A Method for Diabetic Wound-Specific Insole Design, Manufacturing, and Biomechanical Validation for Better Recovery

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Background: Muscle disorders may cause a change in plantar pressures by the misalignment on the foot during gait phases. Therefore, corns or calluses develop at the plantar regions, and diabetic foot ulcers follow for severe cases, although it can be prevented and even treated by podiatric approaches with patient-specific therapeutic insoles and footwear. Although the importance of a threshold value of 200 kPa in peak plantar pressure reduction has been highlighted as a standard to prevent reulceration in the diabetic foot, it may not be possible to ensure this pressure reduction for each patient.

Methods: In this study, three types of ethylene-vinyl acetate have been used to optimize the off-loading performance for predetermined early-stage diabetic foot ulcer scenarios by means of baropodometric plantar pressure analyses and finite element method for each gait phase.

Results: The total cost of the manufacturing for this study was reduced to $10.26 and it was performed in 24.6 minutes. In addition, the off-loaded pressure was increased by 2.3 times and the volume of the off-loading geometry was increased 8.12 times based on the foam polymer used.

Conclusions: Consequently, improved off-loading was obtained and a standard was proposed for the first time to calculate the off-loading performance before manufacturing of the therapeutic insole model to ensure a better recovery period. (J Am Podiatr Med Assoc 114 (3), 2024; doi:10.7547/22-115)

Diabetes mellitus (DM) is a metabolic disorder with many clinical and biochemical findings characterized by hyperglycemia, dyslipidemia, and glycosuria.[1-3] Diabetes mellitus has a high risk of morbidity and early mortality because of vascular, renal, retinal, or neuropathic disorders in the long term in addition to acute metabolic complications. There were 34.2 million Americans who had diabetes according to the Centers for Disease Control and Prevention's Division of Diabetes Translation fact sheet related to DM in 2018 and the number of diagnoses has been doubled in the past 20 years because of aging and being overweight.[4] Consequently, DM has been increasing steadily over the past few decades, and long-term complications may also increase the number of deaths.

One of the major long-term complications of DM is the diabetic foot (DF) that can result in amputation and limit the patient's quality of life. The DF often develops corns or calluses at the plantar region, and ulcers follow for severe cases that may result in amputation if not treated.[5]

Studies have shown that increased load leads to undesired plantar pressures on the foot; this is the main reason for the development of foot ulcers in the DF.[6-8] The aim of off-loading is to develop interventions that decrease and redistribute the mechanical load on the wound to treat and prevent ulceration.[9,10] Off-loading can be measured before and after insole/footwear use through wearable sensors and baropodometric gait systems to evaluate the effectiveness of medical equipment and manage the undesired

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pressures on the foot.[11] Likewise, these pressures can be analyzed with computer-based finite element methods (FEM) to determine the load distribution for any case of designed insole or footwear.[12,13]

Off-loading modalities may be classified as traditional methods (TM), based on casting including conventional foaming, dressing, padding, removable/nonremovable total contact casting and cast walkers, computer-aided design/computer-aided manufacturing (CAD/CAM) applications, and additive manufacturing (AM) approaches according to the manufacturing method of therapeutic shoes and insoles.[14-17] Total contact casting is the standard therapy, but application varies because of state of the wound, cost, patient-limiting factors, and materials required.[14,18]

A more reliable method is CAD/CAM application that prevents hand skill–based manufacturing errors and provides better custom-fitting compared to TM because of numeric systems.[19] Initially, a foot scanner or a static-dynamic walking platform that contains many pressure sensors is used to obtain a plantar pressure map and contour of the foot. A computer-based design package is used to create patient-specific insoles according to these measurements. Then, a computer numeric control (CNC) system is commonly operated with ethylene-vinyl acetate (EVA) foam polymer at a suitable Shore to form the target insole model. Finally, a breathable coating is applied on the insole model and combined with a patient-specific or mass-produced footwear if necessary.[20] Although CAD/CAM systems are considered as expensive, manufacturing of an insole is flexible, more accurate, and easier without messy work than TM.[21] The minimal recent cost of a CAD/CAM-based insole is also determined as $26.19, which may vary between $31.92 and $179.27.[22-24] Additive manufacturing has the possibility to form complex geometries, but manufacturing time may be longer than with the other methods, especially when a fused deposition modeling (FDM) technology–based three-dimensional printer is used, because of the small nozzle sizes.[25]

Detailed research in the literature on the therapeutic insole or footwear design/manufacturing for DF ulcers from past to present has revealed that each mentioned method is required to be supported with foot plantar pressure analysis to determine the functionality of target medical equipment.[26] Although the importance of a threshold value of 200 kPa has been recommended and highlighted as a standard value to prevent reulceration in DF, it may not possible to ensure for all off-loading cases in each clinic.[27-29] Thus, it is important that the therapeutic insole should be designed and analyzed based on this criterion, and high peak plantar pressures (PPP) on the wound region must be reduced and distributed reliably to minimize the reulceration risk in the future.[30,31] In addition, the polymer type used should meet the patient-specific biomechanical needs, and the final manufactured equipment should have the most accurate custom fitting.[26,32] Despite AM technologies being widely used to create patient-specific medical equipment, some parameters such as polymer type, geometry, and manufacturing values directly affect the biomechanical features, and each one should be considered to determine whether additively manufactured insoles will be suitable or at least equivalent to those created traditionally.[33] Therefore, a computer-based manufacturing system is recommended to avoid the major drawbacks of TMs, and this approach should also supported with FEM analyses to assess and virtually optimize the target therapeutic insole according to the suggested standards to have improved off-loading performance.[34]

The aim of this study was to design an optimized protocol and develop a more reliable standard on insole models according to the off-loading amount by means of CAD/CAM-based diabetic insole manufacturing for plantar ulcer treatment during the early stage. Moreover, manufacturing plan, advantages and disadvantages, and costs were compared to known studies in detail. Ethical approval of this study was obtained by the Kocaeli University Hospital (approval number GOKAEK-2023/02.01)

Methods

Predetermined early-stage DF ulcer scenarios were applied on a healthy researcher (for the purpose of testing) to create the undesired peak pressures (especially on the heel and the first metatarsal regions), validate the decrease of PPPs because of the developed insole prototype, measure the suitability of medical equipment according to the standards, and virtually optimize the off-loading amount by means of FEM analyses for different types of ulcer wounds during the gait phases (80 kg man; number of feet, 41; foot plantar areas, 60 cm^2 each). As a first stage, a dynamic baropodometric walking system (Ultrasensor 3D, Diasu, Italy) was used to acquire the foot plantar pressure maps by means of the Milletrix software package (Diagnostic Support, Rome, Italy). Two EVA foam attachments (10 $\times$ 10 $\times$ 10 mm, Shore A, 30; Euroclinic, Turkey) were applied on the heel and the first metatarsal regions on the right foot to create the undesired peak pressures and four measurements (a control wound, a heel wound, a first metatarsal wound, and both a

heel wound and a first metatarsal wound) were obtained. Primarily, insole models were designed using Milletrix software for the control measurement. As a second stage, three different groups of specimens (pink [P], light blue [LB], and dark blue [DB] foams) were prepared in related standard forms and the following polymer tests were performed to obtain mechanical properties and molecular structure of used EVA foam material, based on the standards (ISO 527-2, ASTM D2240): 1) tensile strength (n = 5), Instron 3345A with 5-kN capacity of force transducer; 2) hardness test (n = 5); Zwick Roell (Ulm, Germany); 3) density test (n = 5), Mettler Toledo XS204, and 4) attenuated total reflectance–Fourier transform infrared spectrum test (PerkinElmer Spectrum 100; PerkinElmer, Waltham, Massachusetts). As a third stage, each designed insole model was exported as a Standard Tessellation Language file extension in Milletrix to be prepared for FEM analyses. Polymer test results were used and defined in the material library of FEM software (SolidWorks 2021; Dassault Systèmes, France). Mechanical properties were then assigned on to the insole model and static loads with fixtures were applied on the plantar regions of interest. Finally, meshes with 1 mm were generated on the insole surface geometry and FEM analyses were performed for each gait phase (stance, heel strike, foot flat, midstance, and heel-off).[33] Virtually optimized off-loading results were used to form and ensure the final therapeutic insole model according to the FEM calculations. As a fourth stage, CAD/CAM-based manufacturing of the final insole models were performed by means of PlantarCAM (Diasu Health Technologies, Italy). An optimization was realized in the CAM interface on system tuning parameters before production to accelerate the metric manufacturing. Leather covering at 1 mm was applied on each insole after production. Lastly, each insole was tested with EVA attachments on the Ultrasensor 3D to observe the off-loading performance for each scenario. The off-loading performance and costs of the developed prototype versus known studies were compared and evaluated.

Results

Dynamic baropodometric gait results for each scenario related to the RF (maximum point of pressure [Mpp], without the therapeutic insole: control, PPP at the heel wound, PPP at the first metatarsal wound, and PPP at both wounds) were obtained as follows: 1) 1,105.76 g/cm^2 at the heel region and 1,216.33 g/cm^2 at the first metatarsal region for the control, 2) 2,156.64 g/cm^2 at the heel region and 1,437.76 g/cm^2 at the first metatarsal region for the PPP at heel wound, 3) 1,307.32 g/cm^2 at the heel region and 2,042.70 g/cm^2 at the first metatarsal region for the PPP at the first metatarsal wound, and 4) 1,838.52 g/cm^2 at the heel region and 1,857.10 g/cm^2 at the first metatarsal region for the PPP at both wounds, respectively. In addition, the Mpp results of the therapeutic insole scenarios were measured as follows: 1) 1,007.40 g/cm^2 at the heel region and 1,185.18 g/cm^2 at the first metatarsal region for the control, 2) 1,412.01 g/cm^2 at the heel region and 1,233.48 g/cm^2 at the first metatarsal region for the PPP at the heel wound, 3) 1,374.15 g/cm^2 at the heel region and 1,465.76 g/cm^2 at the first metatarsal region for the PPP at the first metatarsal wound, and 4) 1,295.68 g/cm^2 at the heel region and 1,314.46 g/cm^2 at the first metatarsal region for the PPP at both wounds, respectively. Detailed dynamic gait results of the right foot according to the plantar pressure areas with and without the DB foam-based insole were also measured and listed as given in Table 1.

According to Table 1, the off-loading amounts were obtained as follows: 1) 37% for heel wound scenario on the rear foot (RF), 2) 13.4% for the first metatarsal wound scenario on the forefoot (FF), and 3) 29.7% for the heel and 15.6% for the first metatarsal wounds on both regions. The average off-loading amounts for both scenarios were determined as 33.35% (557.28 g/cm^2) for the heel and 14.5% (196.71 g/cm^2) for the first metatarsal region. Consequently, the off-loading amount was increased 2.3 times, whereas the volume was increased 8.12 times based on the DB EVA used. Likewise, the off-loading amount can be calculated for different types of off-loading geometries, based on the density differences, and when the volume was increased 8.12 times, off-loading amount was increased 2.1 times for the LB EVA and 2.55 times for the P EVA, respectively.

Density results were obtained as 0.213 ± 0.01, 0.233 ± 0.004, and 0.259 ± 0.013 g/cm^3 for the LB, DB, and P samples, respectively. Hardness was measured as 31.60 ± 1.35, 39.12 ± 1.89, and 34.75 ± 1.56 for Shore A for samples in the same order. The softest sample was determined as LB, and the highest density was measured in P; the highest Shore was measured in DB. Although P sample has a higher density than the DB, the DB sample has a higher Shore A than P. Tensile stress of each EVA foam material was measured as 1.82 ± 0.24, 2.11 ± 0.12, and 2.16 ± 0.04 MPa and Young modulus values were obtained as 12.26 ± 4.46, 16.92 ± 4.5, and 10.96 ± 3.27 MPa for the LB, DB, and P samples, respectively. Each mechanical polymer result is illustrated in Figure 1.

Table 1. Detailed Average Dynamic Gait Results According to the Pressure Areas of Plantar Foot

	Region	Control (g/cm^2)	PPP at the Heel (g/cm^2)	PPP at the First Metatarsal (g/cm^2)	PPP at Both (g/cm^2)
Without therapeutic insole					
Rear foot	Medial	987.65	1,843.80	1,347.90	1,634.24
	Lateral	1,046.90	1,684.46	1,302.97	1,485.68
Midfoot	Medial	632.09	728.41	876.13	1,058.54
	Lateral	572.83	561.62	606.55	705.69
Forefoot	Medial	948.14	1,115.38	1,864.59	1,559.96
	Lateral	691.35	853.67	1,123.25	928.55
With therapeutic insole					
Rear foot	Medial	866.86	1,217.25	1,282.54	1,103.68
	Lateral	941.77	1,006.26	1,161.04	1,091.87
Midfoot	Medial	652.82	600.51	608.16	590.40
	Lateral	663.53	632.97	691.10	673.05
Forefoot	Medial	877.56	876.42	1,397.47	1,144.64
	Lateral	717.03	827.73	1,190.93	956.44
Off-loading geometry (radius [mm]/depth, [mm]), volume (cm^3)		None	40/6	20/3	40/6 for heel
			2.03[a]	0.25[a]	20/3 for the first metatarsal

Abbreviations: PPP, peak plantar pressure;
[a]Volume of a section of a sphere: $V = 1/3\pi h^2(3r - h)$

Attenuated total reflectance–Fourier transform infrared spectrum results of different colored EVA foam samples were obtained as illustrated in Figure 2 that no significant changes were observed than the other pure EVA measurements in literature. The first four bands are traces of the ester groups of EVAs, whereas the last five ones are indicators of the ethylene groups of EVAs (typical absorption bands of EVA are found at 1734, 1234, 1018, 607, 2915, 2846, 1460, 1367, and 720 cm^{-1}, respectively).[34]

The total cost of the manufacturing for this study was reduced to $10.26 and 24.6 minutes, whereas the weight of the insole was 70.2 g. Final processing ability was improved by means of following parameters that were set as follows: 1) up to 1,750.2 mm/min for the velocity, and 2) 60 mm/sec^2 for the acceleration in the CAM package. FEA results were obtained as listed in Table 2 for each therapeutic insole in terms of von Mises stress and material displacement values at the following gait phases: 1) stance, 2) heel strike, 3) foot flat, 4) midstance, and 5) heel-off.[33,35,36] According to Table 2, the increase in Young modulus value of each EVA resulted in a proportional increase in von Mises stress values, but a decrease in material displacement values as expected for each gait phase (Young modulus, $P < LB < DB$).

Discussion

According to the dynamic baropodometric gait results, predetermined early-stage DF ulcer scenarios were successfully created on the plantar region of the foot to obtain the undesired peak pressures that required treatment by podiatric approaches with patient-specific therapeutic insoles or footwear. The Mpps values were measured as close as the reulceration threshold that highlighted as a standard in the literature and must be distributed reliably to prevent further risks.[27-29] Therefore, it is required to ensure and virtually optimize the performance of the off-loading geometry by using patient's gait results with polymer properties on the target insole model.[12] Thus, it is required to create a relation between the off-loading geometry and gait analyses for the known insole foam polymers such as EVA used in this study. Thus, it may be possible to obtain a desired decrease on the Mpps values and to calculate the off-loading performance, especially for the commonly used polymers before the insole manufacturing by means of using mechanical polymer properties in FEA package.[33] The average off-loading performance may be calculated, as suggested in this study, by using volume of the off-loading geometry and initial plantar pressure measurements on the region of interest. Furthermore, FEA of each gait phase may guide obtaining further information related to the off-loading performance before the manufacturing of the therapeutic insole, which may guide reshaping the insole geometry when too much PPP is simulated, especially on the wound region. In addition, the off-loading performance of each insole can be tested under predetermined conditions.

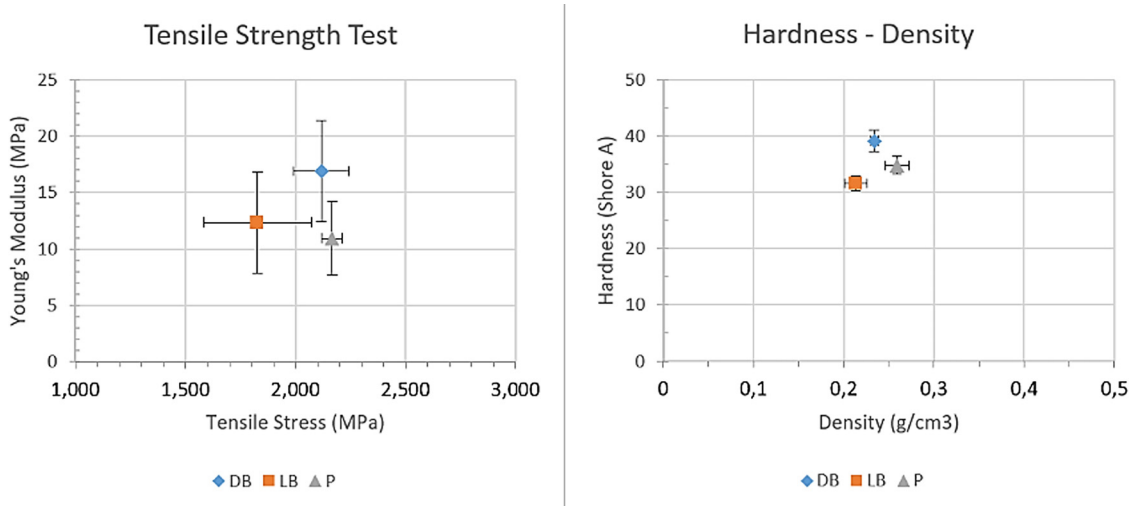


Figure 1. Mechanical polymer results of each test sample (pink [P], light blue [LB], and dark blue [DB]).

This study reveals the numeric relation between the off-loaded pressure and the off-loading geometry based on the used parameters such as material-specific mechanical properties, the volume of the off-loading geometry, and the area of the off-loaded foot plantar region. In this scenario, an increase in calculated volume of the off-loading geometry resulted, with an increase in off-loaded pressures based on the measured foot plantar pressures with or without therapeutic insoles. It should be noted that these foot plantar pressures include material-specific mechanical properties, the volume of the off-loading geometry, the area of the offloaded foot plantar region, the weight of the individual, and the total area of each foot. In this scope, variable parameters such as the volume of the off-loading geometry and the area of the off-loaded foot plantar region create a numeric relation to off-loading amount, whereas the other parameters are constant. Moreover, different types of materials present different numeric relation of off-loading values. Based on these measured off-loaded foot plantar pressures, off-loading amount of different types of off-loading geometries can be calculated for any other individual in terms of grams per square centimeter. Furthermore, the off-loading performance can be evaluated for each gait phase before the manufacturing of the therapeutic insole by means of simulation analyses because the offloaded foot plantar pressures can be calculated for different type of off-loading geometries.

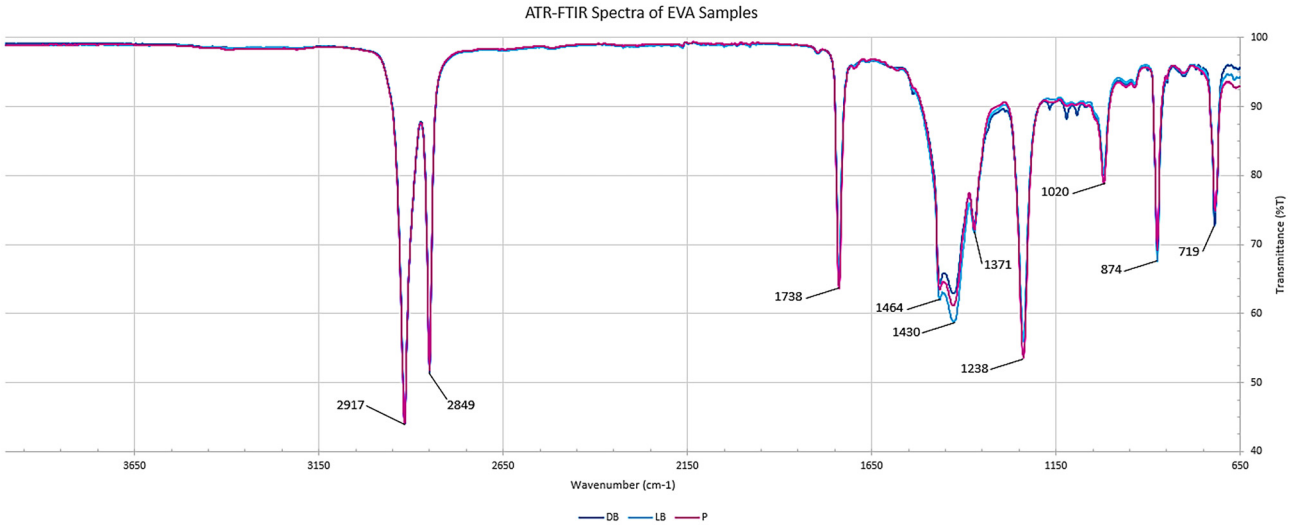


Figure 2. Attenuated total reflectance–Fourier transform infrared spectrum test spectra results of different colored ethylene-vinyl acetate foam samples.

Table 2. FEA Results of Therapeutic Insoles in Terms of von Mises Stress and Material Displacement Values at Each Gait Phase[a]

EVA	Gait Phase	Forces (kgf)	Results (Maximum)	Control	PPP at the Heel	PPP at the First Metatarsal	PPP at Both
LB	S (total, 40 kgf)	Heel, 22.85	von Mises (kgf/cm^2)	2.696	2.849	2.696	3.197
		Forefoot, 17.14	Displacement (mm)	1.237	1.279	1.237	1.405
	HS (total, 80 kgf)	Heel, 80	von Mises (kgf/cm^2)	9.308	9.877	9.308	11.090
		Forefoot, 0	Displacement (mm)	4.281	4.430	4.281	4.855
	FF (total, 80 kgf)	Heel, 51.42	von Mises (kgf/cm^2)	6.155	6.518	6.168	7.320
		Forefoot, 28.58	Displacement (mm)	2.827	2.926	2.832	3.210
	MS (total, 80 kgf)	Heel, 34.28	von Mises (kgf/cm^2)	6.050	6.051	5.412	5.414
		Forefoot, 45.72	Displacement (mm)	2.601	2.603	2.176	2.178
	HO (total, 80 kgf)	Heel, 0	von Mises (kgf/cm^2)	10.610	10.610	9.511	9.511
		Forefoot, 80	Displacement (mm)	4.517	4.517	3.798	3.798
DB	S (total, 40 kgf)	Heel, 22.85	von Mises (kgf/cm^2)	2.713	2.865	2.714	3.215
		Forefoot, 17.14	Displacement (mm)	0.901	0.932	0.901	1.024
	HS (total, 80 kgf)	Heel, 80	von Mises (kgf/cm^2)	9.531	10.100	9.531	11.350
		Forefoot, 0	Displacement (mm)	3.169	3.278	3.169	3.596
	FF (total, 80 kgf)	Heel, 51.42	von Mises (kgf/cm^2)	6.247	6.611	6.249	7.423
		Forefoot, 28.58	Displacement (mm)	2.077	2.149	2.077	2.359
	MS (total, 80 kgf)	Heel, 34.28	von Mises (kgf/cm^2)	6.033	6.034	5.401	5.403
		Forefoot, 45.72	Displacement (mm)	1.884	1.885	1.575	1.592
	HO (total, 80 kgf)	Heel, 0	von Mises (kgf/cm^2)	10.610	10.610	9.495	9.495
		Forefoot, 80	Displacement (mm)	3.290	3.290	2.758	2.758
P	S (total, 40 kgf)	Heel, 22.85	von Mises (kgf/cm^2)	2.688	2.841	2.689	3.189
		Forefoot, 17.14	Displacement (mm)	1.380	1.427	1.380	1.567
	HS (total, 80 kgf)	Heel, 80	von Mises (kgf/cm^2)	9.214	9.780	9.214	10.980
		Forefoot, 0	Displacement (mm)	4.746	4.911	4.746	5.381
	FF (total, 80 kgf)	Heel, 51.42	von Mises (kgf/cm^2)	6.115	6.478	6.117	7.257
		Forefoot, 28.58	Displacement (mm)	3.143	3.254	3.143	3.569
	MS (total, 80 kgf)	Heel, 34.28	von Mises (kgf/cm^2)	6.056	6.057	5.415	5.418
		Forefoot, 45.72	Displacement (mm)	2.909	2.911	2.435	2.437
	HO (total, 80 kgf)	Heel, 0	von Mises (kgf/cm^2)	10.600	10.600	9.511	9.511
		Forefoot, 80	Displacement (mm)	5.035	5.035	4.241	4.241

Abbreviations: DB, dark blue; EVA, ethylene-vinyl acetate; FEA, finite element analysis; FF, forefoot; HO, heel-off; HS, heel strike; LB, light blue; MS, midstance; P, pink; PPP, peak plantar pressure; S, stance.

[a]Total weight of the user for this simulation was 80 kg (number of feet, 41).

Cost of the manufacturing process is significantly reduced, according to the similar CAD/CAM-based studies, as the elapsed time. Minimum cost of a CNC milled insole is determined to be between $25.77 and $31.92, although it may vary up to $150.[37-39] Similarly, the minimum cost of a traditional manufactured custom-molded insole is determined as $35.25, and additive manufactured insole is determined between the $6.88 and $18.17, whereas cost of the optimized method is decreased to $10.26.[24,33,37,38] In addition, minimum manufacturing time of a CNC milled insole is determined as 1 hour 15 min, whereas it may vary up to 15 hours, 8 hours 9 min for the additive manufactured and 6 hours for the cast-based traditional manufacturing method, whereas it is decreased to 24.6 min.[33,38,39] Consequently, the cast-based TM can be accepted as an expensive and a time-consuming approach and the FDM-based additive manufacturing method. Although some AMs have a rapid manufacturing ability such as Continuous Liquid Interface Production, up to 500 mm/h in height, the resin may not meet the desired biomechanical needs or even a new material needs to be developed for this purpose and manufacturing or system costs are expensive when compared with other AMs such as FDM.[40] In contrast, multimaterial manufacturing may not be possible for resin-based AMs, whereas the multilayered EVA milling and the multiprint headed FDM method have a gradual density feature that provides different mechanical properties in the same insole model.

This study was limited to only one individual including 120 simulation analyses with other characterization tests. The reason for performing them on a healthy individual is to reveal a numeric relation and support it with measurements. During this

process, a patient with an ulcer wound was not included because too many dynamic gait analyses were required to ensure the goal. Because the relation obtained and supported, the suggested method can now be applied on more patients by means of simple calculations. Consequently, an expanded future study will be planned in terms of used material and geometric patterns of insoles based on this study for different types of foot disorders on patients.

Conclusions

In this study, an optimized protocol was developed to have a more reliable off-loading application by means of CAD/CAM-based diabetic insole manufacturing for plantar ulcer treatment at early stage. Moreover, costs have been significantly improved in CAD/CAM-based insole manufacturing when compared to TM and AM methods. Consequently, improved off-loading was obtained and a standard was proposed for the first time to calculate the off-loading performance before manufacturing of the therapeutic insole model to ensure a better recovery period.

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Conflict of Interest: None reported.

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