MINERVA ORTOPEDICA E TRAUMATOLOGICA

VOL. 69 · SUPPL. 1 · N. 3 · SETTEMBRE 2018

SUSU 2018

EDIZIONI · MINERVA · MEDICA

PUBBLICAZIONE PERIODICA TRIMESTRALE - POSTE ITALIANE S.P.A. - SPED. IN A.P.D.L. 353/2003 (CONV. IN L. 27/02/2004 N° 46) ART. 1, COMMA 1, DCB/CN - ISSN 0026-4911 TAXE PERÇUE

Minerva Ortopedica e Traumatologica 2018 Settembre;69(3):55-9
DOI: 10.23736/S0394-3410.17.03853-X

ORIGINAL ARTICLE

Individual silicone insole design and assessment of effectiveness

Vitaly EPISHEV, Galina YAKOVLEVA *, Kristina FEDOROVA

Institute of Sports, Tourism, and Service, South Ural State University, Chelyabinsk, Russia

*Corresponding author: Galina Yakovleva, 60 Soni Krivoi, Chelyabinsk 454080, Russia. E-mail: yakovleva.g.v@ya.ru

ABSTRACT

BACKGROUND: Being a frequent pathology that may lead to even more severe disorder, foot deformities should be managed in the most effective manner. Due to high incidence of foot problems which have to be treated using conservative and surgical methods, the available and effective orthotics becomes absolutely necessary both for conservative treatment and for post-surgery rehabilitation. The aim of our research was to design individual silicone insole and to test its effectiveness using specially developed diagnostic methods.

METHODS: We developed the specially designed and easily manufactured silicone insole together with software for express diagnosis of flat foot, which allows the fabrication of custom-made insoles. We created 3D model of prototype insole in SolidWorks, manufactured the original casting mold to be filled with two-component silicone and designed the equipment for diagnosis and custom-made production. The method for assessment of effectiveness was developed, and the series of experiment was conducted for 35 participants: video analysis of running (12 km/h) using Life Fitness treadmill and 600-fps video recording by Phantom Miro eX2.

RESULTS: The analysis showed that 90% of the participants had abnormalities of biomechanics at the stance phase associated with foot hyperpronation; in 55% the observed abnormalities were induced by foot abduction; and in 48%, foot hyperpronation was combined with the compensatory repositioning of the knee joint. Using the correcting insoles was effective in 33 participants and was mainly followed by changes of the ankle joint angle. In 23 participants the compensatory repositioning of the knee joint became less expressed.

CONCLUSIONS: Our findings show that even being used for the first time the custom-made silicone insole corrects the foot-ankle angle and has a positive effect on foot conditions. Ninety-four percent of the participants report improvements in leg fatigue, knee joint pain, and general well-being.

(*Cite this article as:* Epishev V, Yakovleva G, Fedorova K. PIndividual silicone insole design and assessment of effectiveness. Minerva Ortop Traumatol 2018;69(Suppl. 1 al N. 3):55-9. DOI: 10.23736/S0394-3410.17.03853-X)

KEY WORDS: Flatfoot - Mechanical stress - Foot deformities - Rehabilitation - Foot orthoses.

In the modern society the practical medicine in general and rehabilitation in particular focus on maintenance and promotion of the human health. Rehabilitation is a system of interrelated medical, psychological, and social components aimed to maintain the integrity of a person and his/her social status, and, what is the most essential, to restore the human health; the latter has many indicators, one of which is definitely the condition of feet.[1, 2] Planovalgus foot deformity (PVFD) is a complex and socially important medical problem, especially in orthopedics. According to statistics provided by the leading Russian medical institutions, PVFD accounts for 19.7% of all musculoskeletal disorders; according to the World Health Organization (WHO) data, 75% of all population worldwide suffers from foot deformities, and the most frequent pathology is valgus foot deformity.[3]

Due to high incidence of foot problems which have to be treated using conservative and surgical methods, the available and effective orthotics becomes absolutely necessary both for conservative treatment and for post-surgery rehabilitation.[4] One of the most common orthotic means is individual, or custom-made, anatomical correcting insoles (further referred to as insoles).

In orthotic management of foot deformities, there is a complicated and under-investigated problem of adjustment of foot orthoses to the arch of the foot.[5] Using the inappropriate orthoses results in excessive loads applied to some foot areas and affects the gait cycle biomechanics.[6] Furthermore, the special attention should be paid to the insole material in accordance with exact purposes. All the stated above determined the specific of our insole project.

Foot deformity is one of the most common reasons why athletes may need to consult a sport physiologist as even subtle changes of the foot structure affect the complex kinematic chain of the locomotor system responsible for associated movements of muscles, bones and joints, which leads to injuries and, eventually, interrupts the training process. Foot deformities and functional inability trigger many compensatory reactions of superjacent large joints: knees, pelvis, spinal column, and shoulders. Moreover, the distorted information transferred from the foot mechanoreceptors causes the excessive contraction of muscles, formation of “wrong” movement patterns, and, in the end, pain in superjacent areas. In this respect, foot deformity diagnosis and correction are essential in the prevention and treatment of many musculoskeletal disorders.

Considering the vast variety of lifestyle patterns and foot peculiarities, it is necessary to develop the methods for correction and prevention of different forms of PVFD. We started searching for ways to prevent and to eliminate the negative consequences of PVFD, during the rehabilitation process as well. We examined national and local standards of fabrication of custom-made insoles and studied the existing techniques for deformity diagnosis.[7]

Materials and methods

Six women and 29 men (age 18-30; N.=35) were recruited as participants. The statistical processing was performed for the following mean parameters of foot: overall length and length of forefoot, midfoot and hindfoot; angle of deviation of toes 1 and 5; coefficient K determining the condition of the longitudinal arch in the midfoot; and calcaneus angle HC’K associated with the condition of the longitudinal arch in the hindfoot.[8]

To perform the further stage of studies we considered the conditions of the lower limb joints, pelvis bones and the spinal column, biomechanical disorders, individual features of the locomotor system (LMS), and levels of physical activity.

Posturologic examination including stabilometry (MBN Stabilo, Russia) and positioning of bone landmarks (MBN 3D Spine scanner, Russia) makes it possible to determine the postural (pose) status and reveal some diseases and many functional and anatomic asymmetries of the body (Figure 1).[9]

The stated parameters were obtained by the means of conventional diagnostic methods, which means the assessment of changes of the longitudinal arch height under load of the body weight and at rest without load. The special software was developed to perform the diagnostic test (Figure 2).

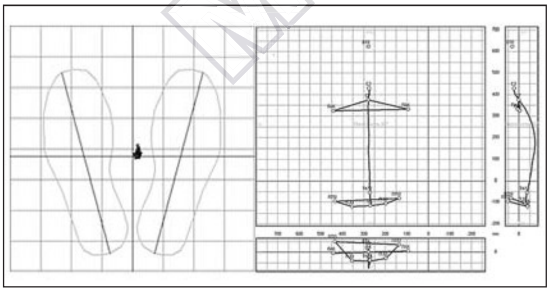

Figure 1.—Posturologic examination.

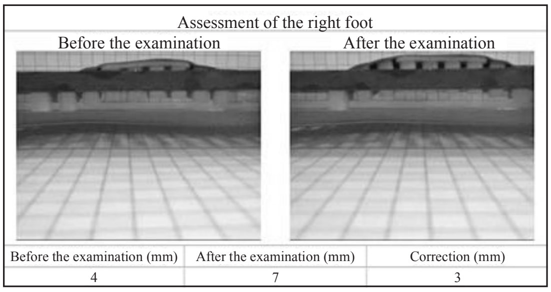

Figure 2.—Longitudinal arch assessment using photo test.

The diagnostic test included the following stages:
— under-load pronation assessment;
— taking a picture of the longitudinal arch under load;
— reposition of the leg under examination: position parallel to the floor, without load;
— changing the height of lamellae for the arch of foot under examination;
— taking a picture of the longitudinal arch without load;
— measuring the longitudinal arch height before and after correction for both feet.

According to the relevant literature,[10, 11] it is very important to study not only the volume of movements, but also supination, pronation, abduction, and adduction in a patient. Most frequently, abduction and adduction may be seen only in the frontal plane when the patient is moving.

In order to assess the active shift (motion) of the ankle joint we used video recording in the frontal plane (600 fps) while the participant was exercising on Life Fitness treadmill at a speed of 12 km/h. The treadmill was necessary to create a permanent cyclic action. The speed was determined by the participant's motion mode.

The diagnostic test included the following stages:
— participant's history recording;
— diagnostic examination (using the treadmill for 10 minutes minimum, video recording, slowing down the video speed);
— primary visual assessment of biomechanics of motion;
— video-processing for assessment of angular changes (Figure 3).

Insole production

Ninety percent of people from our sample needed foot orthoses; 34% of them already used individual orthotic means. The participants reported that they had to re-adjust the insoles every month due to "constant discomfort" or "corns," and that the insole width limited the range of available footwear. We considered these complaints while developing the basic prototype insole.[12, 13]

We searched for the most durable and wear-resisting material so that the insole could keep its shape for as long as possible. Based on the results, we chose platinum- and/or tin-containing silicone rubbers as silicone is a high-tensile material. Another essential criterion was fine elastic properties, or springiness.[14] Using SolidWorks software we created a 3D-model of the prototype insole and then designed and fabricated an original casting mold (Figure 4) [5, 13]

With the help of CIMCORE Stinger II control equipment we obtained a 2D-model of a men's insole outline (USA shoe size 13). Absolute measurement error was only 0.1 mm, which meant the sufficient accuracy of the designed insole. Then based on the obtained outline and national standards we developed the engineering design of device for cutting off the excessive

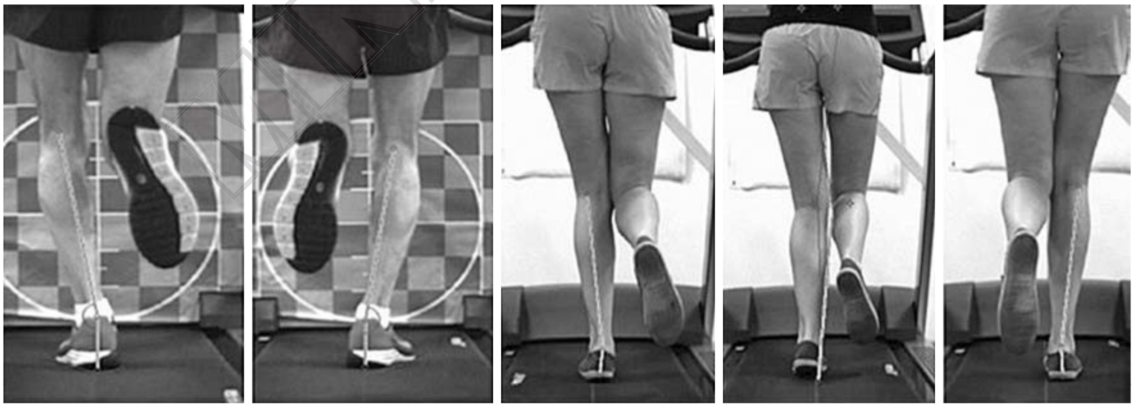

Figure 3.—Video assessment.

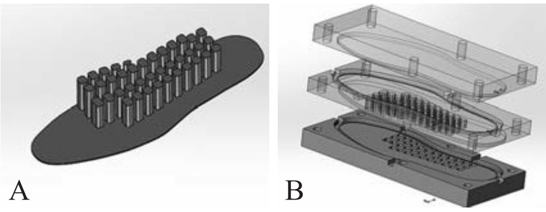

Figure 4.—A) Prototype insole model; B) original casting mold.

length of lamellae in order to form a custom-made insole.[15, 16] Lamellae are cut by the means of a pedal blade sliding on the surface of correcting grid.[17]

Results and discussion

Before correction

The initial analysis revealed that only 3 of 35 participants did not have any signs of foot deformity. The distribution of foot conditions among the participants is presented in Table I.

According to posturologic examination findings, less than 6% of the participants had normal posture; all the rest had postural problems of different severity (Table II).

The correlation analysis revealed some positive correlations: slightly flattened arch – scoliotic posture, slightly flattened arch – first-degree scoliosis, first-degree flatfoot – first-degree scoliosis, third-degree flatfoot – flat back ($P<0.05$).

Frontal plane video analysis showed that 90% of the participants had abnormalities of biomechanics at the stance phase associated with foot hyperpronation; in 55% the observed abnormalities was induced by foot abduction; and in 48%, foot hyperpronation was combined with the compensatory repositioning of the knee joint.

After correction

Using the correcting insoles was effective to different extents in 33 participants and was mainly followed by changes of the ankle joint angle. In 23 participants the compensatory repositioning of the knee joint became less expressed. The immediate effects of correction may be seen from Table III.

The positions of the ankle and knee joints are corrected with the help of developed exercises and correcting insoles. To evaluate the effectiveness of correcting insole and the related reduction of deformities in the ankle and knee joints the repeated video analysis of biomechanics of movement is performed in 30 and 90 days after the correction started. The analysis is based on the described methods for obtaining the data on the longitudinal arch and ankle joint positioning.

Diagnostic procedure

Foot condition is traditionally assessed in the position when the foot hangs loosely (while the patient is sitting on the chair or is kneeling), during

TABLE I.—*Foot conditions observed in the participants (N.=35).*

Foot condition	N. patients	Percentage
Normal arch	3	8.57%
Slightly flattened arch	4	11.43%
First-degree flatfoot	7	20%
Second-degree flatfoot	17	48.57%
Third-degree flatfoot	4	11.43%

TABLE II.—*The results of posturologic examination conducted on the participants (N.=35).*

Postural condition	N. patients	Percentage
Normal posture	2	5.71%
Scoliotic posture (right- and left-curving)	10	28.57%
First-degree scoliosis (right- and left-curving)	12	34.28%
Flat back	8	22.88%
Kyphotic spine	3	8.56%

TABLE III.—*Immediate corrective effects observed in the participants after using the insoles (N.=35).*

Effect on the ankle joint angle	Effect on the knee joint	N. patients	Percentage
No change	No	2	5.71%
Changed by 2-4 degrees	No	8	22.85%
Changed by 5-7 degrees	Reduced microvibration	17	48.57%
Changed by 8-10 degrees	Reduced microvibration	5	14.30%
Changed by >10 degrees	Reduced microvibration	3	8.57%

the forefoot movements, and under load walking and standing. The examination starts from the evaluation of calcaneal area position relative to the ankle. Russian and foreign practice focuses mainly on the volume of movements to assess the foot pronation, in a loose position, when the ankle and talocalcaneonavicular joints are set to motion, and also under load (standing).7, 9

However, in medical literature there are only few sources dedicated to studies of the ankle joint in movement (walking or running).

We developed a diagnostic complex that combines traditional diagnostic means with examination of active motions of the ankle joint and forefoot rotations. This complex also includes the examination of the knee joint positioning as the next element in LMS changes.[11]

Conclusions

The obtained data show that using the correcting insole prototype has a positive effect on foot conditions; 94% of the participants report the improvements: the decreased leg fatigue, knee joint pain relief, and general well-being mend.

Pathological inward movement of the ankle joint and PVFD are a medical challenge, and according to the different estimates up to 80% of population suffer from these deformities. Pre-made insoles are often rigid-frame, which may exacerbate some foot deformities or “remove the ankle joint from active functioning.” The suggested insole prototype is made of silicone rubber; it is flexible and elastic. Thanks to mid-area support the insole is springy at movement thus involving all ligaments and muscles into the walking process, which normalizes the blood flow and prevents edemas and foot muscle atrophy. The insole is custom-made for each foot individually using the mirror technology and correcting grid. The given prototype is the final variant at the first stage of our work.

References

1. Epifanov VA. Medical Rehabilitation. Moscow: MEDpress-inform; 2008.

2. Smychek VB. Rehabilitation of Patients and Physically Challenged People. Moscow: Meditsinskaya literature; 2009.

3. Takhmezov RT. Ethnic Peculiarities of Foot Arch in Women. Saint-Petersburg: SPGPMA; 2013.

4. Boltrukevich SI, Kochergin VV, Lashkovsky VV. Foot formation in school-age children. Grodno Med Univ J 2005;4:55-7.

5. Abzalbekuly B, Dzhanakhmetov OK, Dzhumabekova GB. Study of physical and mechanical properties of novel silicone compositions for orthotic footwear. Vestnik KazNITU 2013;1:25-36.

6. Berko NS, Fitzgerald EF, Amaral TD, Payares M, Levin TL. Ultrasound elastography in children: establishing the normal range of muscle elasticity. Pediatr Radiol 2014;44:158-63.

7. Menz HB. Alternative techniques for the clinical assessment of foot pronation. J Am Podiatr 1998;88:119-29.

8. Shaldin VI, Bibikina OV. Assessment of Foot Condition. Chelyabinsk: UralGUFK; 2008.

9. Hetsroni I, Finestone A, Milgrom C, Nyska M, Radeva D. A prospective biomechanical study of the association between foot pronation and the incidence of anterior knee pain among military infantry recruits. J Bone Joint Surg 2006;88:8-12.

10. Kornilov VN, Gryaznukhin EG. Traumatology and Orthopedics: Medical Guide. Saint-Petersburg: Gippokrat; 2006.

11. Busquet L. Muscle Chains. Moscow: Meridian-S; 2011.

12. Ryabina KE, Fyodorov AV, Epishev VV. Developing the correcting sport insole. Tula State Univ Bull 2014;4:114-20.

13. Ryabina KE, Fyodorov AV, Epishev VV. Innovative approach to fabrication of custom-made sport insole: technical solution. Proceedings of International Conference on Advanced Research in Physical Education, Sport and Tourism 2014;1:355-8.

14. Stell JE, Buckley JG. Controlling excessive pronation: a comparison of casted and non-casted orthoses. Foot 1998;8:210-4.

15. Temnikova IV, Ryabina KE, Epishev VV. Engineering process in custom-made sport insole manufacturing. Molodoi Issledovatel 2015;1:196-9.

16. Ryabina KE, Fyodorov AV, Epishev VV. Justification and design of custom-made correcting insoles. Act Problems Human Nat Sci 2015;5:182-7.

17. Ryabina KE, Fyodorov AV, Epishev VV. Some engineering aspects of design and development of individual insoles. Sci Res Theory Pract 2015;1:136-41.

Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Funding.—The work was supported by Act 211 of the Government of the Russian Federation, contract N° 02.A03.21.0011.

Manuscript accepted: November 27, 2017. - Manuscript received: November 26, 2017.