Designing the Structure of and a Fabrication Process for a Corrective Insole in CAD/CAE/CAM Systems

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Abstract. This paper presents the results of our research into improving the design and fabrication quality of custom-molded corrective insoles by developing modern computer-aided modeling and programming methods that factor in changes in the mechanical properties of materials during use. This paper proposes a method for designing custom corrective insoles using the optimal insole structure and material. We used OrthoModel to design an insole model in a solid-body format and then exported it as an STL file. Then, using FreeCAD, we converted the STL file to a STEP file to better adapt the model for further use and analysis. Using the Ansys environment, we devised a finite element model for insole deformation and investigated the behavior exhibited by the material of the insole arch under different loads and combinations of EVA materials with varying hardness. The model yielded the stresses and deformations experienced by the insole arch during use, depending on the combination of the material and the geometry of the foot, and those stresses and deformations were experimentally verified. The calculated values for insole deformation served as input for programming the processing of the insole with a CNC machine. With a 3D insole model, it is possible to both fabricate the insole with a CNC machine and to print the insole with a 3D printer. The calculated cost price of fabricating custom-molded corrective insoles attests to the competitiveness of the proposed technique.

1. Introduction
We analyzed the existing methods for designing and fabricating custom corrective insoles, considering the physical and mechanical properties of materials and the most common orthosis structures.

Unlike the physical and mechanical properties of metals, which allow the strain–stress state to be described linearly, ethylene-vinyl acetate (EVA) has nonlinear properties and many parameters (from four to six) that affect the strain–stress state [1,2].

EVA corrective insoles undergo complicated dynamic conditions during use because when standing, walking, and running the foot makes various motions with different amplitudes and frequencies [3]. The orthosis is repeatedly exposed to complicated mechanical interactions between the foot, the insole, and the shoe [4,5]. The finite element method can be used to determine material deformation, threshold foot pressure, orthosis deformation, load distribution, and much more besides. There are several interesting examples of orthosis and foot modeling [6].

Reference [7] proposes a 3D foot model to estimate the plantar pressure, with the results compared with literature data. When making the Ansys model, we considered the nonlinear properties of materials, large deformations, and other nuances of the boundary conditions involved in the problem. References [8,9] investigated the effect that the use of orthoses has in a position of maximal contact with the foot arch. The contact pressures exerted by the foot on contoured and flat insoles were
compared. The calculations factored in the nonlinear properties of materials. The finite element analysis showed that the use of corrective insoles with full-contact arch support reduces the contact pressures in the metatarsal and heel regions since the loads are redistributed.

Because of the resilient properties and insufficient rigidity of the EVA insole and the variability of patient weight, custom corrective insoles that provide the desired arch support cannot be fabricated quickly and easily [10,11].

This poses the problem of designing the insole subject to the varying EVA properties and the deformation of insole arch height for different patient-weight groups. In developing methods to evaluate the properties of the orthosis during use, the displacement of the arch can be identified for various patient-weight groups, yielding several indicators determining the orthosis fabrication process.

The purpose of this paper is to facilitate the production of new, competitive custom-molded corrective insoles based on 3D models designed with computer technology to improve fabrication quality, effectiveness, and lead times. To achieve that purpose, we set ourselves the following objectives:

1. Analyze the existing fabrication processes for custom corrective insoles, insole materials, and the most common orthosis structures
2. Investigate the physical and mechanical properties of resilient EVA materials and EVA samples under compression
3. Design a finite element model in Ansys and investigate the deformation of the insole model with different loading forces and material combinations
4. Using CAE analysis, design the model for a custom-molded corrective insole.
5. Design an insole fabrication process, calculate expenses for process engineering, and determine the cost price of fabricating custom-molded orthoses.

2. CAE analysis
To study insole deformation, we simulated the behavior exhibited by the properties of specimen material in Ansys. The specimen material was ethylene-vinyl acetate with two types of hardness: 50±3 Shore (white EVA) and 70±3 Shore (beige EVA). We used the manufacturer’s data on the material [12]. Two-layer specimens were made with different hardness combinations: 70 and 50 Shore (specimen 1) and 50 and 70 Shore (specimen 2). The height of a layer measured 10±1 mm. The specimens were of rectangular cross section sized 20 × 30 mm. The total specimen height was 20±2 mm. As it is known that the height of the longitudinal foot arch may vary from person to person between 12 mm and 30 mm and the most common height is up to 20 mm, the compression test used a specimen height of 20 mm.

The compression test was run, at a room temperature, to GOST 269-66 on the Instron 5988 Bluehill 3 testing system complete with Bluehill 3 software [16,17,18].

The specimens’ mechanical properties were investigated at a loading speed of 0.1 mm/s and an applied force of 300 N.

Figures 1 and 2 show the deformation curves for a static load of 150 N. The investigation determined that the deformation of specimen 1 was about 2.73 mm (fig. 1); of specimen 2, about 6.32 mm—almost twice as much (fig. 2).

The investigation also identified the force—up to 30 N—at which the behavior of EVA followed the linear elasticity law.

The results of the compression test agree well with the behavior of the materials simulated in Ansys. This allows material data to be used for further analysis of the insole structure.

The primary property of any custom-molded corrective insole is the redistribution of foot pressure resulting from the elastic properties of the material (shock absorption) and the geometry of the insole. Reference [10] proves this.

It is known [11] that during walking, the structural material of the orthosis experiences both compressive and impact loads, changing the geometry of the insole and causing the insole—particularly the section supporting the longitudinal arch—to deform.
An important parameter in studying insole deformation is the maximal force experienced by the foot. This parameter was studied by Kevin A. Kirby [13,14,15], who first described the Supination Resistance Test. The test measures the amount of force required to keep the foot in the neutral (corrected) position. The parameter may vary for the right and left foot (on average, between 60 and 300 N).

3. Modeling insole deformation
The finite element model for the insole was created in Ansys in several steps. The insole model designed in OrthoModel was exported as an STL file, which was then converted to STEP with FreeCAD because Ansys works better with solid-body formats.

The geometry was imported into the project created earlier and was assigned the material of the first specimen. Then the model was split into a 4 mm grid, and a loading force of 300 N was set for the arch surface. A support was assigned consistent with the underside of the insole model, and limits set for the Z and Y travel of the model. Figure 3 presents the results of loading the insole arch made of the material corresponding to specimens 1 and 2.

For specimen 1, the deformation peaked at 1.06 mm; for specimen 2, at 1.52 mm.

Table 1 lists the results of investigating the relationship between the height deformation and the load for different hardness combinations.
Figure 3. Deformation for the arch of specimen 1 material: 1.06 mm at a maximal load of 300 N (a); deformation for the arch of specimen 2 material: 1.52 mm at maximal load (b)

Table 1. Arch deformation as a function of the material combination and the loading force

| Item no. | Force (N) | Specimen 1 (70/50 Shore) | Specimen 2 (50/70 Shore) |
|----------|-----------|--------------------------|--------------------------|
|          |           | Displacement (mm)         |                          |
| 1        | 50        | 0.18                     | 0.30                     |
| 2        | 100       | 0.37                     | 0.54                     |
| 3        | 150       | 0.53                     | 0.78                     |
| 4        | 200       | 0.71                     | 1.02                     |
| 5        | 250       | 0.89                     | 1.27                     |
| 6        | 300       | 1.06                     | 1.52                     |

These results allow the insole developer to consider the loads exerted on the foot arch and to improve the efficiency of the insole.

4. Programming insole processing in the CAM system
The route for processing the insole with a CNC milling machine was generated in OrthoMill (see table 2).

Table 2. Designing the insole processing route in OrthoMill

| Item no. | Steps |
|----------|-------|
| 1        | Create a processing file. The arrangement of workpieces to be processed is selected by default. Each position is assigned a number and limits on workpiece dimensions |
| 2        | Place the left insole model in position 1. Set the default increment code for the mill. The workpiece is automatically centered in the designated area. Similarly, place the right-hand insole in position 2 |
| 3        | Position the insoles. Launch the generation of the processing route |
| 4        | The insole models’ color will change as the processing route is generated. |
| 5        | Simulate workpiece processing |
| 6        | Simulate mill machining |
| 7        | Save the processing file |
| 8        | The program for the CNC machine saves two output files—one for milling the orthosis surface, the other for contouring the orthosis—and the files are then sent to the machine |
For purposes of this paper, we calculated the cost price of designing and fabricating one pair of custom-molded insoles to the technique presented in [19, 20]. All data were calculated with Excel and are presented in table 3. We estimated the fabrication time of one insole pair at 0.9 h; and the cost price of machine operation per hour, at RUB 2,111.38.

The aggregate price for one pair of custom-molded insoles totaled RUB 2,600. The profit was estimated at 5.6% of the price. Thus, the proposed process for designing and fabricating custom corrective insoles is competitive and will help clients make informed decisions in finding a manufacturer with better price offers.

5. Primary results
1. We analyzed and conducted compression testing for EVA specimens for purposes of fabricating custom corrective insoles.
2. We designed a finite element model in Ansys to investigate insole deformation. This will allow the relevant loads exerted on the arch to be taken into account in designing orthoses.
3. We also developed a process for fabricating insoles with a CNC machine and calculated the cost price of designing and fabricating one pair of custom-molded insoles. The aggregate price for one pair of custom-molded insoles totals RUB 2,600 while the profit stands at 5.6% of the price.

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