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ASSESMENT OF COMMERCIALLY AVAILABLE CHILDREN'S ORTHOPEDIC FOOTWEAR

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Background. The term "orthopedic shoes" becomes an advertisement through which manufacturers promote their products to the market. Parents face the problem of selecting shoes that ensures normal function and development of the child's foot. In this regard, the situation must be understood.

The aim of the study is to identify the conformity of the footwear design and the parameters of special orthopedic parts to the requirements of the current regulatory and technical documentation for footwear for specific deformation as well as to obtain information regarding consumer information on the indications and contraindications of the designation of children's shoes, set out in the leaflet regarding the use of shoes with special orthopedic parts.

Materials and methods. This study was based on the results of a study of 23 pairs of 155-size children's shoes. The shoes were selected by random sampling from the assortment that is in retail sale. The research was performed by the staff of the Federal State Institution Federal Scientific Center for the Rehabilitation of the disabled named after G.A. Albrecht of the Ministry of Labor of Russia, which are the developers of the national standard (R 544072011 "Orthopedic footwear. General technical requirements").

Results and discussion. The research data showed that virtually all footwear examined was manufactured in violation of the current regulatory and technical documentation. Shoes that go to free sale for selection under the guise of "orthopedic" shoes have a very attractive appearance (seen by the design and bright colors). However, such footwear does not provide the performance of medical purposes because special orthopedic parts have parameters that do not meet the requirements of national standards.

Thus, uncontrolled implementation of orthopedic footwear for selection is unacceptable. In this regard, children without pathology of the foot and musculoskeletal system should wear standard footwear without special details. Children in need of orthopedic footwear should wear shoes strictly according to the doctor's prescription, considering the individual anatomical and functional features of the child's foot.

Keywords: orthopedic footwear; children; foot; musculoskeletal system; special orthopedic details; technical means of rehabilitation.

РЕЗУЛЬТАТЫ ИССЛЕДОВАНИЯ ДЕТСКОЙ ОРТОПЕДИЧЕСКОЙ ОБУВИ, ПОСТАВЛЯЕМОЙ В ТОРГОВУЮ СЕТЬ

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Актуальность. На фоне изобилия обувных изделий термин «ортопедическая обувь» становится рекламой, с помощью которой производители продвигают свою продукцию на рынок. Перед родителями стоит проблема как выбора, так и подбора обуви, которая обеспечит нормальное функционирование и развитие стоп ребенка. В этой связи следует разобраться в сложившейся ситуации.

Цель исследования — выявление соответствия конструкции обуви и параметров специальных ортопедических деталей требованиям действующей нормативно-технической документации к обуви на конкретную

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деформацию; получение сведений об информировании потребителя о показаниях и противопоказаниях назначения ортопедической детской обуви, изложенных в памятке по использованию обуви со специальными ортопедическими деталями.

Материалы и методы. Работа основана на результатах исследования 23 пар детской обуви 155-го размера. Отбор обуви производили методом случайной выборки из ассортимента, находящегося в розничной продаже. Исследования выполнены сотрудниками ФГБУ ФНЦРИ им. Г.А Альбрехта Минтруда России, являющимися разработчиками национального стандарта ГОСТ Р 54407–2011 «Обувь ортопедическая. Общие технические требования».

Результаты и обсуждение. Исследования показали, что фактически вся обследуемая обувь изготовлена с нарушением действующей нормативно-технической документации. Обувь, поступающая в свободную продажу под видом «ортопедическая», внешне имеет весьма привлекательный вид (благодаря дизайнерской проработке и яркой цветовой гамме заготовок верха), чем и обращает на себя внимание. Однако такая обувь не обеспечивает выполнения медицинского назначения ввиду того, что специальные ортопедические детали имеют параметры, не соответствующие требованиям национальных стандартов.

Таким образом, бесконтрольная реализация ортопедической обуви на подбор недопустима. Детям, не имеющим патологии стопы и опорно-двигательного аппарата, следует выбирать стандартную обувь без специальных деталей, а ортопедическую следует носить строго по назначению врача с учетом индивидуальных анатомо-функциональных особенностей стоп.

Заключение. В соответствии с действующим законодательством и нормативно-технической документацией производитель несет за выпускаемую продукцию моральную и юридическую ответственность. Авторы настоящей статьи обязуются регулярно вносить изменения в нормативно-техническую документацию для изготовления функциональной ортопедической обуви для детей.

Ключевые слова: ортопедическая обувь; дети; стопа; опорно-двигательный аппарат; специальные ортопедические детали; техническое средство реабилитации.

Introduction

Nowadays, attention of the parents and doctors is directed to the diagnosis and prevention of pediatric diseases in the early stages. However, this does not always produce a desirable result. In recent years, there has been an increase in the number of children and adolescents with diseases of the musculoskeletal system, with approximately one in five children suffering from such frequent illnesses, as a pathological position, or deformity of the feet [1]. Untimely, late treatment could aggravate the disease condition, leading to a further decrease in the efficiency of conservative treatment and resulting in a permanent dysfunction of the entire musculoskeletal system. According to Rosstat, an increasing trend in the incidence of pediatric musculoskeletal diseases was observed, in which the number of pediatric patients has increased to 759.1 thousand patients by 2000 and to 800.6 thousand patients by 2016. During this period, the number of injuries and other consequences caused by external factors increased to 237.7 thousand [2]. Therefore, rehabilitation products, such as orthopedic shoes, are essential to restore and compensate for the impaired functions of the musculoskeletal system.

According to the Ministry of Labor of Russia, the volume of orthopedic shoes produced in 2015 amounted to 984,503 pairs, which indicates its high demand in the market of technical means for the rehabilitation purposes. A significant part of the demand is represented by the orthopedic shoes for children [2].

Orthopedic footwear is known to be a technical means of rehabilitation. Therefore, orthopedic footwear should be developed to cater the existing deformities and defects of the feet [3]. The design of orthopedic footwear comprises of special details that are distinguishable from the regular shoes [4]. Therefore, it is necessary to strictly use the orthopedic shoes according to the recommendation (prescription) of the doctor. It is improper and unacceptable to consider it as a prophylactic means, supposedly serving to prevent the occurrence of deformities.

Studying the market of pediatric shoes, experts have noticed that under the new economic conditions the term “orthopedic shoes” has become a brand that replaces the concept of “rational shoes.”

Thus, in the pursuit of maximum profit, manufacturers and suppliers advertise their products under various brands, such as “medical shoes,”

"anatomic shoes," etc., despite the fact that GOST R 57761 "Orthopedic shoes. Terms and definitions" does not include such terms [3]. The range of such products is very diverse, and in this regard, it is challenging for the parents to navigate through the nomenclature of the shoe market and choose the correct product for their children.

Striving to raise a healthy child and prevent the occurrence of foot deformities, parents, independently or based on the recommendation of low-skilled specialist, acquire the widely advertised "orthopedic shoes" for children. These orthopedic shoes may have sub-optimal functional properties, and the design often comprises special orthopedic details made with the violations of medical and technical requirements or has parameters that do not correspond to the anatomical and functional structure of the children's foot. Hence, these orthopedic shoes will not provide the expected positive result, and in turn, may negatively affect the foot anatomy and function (and imperceptibly for the parents). At the same time, a normal foot is the one, in which the morphofunctional indicators match a certain interval of variants for this group [5].

To clarify the situation, a selective assessment of the technical characteristics of pediatric shoes acquired in the St. Petersburg distribution network, including the orthopedic stores, has been performed.

Young children move hesitatingly, where the persistent gait stereotype has not been formed. Flat foot in children under the age of 3 years is a physiological norm. The subcutaneous fat pad developed on the plantar surface increases the ability of the foot to withstand loads, whereas the arch area touches the plane of the support and bears the total body weight. Sometimes, this physiological feature of the pediatric foot is deduced as a pathology, which leads to an erroneous opinion of the parents that their children have flat feet. Until the age of seven, the foot arch is not completely developed and the adipose layer is not lost. Therefore, it is not necessary to exert additional influence on the arch of a healthy child with the use of orthopedic elements.

A well-known visual feature of planovalgus deformity is the incorrect position of the calcaneal part of the foot in children. Therefore, if the parents notice a deviation of the calcaneal axis from the longitudinal vertical axis of tibia in children, it is necessary to seek medical consultation and clarify the diagnosis.

Only a physician or orthopedic specialist can prescribe orthopedic shoes to children. Healthy children should wear ordinary footwear, which is manufactured according to the anatomic and functional parameters of a normal foot and does not interfere with the natural growth and development of the feet.

The study aims to receive answers to the following questions:

- whether the design of the footwear and the parameters of the shoe details correspond to the stated regulatory and technical documentation (RTD);
- whether the shoes declared as orthopedic correspond to special aspects of the pathological condition of the child's foot with a specific deformity; and
- whether the consumer is completely informed about the indications and contraindications set forth in the instruction sheet of the footwear being tested.

Materials and methods

The publicly available shoe samples for younger children produced by companies, such as Ortuzzi, Orthoboom, Orthodon, Tapiboo, Sursil-Orto, Ortho pedic, Skorokhod, Totto, and Ortmann, were examined. A total of 23 pairs of shoes dedicated for children aged 3–5 years, size 25 (155), were analyzed. In the salons of orthopedic equipment and shoe stores, the sample shoes were randomly selected.

The studies were performed using organoleptic and instrumental methods according to the documentation [6] and performed by the developers of the national standard GOST R 54407-2011 "Orthopedic footwear. General technical conditions" [7], qualified as a traumatologist-orthopedist, engineering designer, and technician engineer, who are currently leading as well as are senior research associates of the department of orthopedic shoes and special clothing for the disabled of the Albrecht Federal Scientific Center for Rehabilitation of Disabled People.

Results and discussion of the study

According to design features, 21 pairs of tested footwear should be marketed as "orthopedic footwear," due to their special orthopedic details,

namely circular rigid bootleg, special stiffener, and layout of the longitudinal arch and heel with an extended front surface (Thomas's heel). The special orthopedic details could significantly affect the function of the foot. Therefore, the orthopedic details embodied in the footwear should be strictly for medical reasons only. Hence, the manufacturer is obliged to notify the user about the presence of orthopedic details in the shoes. However, none of the manufacturer has indicated the intended use of orthopedic shoes for specific deformity in the instruction sheet.

Moreover, eight pairs (of the total number of shoes with the specified special parts) were declared as "regular shoes" by the manufacturers.

Thus, almost all tested shoe models, regardless of their stated purpose (orthopedic or regular), have special orthopedic details. However, the accompanying documentation for these shoes did not indicate their medical purposes and operating conditions. This is considered as a gross violation of the requirements of the national standard GOST R 54407-2011 "Orthopedic shoes. General technical conditions," which "applies to orthopedic shoes intended for adults and children, having medical indications for its use" and establishes the classification of shoes for functional (medical) purposes in accordance with the specified deformity of the feet (cl. 4.2), and also the violation of the requirements of the Federal Law No. 323 "On the Fundamentals of Public Health Protection" [8].

Besides, the geometrical parameters of the rigid parts are regulated by a list of requirements in the national standards for regular and orthopedic shoes and calculated using specific formulas. The height of the stiffener (HS) can be calculated as follows:

$$HS = 0.15L + 9 \text{ (mm)},$$

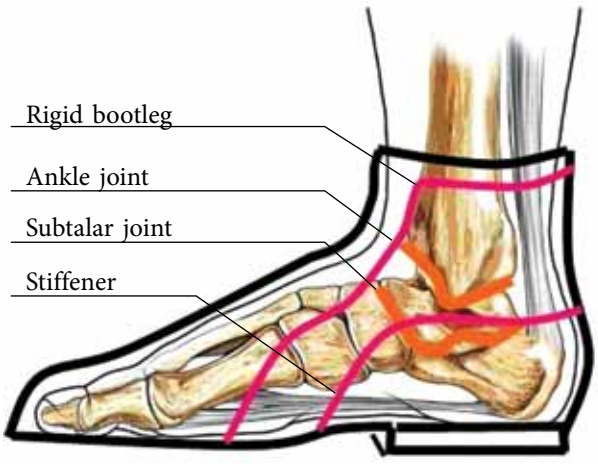

Fig. 1. Location of the special rigid parts of the shoes relative to the foot

where L is the foot length in millimeters (mm), and the height of the rigid bootleg (HRB) is equal to the following:

$$HRB = 0.30L + 59 - 10 \text{ (mm)},$$

i.e., the height of the bootleg should be lower than the standard height of the boot by 10 mm.

A diagram of the optimal location of the rigid bootleg and the counter is shown in Fig. 1.

It is the medical purpose that serves as the rationale for the design requirements in RTD to determine the parameters of special orthopedic parts by considering the anatomical and functional state of the children's foot. Thus, the counter is designed to hold the calcaneus in a functionally advantageous position due to the impact on the subtalar joint, i.e., the counter must be located below the ankle joint and rigid bootleg, fixing and holding the ankle joint. Conversely, it should completely embrace it and prevent lateral deviations of the foot. Variants of the construction of special rigid parts are presented in Fig. 2.

Thus, in the studied age and gender group, with the original size of 155, the HS and HRB should be 32 and 95 mm, respectively.

a *b* *c*

Fig. 2. Configuration and arrangement of special rigid parts (*yellow line*) in orthopedic shoes: *a* — standard counter; *b* — rigid bootleg with the location of the upper edge at the level of the ankles; *c* — rigid bootleg embracing the ankle and metatarsophalangeal joints

Table 1

Main technical characteristics of the tested shoes

No.	Information indicated on the label			Signs of orthopedic shoes	
	Type of footwear	Regulatory technical document	Availability of a marketing authorization for a medical device*	Special orthopedic parts**	Height of the rigid part (mm)***
1	Orthopedic simple	TS 8820-037-53279025-2004	+	Layout of the longitudinal arch, standard counter	36
2	Orthopedic	Not specified	+	Layout of the longitudinal arch, circular rigid bootleg, Thomas's heel	63
3	Orthopedic	TS 8820-001-73943484-2014	+	Layout of the longitudinal arch, circular rigid bootleg with wings extended beyond bundles, Thomas's heel	50
4	Orthopedic selected	TS 8820-001-73943484-2014	+	Extended wing stiffener, Thomas's heel	38
5	Orthopedic selected	TS 8820-001-73943484-2014	+	Circular rigid bootleg with wings extended beyond bundles, Thomas's heel	80
6	Regular anatomic	Not specified	–	Abducted front shoe section, circular rigid bootleg with wings extended beyond bundles, Thomas's heel	80
7	Regular	Not specified	–	Circular rigid bootleg	53
8	Regular	Not specified	–	Circular rigid bootleg	60
9	Regular	Not specified	–	Circular rigid bootleg	60
10	Regular	Not specified	–	Circular rigid bootleg	75
11	Orthopedic	TS 8820-037-53279025-2004	–	Circular rigid bootleg	70
12	Orthopedic	TS 8820-004-71296398-2016	–	Circular rigid bootleg	65
13	Regular	GOST 26165	–	Standard counter	32
14	Regular	Not specified	–	Circular rigid bootleg	60
15	Regular	GOST 26165	–	Stiffener	36
16	Orthopedic low-complex	TS 8820-037-53279025-2004	+	Rigid bootleg	73
17	Orthopedic low-complex	Not specified	+	Special stiffener	46
18	Orthopedic	Not specified	+	Circular rigid bootleg	85
19	Regular	Not specified	–	Special stiffener	50
20	Regular	Not specified	–	Standard counter	36
21	Orthopedic	TS 8820-037-53279025-2004	+	Circular rigid bootleg	60
22	Orthopedic	Not specified	–	Circular rigid bootleg	60
23	Orthopedic	Not specified	–	Circular rigid bootleg	70

Note. * A marketing authorization is issued for a serially manufactured medical product (Federal Law No. 323-FZ dated 21.11.2011 "On the Fundamentals of Public Health Protection in the Russian Federation"); ** Complex orthopedic shoes must have at least two special orthopedic details. Complicated orthopedic shoes should be only with individual manufacturing parameters (GOST R 54407-2011 "Orthopedic shoes. General technical conditions," cl. 6.2.5); *** For shoes of size 155, the heights of the counter and rigid bootleg are 32 and 95 mm, respectively (GOST R 54407-2011 "Orthopedic shoes. General technical conditions," Appendix B).

However, in the tested footwear, the height of the rigid parts shows a wide variation, ranging from 36 to 85 mm (Table 1). Consequently, orthopedic shoes with such structural dimensions did not meet the medical and technical requirements and the functions were not performed.

An erroneously high counter (>32 mm) may adversely affect the foot and injure the Achilles tendon. Therefore, a stiffener with the standard parameters is sufficient to maintain the subtalar joint. Further, shoes with rigid bootleg <95 mm may not confer a reliable fixation to the ankle joint and may impair the dorsal flexion of the foot.

The introduction of a special rigid bootleg to a normal healthy user is unacceptable because it contradicts the requirements of the national standard [7]. Such a detail is installed only in complex orthopedic shoes manufactured according to the individual parameters of the child's foot and strictly according to medical indications.

In addition, the manufacturers are scornful in the technological processes of shoe manufacture, particularly the quality of molding of internal rigid parts. Almost 50% of the total number of tested shoes (11 pairs) has a poorly molded counter and without an expressed contour, which is unacceptable according to the technical requirements for regular and orthopedic shoes. Also, the rigid bootleg was molded without considering the anatomical and functional features of the foot and lower third of the lower leg, which in this case will not provide a stable fixation to the ankle joint and may cause soft tissue trauma.

In the three pairs of shoes tested, the edges of special rigid parts fell on the heads of the metatarsal bones or the ankle joints, which can impair the function of rolling and/or injure the ankles. In the other two pairs of shoes tested, the rigid part simultaneously overlapped the metatarsophalangeal and partially the ankle joint, thereby limiting their movement and disrupting the push function of the foot. This design of orthopedic shoes prevents natural development of the musculoskeletal system in children. In some cases, complex orthopedic shoes of this design should manufactured for specific patients. In the case of severe consequences of cerebral palsy, complex orthopedic shoes could help the wheelchair-bound pediatric patient to hold the foot at a right angle to the lower leg.

Fig. 3. Shoes for clubfoot

As presented in Fig. 3, the shoes left perplexed, and the design includes a set of special orthopedic parts that are prescribed for clubfoot, namely rigid bootleg and Thomas's heel. However, the manufacturer did not declare the shoes as "orthopedic shoes," and the accompanying instruction manual did not indicate the medical purpose and special use.

The following unsatisfactory characteristics of the tested footwear have attracted our attention:

- Shoes were inflexible in bundles and had flat sole without elevation in the toe part and/or artificial roll;
- Backs and bootlegs did not match the shape of the heel contour;
- In some cases, upper parts of the shoe were made of a thick material that exceeded the maximum value specified in the technical documentation.

Some shoe manufacturers utilize split leather with polyurethane coating or composite ("bonded," "collagen") leather instead of natural leather. These materials did not provide a comfortable microclimate inside the shoes and violated the moisture-thermal exchange of the inside shoe space. According to the foreign economic activities nomenclature (FEAN, code 4115), "... are used in the shoe industry to manufacture individual parts of shoes, soles of slippers, insoles, etc."

Thus, virtually all models of the tested footwear are made with the violations of the requirements for regular and orthopedic shoes, which are ignored at the design stage, leading to non-compliance of footwear with the requirements set out in the RTD.

From the aesthetic point of view, the brightly-colored shoe collection in the market had impressed the parents and children. However, the assessment on the publicly available pediatric shoes revealed that the designers focus on the design elaboration without taking the medical and technical requirements into consideration.

Our study indicates that it is challenging for the users to clearly understand a wide variety of orthopedic and regular shoes.

Thus, prior to selecting the orthopedic shoes, parents should seek medical consultation and be guided by professional recommendations but not the seller. Conversely, children who do not have the pathology of the musculoskeletal system should wear regular shoes strictly according to the size of their feet.

Findings

The following data was obtained from the results of the study:

- A total of 13 pairs of the total number of shoes tested (23 pairs) are positioned by manufacturers as "orthopedic shoes," and 10 as "regular shoes." The labeling of >50% of shoe models (12 pairs) has no indication of the regulatory document, which is a violation of the RTD requirements.
- A total of 21 pairs of shoes have design features of orthopedic shoes (i.e., there are special orthopedic details that allow keeping the foot in a correcting position and redistribute the load over the plantar surface).
- The accompanying documents (instructions for use) for 21 pairs have no indications for their use as children's shoes with special orthopedic details.

Conclusion

The results of the present study should be of interest for professionals engaged in the selection and issuance of orthopedic shoes as well as for shoe manufacturers because of their practical orientation. However, it is imperative for the manufacturer to follow the RTD that was drawn up by taking into account the medical and technical requirements. Moreover, proper selection of shoes for children should be strictly performed according to the doctor's instructions, and the manufacturer must inform the buyer about the shoe details.

Therefore, we emphasize that being the developers of national standards for orthopedic shoes, we are ready to share with manufacturers the importance of producing qualified shoes according to the requirements of RTD. Meanwhile, realizing the need for timely updating and specifying the design parameters of orthopedic details, we undertake to regularly revise the current RTD.

In our opinion, the aforementioned statements could help to provide children with high-quality orthopedic footwear manufactured at a high professional level, which ultimately will enable younger generation to maintain and preserve their physical health, because healthy children make a healthy nation.

Additional information

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Conflict of interest. The authors declare no conflict of interest related to the publication of this article.

Contribution of the authors

E.I. Skirmont, E.L. Zimina performed the collection and processing of materials.

Yu.B. Golubeva created the concept and design of the study.

I.K. Gorelova made the analysis of the data and wrote the text.

V.M. Volkova was engaged in the collection and processing of materials and writing the text.

S.V. Karapetyan performed the data analysis.

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