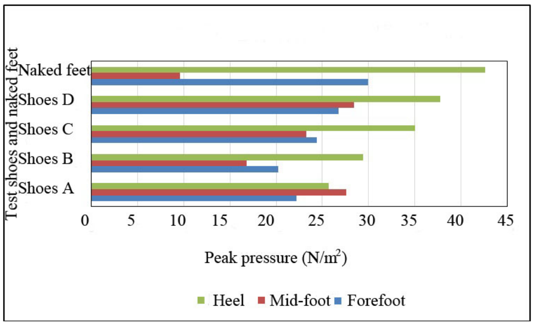

Figure 5. The peak plantar pressure when the subjects did the action of sudden stop

Figure 5 demonstrates that the peak pressure of the forefoot was the largest when the subjects were barefoot, followed by shoes D, C, A and B; the peak pressure of the mid-foot was the largest when the subjects wore shoes D, followed by shoes C, A, B and naked feet; the peak pressure of the heel was the largest when the subjects were barefoot, followed by shoes D, C, B and A.

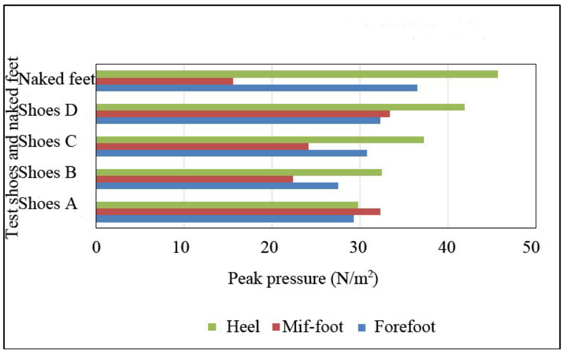

Figure 6. The peak plantar pressure when the subjects did the action of jump shot

Figure 6 suggests that the peak pressure of the forefoot was the largest when the subjects did the action of sudden stop barefoot, followed by shoes D, C, A and B; the peak pressure of the mid-foot was the largest when the subjects wore shoes D, followed by shoes C, A, B and naked feet; the peak pressure of the heel was the largest when the subjects were barefoot, followed by shoes D, C, B and A.

Analysis of the results demonstrated that the peak pressure of the forefoot and heel when the subjects wore one of the four pairs of shoes was smaller than that when the subjects were barefoot, indicating the four pairs of test shoes had certain shock absorption performance; the shock absorption performance of the forefoot of shoes B was excellent, followed by shoes A, C and D; the shock absorption performance of the mid-foot of the four pairs of shoes was poor, while that of shoes B was better; the shock absorption performance of the heel of shoes B was the best, followed by shoes B, C and D.

CONCLUSIONS

Two different basketball technical actions and two different test indicators are enough to display the shock absorption performance of basketball shoes. The experimental results demonstrated that all the four pairs of basketball shoes could absorb shock. The shock absorption performance of the forefoot of shoes B was the best, followed by shoes A, C and D; air Zoom cushion placed on the forefoot of shoes B had excellent shock absorption performance. The shock absorption performance of the forefoot of shoes A was the second best, suggesting that the suspension shock absorption structure had a favorable shock absorption performance on the forefoot. The shock absorption performance of the heel of shoes A was the best, followed by shoes B, C and D, indicating that the suspension shock absorption structure had a favorable shock absorption performance on the heel. The shock absorption performance of basketball shoes A, B and C was much better than that of basketball shoes with ordinary sole structure. But the four pairs of basketball shoes could not produce effective shock absorption effect on the mid-foot part.

In conclusion, basketball shoes A with a suspension shock absorption structure had excellent shock absorption performance on the forefoot and heel, superior to ANTA core technology based basketball shoes. Compared to Nike cushion technology which has been matured, the suspension shock absorption structure which was developed in this study was slightly inferior; hence more practice and optimization are needed to improve the shock absorption performance and provide better protection for the feet of basketball players and better wearing experience.

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VALIDATION OF METHOD FOR DETERMINING THE ISOELECTRIC POINT OF PROTEIN SOLUTIONS

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VALIDATION OF METHOD FOR DETERMINING THE ISOELECTRIC POINT OF PROTEIN SOLUTIONS

ABSTRACT. This paper presents the validation of a method for determining the isoelectric point of collagen hydrolysates used to obtain biomaterials for medical use produced in the Collagen Department of INCDTP – Division ICPI. The advantage of the presented method is that it is easy to apply, as the Zeta potential is the key parameter controlling electrostatic interactions in particle dispersions. The technique used to measure particle movement velocity in the Malvern Zetasizer Nano instrument series is Laser Doppler Velocimetry (LDV). It is an accepted method for measuring electrophoretic mobility of particles in the solution and by calculating the Zeta potential of protein solutions through extrapolation, the isoelectric point of the protein solution is determined.

KEY WORDS: biomaterials, collagen, isoelectric point, method validation

VALIDAREA METODEI PENTRU DETERMINAREA PUNCTULUI IZOELECTRIC LA SOLUȚIILE PROTEICE

REZUMAT. Lucrarea prezintă validarea unei metode de determinare a punctului izoelectric al hidrolizatelor de colagen folosite la obținerea de biomateriale pentru uz medical produse în Departamentul Colagen al INCDTP – Sucursala ICPI. Metoda prezentată are avantajul că este ușor de aplicat, potențialul Zeta fiind parametrul cheie care controlează interacțiunile electrostatice în dispersiile particulelor. Tehnica utilizată pentru măsurarea vitezei de deplasare a particulelor în seria de instrumente Malvern Zetasizer Nano este Laser Doppler Velocimetry (LDV). Este o metodă acceptată pentru măsurarea mobilității electroforetice a particulelor în soluție și din calcularea potențialului Zeta al soluțiilor proteice prin extrapolare se determină punctul izoelectric al soluției proteice.

CUVINTE CHEIE: biomateriale, colagen, punct izoelectric, validare metodă

VALIDATION DE LA MÉTHODE POUR DÉTERMINER LE POINT ISOÉLECTRIQUE DE SOLUTIONS PROTÉIQUES

RÉSUMÉ. L’article présente la validation d’ une méthode de détermination du point isoélectrique des hydrolysats de collagène utilisés pour l’obtention de biomatériaux à usage médical produits dans le Département Collagène d’INCDTP - ICPI. La méthode présentée a l’avantage d’être facile à appliquer, le potentiel Zêta étant le paramètre clé qui contrôle les interactions électrostatiques dans les dispersions de particules. La technique utilisée pour mesurer la vitesse du mouvement des particules dans la série Malvern Zetasizer Nano est la vélocimétrie laser Doppler (LDV). C’est une méthode acceptée pour mesurer la mobilité électrophorétique des particules dans la solution et en calculant le potentiel Zêta des solutions protéiques par extrapolation, on détermine le point isoélectrique de la solution protéique.

MOTS CLÉS: biomatériaux, collagène, point isoélectrique, validation de la méthode

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INTRODUCTION

The quality of products for medical use is a particularly complex concept as they embed physical-chemical, biochemical, microbiological and toxicological characteristics with profound implications on life and are an essential factor for metabolic processes and for the balance of the body.

Proteins are the most versatile macromolecules in living systems and have crucial functions in all biological processes [1]. They function as catalysts, carry and store other molecules such as oxygen, provide mechanical support and immunity, generate movement, send nervous impulses, control the growth and differentiation of organisms. Proteins are linear polymers made up of monomer units, called amino acids, their functions being defined by the sequence of amino acids from the protein polymer and its three-dimensional structure. Proteins are thus the embodiment of the transition from the three-dimensional world of molecules capable of various activities.

Proteins contain a wide range of functional groups, and when they are combined in different sequences, this range of functional groups is the wide spectrum of the protein function.

Collagen has a distinct composition compared to other proteins, as it is rich in glycine, proline and hydroxyproline, and does not contain cystine and tryptophan. As a result of prolonged heating in water, collagen undergoes partial hydrolysis, which occurs with structural changes, due to the breaking of inter-chain bonds, transforming into collagen hydrolysate.

The tertiary structure of collagen represents an advanced degree of spatial organization. It is the result of interactions between the R residues of amino acids in the polypeptide chains, which can establish different types of intramolecular bonds such as: hydrogen bonds, ionic bonds, covalent bonds, van der Waals forces, dipole-dipole interactions.

As with amino acids [2], due to the presence of functional groups ionized in protein molecules, they are characterized by well-defined values of their isoelectric point [3] (or isoelectric pH - pI or pHi) that is defined as that pH value at which the global electrical charge of the molecule is null. This physical-chemical parameter presents a practical importance, underlying electrophoretic methods [4] of separation and determination of different protein fractions in biological fluids. The isoelectric points [5] of the proteins oscillate between very large limits (2-12.5) depending on the number of acidic or alkaline groups that predominate on the surface of the macromolecule and do not depend on their molecular mass.

Due to their amphoteric character, proteins can neutralize small amounts of acidic or alkaline substance, thus having the role of buffer, thereby helping to maintain the acid-alkaline balance of the body. In general, the amphoteric character is imprinted by the free $-NH_2$ and -COOH groups which are not involved in the peptide bonds. If there are several dicarboxylic amino acids in the protein molecule, then the molecule will behave like a weak acid, and those where diamine amino acids predominate behave like weak alkalis. Although there is an equal number of amino and carboxyl groups in a molecule, and theoretically the molecule should be neutral, in fact, due to the much higher degree of ionization of the carboxyl group compared to the amino group, the protein molecule will have a weak acid character, comprising, in its solution, protein amphoteric ions, protein anions and protons (H^+) [6].

By acidification, the equilibrium of the reaction moves towards the formation of protein cations. At a certain concentration of hydrogen ions, the protein becomes electrically neutral since the amine and carboxyl groups are equally dissociated. At that time, amphoteric ions, $-H^+$ hydrogen protons,–HO^- hydroxyl ions will be found in the solution. The pH at which the solution of a protein contains anions and cations in equal proportion is called isoelectric point, being a very important protein constant.

Each protein at the isoelectric point has a specific behavior, having solubility, chemical reactivity, viscosity, osmotic pressure and hydration of the minimum colloidal particles. The precipitation of the protein at the isoelectric point is maximum however, and under the influence of the electric current there is no displacement, which makes it possible to be determined by electrophoretic and potentiometric methods.

A study has been conducted on the methods of analysis used to determine the isoelectric pH of the solutions in order to

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develop a method of analysis for the qualitative assessment of protein solutions for obtaining collagen-based materials for medical use.

The first definitions of the isoelectric point and the first preoccupations for the development of the methods for its identification were conceptualized from the beginning of the 20th century, by W.B. Hardy (1899-1900), Leonor Michaelis (1922), and Søren Peder Lauritz Sørensen, K. Linderstrom-Lang and Lund [6, 7].

In the case of gelatin, the isoelectric point was first determined by Leonor Michaelis and W. Grineff [8], who determined it at a concentration of hydrogen ions [H^+] comprised between 1.6 X10^{-5} and 3.5 × 10^{-5}, the average being 2.5 × 10^{-5}, and the corresponding pH of 4.80, 4.46 and 4.60.

Most of the subsequent determinations for gelatin were based on cataphoresis measurements, and the isoelectric point was not exactly localized. Thus, Jacques Loeb [1] interpreted his observations on the variation of the physical and chemical properties of gelatin, indicating an isoelectric point at pH 4.7.

Kraemer and Dexter [9] showed that previous observations were inconsistent and determined the isoelectric point at pH 5.0, which they located for calf skin gelatins as the pH at which the light dispersion is the maximum (Tyndall effect). They showed, however, that the resulting numbers depend very much on the origin of the skin and on the method of preparing the gelatin.

In order to avoid discrepancies due to the differences between gelatins, the Leather and Gelatin Division of the American Chemical Society presented an isoelectric point study on samples prepared as specified by a committee [10, 11]. The study showed that the method of obtaining and purifying gelatin [12] is very important.

The isoelectric point of such gelatin was reported by Sheppard and Houck [13] at pH 4.9±0.10 by electrical field migration and at pH 4.9±0.05 by both Tyndall effect assessment, and by precipitation with alcohol.

Consequently, it has been found useful to investigate the standard gelatin behavior with respect to the turbidity of standard gelatin solutions in a pH range of 4 to 6 with acetate buffer. In each case, the turbidity was maximal towards the middle of the series, so that from these observations the pH of maximum turbidity was set at 4.85±0.03.

By definition, the most direct way to determine the isoelectric point is to determine the pH for zero migration in an electric field.

Migration was carried out in various types of cells by confirming Smoluchowski's theory.

Zeta potential is the key parameter that controls electrostatic interactions in particle dispersions and as such is an important factor in understanding the stability of colloidal dispersions [14]. It can be used to optimize suspension and emulsion formulations and to help establish their long-term stability.

The potential that occurs at relative movement of phases in contact is called electrokinetic potential (ξ).

At the passage of the electric current through the emulsion, the opposing sign mobile ions from the diffuse layer are directed towards the respective electrodes. The electrokinetic potential, ξ, that appears was calculated according to the Helmholtz-Smoluchowski relationship [15]:

$$\xi = \frac{\eta \cdot u}{\varepsilon \cdot \varepsilon_0 \cdot H} \qquad (1)$$

where: **u** is the velocity of particles; η – medium viscosity; ε – electrical permittivity; ε_0 – vacuum permittivity (8.85x10^{-2} F/m); **H** – potential gradient

Electrophoresis study enabled determination of particle charge in the emulsion and assessment of electrokinetic potential value, ξ.

The most important factor affecting the Zeta potential is the pH. Therefore, a graphical representation of the Zeta potential [16, 17], depending on the pH will be positive at low pH and negative at high pH. The point where the graph goes through zero is the Zeta potential. This point is called the isoelectric point [18] and is very important for practical reasons. It is normally the point where the colloidal system is the least stable.

As a result of the literature study on ways to determine the isoelectric point of proteins, it was chosen to measure electrophoretic mobility. The method is based on the determination of the Zeta potential, of the electrical conductivity depending on the pH variation of some protein solutions [19].

EXPERIMENTAL

Method Principle

Protein molecules have an amphoteric character. Depending on the concentration of H^+ ions in the solution, the molecule is positively or negatively charged. The concentration of hydrogen ions at which the protein molecule has an equal number of positive and negative charges is called an isoelectric point. In most cases, the dissociation constant of the protein as an acid exceeds the dissociation constant of the same protein as an alkali. A particle in aqueous solution is usually negatively charged.

By gradually acidifying such a solution, the degree of dissociation of the protein [20, 21], as alkali increases (the neutralization of OH^- ions). In this way an equal concentration of positive and negative ions can be achieved. At the isoelectric point [22], the colloidal particles become electrically neutral; being less stable, the protein solution precipitates very easily.

The concentration of hydrogen ions at which the isoelectric point is achieved [23] is a protein-specific value that varies between the pH range of 4.1 to 6.7.

Equipment and Reagents

- Zetasizer Nano ZS from MALVERN
- ORION STAR A 211 pH-meter from THERMO SCIENTIFIC
- 0.1 N sodium acetate
- 0.1 N acetic acid solution
- 1% protein solution
- 90% methyl alcohol

Work Method

In order to calculate the isoelectric point [24], 0.1 N sodium acetate, 0.1 N acetic acid solution, and 1% protein solution are added to 6 test tubes, according to proportions given in Table 1.

Table 1: Proportions of solutions required to measure the isoelectric point

Added reagents (ml)	Test tube number					
	1	2	3	4	5	6
0.1N sodium acetate	2	2	2	2	2	1,2
0.1N acetic acid	0,25	0,5	1	2	4	4,8
Distilled water	3,75	3,5	3	2	-	-
1% protein solution	2	2	2	2	2	2

The pH of protein solutions is measured using the pH-meter before and after adding the protein solution in order to see the variation it causes, if applicable, then the electrophoretic mobility is measured using the Zetasizer Nano.

pH variation is plotted depending on Zeta potential and extrapolated to obtain the isoelectric point at 0 potential.

Methyl alcohol is added to the test tubes to highlight the isoelectric point by means of turbidity.

RESULTS AND DISCUSSIONS

pH measurements of protein solutions were determined using ORION STAR A 211 pH-meter from THERMO SCIENTIFIC presented in Figure 1.

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Figure 1. ORION STAR A 211 pH-meter

Electrophoretic mobility was highlighted through the variation of Zeta potential and electrical conductivity with the Zetasizer Nano ZS from MALVERN, presented in Figure 2.

Figure 2. Zetasizer Nano ZS

The essence of a classic micro-electrophoresis system is an electrode cell at each end to which a potential is applied. The particles move to the opposite charge electrode, their velocity being measured and expressed as unit of the field, as mobility.

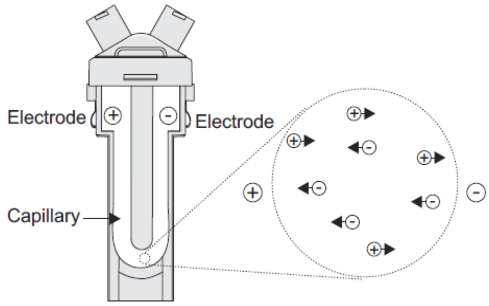


Figure 3. Micro-electrophoresis cell

The technique used to measure the particle movement velocity in the Malvern Zetasizer Nano series is Laser Doppler Velocimetry (LDV).

For all measurements, a 40 V field was applied over a 10 mm electrode spacing at 25°C. Three repeated measurements were performed on each sample to verify the repeatability of the results. All measured electrophoretic mobilities were converted into Zeta potential using the Smoluchowski formula.

Electrophoresis study enabled determination of particle charge in the emulsion and assessment of electrokinetic potential value, **ξ**.

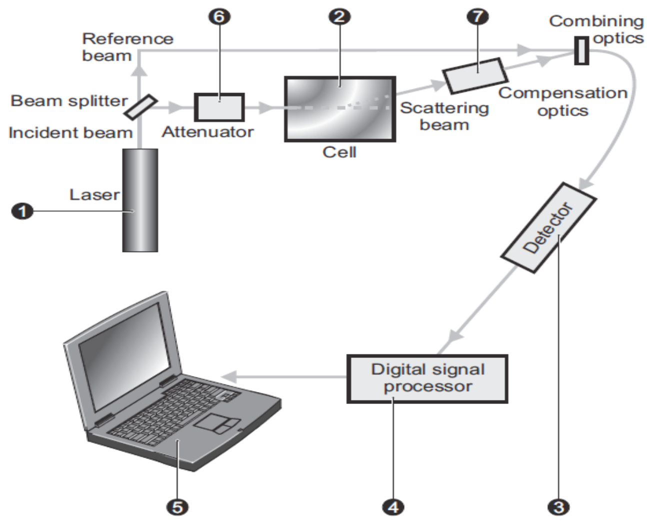


Figure 4. Zetasizer Nano ZS operation flowchart

When an electric field is applied to the **cell (2)**, all the particles moving through the measurement volume will cause light intensity fluctuations detected with a frequency proportional to the particle speed.

A detector (3) sends this information to a **digital signal processor (4)**. This information is then transmitted to a **computer (5)** in which the Zetasizer Nano software produces a frequency spectrum from which the electrophoretic mobility is calculated, and hence the Zeta potential.

An **"attenuator" (6)** is used to reduce the intensity of the laser and hence to reduce the intensity of the dispersion.

Resulting data are plotted to calculate the isoelectric point by extrapolation.

In the resulting solutions, the isoelectric point is also highlighted by adding methyl alcohol in the test tubes and noticing turbidity that indicates aggregation of molecules, with maximum coagulation at the isoelectric point.

Alcohol and some organic solvents fix (extract) water that hydrates the protein molecule; water-free micelles flocculate. About 8-10 ml alcohol are usually necessary.

After adding the alcohol, the test tube content is stirred. Test tubes are left to rest for 30 minutes and the test tube with the highest amount of precipitate is marked. The corresponding pH value is the isoelectric pH of gelatin [17] that must comply with the one found in literature, of 4.7.

An acetic buffer, acetic acid (CH_3COOH) and sodium acetate (CH_3COONa) mixture, was used to determine the isoelectric point.

As the acetic acid dissociation in the presence of the strong CH_3COONa electrolyte, which has a joint anion with the acid, is almost completely suppressed, the equilibrium concentration of the non-dissociated molecules [CH_3COOH] can be taken as the initial acid concentration.

Data Analysis

Statistical calculations were performed in Excel 2010, also used to calculate isoelectric points, standard deviation, bias, repeatability, reproducibility, method reliability and accuracy. All statistical tests were conducted at a confidence level of 95% and k=2.

Validation of Method

Validation of an analytical method is the process by which it is established by laboratory studies if that method meets the conditions for the analytical applications for which it was developed.

Validation is therefore an important step in determining the repeatability, reproducibility, and reliability of the method as it can confirm whether the method is suitable for use for a particular system.

To validate the method, six series of standard gelatin solutions were prepared, namely gelatin solution from MERCK Millipore of the same concentration, and the following were calculated:

- ✓ Standard deviation;
- ✓ Bias;
- ✓ Repeatability;
- ✓ Reproducibility;
- ✓ Reliability;
- ✓ Accuracy.

Table 2: Composition of tested solutions from each series

Added reagents (ml)	Test tube number					
	1	2	3	4	5	6
0.1N sodium acetate	2	2	2	2	2	1.2
0.1N acetic acid	0.25	0.5	1	2	4	4.8
Distilled water	3.75	3.5	3	2	-	-
Resulting pH	5.525	5.229	4.915	4.593	4.271	3.951
1% gelatin solution	2	2	2	2	2	2
Resulting pH after adding gelatin solution	5.528	5.227	4.917	4.589	4.275	3.955
Appearance	Clear solution	Clear solution	Clear solution	Clear solution	Clear solution	Clear solution

Using the pH meter, the pH values were read before and after the addition of the protein solution. pH variations range from 0.003 to 0.004 pH units, are insignificant, demonstrating stability in the buffer solutions used.

Samples were introduced into the ZETASIZER cell to measure electrophoretic mobility, namely Zeta potential, electrical conductivity and then the results were extrapolated to determine the isoelectric point.

The results and graphic representation for the isoelectric point determination of the 6 series of gelatin solutions are presented in Tables 3-8.

Table 3: Determination of isoelectric point - Gelatin 1

1% gelatin solution in water (powder gelatin)

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.968	4.61	4.683
2	4.270	2.29	
3	4.560	0.43	
4	4.892	-0.73	
5	5.194	-3.44	
6	5.484	-4.85	

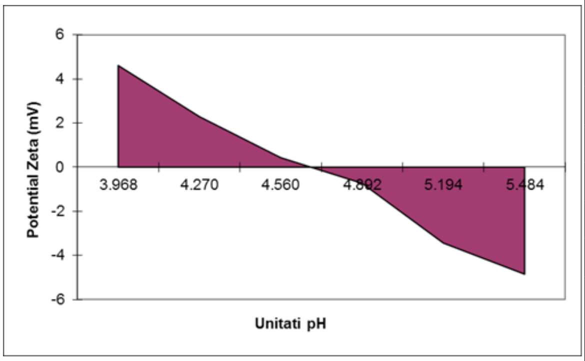


Table 4: Determination of isoelectric point - Gelatin 2

1% gelatin solution in water (powder gelatin)

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.970	4.55	4.678
2	4.272	2.19	
3	4.562	0.45	
4	4.893	-0.83	
5	5.197	-3.69	
6	5.486	-4.35	

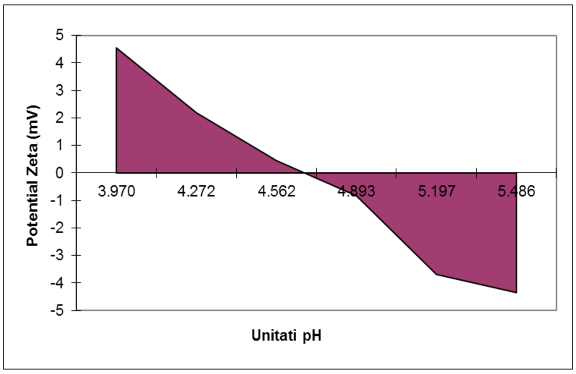


Table 5: Determination of isoelectric point - Gelatin 3

1% gelatin solution in water (powder gelatin)

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.965	4.48	4.699
2	4.268	2.23	
3	4.559	0.82	
4	4.890	-1.12	
5	5.193	-3.71	
6	5.484	-4.38	

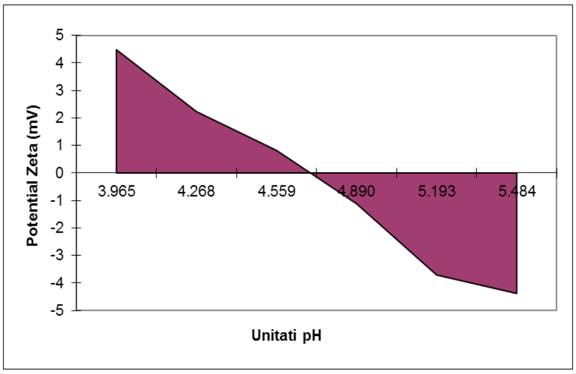


Table 6: Determination of isoelectric point - Gelatin 4

1% gelatin solution in water (powder gelatin)

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.966	4.5	4.692
2	4.269	2.27	
3	4.565	0.71	
4	4.890	-1.11	
5	5.198	-3.68	
6	5.486	-4.45	

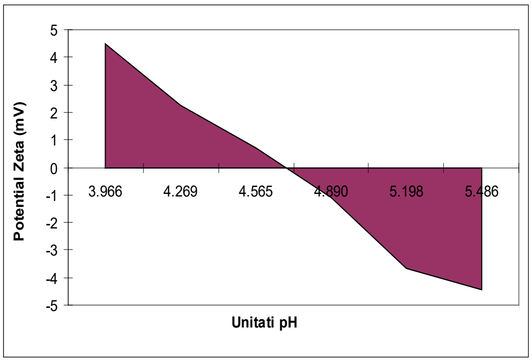


Table 7: Determination of isoelectric point - Gelatin 5

1% gelatin solution in water (powder gelatin)

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.968	4.55	
2	4.271	2.31	
3	4.562	0.82	
4	4.893	-1.25	4.693
5	5.195	-3.67	
6	5.487	-4.54	

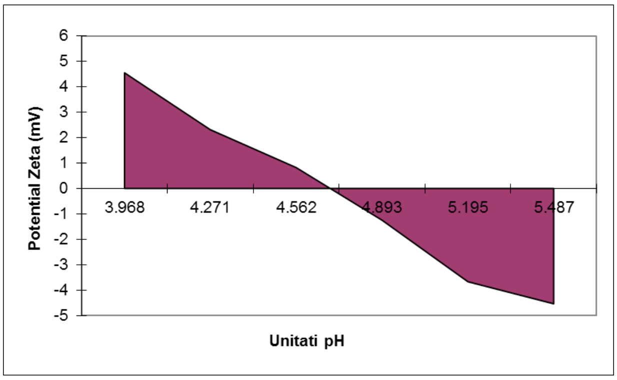
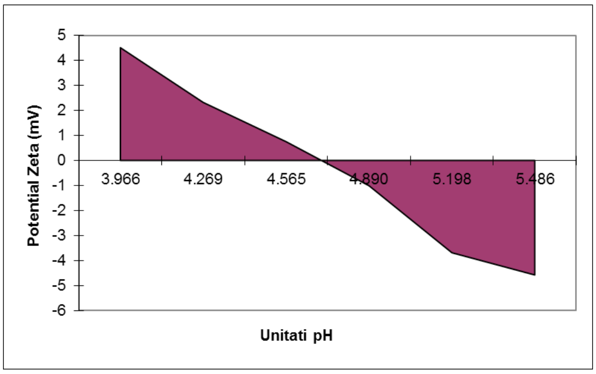


Table 8: Determination of isoelectric point - Gelatin 6

1% gelatin solution in water (powder gelatin)

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.966	4.51	
2	4.269	2.32	
3	4.565	0.75	
4	4.890	-1.01	4.703
5	5.198	-3.69	
6	5.486	-4.58	



Method Performance Parameters

The accuracy of the method represents the closeness between the real value and the value found in the analyzed sample, and is calculated using the formula below:

Accuracy % = $\frac{X_{mediu}}{\mu} 100$ (2)

where:

X_{mean} = mean of 6 determinations

μ = real value of the reference material

Bias % = $\frac{X_{mediu} - \mu}{\mu} 100$ (3)

Confidence interval - the interval where measured values fall: $\bar{x} \pm t \cdot s_x$ where -t – factor Student (for n-1 degrees of freedom and confidence level of 95%).

Table 9: Accuracy

			1	2	3	4	5	6
pHi			4.683	4,678	4.699	4.691	4.693	4.703
Theoretic			4.7					
mean	4.6912	pH units						
Accuracy	99.8121	%						
Bias	-0.1879	%						

Reliability represents the degree of approximation between the results of independent tests obtained under established conditions and is expressed by the coefficient of variation, CV, for a repeated analysis which is calculated with the formula:

$$\textbf{CV (RSD) \%} = (s / Xmean)100 \quad (4) \qquad s = \text{standard deviation.}$$

Table 10: Reliability

			1	2	3	4	5	6
pHi			4.683	4.678	4.699	4.691	4.693	4.703
Theoretic			4.7					
mean	4.6912	pH units						
Standard deviation	0.0094	pH units						
CV (RSD)	0.2011	%						

Repeatability is a measure of the degree of scattering within a confidence interval of the results obtained from the measurement performed by the same analyst under the same working conditions.

Table 11: Repeatability

			1	2	3	4	5	6
pHi			4.683	4.678	4.699	4.691	4.693	4.703
Theoretic			4.7					
mean	4.6912	pH units						
Standard deviation	0.0094	pH units						
r	0.0264	pH units						
RSDr	0.0020	%						

Analyses of Protein Solutions

Four samples of atomized HO8 hydrolysate, and gelatin capsules used for packaging medical use products, were studied and characterized physically and chemically. The results are presented in Table 12.

Table 12: Characterization of collagen products for medical use

Characteristics / Product	Dry substance, %	Ash*, %	Total nitrogen* %	Appearance
COLLAGEN HYDROLYSATE HO8-1	95,64	0,45	17,70	Light yellow powder
COLLAGEN HYDROLYSATE HO8-2	96,24	0,36	17,52	Light yellow powder
COLLAGEN HYDROLYSATE HO8-3	97,02	0,24	17,63	Light yellow powder
COLLAGEN HYDROLYSATE HO8-4	95,91	0,41	17,56	Light yellow powder
Gelatin capsules	97,87	none	17,81	Translucent capsule

Samples, from which 1% collagen hydrolysate solutions in water were made, were distributed in 6 test tubes with the proportions in Table 3. Results were presented in Tables 13-17.

Table 13: Determination of isoelectric point – Hydrolysate H08-1

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.947	1.02	
2	4.242	0.87	
3	4.562	-0.02	
4	4.876	-1.03	4.555
5	5.192	-1.68	
6	5.495	-3.15	

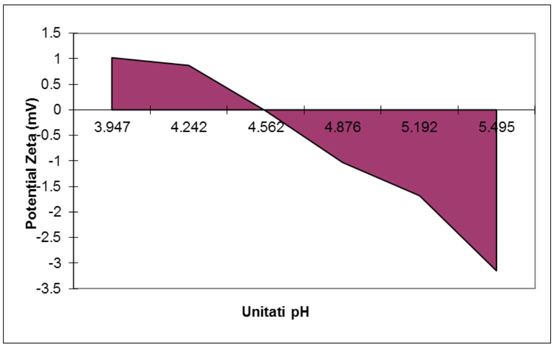


Table 14: Determination of isoelectric point – Hydrolysate H08-2

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.917	3.7	
2	4.216	2.94	
3	4.517	1.03	
4	4.817	-0.689	
5	5.088	-1.96	4.697
6	5.310	-2.35	

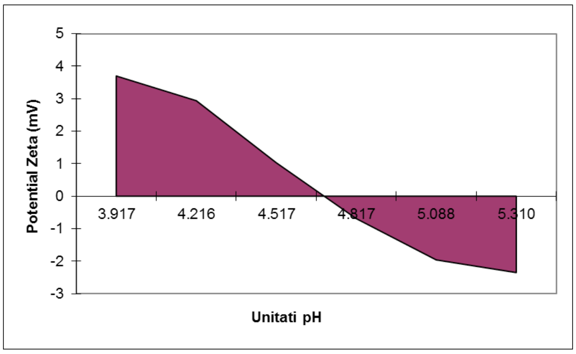


Table 15: Determination of isoelectric point – Hydrolysate H08-3

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.950	1.02	
2	4.239	0.67	
3	4.559	0.252	
4	4.890	-0.91	4.631
5	5.212	-2.68	
6	5.305	-3.55	

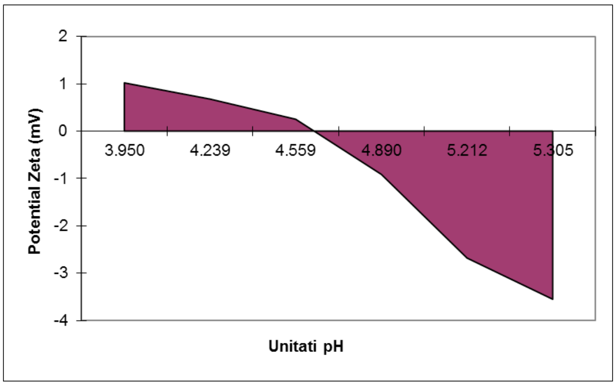


Table 16: Determination of isoelectric point – Hydrolysate H08-4

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.917	3.7	
2	4.216	2.94	
3	4.517	1.53	
4	4.817	-1.21	
5	5.088	-2.36	4.684
6	5.310	-3.35	

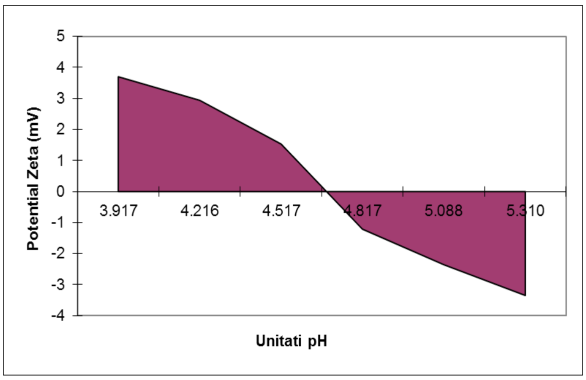
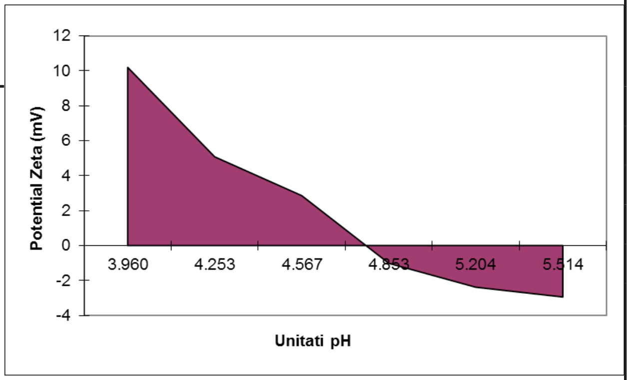


Table 17: Determination of isoelectric point – Gelatin capsules

1% gelatin solution in water (gelatin capsules)

No	pH	Zeta potential (mV)	Isoelectric point (pHi)
1	3.960	10.2	
2	4.253	5.08	
3	4.567	2.86	
4	4.853	-1.01	4.778
5	5.204	-2.38	
6	5.514	-2.94	



The isoelectric points determined for soluble collagen hydrolysates and gelatin capsules are reproducible and in accordance with theoretical data in the literature.

CONCLUSIONS

The analytical method to determine the isoelectric point of protein solutions was performed based on electrophoretic mobility of solutions by determining Zeta potential depending on pH.

The technique used to measure electrophoretic mobility in the Malvern Zetasizer Nano Series is the Laser Doppler Velocimetry (LDV).

For all measurements, a 40 V field was applied over a 10 mm electrode spacing at 25°C.

Three repeated measurements were performed on each sample to verify repeatability of the results.

All measured electrophoretic mobilities were transformed into Zeta potential using the Smoluchowski formula.

The method has been checked to ensure reproducibility and is supported by determinations on samples of soluble proteins, namely HO8 collagen hydrolysates and gelatin capsules, from the Collagen Department of ICPI.

Statistical calculations were performed in Excel 2010, used both to calculate the isoelectric points, standard deviation, bias, repeatability, reproducibility, fidelity and accuracy of the method. All statistical tests were performed at a confidence level of 95% and k=2.

From the calculation of the performance parameters of the studied method, the following is noted:

- The accuracy of the method is 99.8121% and represents the closeness between the real value and the value found in the analyzed sample, based on an established criterion of 99±2%;
- The calculated standard deviation is 0.0094 pH units;
- The reliability of the method is 0.2011%, representing the degree of closeness between the results;
- The repeatability is equal to 0.026% and is a measure of the degree of scattering of the results, within a confidence interval;
- The isoelectric point determined by this method is in the range of 4.6912±0.001 pH units, as compared to 4.7 as specified in the literature;
- The performance parameters comply with acceptability criteria, the method is appropriate for the proposed purpose and as a result it was validated.

Acknowledgements

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NATIONAL AND INTERNATIONAL EVENTS

INTERNATIONAL CONFERENCE "INNOVATIVE SOLUTIONS FOR SUSTAINABLE DEVELOPMENT OF TEXTILES AND LEATHER INDUSTRY" 25-26 MAY 2018, ORADEA, ROMANIA

The International Conference "Innovative solutions for sustainable development of textiles and leather industry" is organized by the Department of Engineering and Industrial Management in Textiles and Leatherwork from University of Oradea, Romania, and will be held in Oradea, May 25 and 26, 2018. Accepted papers will be published in *Annals of the University of Oradea. Fascicle of Textiles, Leatherwork*, publication issued by Publishing House of University of Oradea. Topics fall into three main categories: Textiles, Leather and Leather substitutes, Management and Marketing. Deadline of submission of the abstracts and full papers is the 6th of April 2018.

More information:
http://textile.webhost.uoradea.ro Conferinta/2018/index.html

THE 17TH ROMANIAN TEXTILES AND LEATHER CONFERENCE - CORTEP'2018 7-9 NOVEMBER, 2018, IASI, ROMANIA

The 17th Romanian Textiles and Leather Conference - CORTEP'2018 is organized by "Gheorghe Asachi" Technical University of Iasi, Faculty of Textiles-Leather and Industrial Management and will be held in Iasi, Romania, on 7-9 November, 2018.

The Conference is intended to be a meeting of scientists, researchers and specialists from academy, national research institutes and companies in the textile and leather field and other related.

The topics of the Conference will cover areas such as: textile fibres and advanced materials, textile science and technology, IT applications, textile structures and properties, functional textiles and clothing, machinery developments, fashion design and product development, textile chemistry and technology, advances in leather processing, footwear design and technology, environment protection, marketing and management, engineering education and other related issues.

More information:
http://www.cortep.tuiasi.ro

LESHOW MOSCOW - 21st INTERNATIONAL LEATHER & FUR FASHION FAIR 29-31 MAY 2018, MOSCOW, RUSSIA

LeShow Moscow is the most comprehensive, and the largest professional exhibition on the territory of Russia for the fur-and-leather industries organized on 15.000 sqm covering a wide spectrum of products and attracting professionals from a vast area of Russia. Specialists of fur & leather industry come from 220 of the largest cities in Russia, CIS and foreign countries. LeShow Moscow brand has become synonymous with success for 20 years in the leather & fur exhibition industry in Russia.

LeShow 2018 catwalk show is a must-see event during the exhibition. The fashion shows attract the attention of press and media, whereby larger publicity is attained to benefit the exhibitor by enhancing brand awareness.

We kindly invite you to join this important event and not to miss this chance to visit this exhibition and fashion shows offering you several business opportunities.

More information: http://www.leshow.ru

THE 3rd INTERNATIONAL CONFERENCE – SCIENCE FOR BUSINESS: INNOVATION FOR TEXTILES, POLYMERS AND LEATHER
JUNE 20th, 2018, LODZ, POLAND

The 3rd International Conference – Science for Business: Innovation for Textiles, Polymers and Leather is organized by the Institute of Leather Industry on June 20th, 2018 in Lodz, Poland. The aim of the conference is to connect the world of science and business. Such a hybrid of knowledge and skills of these environments is extremely important and necessary. In the strong economic development of Poland and the majority of European countries, scientists and entrepreneurs should join forces to improve services and products.

The conference gives space for discussion, brainstorming which enables the living functioning of science, which requires constant development, exploration, research and action. In addition, nowadays science creates a strong synergy with business. One could say that both these realities are permeating and complementing. Therefore, we invite people from the world of science and business to jointly create a space for the exchange of knowledge, experience that the conference gives.

More information: http://www.ips.lodz.pl/en

THE 15th INTERNATIONAL CONFERENCE ON NANOSCIENCES & NANOTECHNOLOGIES
3-6 JULY 2018, THESSALONIKI, GREECE

NN Conference is a world-class International event in Nanosciences and Nanotechnologies (N&N) that focuses on the latest advances on N&N and promotes profound scientific discussions between scientists, researchers from different disciplines and market leaders. Front-line experts from multidisciplinary research and application areas are encouraged to join this conference, to discuss the benefits of N&N in their R&D efforts, to advance the networking and collaborating between different academia, research and industry players in the field and to stimulate the exchange of educational concepts.

NN18 conference will be comprised of associated Workshops and Special Events, covering the latest developments in the fields of Nanosciences & Nanotechnologies.

The international Conference program is structured in plenary, keynote, invited, oral and visual presentations and covers the entire range of N&N research, technologies and applications, focusing on the latest scientific, technological and market-related trends

More information:
http://www.nanotexnology.com

20th INTERNATIONAL CONFERENCE ON MATERIALS, METHODS & TECHNOLOGIES
26-30 JUNE 2018, ELENITE HOLIDAY VILLAGE, BULGARIA

The twentieth International Conference on Materials, Methods and Technologies will be held between 26th and 30th June 2018 in Elenite, Bulgaria. The event is organized jointly by Bulgarian Academy of Sciences, Union of Scientists in Bulgaria, Science & Education Foundation, Al-Farabi Kazakh National University, Kavala Institute of Technology (Greece) and Institute of Power Engineering (Belarus).

The purpose of this meeting is to bring together researchers and scientists with interests in materials science, engineering, energy sources, IT and communications, robotics and automation to address recent research results and to present and discuss their ideas, theories, technologies, systems, tools, applications, work in progress and experiences. Representatives of 90 universities, institutes, laboratories and other organizations from 33 countries took part in the previous edition of the conference in 2017.

More information:
https://www.sciencebg.net/en/conferences/materials-methods-and-technologies

THE 4th INTERNATIONAL CONGRESS ON WATER, WASTE AND ENERGY MANAGEMENT (EWWM) 18-20 JULY 2018, MADRID, SPAIN

The 4th International Congress on Water, Waste and Energy Management (EWWM) is organized by academics and researchers belonging to different scientific areas of the University Complutense of Madrid, University Carlos III of Madrid, University of Extremadura and University of Las Palmas de Gran Canaria with the technical support of Sciknowledge European Conferences.

The event has the objective of creating an international forum for academics, researchers and scientists from worldwide to discuss worldwide results and proposals regarding to the soundest issues related to Water, Waste and Energy Management.

This event will include the participation of renowned keynote speakers, oral presentations, posters sessions and technical conferences related to the topics dealt with in the Scientific Program as well as an attractive social and cultural program.

More information: http://waterwaste18.com

THE 4th INTERNATIONAL CONFERENCE ON GREEN CHEMISTRY AND SUSTAINABLE ENGINEERING 23-25 JULY 2018, MADRID, SPAIN

The 4th International Conference on Green Chemistry and Sustainable Engineering is organized by academics and researchers belonging to different scientific areas of the University Complutense of Madrid, University Carlos III of Madrid, University of Extremadura and University of Las Palmas de Gran Canaria with the technical support of Sciknowledge European Conferences.

The event has the objective of creating an international forum for academics, researchers and scientists from worldwide to discuss worldwide results and proposals regarding to the soundest issues related to Green Chemistry and Sustainable Engineering.

This event will include the participation of renowned keynote speakers, oral presentations, posters sessions and technical conferences related to the topics dealt with in the Scientific Program as well as an attractive social and cultural program.

More information:
http://greenchemistry18.com

THE 7th INTERNATIONAL SYMPOSIUM ON ENERGY FROM BIOMASS AND WASTE 15-18 OCTOBER 2018, VENICE, ITALY

The production of energy from alternative sources and its impact on climate change are among the main strategic tools implicated in the sustainable development of our society. Numerous types of biomass and wastes contribute towards the production of energy and reduction in the use of fossil fuels by means of biological, chemical and thermal processes. Existing biomass and waste to energy technologies are currently undergoing rapid development. Despite growing interest in the use of these technologies, in many countries their implementation remains limited.

The aim of the Venice 2018 Symposium is to focus on the advances made in the application of different substrates and biological/thermal technologies for energy recovery from biomass and waste and to encourage discussion in these fields. The conference will feature three days of scientific presentations plus one day of guided technical tours at biochemical and thermochemical plants, with an expected attendance of over 600 delegates from tens of different countries worldwide.

More information:
http://www.venicesymposium.it

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The scientific papers should be presented for publishing in English only. The text of the article should be clear and precise, as short as possible to make it understandable. As a rule, the paper should not exceed fifteen pages, including figures, drawings and tables. The paper should be divided into heads and chapters in a logical sequence. Manuscripts must meet high scientific and technical standards. All manuscripts must be typewritten using MS Office facilities, single spaced on white A4 standard paper (210 x 297 mm) in 11-point Times New Roman (TNR) font.

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