

Original Research Article

Voronoi lattice-based orthotics with modular stiffness for additive manufacturing

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Abstract: The additive manufacturing (AM) of soft polymers supports the creation of increasingly complex structures without molds. In the biomedical field, this also allows the manufacturing of customized devices based on the specific needs of each patient. This paper introduces the design and fabrication of orthotics, or orthopedic insoles, for the correction of abnormal pressure distributions at the plantar level. The solution provided is based on complex lattice structures with variable texture, able to adapt the local stiffness and the reaction force of the insole under the patient weight. Structural design methods are applied for the preliminary modeling of the device and the results validation by experiments. The struts stiffness is optimized by means of a finite element method (FEM) with imposed displacements and uniform pressure distribution target. The insole prototype is finally fabricated starting from the real pressure distribution of the patient, measured from its footprint.

1. Introduction

The use of insoles is one of the most effective treatments for musculoskeletal deformities, such as flat feet. In fact, the long-term application of insoles provides the change of the pressure distribution at the plantar level.

The different behavior of flat, orthopedic and customized insoles during patient walk were observed [1]. The latter, also called plantar pressure redistribution insole (PPRI), was developed from the baropodometric measurements made with a piezoresistive membrane pressure sensor. The pressure peaks and distribution were assessed in the plantar areas: toe, metatarsus, midfoot and heel. The pressure peak is proportional to the subject's gait. In the subjects who have worn customized orthotics, there was a decrease in pressure on the second and third metatarsal and a pressure redistribution of the first area of the metatarsal. Consequently, the PPRI significantly expands the area of contact, compared to flat insoles, and reduces the rest (stance) time. This also provides the increase in gait efficiency. These two effects are due to the improved customization of the insole that makes the walking activity more natural compared to simple flat insoles.

Customized orthotics produced by AM, comparing the effect on the pressure below the heel were discussed [2].

The heel plays an important role in the impact energy absorption during the walk, while the forefoot mitigates the loads by redistributing them on the foot sole. The use of customized insoles based on the lift of the plantar arch improves the plantar pressure distribution, the motion stability, reduces the pressure peaks on the heel and redistributes the loads on midfoot and forefoot.

The principles of AM and its main applications in orthopedics are well summarized in the review of Ejnisman et al. [3]. At industrial production level, the responsiveness and customization provided by AM to orthopedic insoles are promising, as results from specific simulations [4]. AM technique were applied to orthopedic insoles with structural function in [5]: here, special shear stiffening gel (SSG) is printed and encapsulated into the insole elastomer giving +53% impact energy absorption. The authors already proposed lattice-based structural design in previous applications to exploit the potential of AM [6-8].

In conclusion, in the case of custom insoles, the contact area between the insole and the plantar is greater, leading to pressure redistribution [9-13]. In addition, the insole provides shock absorption at heel and provides greater propulsion at the foot toe [14].

The material of the orthopedic insole affects the plantar

pressure by acting on the contact area or by concentrating the contact force in certain regions of the plantar [15].

Traditional materials are biological, as leather, cork, wood and felt, or synthetic, as plastic foams and viscoelastic polymers. The first ones are of older conception, they are elastic and soft, they allow the transpiration of the foot, but they suffer a rapid wear and do not have shape stability. Synthetic materials have different stiffness, depending on their composition and production process. The ethylene vinyl acetate (EVA) is a largely used synthetic material available in different values of stiffness. Its properties allow shock-absorbing action. An EVA-derivate is called Multiform, a spongy material with medium stiffness and good damping properties. Silicone is used for building inserts for impact energy absorption. Carbon fibers are used for the fabrication of orthopedic insoles, for example used in sports, and to reinforce orthotics made of synthetic materials. In fact, carbon has a high resistance even for small ones thicknesses, allowing the manufacture of thin and light but resistant insoles.

The goal of this work is to build an insole with modulated stiffness and able to provide uniform pressure distribution to the foot sole. The design is provided under the assumption of static loading and zero hysteresis associated to the soft materials and biological tissues. At this purpose, the AM stereolithographic process is applied to flexible resins and cellular design approach is used [16-19]. The experimental measurement of the pressure distribution is replaced with the direct measure of the local displacement imposed by the foot to a soft ground, reproduced with sand. The displacement map is then used as reference to modulate the local lattice stiffness on each area of the insole.

II. Materials and technology

Two different photosensitive resins are considered for this work: an elastic resin (50 Shore A hardness) and a flexible resin (80 Shore A hardness). The first one is a soft resin suitable for prototyping components as alternative to silicone. This material can support stresses of traction, compression, bending and repeated load cycles without tearing. After load release, the material quickly recovers its initial shape. The 80 Shore A resin is less flexible and it is able to withstand bending, compression and load cycles without tearing. Generally, it is used as alternative to TPU (thermoplastic polyurethane) or rubber. The elastic return of this resin is slower than the other one.

The mechanical properties of the two materials are available on the producer website [20]. However, the available data are not sufficient for the design and simulation activities, than dedicated characterization tests are performed. At this purpose, tensile and compression samples are fabricated with both resins.

Stereolithography (SLA) is an additive manufacturing (AM) process that exploits an ultraviolet (UV) light beam to activate polymerization reactions in thermosetting resins [21, 22]. It is the first AM technique and one of the most used today. The resin in liquid form is contained in a tank and it is exposed to the laser from above. At the end of the

printing process, the piece is treated with isopropanol or ultrasounds to remove the uncured resin. Finally, a post-polymerization or post-curing process in UV light ovens follows. The Form3 system [23] has been used for the fabrication of the components.

I.1. Mechanical characterization of materials

The tensile sample reported in Fig. 1a and the compression sample given by a 10 mm cube are used for the characterization tests. The samples fabricated by SLA are represented in Fig. 2. The growth direction is varied respect the sample orientation to validate the effect of process anisotropy. The tensile and compression tests are performed with the system Bose ElectroForce 5500 (max load 200 N, max displacement 5 mm). Some of the results (50 Shore A resin with vertical orientation) are reported in Fig. 3a (tensile tests) and 3b (compression tests) as an example. The results of Young's moduli are reported in Tab. 1.

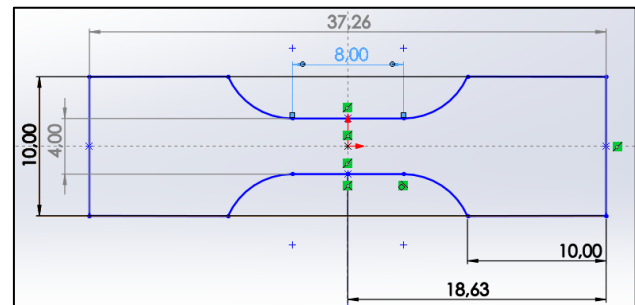


Figure 1: Tensile test specimen.

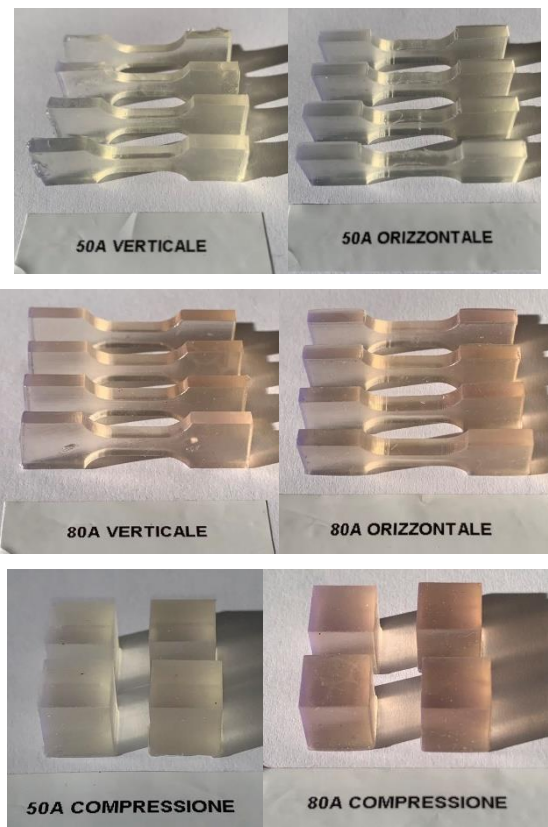


Figure 2: Samples for resins characterization.

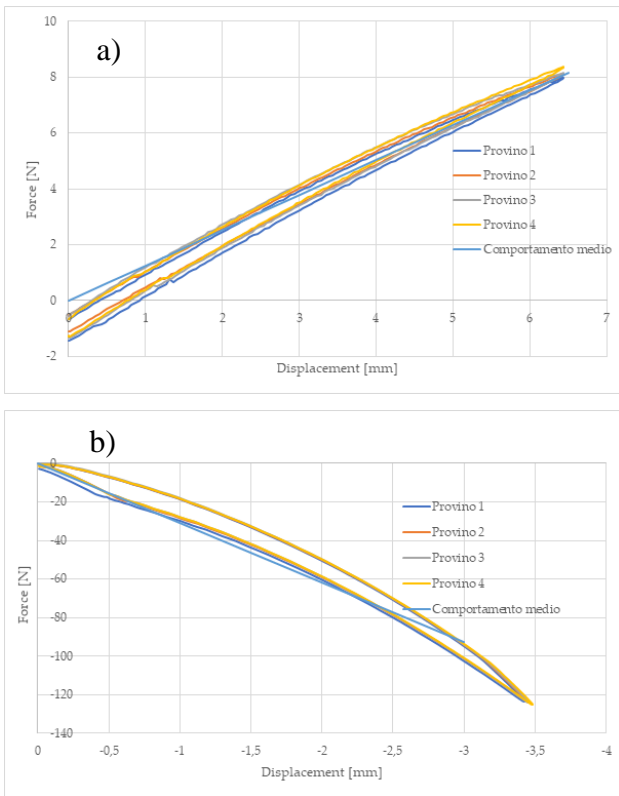


Figure 3: Characterization results on the 50 Shore A resin with vertical growth direction: tensile (a) and compression (b) tests.

III. Design of lattice parameters

In this section, the compression behavior of some cellular geometries to be used in the insole are investigated. At this purpose, parallelepiped samples measuring $30 \times 30 \times 10 \text{ mm}^3$ are shaped with the software nTopology and then used to generate a FEM model. The discretized geometry is used to run static compression simulations with the software Ansys. The samples geometry is defined by the Voronoi lattice, where the distance among generation points is made variable in the range from 2 to 7 mm with steps of 1 mm (Fig. 4). The FEM modeling of the lattice structure is represented for the 4 mm Voronoi lattice as an example in Fig. 5, where the blue-colored nodes are constrained.

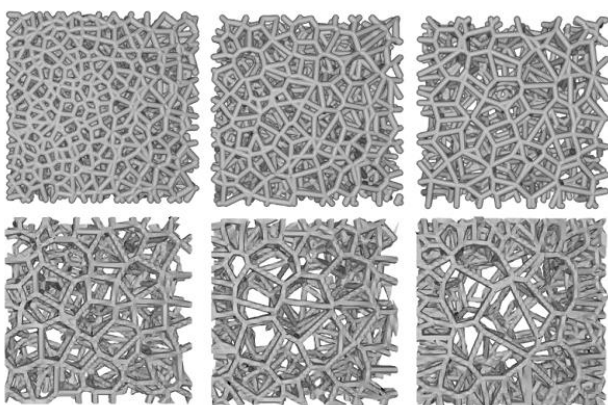


Figure 4: Voronoi lattice structures with generation points ranging from 2 to 7 mm.

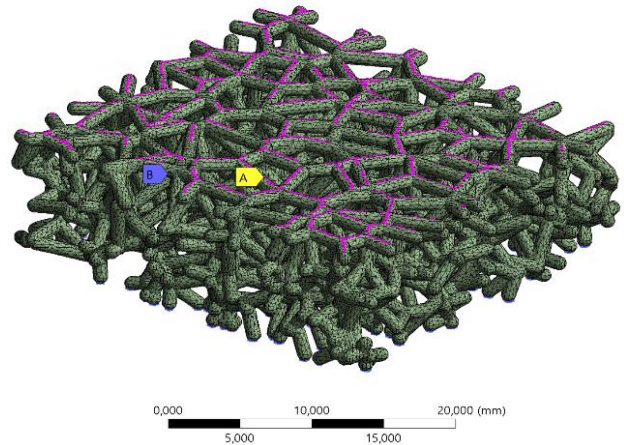


Figure 5: FEM model of the 4 mm Voronoi lattice structures for compression simulation response.

The simulation results are compared with experimental tests on the same Voronoi lattice samples fabricated with the same materials and SLA technology already described in the previous section. In Fig. 6, one of the compression tests on the lattice sample is reported.

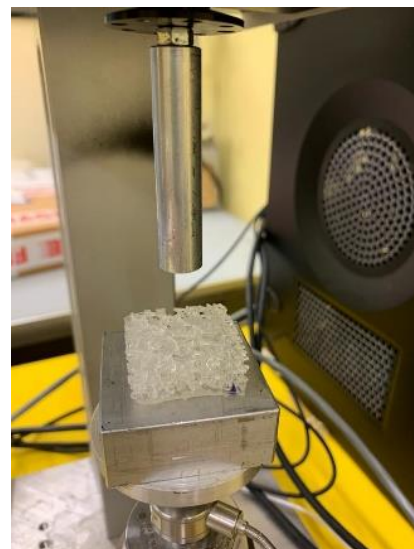


Figure 6: Compression test on one Voronoi lattice structure.

IV. Footprint measurement

The displacement of the footprint is not measurable from the data provided by the baropodometric platform. Therefore, specific experimental tests are conducted to measure the local vertical displacement of the plantar. At this purpose, a chalk mold of the footprint is generated and then measured. A tank of $550 \times 390 \times 190 \text{ mm}^3$ volume is filled with fine sand. The patient footprint is impressed on the sand when standing on two feet. Then, the footprint is filled with liquid chalk mixed with glue, up to a few millimeters above sand level. After solidification, the mold is extracted and cleaned with brush. The operation sequence is reported in Fig. 7.

Table 1: Experimental Young's moduli of the resins.

	Young's modulus [MPa]	
	50 Shore A	80 Shore A
Traction	4.86	11.16
Compression	4.28	5.91



Figure 7: Sequence of the fabrication of the footprint mold, followed by the schematics of the foot region map and the mold characterization to measure the local height of the footprint.

IV. Insole design and fabrication

The experimental values of footprint height, that are different from patient to patient, are used to generate a preliminary FEM analysis on an insole model with uniform Voronoi lattice. The results of the analysis are the basis for the optimization process of the lattice structure, with the goal to provide different local stiffness depending on the local displacement. This will result in the target function of uniform pressure distribution.

The surface of the plantar (and insole) is divided into 12 zones referred to the footprint mold and the local displacement is applied to the superficial nodes. The Voronoi lattice is modeled with 1D struts to reduce the computational heaviness of the simulation. The overall

displacement of the insole with uniform Voronoi lattice is represented in Fig. 8, after imposing local displacements measured from the footprint mold.

The Voronoi lattice structure is then differentiated according to the schematics of Fig. 9. Here, different Voronoi densities are applied to each insole region, according to the lattice stiffness values previously simulated. The local stiffness of the lattice is defined to provide the same elastic reaction force under the local displacement of the footprint. The final configuration of the lattice insole with locally variable stiffness of Fig. 10 is obtained.

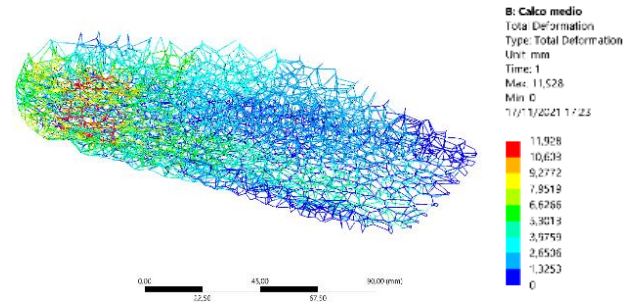


Figure 8: Overall displacement of the insole with uniform Voronoi lattice structure under footprint constraints.

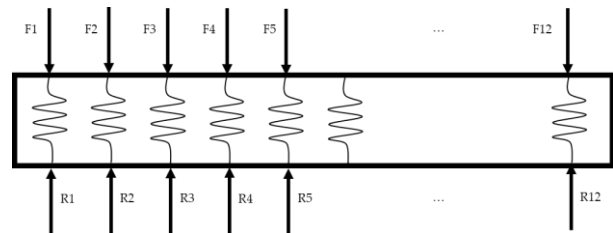


Figure 9: Differentiation of the Voronoi lattice density (and stiffness) at the insole regions.

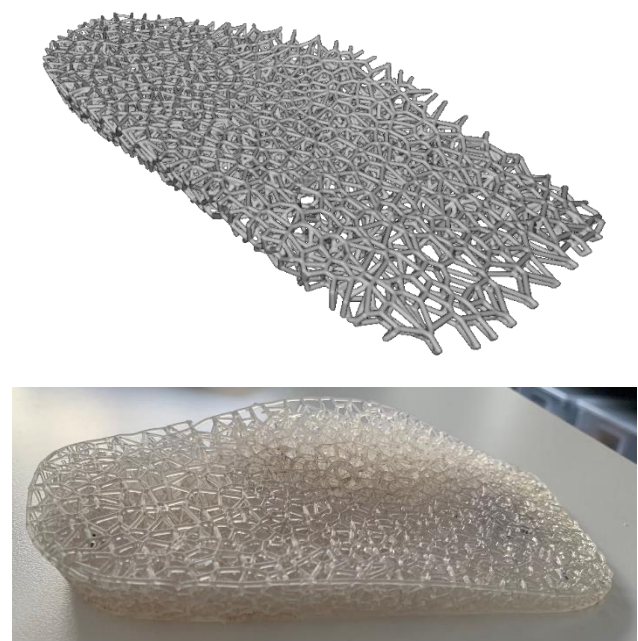


Figure 10: Final configuration of the Voronoi lattice-based insole with uniform pressure distribution.

V. Conclusions

This paper introduces the design, optimization and fabrication of customized orthopedic insoles based on lattice structures for uniform pressure distribution. The study was carried out both numerically, through FEM simulations, and through experimental tests. The use of additive technology for the realization of the device allows to obtain complex structures. The methodology described allows the customization of the insole and the digital management of the design, optimization and fabrication process. In future activities, the experimental measurement of the pressure distribution provided by the orthopedic insole can provide the validation of simulations.

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AUTHOR'S STATEMENT

Authors state no conflict of interest. Informed consent has been obtained from all individuals included in this study.

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