Online Early

DOI: 10.7547/22-115

apma Advancing foot and ankle medicine and surgery | Journal of the American Podiatric Medical Association

ORIGINAL ARTICLE

A METHOD FOR DIABETIC WOUND SPECIFIC INSOLE DESIGN, MANUFACTURING AND BIOMECHANICAL VALIDATION FOR BETTER RECOVERY

Ayfer Peker[1], Levent Aydin[2], Berrin Cetinarslan[3], Zeynep Canturk[4], Alev Selek[5]

[1,2] Department of Podology, Faculty of Medicine, Kocaeli University, Kocaeli, Turkey

[3,4,5] Department of Endocrinology and Metabolism, Faculty of Medicine, Kocaeli University, Kocaeli, Turkey

[1]Ayfer Peker Karatoprak

ayfer.peker@kocaeli.edu.tr, +90 262 303 78 48

[2]**Corresponding Author:** Levent Aydin

levent.aydin@kocaeli.edu.tr, +90 506 125 97 50

[3]Berrin Cetinarslan

barslan@kocaeli.edu.tr, +90 262 303 75 35

[4]Zeynep Canturk

zeynepcanturk@kocaeli.edu.tr, +90 262 303 75 33

JAPMA 114 (1): e1-e29; doi: http://doi.org/10.7547/22-115.

Online Early

DOI: 10.7547/22-115

apma Advancing foot and ankle medicine and surgery | Journal of the American Podiatric Medical Association

[5]Alev Selek

alevselek@gmail.com, +90 262 303 75 35

Total Words Of: Manuscript: 3499, Abstract: 206

Number Of: Figures: 2, Tables: 2, References: 57

Keywords: Diabetic Wound, Gait Phase, Off-loading Performance, FEM, Biomechanics, Therapeutic Footwear

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

Abstract

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 insole and footwear. Although the importance of a threshold value of 200 kPa in peek plantar pressure reduction has been highlighted as a gold standard to prevent re-ulceration in diabetic foot, it may not be possible to ensure this pressure reduction for each patient. In this study, 3 types of ethylene-vinyl acetate have been utilized to optimize the off-loading performance for pre-determined early-stage diabetic foot ulcer scenarios by means of baropodometric plantar pressure analyses and finite element method for each gait phase. The total cost of the manufacturing for this study was reduced down to $10.26 and was performed in 24.6 minutes. In addition, the offloaded pressure was increased by 2.3 times while the volume of the off-loading geometry was increased 8.12 times based on the utilized foam polymer. 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.

Keywords
Diabetic Wound, Gait Phase, Off-loading Performance, FEM, Biomechanics, Therapeutic Footwear

1. Introduction

Diabetes Mellitus (DM) is a metabolic disorder with many clinical and biochemical findings characterized by hyperglycemia, dyslipidemia, and glycosuria (Cole and Florez, 2020; Savelieff et al., 2020; Venkatesan, 2021). DM has a high risk of morbidity and early mortality due to 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 (CDC) Division of Diabetes Translation fact sheet related to DM in 2018 and the number of diagnoses has been doubled in the last 20 years due to aging and being overweight (CDC diabetes, 2022). Consequently, DM has been steadily increasing over the last 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. DF often develops corns or calluses at the plantar region, and ulcers follow for severe cases that may result in amputation if not treated (Pastore et al., 2022).

Studies showed that increased load leads to undesired plantar pressures on the foot is the main reason for the development of foot ulcers in DFs (Abbott et al., 2022; López-Moral et al., 2021; Chuter et al., 2021). The aim of offloading is to develop interventions that decrease and redistribute the mechanical load on the wound to treat and prevent ulceration (Jarl et al., 2021; Collings et al., 2020). Off-loading can be measured before and after insole/footwear usage, through wearable sensors and baropodometric gait systems to evaluate the effectiveness of medical equipment and manage the undesired pressures on foot (Brognara et al., 2021). 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 (Shaulian et al., 2021; Telfer et al., 2017).

Off-loading modalities may be classified as Traditional Methods (TM), based on casting including conventional foaming, dressing, padding, removable - nonremovable Total Contact

Casting (TCC) and Cast Walkers (CW), Computer Aided Design/Computer Aided Manufacturing (CAD/CAM) applications, and Additive Manufacturing (AM) approach according to the manufacturing method of therapeutic shoes and insoles (Birke et al., 2002; D'Amico et al., 2021; Mandolini etl al., 2017; Paulick et al., 2014). TCCs are the gold standard, but application varies due to state of the wound, cost, patient limiting factors, and materials required (Birke et al., 2002; Armstrong et al., 2002).

A more reliable method is CAD/CAM application that prevents hand skill based manufacturing errors and provides better custom-fitting compared to TM owing to numerical systems (Gatt et al., 2016). Initially, a foot scanner or a static-dynamic walking platform that contains many pressure sensors is used to obtain plantar pressure map and contour of the foot. A computer based design package is utilized to create patient specific insole according to these measurements. Then, a Computer Numerical 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 a mass produced footwear if necessary (Ki et al., 2008). Although CAD/CAM systems are considered as expensive, manufacturing of an insole is flexible, more accurate, and easier without messy work than TM (Udiljak et al., 2000). 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$ (Indiamart, 2022; Davia-Aracil, 2018; Paton et al., 2012).

AM has the possibility to form complex geometries but manufacturing time may take longer than the other methods especially when an FDM technology based 3D printer is utilized owing to the small nozzle sizes (Twitter., 2022).

Detailed research in literature on the therapeutic insole or foot wear 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 (Nouman et al., 2019). Although the importance of a threshold value of 200 kPa has been recommended and highlighted as a gold standard to prevent re-ulceration in DF, it may not possible to ensure for all off-loading cases in each clinic (Parker et al., 2019; Waaijman et al., 2014; Preece et al., 2017). Hence, it is important that the therapeutic insole should be designed and analyzed based on this criteria and high Peak Plantar Pressures (PPP) on wound region must be reduced and distributed reliably to minimize the re-ulceration risk in future (Korada et al., 2020; Jafarzadeh et al., 2021). In addition, used polymer type should meet the patient specific biomechanical needs as well as the final manufactured equipment should have the most accurate custom fitting (Nouman et al., 2019; Haris et al., 2021). Despite the AM technologies are 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 insole will be suitable or at least equivalent of the traditionally created (Peker et al., 2020). 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 (Shaulian et al., 2021).

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 at early stage. Moreover, manufacturing plan, advantages - disadvantages, and costs were compared to known studies in detail.

2. Materials and methods

Pre-determined early stage DF ulcer scenarios were applied on a healthy researcher (for testing purpose) to create the undesired peak pressures (especially on the heel and the first metatarsal regions), validate the decrease of PPPs owing to 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, male, foot number: 41, foot plantar areas: 60 cm^2 each). As a first stage, a dynamic baropodometric walking system (Ultrasensor 3D, Diasu, Italy) was utilized to acquire the foot plantar pressure maps via Milletrix software package (Diagnostic Support). Two EVA foam attachments (10x10x10mm, shore A: 30, Euroclinic, Turkey) were applied on the heel and the first metatarsal regions on the right foot (RF) to create the undesired peak pressures and four measurements (a control, a heel wound, a first metatarsal wound and both scenarios) were obtained with respectively. Primarily, insole models were designed in Milletrix software for the control measurement. As a second stage, 3 different group of specimens (brand name: pink - P, light blue - LB and dark blue - DB foams) were prepared in related standard forms and 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): i) Tensile strength (n = 5), Instron 3345A with 5-kN capacity of force transducer, ii) Hardness test (n = 5), Zwick Roell and iii) Density test (n = 5), Mettler Toledo XS204 and iv) ATR FTIR spectrum test, Perkin Elmer Spectrum 100. As a third stage, each designed insole model was exported as an STL (Standard Tessellation Language) file extension in Milletrix to be prepared for FEM analyses. Polymer test results were utilized and defined in the material library of FEM software

(SolidWorks 2021, Dassault Systèmes). 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 1mm 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) (Peker et al., 2020). Virtually optimized off-loading results were utilized 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 via PlantarCAM (Diasu, Italy). An optimization was realized in the CAM interface on system tuning parameters before production to accelerate the metric manufacturing. Leather covering at 1mm 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 developed prototype versus known studies were compared and evaluated.

3. Results

Dynamic baropodometric gait results for each scenario related to the RF (maximum point of pressure - Mpp, without the therapeutic insole: control, PPP at heel wound, PPP at first metatarsal wound and PPP at both wounds) were obtained as: i) 1105.76 g/cm^2 at heel region and 1216.33 g/cm^2 at first metatarsal region for the control, ii) 2156.64 g/cm^2 at heel region and

1437.76 g/cm^2 at first metatarsal region for the PPP at heel wound, iii) 1307.32 g/cm^2 at heel region and 2042.70 g/cm^2 at first metatarsal region for the PPP at first metatarsal wound and iv) 1838.52 g/cm^2 at heel region and 1857.10 g/cm^2 at first metatarsal region for the PPP at both wounds respectively. In addition, the Mpp results of the therapeutic insole scenarios were measured as i) 1007.40g/cm^2 at heel region and 1185.18 g/cm^2 at first metatarsal region for the control, ii) 1412.01 g/cm^2 at heel region and 1233.48 g/cm^2 at first metatarsal region for the PPP at heel wound, iii) 1374.15 g/cm^2 at heel region and 1465.76 g/cm^2 at first metatarsal region for the PPP at first metatarsal wound and iv) 1295.68 g/cm^2 at heel region and 1314.46 g/cm^2 at first metatarsal region for the PPP at both wounds respectively. Detailed dynamic gait results of the RF according to the plantar pressure areas with/without the DB foam based insole were also measured and listed as given in Table 1.

Table 1. Detailed average dynamic gait results according to the pressure areas of plantar foot.

According to the Table 1, the off-loading amounts were obtained as: i) 37% for heel wound scenario on RF (Rear Foot), ii) 13.4% for 1st metatarsal wound scenario on FF (Fore Foot) and iii) 29.7% for heel and 15.6% for 1st metatarsal wounds on both regions respectively. The average offloading amounts for both scenarios were determined as 33.35% (557.28 g/cm^2) for heel and 14.5% (196.71 g/cm^2) for 1st metatarsal regions. Consequently, the offloading amount was increased 2.3 times while the volume was increased 8.12 times based on the utilized DB EVA. Likewise, the offloading amount can be calculated for different type of offloading geometries, based on the density differences, and when the volume was increased 8.12 times, offloading 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 Shore A for samples in the same order. The softest sample was determined as LB while the highest density was measured in P and highest shore was measured in DB. Although P sample has a higher density than the DB, 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, 2.16 ± 0.04 MPa and Young modulus were obtained as 12.26 ± 4.46, 16.92 ± 4.5, 10.96 ± 3.27 MPa for the LB, DB and P samples respectively. Each mechanical polymer result is illustrated in Figure 1.

Figure 1. Mechanical polymer results of each test sample

ATR-FTIR spectra 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 while 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) (Adelnia et al., 2015).

Figure 2. ATR-FTIR spectra results of different colored EVA foam samples.

The total cost of the manufacturing for this study was reduced down to \$10.26 and 24.6 minutes while the weight of the insole was 70.2 g. Final processing ability was improved via following parameters that were set as: i) up to 1750.2 mm per min for the velocity, ii) 60 mm/sec^2 for the acceleration in CAM package. FEA results were obtained as listed in Table 2 for each therapeutic insole in terms of vonMises stress and material displacement values at the following gait phases: i) Stance (S), ii) Heel Strike (HS), iii) Foot Flat (FF), iv) Midstance (MS), and v) Heel Off (HO) (Peker et al., 2020; Mariani et al., 2013; Lou et al., 2017).

Table 2. FEA results of therapeutic insoles in terms of maximum vonMises stress and material displacement values at each gait phase.

According to the Table 2, the increase in Young modulus value of each EVA was resulted with a proportionally increase in von Mises stress values, but a decrease in material disiplacement values as expected for each gait phase (Young modulus: P < LB < DB).

Discussion

According to the dynamic baropodometric gait results pre-determined early stage DF ulcer scenarios were succesfully created on plantar region of the foot to obtain the undesired peak pressures that required to be treated by podiatric approaches with patient specific therapeutic insole or footwear. The Mpps were measured as close as the re-ulceration threshold that highlighted as a gold standard in literature and must be distributed reliably to prevent further risks (Parker et al., 2019; Waaijman et al., 2014; Preece et al., 2017). Therefore, it is required to be ensure and virtually optimize the performance of the off-loading geometry by utilizing patient's gait results with polymer properties on the target insole model (Shaulian et al., 2021). Hence, it is required to create a relation between the off-loading geometry and gait analyses for the known insole foam polymers such as EVA as used in this study. Thus, it may possible to obtain a desired decrease on the Mpps and possible to calculate the off-loading performance especially for the commonly used polymers before the insole manufacturing by means of utilizing mechanical polymer properties in FEA package (Peker et al., 2020). The average off-loading performance may be calculated, as suggested in this study, by utilizing volume of the off-loading geometry and initial plantar pressure measurements on region of interest. Furthermore, FEA of each gait phase may guide to obtain further information related to the off-loading performance before the manufacturing of the therapeutic insole which may guide to reshape 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 pre-determined conditions.

This study reveals the numerical relation between the offloaded pressure and the off-loading geometry based on the utilized parameters such as material specific mechanical properties, the volume of the off-loading geometry and the area of the offloaded foot plantar region. In this scenario, increase on calculated volume of the off-loading geometry resulted with an increase on offloaded pressures based on the measured foot plantar pressures with/without therapeutic insole. It should be noted 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 offloaded foot plantar region create a numerical relation to off-loading amount while the other parameters are constant. Moreover, different type of materials presents different numerical relation of off-loading values. Based on these measured offloaded foot plantar pressures, off-loading amount of different types of off-loading geometries can be calculated for any other individual in terms of g/cm2. Furthermore, the off-loading performance can be evaluated for each gait phase before the manufacturing of the therapeutic insole via simulation analyses since the offloaded foot plantar pressures can be calculated for different type of off-loading geometries.

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 between the $25.77 and $31.92 while it may vary up to $150 (Nosov and Zyabochkina, 2020; Jandova and Mendricky, 2021; Watasuntonpong et al., 2019). 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 while cost of the optimized method is decreased down to $10.26 (Nosov and Zyabochkina, 2020; Jandova and Mendricky, 2021; Peker et al., 2020; Paton et al., 2013). In addition, minimum manufacturing time of a CNC milled insole is determined as 1h 15min while it may vary up to 15h, 8h 9min for the additive manufactured and 6h for the cast based traditional manufacturing method while it is decreased down to 24.6min

(Jandova and Mendricky, 2021; Watasuntonpong et al., 2019; Peker et al., 2020). Consequently, cast based traditional method can be accepted as an expensive and a time consuming approach as well as the FDM based additive manufacturing method. Although, some AMs have a rapid manufacturing ability such as Continuous Liquid Interface Production (CLIP), up to 500 mm/h in height, the resin may not meet the desired biomechanical needs or even a new material required to be developed for this purpose and manufacturing or system costs are expensive when compared with other AMs such as FDM (Tumbleston et al., 2015). On the other hand, multi material manufacturing may not be possible for resin based AMs while multi layered EVA milling and multi print headed FDM method have gradual density feature that provide to obtain 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 of performing on a healthy individual is to reveal a numerical relation and support it with measurements. During this process a patient with an ulcer wound was not included because of too many dynamic gait analyses were required to be performed to ensure the goal. Since the relation obtained and supported, suggested method can now be applied on more patients via simple calculations. Consequently, an expanded future study will be planned in terms of used material and geometrical patterns of insoles based on this study for different type of foot disorders on patients.

Conclusion

In this study, an optimized protocol developed to have a more reliable off-loading application via 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 traditional and additive manufactured methods. Consequently, an 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.

Ethical Approvement

Ethical aprovement of this study is obtained by the Kocaeli University Hospital (Approvement Number: GOKAEK-2023/02.01)

Conflict of interest statement

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version. Additionally, there are no conflicts of interest in connection with this paper, and the material described is not under publication or consideration for publication elsewhere.

Acknowledgments

Authors declare that no funding was received for this work.

References

1. Abbott, C. A. Chatwin, K. E. Rajbhandari, S. M. John, K. M. Pabbineedi, S. Bowling, F. L. Reeves, N. D., 2022. Site-specific, critical threshold barefoot peak plantar pressure associated with diabetic foot ulcer history: a novel approach to determine dfu risk in the clinical setting. Medicina 58(2), 166.
2. Adelnia, H. Bidsorkhi, H. C. Ismail, A. F. Matsuura, T., 2015. Gas permeability and permselectivity properties of ethylene vinyl acetate/sepiolite mixed matrix membranes. Separation and Purification Technology 146, 351-357.
3. Armstrong, D. G. Short, B. Espensen, E. H. Abu-Rumman, P. L. Nixon, B. P. Boulton, A. J., 2002. Technique for fabrication of an" instant total-contact cast" for treatment of neuropathic diabetic foot ulcers. Journal of the American Podiatric Medical Association 92(7), 405-408.
4. Birke, J. A. Pavich, M. A. Patout Jr, C. A. Horswell, R., 2002. Comparison of forefoot ulcer healing using alternative off-loading methods in patients with diabetes mellitus. Advances In Skin & Wound Care 15(5), 210-215.
5. Brognara, L. Mazzotti, A. Di Martino, A. Faldini, C. Cauli, O., 2021. Wearable sensor for assessing gait and postural alterations in patients with diabetes: a scoping review. Medicina, 57(11), 1145.
6. CDC diabetes, 2022. [Online] Available at: https://www.cdc.gov/chronicdisease/ resources/publications/aag/diabetes.htm [Accessed 5 Feb. 2022].
7. Chuter, V. H. Spink, M. J. David, M. Lanting, S. Searle, A., 2021. Clinical foot measurements as a proxy for plantar pressure testing in people with diabetes. Journal Of Foot And Ankle Research 14(1), 1-9.
8. Cole, J. B. Florez, J. C., 2020. Genetics of diabetes mellitus and diabetes complications. Nature Reviews Nephrology 16(7), 377-390.
9. Collings, R. Freeman, J. Latour, J. Paton, J., 2020. Footwear and insole design features for offloading the diabetic at risk foot-A systematic review and meta-analyses. Endocrinology, Diabetes & Metabolism 4(1), 1.
10. D’Amico, M. Kinel, E. Roncoletta, P. Gnaldi, A. Ceppitelli, C. Belli, F. Vermigli, C., 2021. Data-driven CAD-CAM vs traditional total contact custom insoles: A novel quantitative-statistical framework for the evaluation of insoles offloading performance in diabetic foot. PloS One 16(3), e0247915.

11. Davia-Aracil, M. Hinojo-Pérez, J. J. Jimeno-Morenilla, A. Mora-Mora, H., 2018. 3D printing of functional anatomical insoles. Computers in Industry 95, 38-53.
12. Gatt, A. Formosa, C. Chockalingam, N., 2016. The application of generic CAD/CAM systems for the design and manufacture of foot orthoses. The Foot and Ankle Online Journal 9(3), 6.
13. Haris, F. Liau, B. Y. Jan, Y. K. Akbari, V. B. H. Primanda, Y. Lin, K. H. Lung, C. W., 2021. A review of the plantar pressure distribution effects from ınsole materials and at different walking speeds. Applied Sciences 11(24), 11851.
14. Indiamart, 2022. [Online] Available at: https://www.indiamart.com/hochstehealthcare/foot-ulcer-footwear.html [Accessed 8 May. 2022].
15. Jafarzadeh, E. Soheilifard, R. Ehsani-Seresht, A., 2021. Design optimization procedure for an orthopedic insole having a continuously variable stiffness/shape to reduce the plantar pressure in the foot of a diabetic patient. Medical Engineering & Physics 98, 44-49.
16. Jandova, S. Mendricky, R., 2021. Benefits of 3d printed and customized anatomical footwear insoles for plantar pressure distribution. 3D Printing and Additive Manufacturing 1(1), 1.
17. Jarl, G. van Netten, J. J. Lazzarini, P. A. Crews, R. T. Najafi, B. Mueller, M. J., 2021. Should weight-bearing activity be reduced during healing of plantar diabetic foot ulcers, even when using appropriate offloading devices?. Diabetes Research And Clinical Practice 175, 108733.
18. Ki, S. W. Leung, A. K. L. Li, A. N. M., 2008. Comparison of plantar pressure distribution patterns between foot orthoses provided by the CAD-CAM and foam impression methods. Prosthetics And Orthotics International 32(3), 356-362.
19. Korada, H. Maiya, A. Rao, S. K. Hande, M., 2020. Effectiveness of customized insoles on maximum plantar pressure in diabetic foot syndrome: A systematic review. Diabetes & Metabolic Syndrome: Clinical Research & Reviews 14(5), 1093-1099.
20. López-Moral, M. Molines-Barroso, R. J. García-Morales, E. García-Álvarez, Y. Álvaro-Afonso, F. J. Lázaro-Martínez, J. L., 2021. Predictive values of foot plantar pressure assessment in patients with midfoot deformity secondary to Charcot neuroarthropathy. Diabetes Research and Clinical Practice 175, 108795.
21. Lou, C. Wang, S. Liang, T. Pang, C. Huang, L. Run, M. Liu, X., 2017. A graphene-based flexible pressure sensor with applications to plantar pressure measurement and gait analysis. Materials 10(9), 1068.

22. Mandolini, M. Brunzini, A. Manieri, S. Germani, M., 2017. Foot plantar pressure offloading: How to select the right material for a custom made insole. In Proceedings of the 21st International Conference on Engineering Design (ICED 17) Vol 1: Resource Sensitive Design, Design Research Applications and Case Studies, Vancouver, Canada.
23. Mariani, B. Rouhani, H. Crevoisier, X. Aminian, K., 2013. Quantitative estimation of foot-flat and stance phase of gait using foot-worn inertial sensors. Gait & Posture 37(2), 229-234.
24. Nosov, N. V. Zyabochkina, A. P., 2020. Designing the structure of and a fabrication process for a corrective insole in CAD/CAE/CAM systems. In Proceedings of the IOP Conference Series: Materials Science and Engineering 709(2), 022105.
25. Nouman, M. Dissaneewate, T. Leelasamran, W. Chatpun, S., 2019. The insole materials influence the plantar pressure distributions in diabetic foot with neuropathy during different walking activities. Gait & Posture 74, 154-161.
26. Parker, D. J. Nuttall, G. H. Bray, N. Hugill, T. Martinez-Santos, A. Edwards, R. T. Nester, C., 2019. A randomised controlled trial and cost-consequence analysis of traditional and digital foot orthoses supply chains in a National Health Service setting: application to feet at risk of diabetic plantar ulceration. Journal Of Foot And Ankle Research 12(1), 1-13.
27. Pastore, D. Deja-Simoni, A. De Stefano, A. Pacifici, F. Cela, E. Infante, M. Donadel, G., 2022. Risk factors for diabetic foot ulcers: an Albanian retrospective study of inpatients with type 2 diabetes. European Review for Medical and Pharmacological Sciences 26(2), 558-572.
28. Paton, J. S. Stenhouse, E. A. Bruce, G. Zahra, D. Jones, R. B., 2012. A comparison of customised and prefabricated insoles to reduce risk factors for neuropathic diabetic foot ulceration: a participant-blinded randomised controlled trial. Journal Of Foot And Ankle Research 5(1), 1-11.
29. Paulick, P. E. Pham, A. L. Bachman, M. Worobets, J. T. Panizzolo, F. Hung, S. Zhang, Z., 2014. Combining dynamic foot scanning and additive manufacturing for the production of ınsoles: a case study andré s. salles, diane e. gyi and timo schmeltzpfenning 1 ınstrumented ınsoles for designing and evaluating footwear. Research Journal of Textile and Apparel 18(2), 1.
30. Peker, A. Aydin, L. Kucuk, S. Ozkoc, G. Cetinarslan, B. Canturk, Z. Selek, A., 2020. Additive manufacturing and biomechanical validation of a patient-specific diabetic insole. Polymers for Advanced Technologies 31(5), 988-996.

31. Preece, S. J. Chapman, J. D. Braunstein, B. Brüggemann, G. P. Nester, C. J., 2017. Optimisation of rocker sole footwear for prevention of first plantar ulcer: comparison of group-optimised and individually-selected footwear designs. Journal of Foot and Ankle Research 10(1), 1-10.
32. Savelieff, M. G. Callaghan, B. C. Feldman, E. L., 2020. The emerging role of dyslipidemia in diabetic microvascular complications. Current Opinion in Endocrinology, Diabetes and Obesity 27(2), 115-123.
33. Shaulian, H. Gefen, A. Solomonow-Avnon, D. Wolf, A., 2021. Finite element-based method for determining an optimal offloading design for treating and preventing heel ulcers. Computers in Biology and Medicine 131, 104261.
34. Shaulian, H. Gefen, A. Solomonow-Avnon, D. Wolf, A., 2021. Finite element-based method for determining an optimal offloading design for treating and preventing heel ulcers. Computers in Biology and Medicine 131, 104261.
35. Telfer, S. Woodburn, J. Collier, A. Cavanagh, P. R., 2017. Virtually optimized insoles for offloading the diabetic foot: a randomized crossover study. Journal Of Biomechanics 60, 157-161.
36. Twitter, 2022. [Online] Available at: https://twitter.com/lewihe [Accessed 3 May. 2022].
37. Udiljak, T. Obrovac, K. Ištef, I., 2000. CAD/CAM system for insole production. Communications-Scientific Letters Of The University Of Zilina 2(1), 70-76.
38. Venkatesan, S. K., 2021. Classification of Diabetes Mellitus: A review. International Journal of Diabetes Management 1(1), 20-22.
39. Waaijman, R. De Haart, M. Arts, M. L. Wever, D. Verlouw, A. J. Nollet, F. Bus, S. A., 2014. Risk factors for plantar foot ulcer recurrence in neuropathic diabetic patients. Diabetes Care 37(6), 1697-1705.
40. Watasuntonpong, P. Pimsarn, M. Tantrapiwat, A., 2019. Dynamic feed rate in multiple independent spindles CNC milling machine for orthotic insole manufacturing. International Journal of Innovative Computing, Information and Control 15(1), 2149-2163.

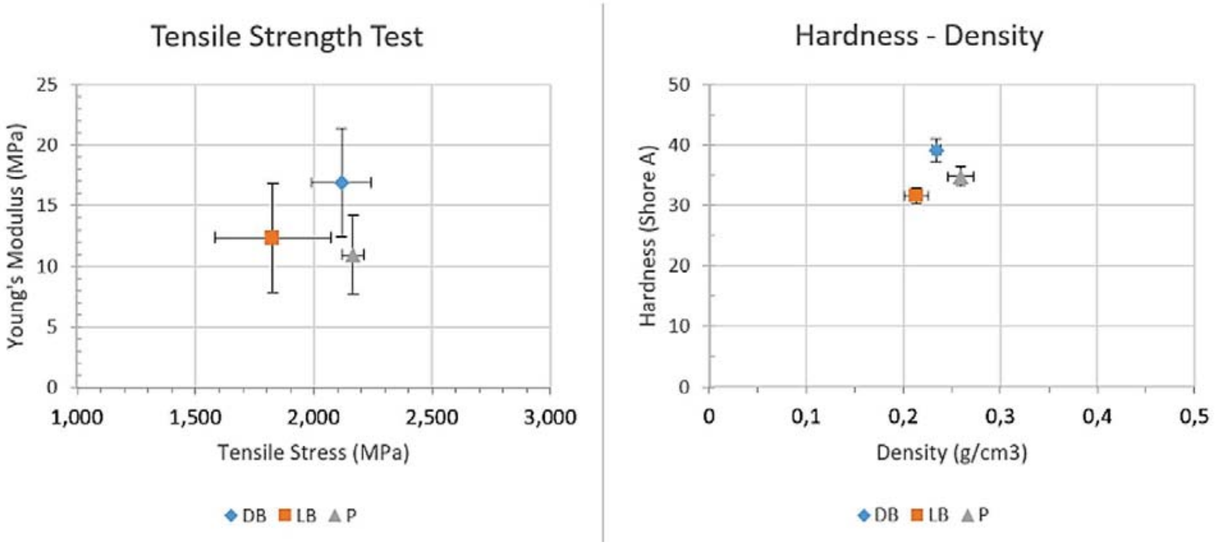

Figure 1. Mechanical polymer results of each test sample (pink - P, light blue - LB and dark blue - DB).

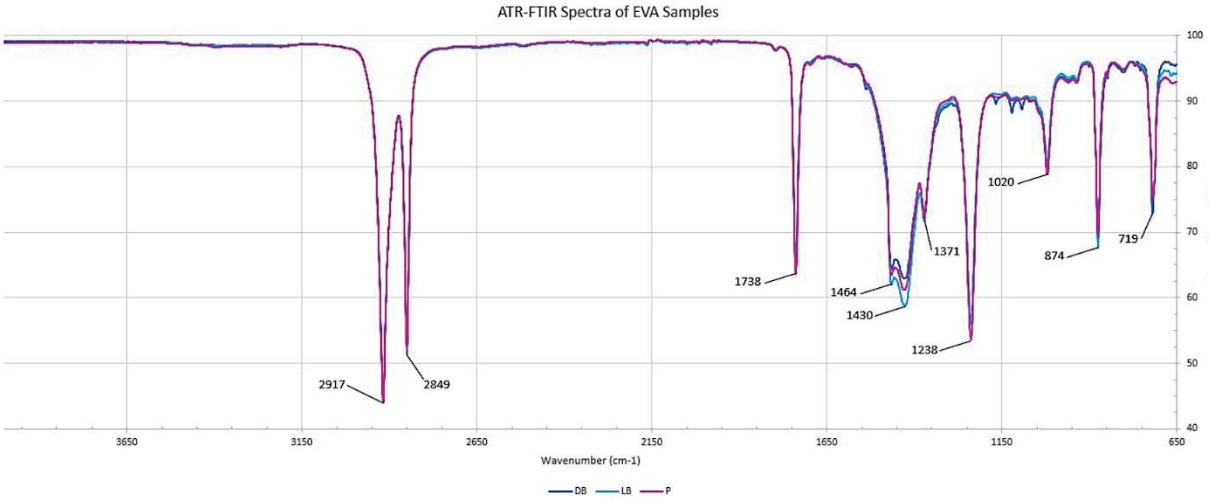

Figure 2. ATR-FTIR spectra results of different colored EVA foam samples.

Table 1. Detailed average dynamic gait results according to the pressure areas of plantar foot.

		Region	**Control (g/cm^2)**	**PPP at Heel (g/cm^2)**	**PPP at 1st Metatarsal (g/cm^2)**	**PPP at Both (g/cm^2)**
Without therapeutic insole	Rear Foot	Medial	987.65	1843.80	1347.90	1634.24
		Lateral	1046.90	1684.46	1302.97	1485.68
	Mid Foot	Medial	632.09	728.41	876.13	1058.54
		Lateral	572.83	561.62	606.55	705.69
	Fore Foot	Medial	948.14	1115.38	1864.59	1559.96
		Lateral	691.35	853.67	1123.25	928.55
With therapeutic insole	Rear Foot	Medial	866.86	1217.25	1282.54	1103.68
		Lateral	941.77	1006.26	1161.04	1091.87
	Mid Foot	Medial	652.82	600.51	608.16	590.40
		Lateral	663.53	632.97	691.10	673.05
	Fore Foot	Medial	877.56	876.42	1397.47	1144.64
		Lateral	717.03	827.73	1190.93	956.44
	Off-loading Geometry (Radius, mm - Depth, mm), *Volume		None	40 - 6 2.03 cm^3	20 - 3 0.25 cm^3	40 - 6 for heel 20 - 3 for 1st metatarsal
	*Volume of a section of a sphere: $V = \frac{1}{3}\pi h^2(3r - h)$					

Table 2. FEA results of therapeutic insoles in terms of vonMises stress and material displacement values at each gait phase.

EVA	Gait Phase	Forces (kgf)	Results (max)	Control	PPP at Heel	PPP at 1st Metatarsal	PPP at Both
LB	S *(Total: 40 kgf)	Heel: 22.85 Forefoot: 17.14	vonMises (kgf/cm^2)	2.696	2.849	2.696	3.197
			Displacement (mm)	1.237	1.279	1.237	1.405
	HS *(Total: 80 kgf)	Heel: 80 Forefoot: 0	vonMises (kgf/cm^2)	9.308	9.877	9.308	11.090
			Displacement (mm)	4.281	4.430	4.281	4.855
	FF *(Total: 80 kgf)	Heel: 51.42 Forefoot: 28.58	vonMises (kgf/cm^2)	6.155	6.518	6.168	7.320
			Displacement (mm)	2.827	2.926	2.832	3.210
	MS *(Total: 80 kgf)	Heel: 34.28 Forefoot: 45.72	vonMises (kgf/cm^2)	6.050	6.051	5.412	5.414
			Displacement (mm)	2.601	2.603	2.176	2.178
	HO *(Total: 80	Heel: 0 Foref	vonMises (kgf/cm^2)	10.610	10.610	9.511	9.511

DB									
HO *(Total : 80	MS *(Total: 80 kgf)		FF *(Total: 80 kgf)		HS *(Total: 80 kgf)		S *(Total: 40 kgf)		
Heel: 0 Forefo ot: 80	Heel: 34.28 Forefoot: 45.72		Heel: 51.42 Forefoot: 28.58		Heel: 80 Forefoot: 0		Heel: 22.85 Forefoot: 17.14		
vonMises (kgf/cm^2)	Displacement (mm)	vonMises (kgf/cm^2)	Displacement (mm)	vonMises (kgf/cm^2)	Displacement (mm)	vonMises (kgf/cm^2)	Displacement (mm)	vonMises (kgf/cm^2)	Displacement (mm)
10.610	1.884	6.033	2.077	6.247	3.169	9.531	0.901	2.713	4.517
10.610	1.885	6.034	2.149	6.611	3.278	10.100	0.932	2.865	4.517
9.495	1.575	5.401	2.077	6.249	3.169	9.531	0.901	2.714	3.798
9.495	1.592	5.403	2.359	7.423	3.596	11.350	1.024	3.215	3.798

P									
HO *(Tot al: 80	MS *(Total: 80 kgf)		FF *(Total: 80 kgf)		HS *(Total: 80 kgf)		S *(Total: 40 kgf)		
Heel: 0 Foref	Heel: 34.28 Forefoot: 45.72		Heel: 51.42 Forefoot: 28.58		Heel: 80 Forefoot: 0		Heel: 22.85 Forefoot: 17.14		
vonMises (kgf/cm^2)	Displacement (mm)	vonMises (kgf/cm^2)	Displacement (mm)	vonMises (kgf/cm^2)	Displacement (mm)	vonMises (kgf/cm^2)	Displacement (mm)	vonMises (kgf/cm^2)	Displacement (mm)
10.600	2.909	6.056	3.143	6.115	4.746	9.214	1.380	2.688	3.290
10.600	2.911	6.057	3.254	6.478	4.911	9.780	1.427	2.841	3.290
9.511	2.435	5.415	3.143	6.117	4.746	9.214	1.380	2.689	2.758
9.511	2.437	5.418	3.569	7.257	5.381	10.980	1.567	3.189	2.758

			Displacement (mm)	5.035	5.035	4.241	4.241

* Total weight of the user for this simulation was 80 kg (foot number: 41).