Journal of the Korean Society of Manufacturing Technology Engineers 32:4 (2023) 198~205

https://doi.org/10.7735/ksmte.2023.32.4.198

J. Korean Soc. Manuf. Technol. Eng.
ISSN 2508-5107(Online)

A Study on the Effect of Flexcage Apparatus on Bone Density

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ARTICLE INFO

Article history:

Received	24	May	2023
Revised	22	June	2023
Accepted	27	June	2023

Keywords:
Shoe apparatus
Flexcage
Human body
Bone density
Impact force

ABSTRACT

The purpose of this study is to investigate the effect of functional shoe apparatus on bone density. To evaluate the usefulness of the flexcage apparatus inserted into the shoes, an appropriate impact force was applied to the feet. The model with the proposed structure had an effective stress of approximately 20–100% higher than that of the model without it, among most of 15 bone extraction points. Although the finite element analysis data from the human body model were not the values of mineral bone densities measured directly but those of the effective bone stresses against impact, the proposed structure was designed to increase the bone mass and improve the mineral bone density by actually improving the density of mineral bone. In conclusion, shoes with flexcage inserts were evaluated to improve the bone density compared with those without inserts.

1. Introduction

Among various factors that can improve the quality of walking, attention to good bone density is necessary. Osteoporosis is a representative disease related to bone density. Prevention of osteoporosis requires improving lifestyle habits centered around nutrition and exercise, and increasing maximum bone mass from childhood to middle age in order to minimize the rate of bone loss with age[1]. During walking, numerous skeletal muscles and nerves in the legs react collectively, and walking is the most frequent human activity performed naturally in daily life, acting as an important factor in determining quality of life[2]. Generally, bone density reaches its peak in the early 30s and gradually decreases by about 1% per year after the age of 35, with the rate of decline accelerating especially after menopause, causing approximately 7% of bone loss per year[3]. Risk factors that contribute to osteoporosis, a disease related to bone density, include race, genetics, aging, low body weight, calcium and vitamin D deficiency, smoking, early menopause, family history of osteoporosis, and lack of physical activity. Many research reports suggest that physical activity is a crucial factor in the treatment and prevention of osteoporosis, as it is closely related to bone density[4]. Weight bearing exercise in daily life is an important external factor for the development and remodeling of bones. The anatomist Wolff from Germany stated in his law of bone remodeling that changes in bone mass during the process of bone remodeling follow changes in the load-bearing load. All changes in skeletal function are manifested as changes in internal structure and external form that precisely match mathematical laws[5].

Research on the effects of exercise on bone density, such

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as the decrease in bone density seen in long-term bed rest and zero gravity, and aerobic exercise, indicates that weight bearing exercise has a positive effect on maintaining bone density[6,7]. It has also been reported that the maximum bone mass and bone density in the human body can be improved or increased by weight-bearing exercise[8]. In particular, for elementary school students in their growth period, regular weight-bearing exercise such as running, jumping, and kicking as a long-term physical training can increase bone density by accelerating the process of bone remodeling, which can help prevent bone fractures[9]. Therefore, all exercises performed by gravity itself act as their own load, and stretching that relaxes joints and ligaments can also have beneficial effects on the skeletal system by applying light resistance. Various preceding studies have suggested a positive correlation between regular stimulation and increased bone density[10]. If you have shoes that do not fit your feet or have a walking habit that does not match your foot type, it can decrease the muscle strength supporting your body and result in increased stress on the knees, waist, and other areas, leading to disability[11]. In addition, repetitive foot stress due to weight and ground reaction force during walking is a significant cause of various foot conditions such as foot ulcers and mid-foot pain[12]. Therefore, taking into account many research results that identify shock as a cause of injury, a structural approach to shoes is needed to apply appropriate shock while not causing foot conditions.

In this study, the finite element method is introduced to analyze and verify the main functions of the flexcage structure, which is designed to improve bone density, in order to reduce the time and cost of technical development and performance verification in real field tests. Additionally, the analysis aims to evaluate the comfort of wearing shoes by measuring changes in pressure distribution, including differences in average pressure, through evaluating the pressure distribution between shoes with and without the flexcage structure.

The purpose of this study is to establish experimental evidence for the impact of the flexcage structure's foot shock on bone density through finite element analysis, and to evaluate whether the structure applied in the developed shoes provides comfort when pressure distribution is analyzed.

2. Research content

In this study, the flexcage, a structure designed to improve bone density, was inserted into shoes and compared to shoes without the flexcage. First, using finite element analysis, the effective stress difference of the impact force on the foot bones between the model with the inserted flexcage and the model without it during walking was investigated. Second, through the analysis of the pressure distribution on the foot during walking, the difference in contact area and maximum peak pressure between the shoes with the inserted flexcage and those without it was examined to compare the degree of footwear and load. In conducting this study, the following limitations were imposed: firstly, only individuals without any current history of foot problems were included in the assessment of plantar pressure distribution. Secondly, individuals without any morphological foot alterations such as rigid feet, hallux valgus, and pes planus were included. Thirdly, participants were required to wear shoes that fit their foot size and walk on a treadmill at a speed of 4.2 km/h to control for factors such as stride length and gait width due to foot size. Fourthly, the shoe for finite element analysis was composed of a sole with an outsole, midsole, insole, and flex cage structure, and an upper. Fifthly, a three-dimensional CAD modeling that reflected the anatomical structure and a finite element analysis model for simulation were applied to the human-foot coupling model. Lastly, the lower extremities were limited to the knee in the human model for finite element analysis.

3. Structure design

3.1 Design of shoes flexcage

Previous research has focused on the potential for foot shock to cause injury to the human body, and numerous studies have been conducted on this topic[13,14]. In shoe development to date, there has been a strong emphasis on creating shoes that incorporate the findings of this research. However, in another area, various studies have been conducted on the positive effects of shock-loading exercises on bone density[15]. Researchers have paid attention to the results of the latter studies, which indicate that shock applied to the feet during walking can improve the bone density of the lower leg (below the knee joint) that is connected to the feet. The design process for incorporating this finding involves creating appropriate shock absorption in the footwear.

3.2 Flexcage and manufacture of shoes

Polymer materials (elastomers) are materials that have both shock absorption and rebound elasticity, but if one function is improved, the other function tends to decrease. Currently, the shock absorption function by the material and the rebound elasticity function by the structure are both satisfied in the shock-absorbing system of a shoe brand, but it is insufficient to satisfy both functions. However, a newly designed shoe structure called the flexcage structure, which is composed of appropriately arranged shock absorption, absorption, and rebound elasticity of the material and structure, performs the function of maintaining the balance of compression stress and energy return, and transmitting shock and waves to the bone, using the injection of the 1st and 2nd structure (TPU material) and gel material.

The initial design attempted to maintain each structure as an independent form to control shock. However, there were many issues with functional implementation due to various obstacles in the manufacturing process. Therefore, the direction was revised to an improved design as shown in Fig. 1.

The initial flexcage structure attempted structural improvements due to difficulties in commercialization with regard to practicality and performance. A structural verification was performed using 3D printing as an optimization process for the improved design, and based on this, the feasibility of functional implementation such as coupling, structural suitability, and visual appearance were tested when inserting the shoes. Fig. 2 is the starting piece of the flexcage structure for improvement using 3D printing, and Fig. 3 shows the first structure of the improved design.

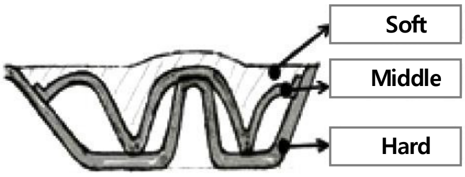

Fig. 1 Design model of flexcage structure

Fig. 2 3D printed product of flexcage apparatus

Fig. 3 First apparatus of flexcage

The primary structural gel performs a role in dispersing impact like the skin of the foot and enhancing comfort, and the injection molded product connected with the gel serves as a catalyst not only for energy return of the secondary structure but also as a bridge connecting the two structures by repeating the transmission process of waves for deformation loads. Furthermore, it is designed to amplify shock waves from loads through a waveform structure. Fig. 4 shows the secondary structure of the improved structure.

The secondary structure is a structure that maximizes shock absorption at the point of maximum load transmitted from the primary structure to act as a storage for force for energy return in the structure, transmitting waves caused by compression deformation to the goal, and transmitting the force of the load through a dual-angle structure. Mold development proceeded by dividing into structure molds for the structure and shoe molds for shoe production. The structure mold was made using a simultaneous injection mold capable of molding gel and injection molding simultaneously for the primary structure, and the injection molding for the secondary structure, injection molding was made with a single mold[16,17]. The combination

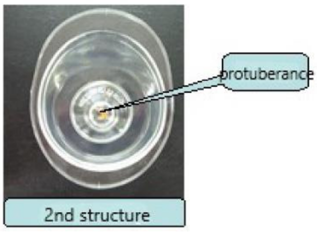

Fig. 4 Second apparatus of flexcage

Fig. 5 Simultaneous injection mold for first and second apparatus of flexcage

Fig. 6 Running shoe outsole, injection mold with flexcage and PU, pylon midsole molds

Fig. 7 Shoes equipped with a designed flexcage structure

of these two used the traditional bonding method in shoe production. Fig. 5 shows simultaneous injection mold for first and second apparatus of flexcage. The shoe mold was completed by separating the heel and toe parts in a form that allows the flexcage structure to be visible in the shoe's appearance. The heel part was made of polyurethane (PU) material, and the toe part was made of pyron material. Fig. 6 shows running shoe outsole, injection mold with flexcage and PU and pylon midsole molds. Fig. 7 shows shoes equipped with a designed flexcage structure. The shoe production process involved creating a sole with an innovative flexcage structure and combining it with a separately manufactured upper to complete the shoe.

4. Numerical analysis

The appropriate impact rate on the feet during walking and exercise actually increases bone density. In this study, finite element analysis was used to understand the landing impact characteristics of flexcage structures inserted into shoes and to compare and analyze their effects on bones. Fig. 8 shows the shape of the flexcage (1/2 model) and its insertion into the shoe.

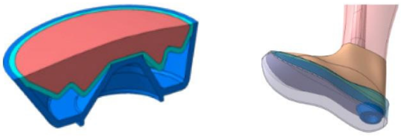

Fig. 8 Shape of flexcage (1/2 model) and inserted into the shoe

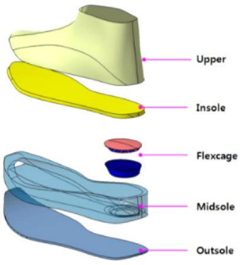

Fig. 9 Model of a shoe with flexcage

Fig. 9 shows a modeled shoe, which typically consists of a sole made up of an outsole, midsole, and insole, as well as an upper made up of the upper material. In this study, the developed flexcage is inserted into the midsole. Finite element analysis was introduced to analyze and verify the main function of improving the bone density of the applied flexcage structure. This was done to save time and costs in technology development, as well as to provide an alternative to performance verification in field testing.

Flexcage is composed of gel and injection material, and the behavior of the gel can be expressed by its hyperelastic properties, which are nonlinear, incompressible, and highly deformable. In this study, the Mooney-Rivlin function, which is the most commonly used strain energy function represented by the constant of the constitutive equation, was used based on the invariance of the elongation rate[18]. The material constants of rubber were determined by curve fitting the stress-strain data obtained from uniaxial tensile tests of flexcage gel and injection samples using ANSYS^{TM}. Using this concept, the properties of rubber materials such as midsole and insole are numerically expressed through similar processes. In this study, dynamic analysis was performed using the ANSYS^{TM} LS-DYNA impact finite element analysis program. A coupled numerical analysis model for the sole and shoe was completed by integrating a solid model with the commercial analysis program ANSYS^{TM}. Fig. 10 shows the geometric model and

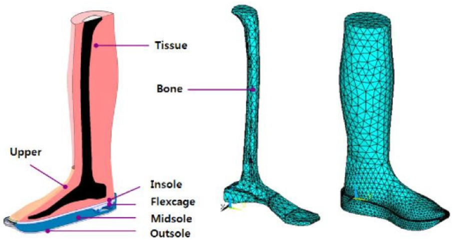

Fig. 10 Geometric and finite element models of the human-shoe interaction model

finite element model.

5. Plantar pressure test

This study completed the production of shoes with flexcage structures designed to improve bone density, and measured changes in pressure distribution, such as differences in average pressure, between shoes with inserted structures and shoes without them, using pressure measurement equipment. The study evaluated the level of comfort and load when wearing the shoes by measuring changes in pressure distribution.

In this study, we conducted measurements of plantar pressure distribution to establish data for the research purpose and final results. The study participants wore tight-fitting tights, and each subject randomly wore shoes with an inserted structure developed for the experiment and regular shoes without the structure while maintaining a normal walking speed (4.2 km/h) on a treadmill. The experimental method compared and analyzed the plantar pressure distribution measurement values for daily walking for shoes with and without the inserted structure on the treadmill at a normal walking speed of 4.2 km/h. This was conducted based on the average walking speed of Koreans of 0.66 m/step, which was estimated to be approximately 4.2 km/h per hour at a walking speed of 1.17 m/s per second[19].

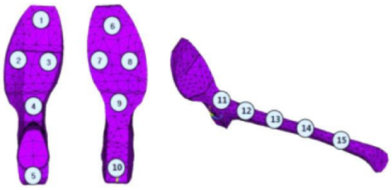

Fig. 11 Points for measuring of bone stress

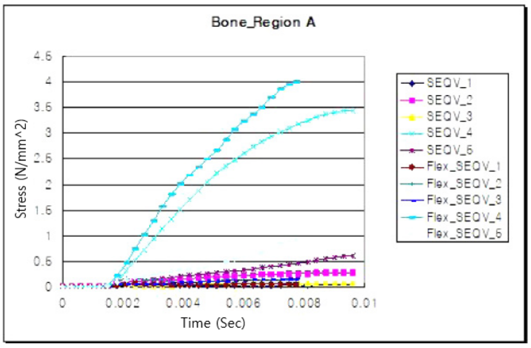

Fig. 12 Distribution of effective stress of bone (area A)

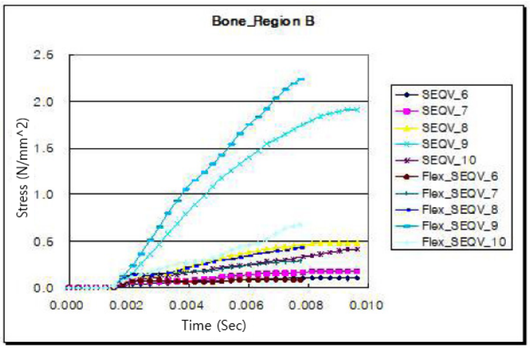

Fig. 13 Distribution of effective stress of bone (area B)

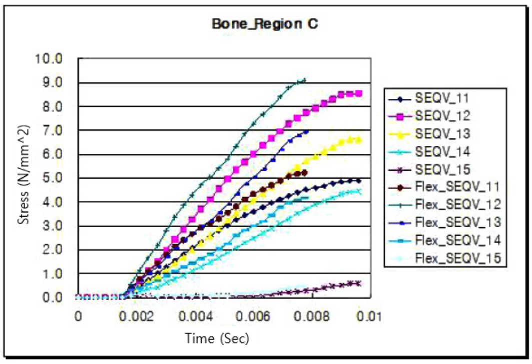

Fig. 14 Distribution of effective stress of bone (area C)

6. Results and discussions

Taking into consideration the weight of the human body, mass elements were created at the center of gravity of the lower limbs using the ANSYS^{TM} LS_DYNA impact finite element analysis program. To analyze the effects on bone density improvement, a flexcage structure designed to influence the analysis was inserted into the model, and the impact of the models with and without the flexcage structure on the bone was analyzed by dividing them into A, B, and C regions. The A region was defined as the forefoot (1-5), the B region as the sole of the foot (6-10), and the C region as the leg (11-15), and the positions for extracting stress from

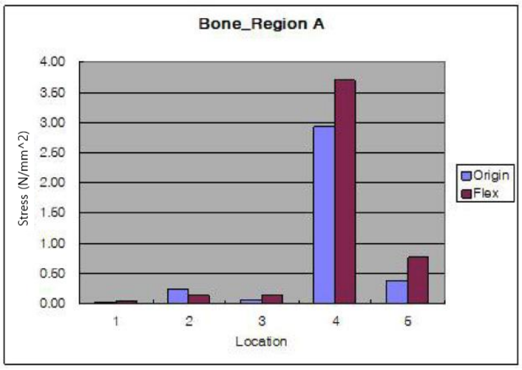

Fig. 15 Comparison of effective stress of bone (area A)

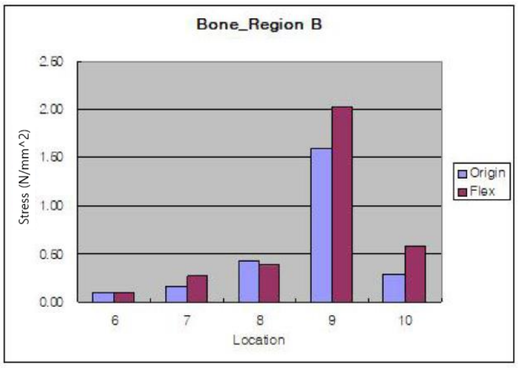

Fig. 16 Comparison of effective stress of bone (area B)

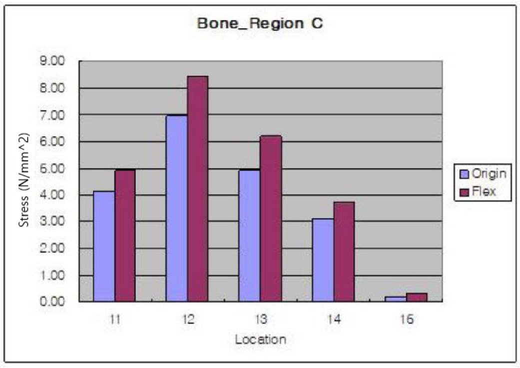

Fig. 17 Comparison of effective stress of bone (area C)

the bone model were selected and shown in Fig. 11.

The trends of effective stress for the time history are shown in Fig. 12, 13, 14. The effective stress name for the non-inserted model is represented as SEQV, and for the inserted model as Flex_SEQV, allowing the values at each extraction location to be examined.

Based on the results above, the model with the inserted structure showed about 20-100% higher effective stress in most of the areas of the sole compared to the model without the insertion. Additionally, analysis of the plantar pressure distribution revealed that the flexcage structure acts as a shock structure, transmitting higher impacts while maintaining the fit of the regular shoe in the shoe with the inserted structure. Therefore, it is concluded that the flexcage structure performs the role of a shock structure.

The results comparing the effective stress on the bone between the model with inserted flexcage (Flex) and the model without insertion (Origin) at Time = 6.9E-3 [s] are shown in Fig. 15, 16, and 17.

7. Conclusions

The developed flexcage structure is considered to be able to improve bone density, as it has been shown to have about 20-100% higher effective stress in most areas of the bone compared to the non-inserted model, and to deliver higher impact while maintaining the comfort of regular shoes in shoes with the inserted structure, according to the results of the analysis of plantar pressure distribution. This is similar to the findings reported in various previous studies (references [8], [9], [10], [15], etc.) that indicate that impact loading has a positive effect on maintaining bone density, and regular stimulation on the feet gradually improves or increases peak bone mass and bone density in the human body. Therefore, applying a structure and material that can maintain the comfort of shock load insertion shoes based on the verification results of finite element analysis and the analysis of plantar pressure, where the data on maximum pressure is similar in shape, is expected to be a desirable research direction for developing shoes with impact load structures in the future. However, there is a limit to the values of the data obtained from the finite element analysis of the human-body coupled model applied to the structure designed to perform the role of increasing bone mass and bone density, as they represent the effective stress on the bone due to impact, rather than a direct measurement of bone density. Nevertheless, the likelihood of the predicted design structure affecting bone density improvement was found. Furthermore, it is suggested that additional clinical validation studies are needed to provide positive effects, such as performing high-impact activities during daily walking, for individuals in groups with limited physical activity, such as the elderly or frail.

In future research, based on the results of this study, we plan to develop a structure and materials for shock-absorbing footwear inserts that can provide positive effects, such as performing high-impact exercises during everyday walking, while maintaining comfort. Additionally, we aim to derive more practical results through specific clinical studies.

Acknowledgement

This work was supported by a Research Grant of Pukyong National University(2023).

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