Personalized 3D printed offloading insole

to reduce plantar pressure at high-pressure areas

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Technical Medicine

Master Thesis

UMC Utrecht

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General information

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Preface

In 2016, I started the Technical Medicine program with great enthusiasm, as I wanted to improve current health care by improving therapeutic and diagnostic technologies. With a passion for mathematics, physics, and the human body, I enjoyed my academic journey. Throughout my clinical internships, I came across valuable experiences, and had to deal with both ups and downs. Looking back on my internships, I found joy in addressing challenges associated with existing medical technologies, and finding innovative solutions to address these challenges by combining both my technical and medical background. The knowledge and skills I have gained over the years, especially through unique internship experiences, will undoubtedly benefit me throughout my future career.

This graduation internship would not have been possible without the collaborative energy of the department of Vascular Surgery at the UMC Utrecht. A special acknowledgement goes to Stijn Hazenberg, for giving me the opportunity to contribute to this innovative research project, providing opportunities such as speaking at an international conference in London, and for engaging me in clinical activities. I enjoyed our casual conversations, as well as in-depth discussions about my thesis, and I valued your critical approach that taught me significantly. I highly appreciated the approachable manner in which you guided and supervised me, and I am optimistic that our collaboration will extend beyond this thesis.

Moreover, I would like to express my gratitude to the 3D Lab UMC Utrecht, particularly to Chien Nguyen. Your critical view was valuable, and I appreciated the way you encouraged me to take on a critical perspective, creating an environment where I gained substantial knowledge in the field of conducting proper research, and creating personalized saw guides for osteotomies. Your willingness for both informal chats, and formal discussions about my project, with an always open door, was highly appreciated. I am excited to continue pursuing my passion, using my medical technology background, to contribute to improving patient-specific treatments through 3D printing, and designing. I am looking forward to collaborate with you as a colleague.

In addition, I extend my gratitude to Erik Groot Jebbink for the technical supervision during my graduation year, offering insights that expanded my understanding. I would also like to thank Jurre Klaassen, who not only provided me with the opportunity to delve into the use of 3D roadmaps in vascular procedures, but also actively engaged me in all research group activities. Furthermore, I would like to thank Nicole Cramer Bornemann, for supervising me during the process of my internships in the past two years. I appreciate all the insights you gave me regarding my personal development. Moreover, the Gait Lab at Amsterdam UMC allowed me to conduct pressure measurement at their laboratory. I extend my gratitude for offering this opportunity, and for providing valuable insights into my research. Lastly, I have always felt more than welcome to discuss my ideas and ask for advice at the plaster cast room. Your enthusiasm, and collaborative mindset, highly contributed to the progression of my thesis.

I hope that reading my thesis brings you as much enjoyment as I experienced throughout my past year.

Manouk Ramselaar
Utrecht, January 29, 2022

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Introduction

An estimated 435 million people suffer from diabetes worldwide.[1] Between 19-34% of the diabetic population is expected to develop foot ulcers during their lifetime.[2] Diabetic foot ulcer (DFU) pose a considerable risk of infection, which can lead to an amputation.[3] Within the first year after the development of a DFU, 17-20% of patients undergo a minor amputation and 5% undergo a major amputation.[4] Furthermore, the mortality rate among patients developing a DFU is 2.5 times higher compared to diabetic patients without a DFU. [5] Timely and proper DFU treatment is therefore crucial to prevent infections and to minimize the need for amputations.[6] Treatment options for DFUs include infection management, plantar offloading, tissue revascularization, and local ulcer care by debriding necrotic tissue and surrounding callus.[7]

The primary treatment approach of DFUs is to reduce plantar tissue stress from the plantar surface through the use of offloading interventions.[3,8] When choosing the most appropriate offloading device for patients presenting DFUs, it is crucial to carefully consider the potential clinical advantages and disadvantages of offloading devices.[6] In 2023, the International Working Group on the Diabetic Foot (IWGDF) evaluated various offloading devices, considering outcomes such as ulcer healing, adherence rates, plantar pressure reduction, new lesions, infections, and amputations.[9] Based on these outcomes, the IWGDF published evidence-based guidelines on the prevention and management of diabetic foot disease. Overall, the quality of evidence of these guidelines is only of low-to moderate certainty, posing a challenge in the decision-making process for treating DFUs.

The effectiveness of various offloading devices in promoting ulcer healing, depends on the ability to reduce plantar pressure.[6,10–12] The success of a custom-made offloading device in reducing plantar pressure is dependent on the practitioner's expertise.[9] As these devices are hand-crafted, variations between designs are common, making the custom-made offloading device susceptible for inter- and intra-variability. Using a reproducible workflow for the design of offloading devices, is essential for a reliable and quantitative evaluation of offloading devices[13,14]. A quantitative evaluation is crucial for ensuring effective prevention and healing treatments.

Current concepts of DFU healing also rely on restricting weightbearing activity to decrease plantar tissue stress.[9] The IWGDF acknowledged that it is uncertain whether restricting weight-bearing activity has a positive or negative effect on DFU healing and various health outcomes. [9] It is therefore questionable whether restraining a patient with a DFU from weight-bearing activity is a proper approach, as weight-bearing activity is necessary for some daily life activities and promotes overall health.[15,16] Besides, various studies demonstrated that relatively normal levels of weight-bearing activity do not impede DFU healing when adequate offloading is provided.[17] The ideal offloading device should effectively promote healing while allowing individuals to maintain or improve activity levels for better cardiovascular health, and quality of life.

Despite the proven effectiveness of offloading devices in healing DFUs, there is room for improvement in various design aspects. To our knowledge, an offloading device that effectively promotes ulcer healing while allowing individuals to maintain or improve activity levels is non-existent. To assess the influence of weight-bearing activity on DFU healing, it is essential to design a device that effectively offloads the DFU during weight-bearing activity. Furthermore, standardized design workflows are needed to address design inter- and intra-variability, allowing for a quantitative evaluation of offloading devices. A potential solution to enhance reproducibility, is creating insoles using computer-aided design and 3D print technology. The goal of this thesis was to create a personalized offloading insole using computer-aided design and 3D print technology, facilitating adequate offloading so that regular weight-bearing activity can be continued.

Aims

Two studies were conducted: a systematic review and a pilot experiment. The systematic review was conducted to explore the advancements in computer-aided design and 3D print technology for creating personalized offloading insole to reduce plantar pressure in patients at risk of diabetic foot ulcer. This review served as foundation to establish important design requirements for personalized 3D printed offloading insoles.

The goal of the pilot experiment was to create a personalized offloading insole using computer-aided design and 3D print technology, facilitating adequate offloading so that regular weight-bearing activity can be continued. The personalized insoles should comply with the following sub aims:

1. The insoles should result in lower plantar pressures at identified high-pressure areas compared to a standard flat insole.
2. The insoles should not increase overall plantar pressure compared to a standard flat insole.
3. The insoles should redistribute plantar pressure from the identified high-pressure areas to other parts of the plantar surface.

Clinical background

Diabetic foot ulcers (DFUs) are caused by a combination of nerve and vascular problems that are related to the hyperglycemic state of diabetes (Figure 1).[2] Hyperglycemia causes damage to nerve cells, resulting in polyneuropathy, in which sensory, motor, and autonomic functions can be affected in various degrees. Polyneuropathy contributes to the development of DFUs, as the loss of sensation and muscle function can result in an unnoticed elevated skin pressure on the foot, while a decreased autonomic sweat gland function and dry skin increase the likelihood of skin breakdown and injury. [18,19] Furthermore, diabetic patients have a higher risk of developing peripheral artery disease, which increases the risk of DFU formation and impedes ulcer healing due to a reduced skin perfusion.[20] Treatment options for DFUs include infection management, plantar offloading, tissue revascularization, and local ulcer care, which involves debriding necrotic tissue and surrounding callus.[7]

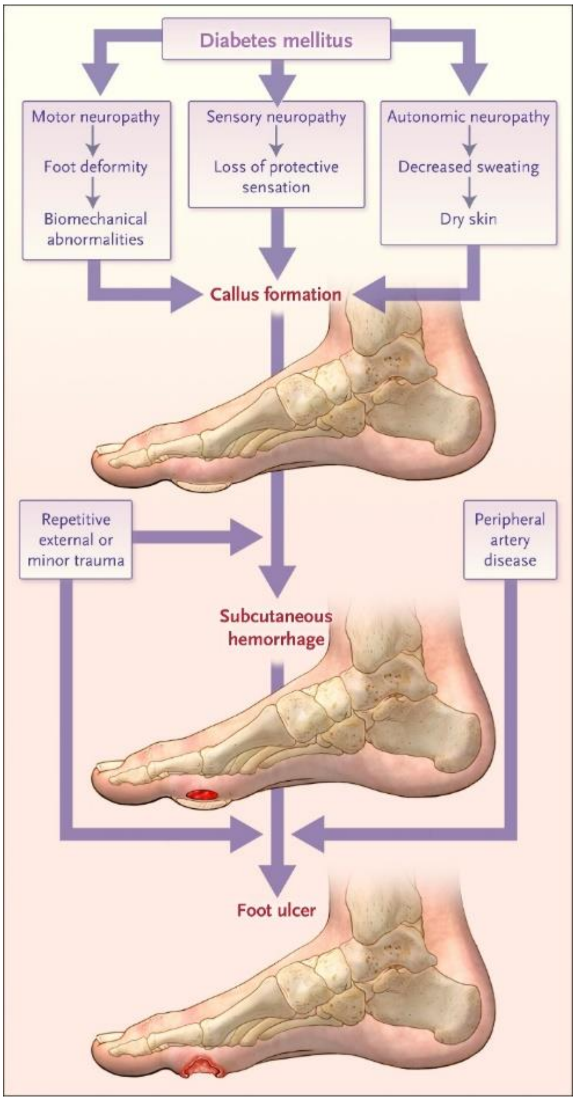


***Figure 1**: Common pathway of DFU occurrence* [2]

Offloading the diabetic foot ulcer

Multiple offloading devices are available, which can be categorized into two main types: non-removable and removable devices. Additionally, they can be differentiated into knee-high and ankle-high offloading devices. The International Working Group on the Diabetic Foot (IWGDF) evaluated the advantages and disadvantages of various offloading devices for patients with a DFU with the focus on several clinical outcomes. The IWGDF offloading guidelines were created to assist healthcare professionals in selecting the best suitable offloading device for patients presenting a DFU. This involved considering various factors, including patient's acceptability and undesirable effects, such as new lesions, hospitalization, infections, and amputations.[9]

Non-removable versus removable offloading devices

For patients with a neuropathic DFU on the plantar forefoot or midfoot, the IWGDF strongly recommends using a non-removable knee-high offloading device as first choice of intervention. Compared to removable offloading devices, non-removable knee-high devices are more effective in ulcer healing, decreasing infections, and prevention of amputations.[9]

However, when concerning patient acceptance, removable devices may be preferred over non-removable devices. [9] Removable devices may be preferred in situations when patients refuse to use a non-removable device or when the patients' circumstances hinder its use, such as being unable to incorporate it into their job responsibilities. A removable knee- or ankle-high offloading device may be a solution to overcome these challenges.

Removable knee-high versus ankle-high offloading devices

Removable knee-high devices show a higher reduction in plantar pressure compared to removable ankle-high offloading devices. However, wearing a removable knee-high offloading device often results in lower patient satisfaction compared to using an ankle-high offloading device. Accordingly, adherence to knee-high offloading devices is lower than adherence to ankle-high offloading devices. Thus, even though removable knee-high devices show higher reduction in plantar pressure, as adherence to the devices was lower, the IWGDF found no difference in plantar DFU healing between wearing a removable knee-high and ankle-high devices.[6,9]

Success of offloading device

The effectiveness of the various offloading devices in promoting ulcer healing strongly depends on the patient's adherence to the device and the ability to reduce plantar pressure.[6,10–12] Adherence to the offloading device is crucial, as worse healing outcomes were observed with lower adherence rates. A device that is less capable in reducing plantar pressure, yet consistently worn, may yield comparable or superior outcomes in ulcer healing compared to a device demonstrating an increased pressure reduction but worn less frequently.[9] For this reason, it is important to consider the device's offloading capacity as well as the individual's adherence to wearing it when choosing an offloading device.

Reducing plantar tissue stress

During weight-bearing (WB) activity, various pressures are exhibited on the foot. To achieve effective plantar offloading by using an offloading device, it is essential to stratify between pressure types during WB activity.

'The accumulation of all mechanical stresses on an area of the plantar foot tissue from all weight-bearing activity over time' is described by the term plantar tissue stress.[11] Plantar tissue stress is a combination of plantar pressures, shear stresses, and the frequency in which these pressures are applied through WB activity (Figure 2). The magnitude of plantar tissue stress can be lowered by reducing either plantar pressure, shear stress, and/or the amount of WB activity.

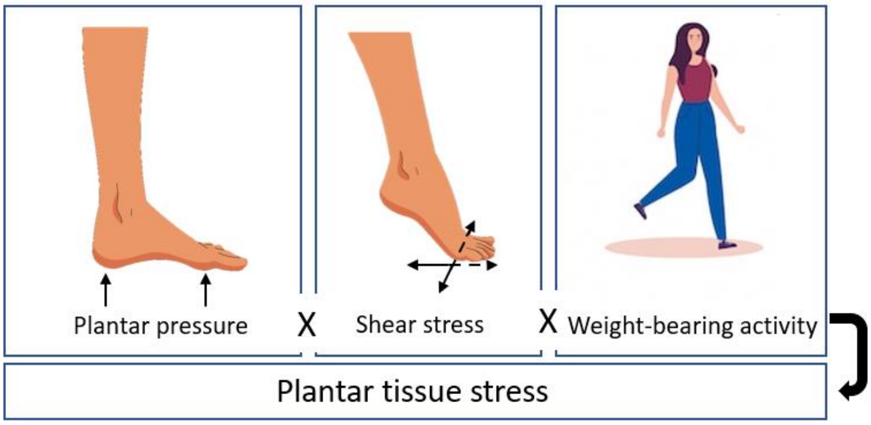


Figure 2. *Plantar pressure is a pressure applied perpendicular to the plantar surface, and shear stress acts horizontally to the plantar contact surface. The frequency in which plantar pressures and shear stresses are applied to the plantar foot tissue due to weight-bearing activities are of influence on plantar tissue stress.* [11]

Shear stress

Shear stress is typically a result of friction and acts horizontally to the plantar foot surface. Shear stress is a combination of medial-lateral and anterior-posterior forces.[11] Despite the awareness of the pathogenic nature of shear, the relationship between shear stress and ulcer formation remains unclear. This lack of clarity is attributed to the technical challenges that are associated with shear stress measurement. There exists a great diversity in technologies used to measure shear stress, leading to a wide range of reported shear stress values across different studies.[21] Besides, currently no valid commercially available measurement device exists to measure in-shoe shear stress across the plantar surface.[22] Even though shear stress emerges as a potential modifiable risk factor in the development of ulcers, additional research is necessary to identify associations between shear stress and ulcer formation. Only then strategies can be formulated to mitigate the impact of shear stress on DFU formation.[23]

Weightbearing activity

Various studies[24–26] investigated the risk of DFU development after WB activity, defined as any activity that is performed on one or both feet[27]. These studies concluded that in diabatic patients suffering from diabetic peripheral neuropathy or having a history of prior foot ulcer, the risk of developing a DFU was significantly lower when more WB activity was performed. The theory of physical stress[28] suggests that prolonged periods of physical stress increases collagen content and the diameter of the collagen fibers, resulting in a thickened softer skin with improved strength.[28] A greater amount of WB activity has a positive impact on the skin's ability to withstand pressure. This prevents the plantar skin from breaking down when being exposed to higher pressures experienced during walking. A study[29] involving individuals with diabetes mellitus type 2, revealed that less WB activity results in a worsened plantar microcirculation, and increased hardness of plantar tissue. The theory of physical stress therefore suggests that less WB physical activity could lead to atrophy of the plantar skin tissue, resulting in a decreased ability to tolerate plantar pressures.[29]

Although it is evident that physical activity is beneficial for physical health and decreases the risk of developing a DFU in diabetic people, it is uncertain what the appropriate dosage is for exercise in diabetic individuals with an active DFU.[9,30] Little research is conducted about the effect of WB activity on DFU healing while wearing an offloading device. WB activity is in most studies defined as the number of daily steps[31]. Although results were not statistically significant, most studies directed towards a negative association between WB and DFU healing, implying that a larger number of daily steps resulted in a slower DFU healing. In a RCT by Najafi et al.[32] it was suggested that up to 3000 daily steps would not have a negative effect on DFU healing while wearing an offloading device. According to the RCT by Van Netten et al.[33] it was suggested that diabetic individuals, whilst wearing a removable offloading device, could safely perform 7000 steps a day while still attaining successful healing of DFUs within 12 weeks. Considering that an average person walks approximately 5000 steps a day[34], this indicates that it may be possible to maintain relatively normal levels of WB activity while achieving DFU healing within a 12-week timeframe.

Even though no clear evidence exists with respect to WB activity and DFU healing, most studies advice to be cautious with performing WB activity during the DFU healing process, as an offloading device cannot completely eliminate plantar pressures.[35] As a result, WB activity may still exert unnecessary pressure on the DFU, leading to a delayed healing.[15] On the other hand, restricting WB activity can result in weight gain, a loss in muscle mass, worse joint flexibility, and lower bone mass. Moreover, physical activity contributes to an optimized regulation of blood glucose levels, minimizing the likelihood of diabetes complications, and physical activity also promotes overall physical and mental health.[15] Furthermore, WB activity may result in an improved blood supply to the distal foot, improving wound blood perfusion and promoting DFU healing, as it provides the necessary nutrients.[36] Besides, people with diabetes-related foot disease tend to be more active indoors than outdoors, with an average of 4047 steps taken indoors versus a 2514 steps taken outdoors.[31] This means that WB activity is also part of performing daily activities such as household activities and moving from A to B, making it challenging to limit such activities. Moreover, considering its crucial role in maintaining health, WB activity may also contribute to supporting the healing process of diabetic foot ulcers.

In theory, limiting WB activity can potentially reduce plantar tissue stress. However, due to limited available research, the IWGDF acknowledged that it remains uncertain whether weight-bearing activity has a positive or negative effect on DFU healing and various health outcomes whilst wearing an offloading device. These outcomes include ulcer healing, quality of life, and general health outcomes.[9] The ideal offloading intervention should effectively promote healing while allowing individuals to maintain or improve activity levels for better cardiovascular health and quality of life.[15,16] To our knowledge, such an offloading device is non-existent.

Plantar pressure

As shear stress cannot be accurately measured, and reducing WB activity is less favorable, an alternative strategy to lower plantar tissue stress is reducing plantar pressure. Plantar pressure is defined as the normal pressure that is applied perpendicular to the plantar surface. Plantar pressure is calculated by dividing the ground reaction force by the contact area of the foot. The magnitude and distribution of the ground reaction forces are influenced by the body-mass, walking speed, and footwear conditions.[11]

Plantar pressures can be reduced by using an offloading device. The effectiveness of the various offloading devices in promoting ulcer healing, depends on their ability to reduce plantar pressure. The most common used parameter to express plantar pressure is the peak pressure (PP), which is the maximal pressure in an area under the foot.[37,38] However, the level of stress experienced at an ulcer location is not only determined by the magnitude of plantar pressure, but also by the duration at which this pressure is applied. The pressure time integral (PTI), also known as cumulative pressure, is a variable that incorporates duration as well as the magnitude of the applied plantar pressure.[38,39]

In a study by van Netten et al.[33] the difference in PP and PTI between healed and non-healed ulcers was explored in 31 patients wearing a removable offloading device. In total, 27 patients reported to be self-adherent to the offloading device, meaning they wore the device ≥50% inside the house and ≥80% outside the house. The self-adherent patients who had more than 75% reduction in ulcer surface area at four weeks, had a 24% lower PP and a 30% lower PTI than self-adherent patients who had less than 75% reduction in ulcer surface area after four weeks. Results were not statistically significant due to the small patient group. Nevertheless, PP and PTI might both be good and measurable predictors for DFU healing while wearing offloading devices.

Measuring plantar pressures

Plantar pressures (PP and PTI) can be quantified using the Pedar®-X system (Novel, GmbH, Munich, Germany). This system uses an insole to measure the in-shoe PP and PTI.[37] The insole has a thickness of 2 mm and is constructed with 99 capacitive sensors divided over a homogeneous grid (1 sensor/cm^2) and measures with a high repeatability and accuracy, using a sample rate of 50 Hz.[37,40] The variable PP (kPa) is defined as the highest pressure experienced by the plantar surface within a timeframe. The PTI (kPa*s) is the area under the peak pressure-time curve in a defined sole area and provides a summation of the peak pressures at each frame multiplied by the time per frame.[37,39] The PTI and PP can be calculated for one step or for the entire data collection period. Additionally, the PTI and PP can be calculated for one sensor, for a defined plantar area or for the entire plantar surface.

$$PTI = \sum_{i\_0}^{i\_x} p_i \times \Delta t$$

In a study by Hulshof et al. [41], it was shown that the walking speed has a statistically significant effect on the PP and PTI in patients with a diabetic foot. At a higher walking speed, the ground reaction forces increase due to an increase in ankle push-offs, resulting in a higher PP in the forefoot regions. The PTI on the other hand, is time dependent and decreases with an increased walking speed, due to the shorter step duration. An increased walking speed thus results in a statistically significant increased PP and a decreased PTI. In-shoe plantar pressure is often evaluated while patients are walking at a self-selected speed in a laboratory setting. This speed is faster than the average walking speed of these patients in daily life.[42,43] The PP and PTI values obtained in a laboratory may therefore not accurately reflect the PP and PTI experienced during everyday activities outside the laboratory.[41]

Thesis outline

Two studies were conducted: a systematic review and a pilot experiment. The review explores the state-of-the-art applications of computer-aided design technology and 3D printing in designing personalized insoles for plantar pressure reduction in diabetic patients. The second study used computer-aided design to create personalized insoles for healthy subjects, based on a semi-weightbearing foot shape and with reduced stiffness in measured high-pressure areas. The insoles were 3D printed and aimed to reduce plantar pressure at high-pressure areas without increasing overall plantar pressures.

Computer-aided design and 3D print technology for personalized offloading insole to reduce plantar pressure in patients at risk of diabetic foot ulcer: a systematic review

***Introduction**: An essential cornerstone for the treatment of diabetic foot ulcers (DFUs), is plantar tissue stress offloading. The creation of personalized offloading devices, often handcrafted, exhibits high inter- and intra-variability in design. A potential solution to enhance reproducibility involves utilizing computer-aided design (CAD) and 3D printing. This review explores the state-of-the-art applications in (CAD) and 3D printing of personalized insoles for plantar pressure reduction of DFU.*

***Methods**: The Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines were followed. Eligibility criteria included studies creating 3D printed personalized offloading insoles, potentially using CAD and finite element (FE) modeling, with primary outcome focused on plantar pressure reduction.*

***Results**: Seven studies met the eligibility criteria, encompassing both in silico and in vivo approaches. Studies focused on designing total contact insoles and adjusting insole stiffness through lattice structures using CAD. In silico studies demonstrated the potential of optimizing insole shape and stiffness using FE models, while in vivo studies used FE modelling and/or in-shoe pressure measurements to optimize shape and/or stiffness of a 3D printed insole.*

***Conclusion**: This review presents promising outcomes in reducing plantar pressure with 3D printed personalized offloading insoles, designed through a potentially more reproducible workflow using CAD and FE modeling. This approach will potentially allow for a reliable and quantitative evaluation of offloading devices. Further research with larger sample sizes, including diabetic patients with a DFU, and longitudinal studies is essential to establish the clinical efficacy these offloading devices in treating, and preventing DFU in diabetic patients.*

Introduction

An estimated amount of 435 million people suffer from diabetes worldwide.[1] Between 19-34% of the diabetic population is expected to develop foot ulcers during their lifetime.[2] Diabetic foot ulcer (DFU) pose a considerable risk of infection, which can lead to an amputation.[3] Within the first year after the development of a DFU, 17-20% of patients undergo a minor amputation and 5% undergo a major amputation.[4] Furthermore, the mortality rate among patients presenting a DFU is 2.5 times higher compared to diabetic patients without a DFU. [5] Timely DFU treatment is therefore crucial for preventing infections and minimizing the need for amputations.[6]

An essential cornerstone for the treatment of diabetic foot ulcers (DFUs), is plantar tissue stress offloading.[3,8,9] When choosing the most appropriate offloading device for patients presenting DFUs, it is crucial to comprehend and carefully weigh the potential clinical advantages and disadvantages of offloading devices.[6] In 2023, the International Working Group for Diabetic Foot (IWGDF) evaluated various offloading devices, considering outcomes such as ulcer healing, adherence rates, plantar pressure reduction, new lesions, infections, and amputations. Based on these outcomes, the IWGDF published evidence-based guidelines on the prevention and management of diabetic foot disease. [9] Overall, the quality of evidence of these guidelines is only of low-to moderate certainty, posing a challenge in the decision-making process for treating DFUs.

The current standard of care focusses on reducing plantar pressure using accommodative shoes and custom insoles crafted by specialized clinicians. These standard of care insoles utilize layers of foam with varying material hardness, along with strategically placed additions such as heel lifts or metatarsal pads.[44] The choice of material impacts the effectiveness of the insole design, as the mechanical and physical material properties influence its ability to redistribute or reduce forces.[45]

Insole customization can be based on castings, which involves capturing the geometric shape of the patient's foot to customize the insole design.[45] Besides casting, several studies[12–14,46,47] utilized in-shoe plantar pressure measurement as a tool to iteratively test and modify the shape of a customized insole until optimal in-shoe plantar pressure distribution was achieved. According to the review of Collins et al.[45], only one study[48] incorporated barefoot plantar pressure data to inform the design of insoles. [47]

Despite the proven effectiveness of offloading devices in healing DFUs, further enhancement can be made in various design aspects. Hand-crafted offloading devices are prone to design variability, requiring skilled application to obtain successful pressure reduction.[9] Using a reproducible workflow for the design of offloading devices is crucial for a reliable and quantitative evaluation of offloading devices. A quantitative evaluation is crucial for ensuring effective DFU prevention and healing treatments.[13,14] Furthermore, designing custom-made offloading devices is a labor-intensive and time-consuming fabrication process.[49] Producing a personalized offloading device with the use of computer-aided design (CAD) and 3D printing, is a possible solution in limiting inter- and intra-variability, also offering a faster and more efficient approach.

CAD is the use of computer-based software to assist in design modelling, design analysis, and design optimization.[50] CAD technology facilitates designing personalized offloading insoles, ensuring an optimal fit while minimizing production costs and design time.[51] It also facilitates the digital storage of designs, and therefore enables accelerated development through (partially) reusing previous models.[52] Finite element (FE) modelling is often used in conjunction with CAD. It involves analysing individual finite elements of the design, to predict overall design behaviour under various conditions.

When manufacturing offloading insoles using 3D print technology, CAD technology can be used to adjust insole shape and stiffness (indicated by Young's Modulus). Insole shape is personalized using foot shape, and the stiffness of a 3D printed insole is determined by the unit cell topology, unit cell size, and unit cell strut diameter of its lattice structure.[53,54] Insole shape and stiffness are important design parameters for designing a personalized offloading insole.[55]

To our knowledge, there are no personalized 3D printed offloading insoles clinically in use. This review explores the state-of-the-art applications in designing personalized insoles for plantar pressure reduction in diabetic patients using CAD and 3D print technology.

Methods

This systematic review was performed using the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.[56] This review focuses on individuals at risk of or with a DFU (P). Included studies(I) used 3D print technology to create personalized offloading insoles or employed 3D FE model for designing such insoles. Both in silico and in vivo studies were included. The primary outcome (O) was the reduction of plantar pressure, compared (C) to no offloading device or standard of care insoles. Inclusion criteria encompassed full-text studies in English, including technical reports, while conference reports, reviews and newspaper articles were excluded, along with studies lacking a description of the design or manufacturing method.

Four electronic databases were consulted in June 2023 (Pubmed, Scopus, Cochrane and Embase) using medical subject heading, followed by an intervention subject heading, and a 3D print technique. The search was performed in June 2023 and not limited by date. Search terms are shown in Table 1, and the string used is shown in Attachment A1.

And →

OR ↓

Patients	Intervention	3D technique
Diabet* Ulcer*	Insole	3D
	midsole	Three dimensional
	Shoe	Three-dimensional
	Footwear	3-dimensional
	Ortho*	Additive manufacturing
	Device	Computer aided Computer-aided
	Heal*	Finite element
	Pressure	
	Offload*	
	Off-load*	
	Treat*	

Table 1. Search terms

Two reviewers (MR, CN) independently assessed all obtained records based on title and abstract to determine eligibility. After inclusion based on title and abstract, MR and CN also independently examined the articles on full text which led to the final eligibility for inclusion. Any discrepancies between reviewers were resolved through discussion. In cases where consensus was not reached, a third reviewer (CH) was consulted for a third opinion to make a final decision.

Data of interest was extracted from the included studies and summarized. The data of interest included the problem statement, goal, details on FE model creation and/or insole design method, findings regarding plantar pressure reduction, conclusions, and limitations of each study. MR extracted the data and the other authors checked this for content and presentation.

Results

The literature search identified 832 articles of which only 7 met the eligibility criteria to be included in the review, see Figure 1. The study designs included 3 in silico studies and 4 in vivo studies. A description on insole personalization method, offloading capability and overall findings is summarized in Attachment A2. The information was organized into in silico studies (table A2.1) and in vivo studies (table A2.2).

Offloading capacity of the insoles was tested by measuring in-shoe plantar pressure. Plantar pressure was defined by peak pressure (PP) and/or pressure-time integral (PTI), with PP representing maximal plantar pressure and PTI reflecting cumulative plantar pressure.

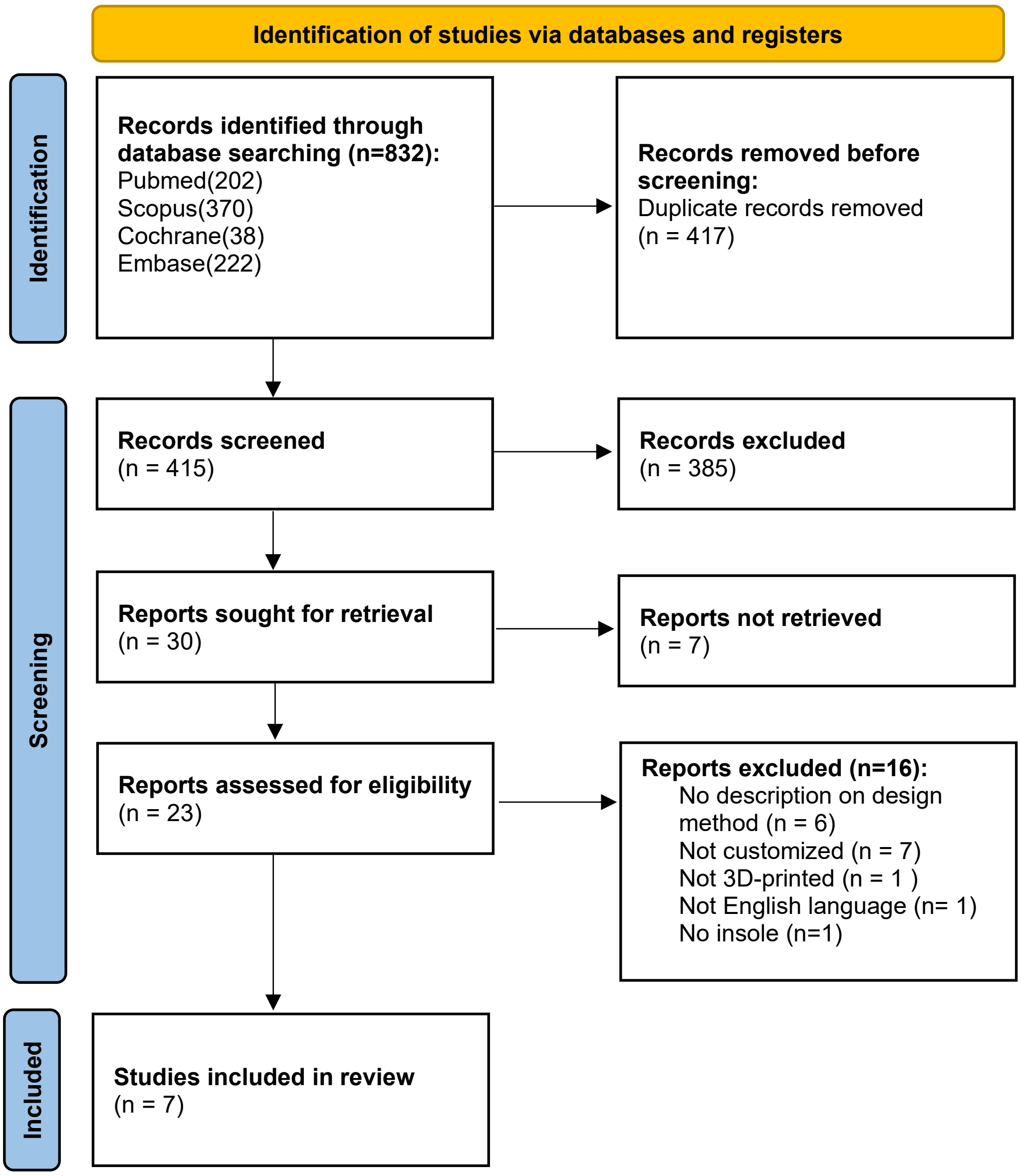


Figure 1. Prisma study selection flow diagram

In silico studies

Three studies deployed an in-silico test method for the design of offloading insoles with the potential for 3D printing. The objective of the studies was optimizing the shape and/or stiffness of the insole using CAD and FE modelling. All FE models included a foot and an insole model and were employed to analyse stress-strain insole material properties, and predict plantar pressures.

The goal of Tang. et al[57] was to reduce peak plantar pressure by integrating a total contact insole with a porous lattice structured insole. They used a FE model to locally optimize the stiffness of the porous insole. Insole shape was based on a 3D scan of the plantar surface of the patient, making it a total contact insole. The location of the high- and low-pressure area at the plantar surface was subjectively defined by manually drawing the metatarsal and heel region on the insole surface. The insole material properties of the defined low and high-pressure regions were optimized by changing the regional stiffnesses of the Thermoplastic Polyurethane (TPU) insole using a FE model. During the optimization procedure, the researchers altered the strut thickness of the diamond lattice (size 10 x 10 x 20 mm) structured insole. They concluded that an insole with a lower stiffness in the high-pressure region (with optimal strut thickness = 2.06 mm), and a higher stiffness in the low-pressure region (with optimal strut thickness = 2.76 mm), can further reduce the overal peak plantar pressure from 75.6 kPa to 66.5 kPa compared to an insole with a homogenous stiffness, as calculated by the FE model. According to their in-silico test, they concluded that it is possible to reduce peak plantar pressure of a foot, by using a data-driven model to adjust the elastic modulus.

The study by Geiger et al.[58] also focussed on customizing a total contact insole by locally adjusting insole stiffness. They share a comparable methodology as Tang et al., however, instead of subjectively defining the high-pressure area, the high-pressure areas were objectively determined. The high-pressure areas were identified based on regions displaying an in-shoe peak plantar pressure exceeding 100 kPa. Geiger et al. solely adjusted the stiffness of these high-pressure regions, while maintaining a fixed stiffness (Young's Modulus of 4MPa) for the low-pressure areas. The Young's modulus of the high-pressure area was altered to 1.5 MPa, 1 MPa, and 0.5 MPa. Subsequently, the FE model was employed to compute plantar pressures corresponding to these varied stiffness settings. The largest reduction in PP at the high-pressure area was obtained using a Young's modulus of 0.5 MPa. Despite large absolute deviations (234 kPa) between experimentally measured and simulated calculated peak plantar pressures, the objectively defined location of the high-pressure area was similar in both experiments. Due to this inaccuracy, the FE model cannot be used to predict the absolute change in plantar pressure distribution resulting from a variation in the stiffness of the insole material. However, the FE model was regarded as a valuable tool for identifying high pressure areas.

Different to the other two in silico studies, Jafarzadeh et al.[59] did not only use a FE model to adjust material properties, but also used the FE model to optimize insole shape. The FE model was used to calculate foot plantar pressure during standing position, and to identify high pressure areas. An iterative method was developed based on the FE analysis to modify insole shape and stiffness, aiming to decrease plantar pressure and homogenize the pressure distribution. Using this iterative method, insole thickness and Young's modulus were decreased at identified high-pressure areas, and Young's modulus was increased at low-pressure areas. After modifying Young's modulus, the FE analysis was conducted again to recalculate plantar pressures. In this optimization procedure, the Young's modulus was modified until changes in Young's modulus from one iteration to another became negligible. The FE model showed that an insole with continuously variable stiffness resulted in a better pressure reduction than an insole with continuously variable shape. A uniform soft material, using a low Young's modulus, resulted in a reduction of 30% in plantar pressure when compared to a material with a higher Young's modulus. The plantar pressure could be even further reduced with 16% when this insole with a uniform soft material was also optimized for insole shape. Jafarzadeh et al. concluded that the stiffness of the footwear, defined by the Young's modulus, is the most important factor to consider in plantar pressure reduction. According to this study, the most effective model to reduce plantar pressure is a uniform soft material with an optimized insole shape.

In vivo studies

In total, four studies designed a personalized 3D printed insole and tested the effect of the insole on in-shoe plantar pressure reduction in vivo. These studies optimized material stiffness and/or insole shape.

Hudak et al.[44] aimed to create a 3D printed insole material that replicated the stiffness of the standard of care insole, demonstrating enhanced durability. Simultaneously, they aimed to enable customization of the insole stiffness based on plantar pressure data through a repeatable workflow and reducing shear stiffness while wearing the 3D printed insole compared to the Standard of Care insole. Firstly, they used a lattice design engine to iteratively adjust lattice unit size and strut thickness until stiffness comparable to that of the Standard of Care insole was achieved. The lattice structures were 3D-printed, and compressive stiffness was tested. This process was repeated until the lattice sample closely matched the foam material used in the Standard of Care insole. Insole shape was customized using a foam crush box impression. An in-shoe plantar pressure measurement was obtained to divide the insole into offloading segments (>200 kPa) and normal-pressure segments. The normal-pressure segments consisted of the lattice matching the stiffness of the Standard of Care insole and the offloading segments consisted of a more porous lattice. Two types of insoles were manufactured through 3D printing. The first type was a fully 3D printed insole produced from Elastomeric Polyurethane 41 (EPU 41). The other insole was a hybrid 3D printed insole, having a surface texture preferred by both patients and clinicians. This involved substituting the top 4mm layer of EPU 41 with a Poron-plastazote bi-laminate. In the offloading region, the hybrid (207 kPa) and fully 3D printed insole (209 kPa) showed a larger decrease in maximum PP compared to the Standard of Care insole (268.8 kPa). This study was the only study that tested durability via benchtop simulation of one year of use. It was concluded that the hybrid and fully 3D printed insole were at least as durable as the Standard of Care insole. Furthermore, the 3D printed insoles also demonstrated the ability to reduce PP at the offloading regions.

Muir et al.[60] developed fully 3D printed and hybrid 3D printed insoles for fourteen adults without existing ulcers, neuropathy, and deformity. These insoles were personalized following the design and manufacturing process from the previous study by Hudak et al.[44], using a foam box impression for insole shape, an in-shoe plantar pressure measurement to define offloading regions (>200 kPa). A more porous lattice structure was added in these regions to reduce insole stiffness. The hybrid insoles (of EPU 41 and with a layer of Poron-plastazote bi-laminate) and fully 3D printed (in EPU 41) insoles were subjectively and objectively compared to the Standard of Care insole. No visual signs of malperformance (e.g. skin blister or irritation) were found and participants did not feel any discomfort of the insoles. When the participants were asked for their favourite insole, 58% chose the fully 3D printed insole, 42% chose the hybrid 3D printed insole, and none chose the Standard of Care insole as their favourite insole. Compared to the Standard of Care insole, the hybrid 3D printed insole significantly reduced PP in the offloading region by 20% and the fully 3D printed insole significantly reduced PP by 14% in the offloading region. Mean PTI was also significantly reduced in the offloading region by the hybrid insole (21%) and fully 3D printed insole (15%) when comparing to the Standard of Care. This research demonstrated the ability to manufacture 3D printed insoles that result in a significantly higher reduction in PP and PTI in the offloading region compared to the Standard of Care insole. Moreover, PP and PTI in areas neighbouring the offloading regions did not exhibit a significant increase when comparing the hybrid and fully 3D printed to the Standard of Care insole. The studies by Hudak et al. and Muir et al. prove the potential to offload plantar pressure in desired regions by controlling material properties, achieved through adjustment of stiffness via lattice porosity.

Tang et al.[55] aimed to develop an alternative method for insole stiffness optimization and reduce peak plantar pressure in the forefoot and rearfoot by applying functional gradient structural properties in a flat and total contact insole. They designed a total contact insole for one healthy subject, using a flat insole and the plantar surface topology of a simplified foot model, derived from a CT reconstruction of the subject. In addition, a FE model for the foot and insoles was created. The goal of the FE model was homogenizing stress distribution over the plantar surface, achieved by iteratively optimizing the Young's modulus for each insole section. Once the Young's moduli were determined, a correlation between the Young's moduli and the mechanical properties of TPU lattice structures was established. Mechanical properties of TPU were manipulated by creating various lattice structures with different unit cell topologies and strut sizes. The relationship between the mechanical properties of the lattice structures featuring distinct unit cell topologies and strut sizes, were determined by FE analysis and mechanical tests. Experimental measurements were carried out to validate these results. Subsequently, lattice structures closely matching the desired Young's modulus for each insole section, as defined by the FE model, were integrated into the flat and total contact insole. The lattice structure of the insole had a lattice size of 6 mm and a varying strut size from 0.6 mm to 2.0 mm. At the high-pressure regions of the rearfoot and forefoot, stiffnesses were decreased using a smaller strut thickness, leading to a lower Young's modulus. The optimized insoles were 3D printed in TPU and contact pressure between the foot and insoles were measured using an in-shoe pressure measurement system. Comparing to an ordinary flat insole, peak plantar pressure was reduced by 20% when wearing the flat insole with optimized stiffness and reduced by 33.67% when wearing the total contact insole optimized for stiffness. Instead of defining an offloading region and normal pressure area, this study showed the possibility to optimize stress distribution over the entire plantar surface, using various lattice structures within the insole, indicated by a FE model.

In contrast to the other studies, Telfer et al.[61] focussed on shape optimization of the personalized insole, instead of focussing on optimizing material stiffness. A foot model and a standard insole were incorporated in a FE model. A series of iterative simulations were conducted, adjusting forefoot geometry of the insole by gradually raising metatarsal bar height and removing insole material under each metatarsal head. This process was continued until regional peak plantar pressures were predicted to be lower than 200 kPa, or until the limits of possible modifications had been reached. The optimized insole design was milled using Ethylene-vinyl acetate material and 3D printed in soft poly-lactic acid (PLA) for 18 subjects with type 2 diabetes and peripheral neuropathy, with elevated barefoot plantar PP (>750 kPa). In total, 76 regions were defined as a region of interest (ROI) due to elevated pressures of more than 450 kPa. Compared to the standard insole, the virtually optimized milled insole showed a significantly lower in-shoe PP in 88% of the ROIs with a mean difference of 41.3 kPa, and the virtually optimized 3D printed insole showed a significantly lower in-shoe PP in 74% of the ROI's with a mean difference of 40.5 kPa. At the midfoot, the in-shoe PP was increased when wearing the virtually optimized milled insole (14.1 kPa) and 3D printed insole (20.6 kPa) compared to the standard insole. No significant difference in PP between the virtually optimized milled and 3D printed insoles were found. This study shows that the virtually optimized insoles are effective in enhancing forefoot offloading performance of both the milled and 3D printed insole.

Discussion

The current review provides an overview of the state-of-the-art applications in using CAD technology and 3D printing to create personalized insoles, with the purpose of reducing plantar pressure of diabetic patients. This review demonstrated the feasibility of decreasing plantar pressure using personalized 3D printed insoles.

Based on the results of the in silico studies, it could be concluded that FE modelling can serve as valuable tool for identifying high pressure areas for the optimization of insole shape[59] and stiffness[55,58]. The feasibility to reduce peak plantar pressure and to achieve a more uniform pressure distribution using a FE model by modifying insole shape and stiffness was demonstrated.

Plantar pressures predicted by the FE models, deviated from the experimentally measured plantar pressures.[58,61] An explanation for this discrepancy, is that FE models are a simplification of reality, and therefore only an approximation of reality. The foot is a complex structure with numerous ligaments, joints, and musculature. The more complexity is added to the model, the more challenging it is to construct the model.[61] As the model's detail increases, more computational time is demanded, and the difficulty of obtaining a reliable outcome increases.[62] The included studies made several assumptions to simplify the modeling procedure.[55,58,59,61] The variation in results between virtually and experimentally measured plantar pressures can therefore be attributed to the disparities in mechanical properties between the FE model and the real human foot.

The in vivo studies demonstrated a successful reduction in plantar pressures in high-pressure areas when wearing 3D printed insoles, without significantly increasing plantar pressures in surrounding tissues of the high-pressure areas.[44,55,60,61] Previous research has demonstrated the efficacy of personalized Standard of Care insoles in reducing PP[13,46,48,62] or PTI[48] in diabetic feet with neuropathy or ulceration. Included studies[44,55,60,61] demonstrated that personalized 3D printed insoles were also able to reduce PP and/or PTI in desired high-pressure regions. The 3D printed insoles were also considered at least as comfortable as the Standard of Care insole[60], however they showed that adding a top layer of Poron bi-laminate Plastazote can be a valuable strategy to give extra comfortability to the 3D printed insole.

The reduction in plantar pressure was more pronounced when the use of multiple design factors was combined. Insole shape and stiffness were recognized as key design parameters.[55,59] 3D printed insoles, customized using both foot shape and in-shoe pressure measurement for stiffness adjustment, showed superior results in offloading performance in in silico, and in vivo studies, compared to insoles based solely on shape.[53,55,59]

Previously, several studies[12–14,46,47] utilized in-shoe plantar pressure measurement as a tool to evaluate offloading footwear performance, and modified the customized insole accordingly to optimize pressure distribution. To the best of our knowledge, no studies used in-shoe pressure measurement to inform the initial milled insole design, and only one study[48] included barefoot pressure measurement as input parameter for the initial insole design. This study demonstrated that insoles customized using both foot shape and barefoot plantar pressure measurement data, showed superior offloading performance compared to customized insoles based solely on shape. The studies included in this review demonstrated that using in-shoe pressure measurements for optimizing insole shape and stiffness of the initial design, is feasible through the application of 3D printing technology.

According to the current IWGDF guidelines[9], effective offloading is achieved through the utilization of cushioning materials with suitable stiffness. For Standard of Care offloading insoles, cushioning is determined by insole material and thickness only. The included studies employed diverse lattice structures within the insole for improved cushioning and optimal stress distribution.[44,55,60] The lattice structure determined the stiffness of the 3D printed material. More flexible lattice structures with a lower Youngs Modulus were preferred in high-pressure areas and stiffer lattice structures with a higher Youngs Modulus were preferred in low-pressure areas.[53] The balance in lattice stiffnesses was important to provide adequate support without deploying too high plantar pressures due to a lack of deformation.[53] This current review illustrated that the use of 3D printing facilitates locally adjustable insole stiffnesses based on in-shoe plantar pressure measurements, offering an advantage over traditional methodologies for designing offloading insoles.

Clinical implications

This review demonstrates the potential application of CAD and FE modeling for designing 3D printed insoles, customizing the important design parameters shape and/or (local) stiffness. The 3D printed insoles are effective in reducing plantar pressure in high-pressure areas, without increasing overall plantar pressure. Additionally, they are also considered comfortable, which is crucial for patient adherence to treatment plans. [63,64] The demonstrated offloading capability of the personalized 3D printed insoles, holds promise in preventing and treating DFUs, while also reducing production costs and design times.[51,52] Although studies did not test reproducibility of the design method, using CAD and 3D printing can potentially reduce inter- and intra-variability. This potentially more reproducible workflow for insole design, may enable a reliable and quantitative assessment of the influence of offloading devices on DFU healing. [13,14]

Limitations

Included studies also highlighted a few limitations when using CAD, FE modeling, and 3D printing for creating personalized offloading insoles. A drawback of FE modeling is the substantial amount of time needed for development. Telfer et al.[61] invested approximately two days in building and running the optimization process for each insole. Moreover, FE models are typically tailored for a single individual, posing challenges to scalability. This makes FE modeling a valuable tool in testing feasibility and defining important design requirements, but impractical for clinical implementation.

Durability is recognized as a key parameter to obtain clinical effectiveness of insoles.[65–67] The ability of an insole to retain its soft elasticity after a period of use is critical, as the ability to absorb plantar pressures will change as the device stiffens. The insoles were 3D printed in TPU, soft PLA, and EPU 41. While Hudak et al.[44] demonstrated good durability of a lattice created with EPU 41, comparable evaluations for TPU and PLA lattices were lacking. TPU is known for its flexibility, and prior research has demonstrated its ability to absorb energy during compression[68]. Similarly, PLA is recognized for its high durability, flexibility, and smoothness to the touch.[69] Despite the known flexibility of these 3D print materials, their mechanical performance of the insoles has not been tested during long-term use, leaving their (long-term) offloading capability uncertain.

Furthermore, the 3D printed insoles were only tested with a relatively limited sample size, including healthy individuals, and type 2 diabetes patients with neuropathy exhibiting elevated barefoot plantar PP. The in vivo studies solely assessed in-shoe plantar pressures while wearing personalized 3D printed insoles and lacked follow-up data to monitor the occurrence of new DFU formations in patients. While the 3D printed insoles proved effective plantar pressure reduction, their impact on preventing the formation of new ulcers remains uncertain. Additionally, the 3D printed insoles have not yet been tested on individuals with active DFUs, leaving their potential efficacy as an offloading treatment for DFU healing unknown.

Future directions

Due to the significant time required for creating a FE model, often tailored to one individual, we perceive limited potential in employing FE models when scaling up the production of 3D printed personalized offloading insoles. Nevertheless, FE models are a valuable tool for identifying important design requirements. The use of CAD and 3D print technology have demonstrated high potential for the design of offloading insoles. It is hypothesized that the use of CAD and 3D printing can be a valuable tool in reducing inter- and intra-variability when designing personalized insole design, potentially allowing for a more reliable and quantitative evaluation of offloading devices, while also offering a faster and more efficient approach than current design methods. However, before clinical use, it is important to conduct thorough testing on the 3D printed insoles, assessing insole comfortability, offloading performance, durability, and the influence on DFU development and healing during long-term use.

Conclusion

In summary, this review highlights promising outcomes in reducing plantar pressure with 3D printed personalized offloading insoles, designed through a potentially more reproducible workflow using CAD and FE modeling. This approach will potentially allow for a reliable and quantitative evaluation of offloading devices. Further research with larger sample sizes, including diabetic patients with a DFU, and longitudinal studies is essential to establish the clinical efficacy of these offloading devices in treating DFU, and preventing DFU in diabetic patients.

Personalized 3D printed offloading insole to reduce plantar pressure in high-pressure areas

Goal: *Hand-crafted offloading devices are prone to design variability, requiring skilled application to obtain successful pressure reduction. A potential solution to limit inter- and intra-variability, involves the creation of a personalized offloading insole using computer-aided design (CAD) and 3D printing. This study used CAD and 3D print technology to develop personalized offloading insoles, with the aim to reduce plantar pressure at high-pressure areas without increasing overall plantar pressures.*

Method: *Personalized insoles for healthy subjects were designed using CAD. The insoles were personalized based on a semi-weightbearing foot shape, and had reduced stiffness in measured high-pressure areas. The insoles were 3D printed in Thermoplastic Polyurethane (TPU), and evaluated through in-shoe plantar pressure measurements. Comfortability was assessed using a Numeric Rating Scale.*

Results: *At high-pressure areas, the 3D-printed insoles effectively reduced peak pressures by 58%, and pressure time integral was reduced by 37%. Pressure distribution shifted, reducing plantar pressures on metatarsals, and redistributing them to the midfoot and heel. Subjective assessments indicated increased comfortability wearing the 3D-printed insoles.*

Conclusion: *This study showed promising results in using CAD and 3D print technology for customizing shape and locally adjusting stiffness of offloading insoles. In contrast to using a standard flat insole, the 3D printed insoles effectively reduced plantar pressure at high-pressure areas, without increasing overall plantar pressures. Additionally, overall comfort was enhanced.*

Introduction

Approximately 19% to 34% of the diabetic population is expected to develop diabetic foot ulcers (DFUs) during their lifetime.[2] Timely DFU treatment is therefore crucial for preventing infections and minimizing the need for amputations.[3,6] According to the international guidelines on DFU treatment, as authored by the international working group on the diabetic foot (IWGDF), plantar pressure offloading is one of the cornerstones for treating DFUs.[9]

While peak pressure (PP), a parameter for maximum plantar pressure, is often valuated to assess plantar pressure distribution, a decrease in pressure time integral (PTI), a measure for cumulative plantar pressure, is also associated with higher likelihood of successful ulcer healing when wearing an offloading device.[33] This suggests that not only PP is an important predictor for DFU healing during offloading therapy, but also that PTI represents a potential parameter.

Offloading footwear insoles can be customized for optimal pressure reduction by adding depressions or elevations to the insole contact surface. These modifications can be based on casting, which involves capturing the geometric shape of the patient's foot to customize the insole design.[45] It has been proven that a total contact insole, which is customized for foot shape, is more effective in reducing PP in both forefoot and rearfoot compared to a flat insole.[70,71] Total contact insoles that are based on a semi-weightbearing foot shape have a tendency for higher plantar pressure reduction compared to total contact insoles based on full-weight-bearing or non-weightbearing foot shape.[45,72]

Several studies[12–14,46,47] utilized in-shoe plantar pressure measurement as a tool to iteratively test and modify the insole shape until optimal in-shoe plantar pressure distribution was reached.

According to the review of Collins et al., only one study[48] incorporated barefoot plantar pressure data to inform the design of the insoles. They used barefoot pressure measurements to define the location and contour of a metatarsal bar, to add depressions to the insole on locations of high plantar pressure, and elevations to the insole on locations of low plantar pressure. Insoles that were customized using both foot shape and barefoot plantar pressure measurement data, demonstrated superior offloading performance compared to insoles based solely on shape.

Although offloading devices have demonstrated effectiveness in healing DFUs, further improvements can be made in various design aspects. Hand-crafted offloading devices are prone to design variability, requiring skilled application to obtain successful pressure reduction.[9] Pressure relieving properties of personalized offloading insoles are often evaluated based on clinical experience and trial-and-error approach, instead of performing objective quantitative evaluation.[73]

Creating a reproducible workflow for the design of offloading devices, will allow for a more reliable evaluation of offloading performance. [13,14] To prevent re-ulceration, plantar pressures should be reduced below 200 kPa[14,74,75]. An equivalent threshold for first ulceration and a threshold for ulcer healing is non-existent[76]. Although personalized offloading devices have demonstrated significant offloading performance, effects have only been studied in small patient groups and outcomes within these studies were variable[45,71,77,78]. As long as a standardized workflow is absent, the results of quantitative assessments for personalized offloading devices are debatable[79]. Creating a reproducible workflow for the design of offloading devices has the potential to enhance the reliability of quantitative evaluations regarding the impact of offloading devices on both the prevention and healing of DFUs[13,14].

A potential approach to limit inter- and intra-variability, is using computer-aided design (CAD) and 3D print technology for development of personalized insoles.[51] When manufacturing offloading insoles using 3D print technology, CAD can be used to customize insole shape and stiffness, which are the most important design parameters. [55] Insole shape can be personalized using foot shape, and insole stiffness can be influenced by using a lattice structure. The stiffness of a 3D printed insole is determined by the unit cell topology, unit cell size, and unit cell strut diameter of this lattice structure.[53–55]

According to the current IWGDF guidelines[9], effective offloading is improved through the utilization of cushioning insole materials with suitable stiffness. The optimum stiffness is crucial for the material to deform just enough for maximum offloading, while absorbing and distributing loads during daily life activities.[80] 3D-printed insoles consisting of variable stiffnesses have a better plantar pressure reduction than insoles with a homogenous stifness.[59] Studies that performed in-vivo tests using 3D printed insoles, showed that it was possible to reduce plantar pressure in the high-pressure areas (with a initial PP of more than 200 kPa) by using a more porous lattice structure in these high-pressure areas than in the normal-pressure areas. A review by Ramselaar et al.[81] demonstrated the feasibility of decreasing plantar pressure using 3D-printed insoles that were adapted for both insole shape and stiffness.

This study used CAD and 3D print technology to develop personalized offloading insoles for healthy subjects. The aim was to reduce plantar pressure at high-pressure areas without increasing overall plantar pressures.

Methods

This study underwent several steps to create personalized insoles for the purpose of plantar pressure offloading. Two types of 3D printed insoles were designed and tested: a total contact PP insole with reduced stiffness at high PP areas, and a total contact PTI insole with reduced stiffness at high PTI areas. Insoles were designed for five right feet and one left foot of five healthy subjects. The 3D-printed insoles were designed to fit into an ankle-high prefabricated Darco-shoe (Darco, Halesworth, United Kingdom).

3D foot scan

Insole shape customization involved acquiring a 3D foot scan of a foam box impression. To obtain a semi-weightbearing foot impression, the subject's foot was positioned directly above the foam box at a 90° angle in a seated position. An assistant applied vertical pressure with one hand on the knee, and the other hand on the foot (see attachment B1). This semi-weightbearing foam box impression of the foot was scanned using a Structure Sensor Pro (Structure Sensor Pro, Occipital Inc. San Francisco, CA, USA), attached to an iPad (4th generation, Apple Inc. Cupertino, USA). This is a 3D scanner based on infrared structured light[82]. The 3D foot scan was essential for insole shape customization. The methodology for 3D scanning is described in attachment B1.

In-shoe pressure measurement

Insole stiffness customization involved acquiring an in-shoe plantar pressure measurement. In-shoe pressure measurements were acquired using the pedar®-X system (Novel, GmbH, Munich, Germany), which utilizes a 2 mm thick insole equipped with 99 sensors. The Pedar-X system is a reliable and validated in-shoe pressure measurement system.[83–85] The size of the Pedar-X insoles was tailored to each individual's shoe size, and calibration of the insole sensors was executed prior to data collection. The Pedar-X system was used to measure the mean in-shoe PP and PTI for each sensor during a walking trial covering a distance of 22 meters, while wearing a standard flat Darco insole.

Earlier research[41] has demonstrated that walking speed significantly affects PP and PTI in patients with a diabetic foot. Increased walking speed results in higher PP in the forefoot regions due to elevated ground reaction forces from increased ankle push-offs. Conversely, PTI, being time-dependent, increases with decreased walking speed due to larger step duration.

To maximize in-shoe PP, an in-shoe pressure measurement was conducted at a faster walking speed (indicated by a metronome set at 116 bpm). Similarly, in-shoe PTI was maximized and measured by having the subject walk at a slower walking pace (indicated by a metronome set at 73 bpm). The metronome speed (bpm) was determined based on a review that evaluated walking speeds for healthy adults.[86]

Localizing high pressure area

The 3D foot scan and in-shoe pressure measurements were used to identify the high PP and PTI pressure areas. Firstly, the 3D foot scan underwent reorientation and smoothing using 3-Matic (version 16.0; Materialise, Leuven, Belgium). This reorientation process involved identifying the weightbearing plantar surface by manually localizing the midpoint of the heel, the first metatarsal, and fifth metatarsal[87].

The high PP area was identified based on the input data from the in-shoe PP measurement during the fast-walking trial. The area characterized by a high PTI was determined using input data from the in-shoe PTI measurement during the slow-walking trial. Pressure measurements with less than 30 steps were excluded, as mean outcomes were considered less reliable.

The fully automatic methodology for defining the high-pressure area using Matlab (version R2021A, The MathWorks, Inc., Natick, MA, USA), is illustrated in Figure 1. The reorientated 3D foot scan, and the in-shoe PP or PTI measurement data served as input parameters (Fig 1.1). The original pressure image resolution of 1 cm^2 was interpolated to 1 mm^2 through bicubic interpolation (Fig 1.3). The contact area (depicted in white in Fig 1.4) was determined by aligning the binary 2D foot scan (Fig 1.2) as a mask over the interpolated pressure image (Fig 1.4).

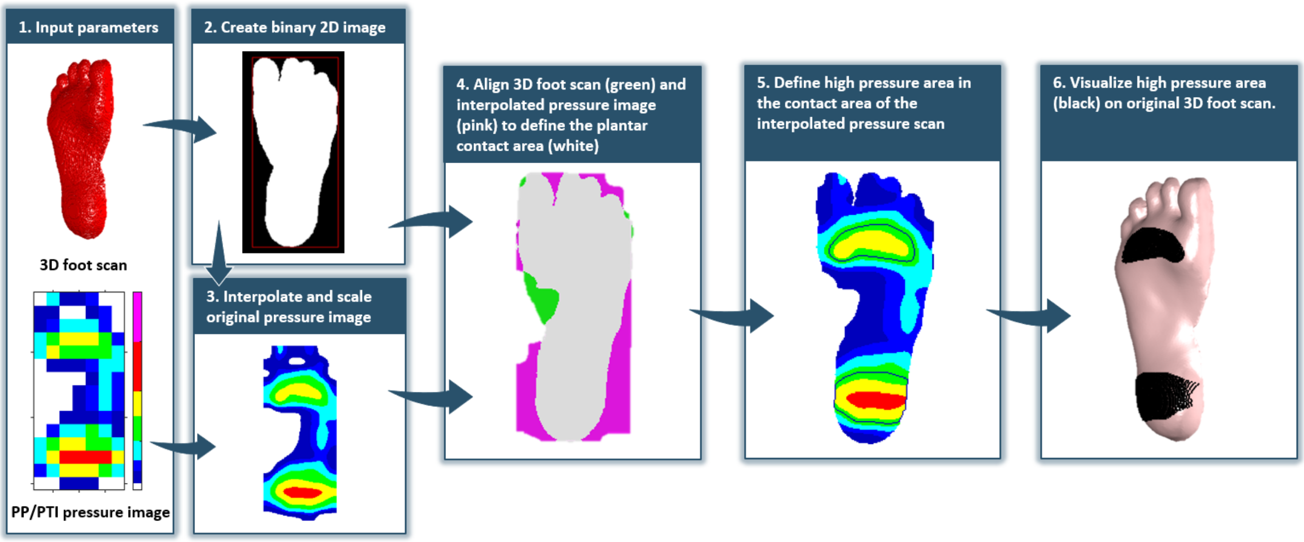


Figure 1. Automatic high-pressure area definition method

The next step involved determining the 75th percentile of all pressures. The high-pressure area was then identified by all pressure values higher than the 75th percentile, and this area was surrounded by a black contour (Fig 1.5). Finally, the high-pressure area was projected on the 3D foot-scan and exported (Fig 1.6). The files were exported in a 3D Manufacturing Format (3MF), to ensure compatibility with the design software. For each subject, a high PP area and high PTI area 3MF file was exported.

Insole design

Two type of 3D printed insoles were developed: a peak pressure insole (PP insole) and a pressure time integral insole (PTI insole). The insoles were designed using the 3-Matic software (version 17.0; Materialise, Leuven, Belgium) and 3D printed in Thermoplastic Polyurethane (TPU).

Firstly, a 20 mm thick flat insole base was designed. This involved acquiring a 3D scan of the standard flat Darco insole. A (thicker) replica of the standard flat Darco insole was designed in 3-Matic software, using the contour extracted from the 3D scan of the standard flat Darco insole.

The 20 mm thick flat insole base was then personalized following the workflow illustrated in Figure 2. Insole shape personalization involved aligning the insole with the foot's plantar surface (Fig 2.2A), translating the insole upward by 5 mm, performing a Boolean subtraction by removing the foot from the insole (Fig 2.2B) and smoothing the contact surface of the insole. To enhance comfort through cushioning, the insole's interior was filled with a lattice structure, composed of diamond unit cells (5 mm in size with a 1 mm strut thickness). Diamond unit cells are known for its softness, ensuring effective plantar contact area, and uniform stress distribution when printed in TPU, enhancing overall comfort.[68]

For improved offloading in high-pressure areas, these high-pressure areas were filled with a more porous lattice structure consisting of larger diamond unit cells (7 mm in size with a 1 mm strut thickness), as illustrated by the red lattice in Fig 2.3B. This high-pressure area was delineated by the red contour (Fig 2.3A), surrounding the black high-pressure areas of the 3MF pressure file (Fig 1.6). For the PP insole, the high-pressure area was indicated by the PP measurement, and for the PTI insole, the high-pressure area was indicated by the PTI measurement.

The outer shell of the insole had a thickness of 1.5 mm. The porous insole interior at the location of the high-pressure areas, had a porosity of approximately 90%, and the remainder of the insole interior had a porosity of 80%. Lastly, openings in the outer shell were added to facilitate removal of TPU printing

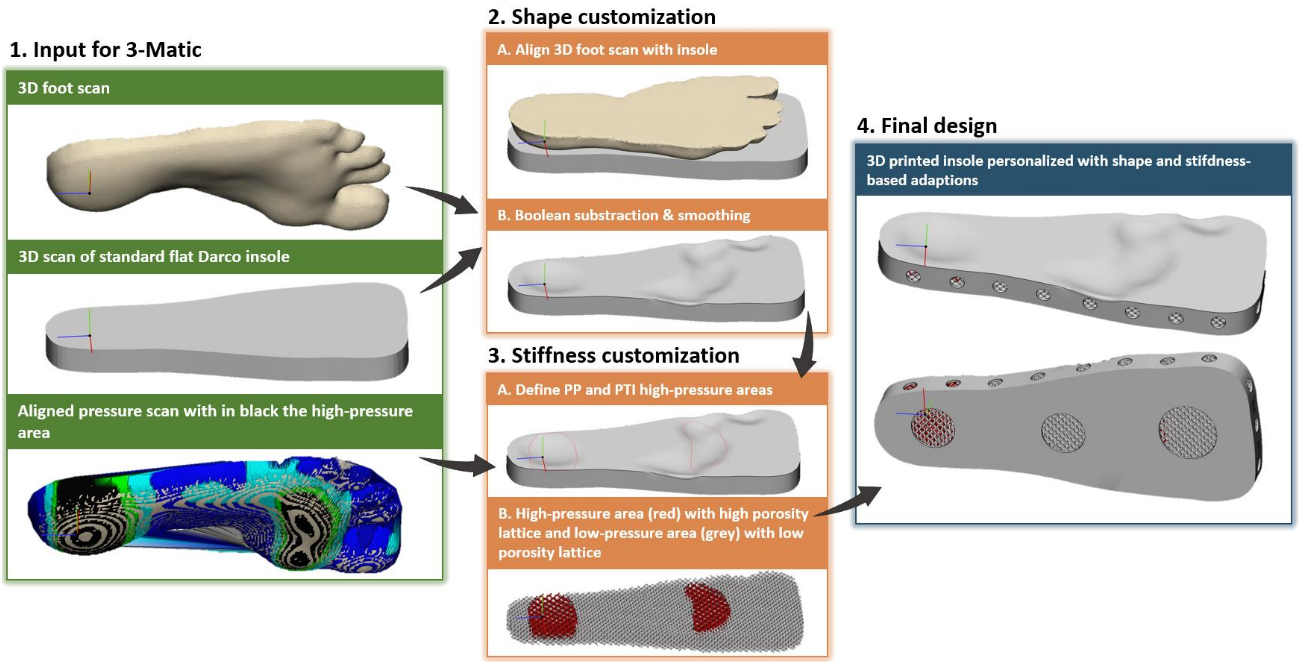


Figure 2. *Design method for a personalized 3D printed offloading TPU insole*

powder after manufacturing (Fig 2.4). Two types of insoles were designed: a PP insole and a PTI insole.

3D printing

The designed insoles were manufactured through 3D printing at Oceanz (Oceanz, Ede, The Netherlands) with a SLS printer (EOS formiga p100) using Flexible TPU. Printing was performed at a temperature of ± 110 °C and filament thickness was 0.10 mm. The wall thickness of the insole was 1.5 mm.

Insole evaluation

In-shoe PP and PTI was measured using the Pedar-X system, while the subjects were wearing the 3D printed insole inside the Darco shoe, and walked at a preferred, slow, and fast walking speed, covering a distance of 22 m. The slow walking speed was indicated by a metronome set at 73 bpm, and the fast walking speed was indicated by a metronome set at 116 bpm. Walking speeds were measured, considering the impact of walking speed on PP and PTI. The walking speed while wearing the 3D printed insoles should remain within 10% deviation from the speed measured when wearing the flat insole. Furthermore, average walking speeds across all subjects for the preferred, slow, and fast-walking trial were calculated.

The mean PP (MPP) and mean PTI (MPTI) while wearing the PP and PTI insole were calculated for the overall plantar surface and compared to the MPP and MPTI while wearing the standard flat insole. For this analysis, the original pressure images with a resolution of 1 cm^2 were used.

MPP and MPTI were also calculated at the pre-defined high PP and high PTI areas, using pressure images that were interpolated through nearest interpolation to a resolution of mm^2. We only calculated the MPP and MPTI within the high-pressure areas of the pressure images from the walking trial that, on average, most closely represented the average walking speed of 0.9 m/s observed in patients at risk of DFU [88].

Additionally, it was examined whether the 3D printed insoles altered plantar pressure distribution over the heel, midfoot, first metatarsal, second and third metatarsal, fourth and fifth metatarsal, hallux, and dig 2, in comparison to the flat insole during slow walking.
Furthermore, an assessment was made to verify whether the location of the high PP area changed when wearing the PP insole, and whether the location of the high PTI area changed while wearing the PTI insole.

Lastly, subjects were asked to indicate the value of comfortability on a numeric rating scale (with 0 uncomfortable and 10 very comfortable), giving opinion on overall comfort, heel comfort/cushioning, forefoot comfort/cushioning, insole heel width, shoe forefoot width, and toe comfort.

Results

The average walking speed of the slow walking trial most closely represented the average walking speed of patients at risk of DFU. For one subject, a PTI insole was not designed, as the slow walking trial consisted of less than 30 steps.

Overall MPP & MPTI

During slow and preferred walking speeds, the 3D-printed insoles demonstrated comparable PP on the plantar surface to those observed when walking at similar speed while wearing the flat insole, with a MPP difference not exceeding 10%. Conversely, during the fast walking trial, both the PP and PTI insoles exhibited, on average, slightly elevated MPP in comparison to the flat insole (18% and 19%, respectively). For all walking speeds, the MPTI measured while wearing the 3D-printed insoles did not deviate more than 10% from the MPTI measured while wearing with the flat insole.

Figure 3 depicts the average MPP profiles of all subjects whilst wearing the flat, PP and PTI insole during slow, preferred, and fast walking speeds of all subjects. In Figure 4, the average MPTI profiles of all subjects whilst wearing the three insole types are presented for slow, preferred, and fast walking speeds. These results are presented as box plots, indicating upper and lower quartiles, and the median is represented by the middle line within the box. Statistical testing for all outcomes was not feasible, due to the limited sample size of six feet.

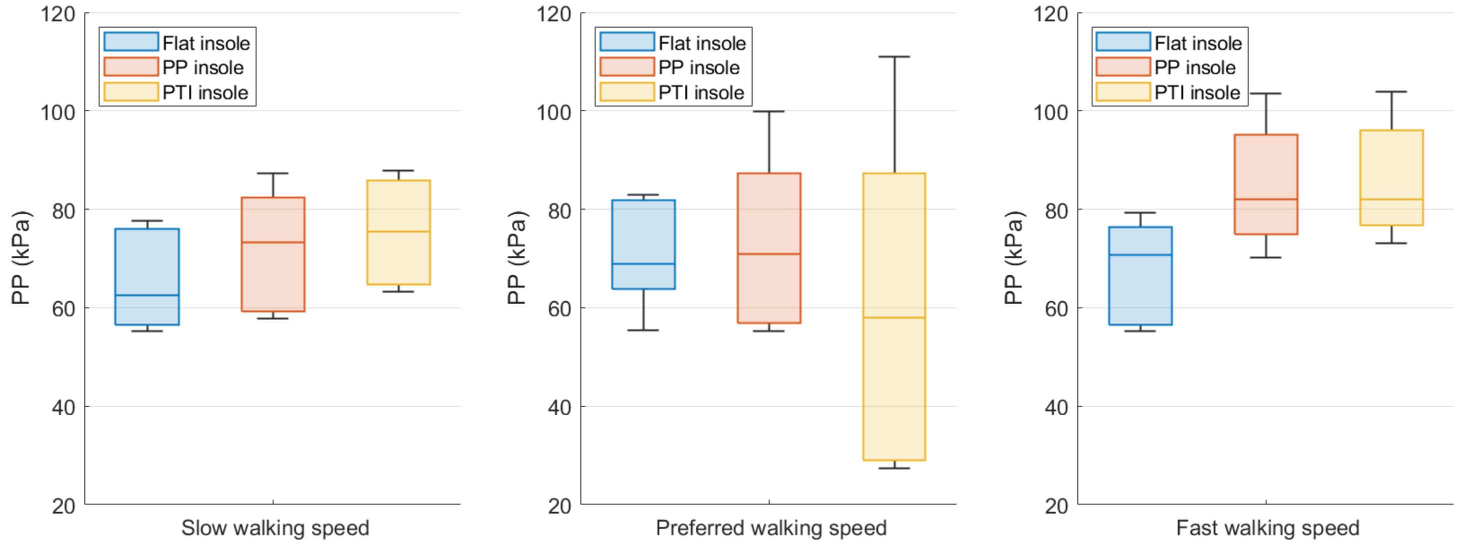


Figure 3. *Average MPP of all subjects over the entire plantar surface during the slow, preferred, and fast walking trial while wearing the flat, PP, and PTI insole.*

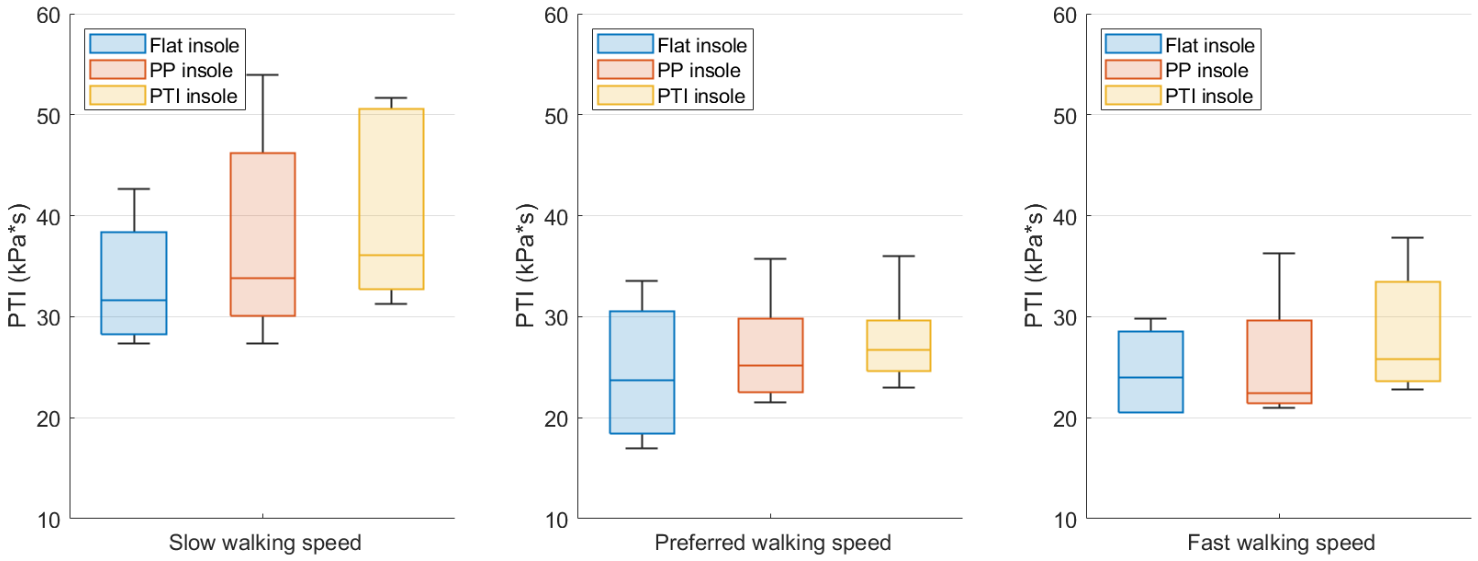


Figure 4. *Average MPTI of all subjects over the entire plantar surface during the slow, preferred, and fast walking trial while wearing the flat, PP, and PTI insole.*

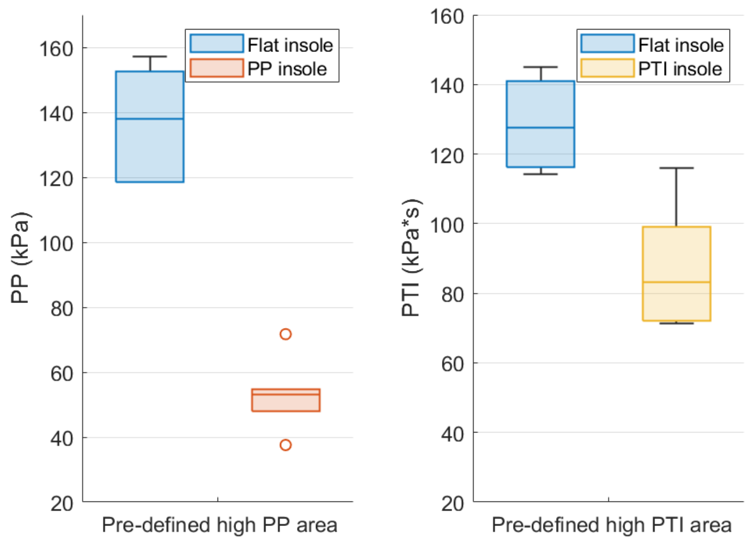


Figure 5. *Average MPP and MPTI of all subjects within the high pressure areas during the slow walking trial.*

MPP & MPTI at high-pressure areas

During the slow walking trial, the PP insole showed an average decrease of 58% in MPP at the pre-defined high PP area compared to the flat insole. The PTI insole showed an average decrease of 37% in MPTI at the pre-defined high PTI area compared to the flat insole during slow walking. Figure 5 illustrates these findings in boxplots, displaying the median, upper and lower quartiles, and any outliers.

Pressure distribution

PP and PTI were measured at specified foot regions. Wearing a 3D printed insole resulted in plantar pressure redistribution from the first, second and third metatarsals to the midfoot and heel. Compared to a flat insole, the 3D printed insoles demonstrated an average reduction of 23% in PP, and 38% in PTI at the first metatarsal. Additionally, there was a 21% reduction in PP, and a 25% reduction in PTI at the second and third metatarsals. Furthermore, the 3D printed insoles showed an average increase of 20% in PP at the heel, 49% increase in PP, and 38% increase in PTI at the midfoot, and an average 12% increase in PTI at metatarsals four and five. Figure 6 and Figure 7 demonstrate the average PP and PTI, respectively, of all subjects within the specified foot regions, along with the corresponding standard deviation.

In contrast to the flat insole, the wearing of 3D-printed insoles resulted in a shift of high-pressure regions away from the first, second and third metatarsals towards the back of the heel, midfoot, and lateral side of the plantar surface. The masks of the high-pressure areas when wearing the flat, PP, and PTI insole are shown in attachment B2.

Subjective comfortability assessment

Except for insole heel width, the 3D printed insoles were considered more comfortable than the flat Darco insole. The average NRS scores are shown in table 1.

	Flat insole	***PP insole***	***PTI insole***
Overall comfort	6.8	7.6	8.2
Heel comfort/cushioning	5.7	8.4	8.6
Forefoot comfort/cushioning	5.8	8	8
Insole heel width	6.8	6.8	5.8
Shoe forefoot width	5.3	7.6	6
Toe comfort	6.5	7.6	6.8

Table 1. *Average NRS scores with 0 very uncomfortable and 10 very comfortable.*

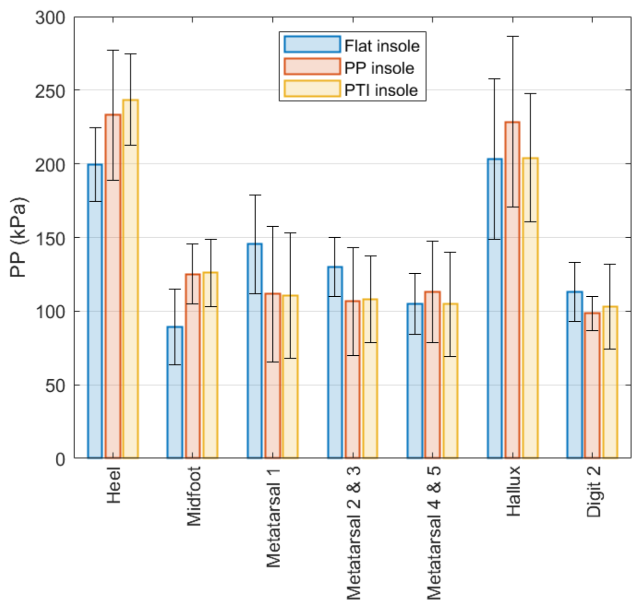


Figure 6. *Peak pressure within various foot regions with regular, PP, and PTI insole during the slow walking trial.*

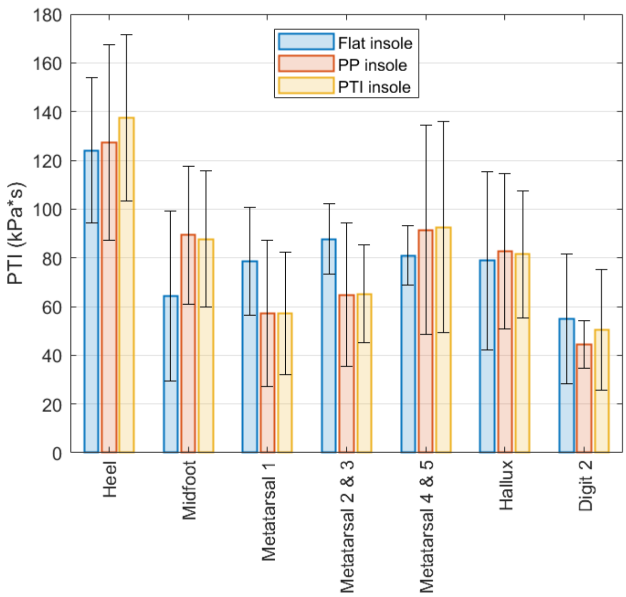


Figure 7. *Pressure time integral within various foot regions with regular, PP, and PTI insole during the slow walking trial.*

Discussion

Total contact insoles were designed using CAD and 3D print technology. Although the number of healthy subjects was limited, the 3D printed insoles clearly showed their ability to reduce mean plantar pressure in high-pressure areas without increasing overall plantar pressure, when comparing to a standard flat Darco insole. Besides, the 3D printed insoles were considered more comfortable than the flat Darco insole.

This study has shown the potential of using CAD and 3D print technology for customizing both shape and stiffness of offloading insoles. 3D-printing allows for adjusting stiffness of the insole, by changing the unit cell topology, size, and strut thickness.[53–55] A lattice structure with a porosity of 90%, has shown to be effective in reducing plantar pressure at high-pressure areas. Based on the 2023 IWGDF guidelines, successful PP reduction is achieved with a PP reduction of more than 30% at high PP area when measured with a validated, reliable, calibrated in-shoe pressure measurement with sensors sized 2 cm^2.[9] As PP was measured with a validated, reliable, calibrated in-shoe pressure measurement system with sensors sized 1 cm^2, and a pressure reduction of more than 30% was observed, it can be concluded that the 3D printed insoles showed a plantar pressure relieving effect.

Several other studies used 3D printed insoles to decrease plantar pressures at high pressure areas in diabetic patients. Telfer et al.[61] tested 3D printed insoles on 18 diabetic patients with elevated plantar pressures (>750 kPa) and showed a MPP reduction of 40.1 kPa compared to a Standard of Care insole. Muir et al.[60] tested 3D printed insole on 12 diabetic patients without existing ulcer/deformities, and compared these to a Standard of Care insole. The fully 3D printed insole showed a MPP reduction of 14% and a MPTI reduction of 15%. Compared to these study outcomes, our 3D printed insoles showed a higher reduction in both relative and absolute values of plantar pressures.

Telfer et al.[61] and Muir et al.[60] compared their 3D-printed insoles with Standard of Care insoles, while our study involved a comparison of 3D-printed insoles with flat insoles. Standard of Care insoles are customized, and thus provide a better plantar pressure-relieving effect than flat insoles.[70,71] Consequently, when comparing 3D printed insoles with flat insoles, we anticipate a larger magnitude in both absolute and relative differences regarding plantar pressure reduction, compared to plantar pressure differences between 3D printed insoles and Standard of Care insoles. This distinction is a potential explanation for the variations between our study results and those of previous studies.

As plantar pressure cannot be eliminated, the common approach to reduce PP and PTI in high-pressure areas, involves redistributing the load from one plantar area to another. Earlier studies have proven that transferring pressures from the metatarsals to the midfoot is an effective offloading strategy[48,89]. While wearing our 3D printed insoles, the primary load transfer from the first, second and third metatarsals, was not only directed towards the midfoot, but also transferred to the heel. This is in contrast with earlier research by bus et al.[71] Their study not only demonstrated load transfer from the first metatarsal head regions to the medial foot regions, but also indicated a significant reduction in plantar pressures in the lateral heel area, when comparing custom-made insoles to flat insoles.

A possible explanation for the higher PP in the heel area while wearing our 3D printed insoles, might be attributed to the nature of 3D printing, where the outer layer forms a solid shell, and the interior is filled with a more porous structure. The 1.5 mm thick external shell may lead to increased stiffness at areas with distinct contours. As the insole design had a smaller width than the flat Darco insole (approximately 10%), this hard external shell may result in higher plantar pressures at the border of the heel and lateral side of the plantar surface.

Higher pressures at insole borders were also subjectively confirmed by the included subjects, as heel width was the only design parameter that was considered less comfortable when comparing the 3D printed insoles to the flat insole. Proper insole comfortability is crucial for patient adherence to treatment plans. [63,64] In future designs, the insole width should be large enough to prevent increased pressures at the outer edge of the insole, as these increased pressures might result in DFU formation. An alternative approach is removing the harder outer shell on the sides of the insole; however, such an insole might lose insole stability.

The PP and PTI insoles exhibited comparable outcomes in reducing plantar pressure. Given the limited sample size, determining which insole performs better in reducing plantar pressure is challenging. Furthermore, it is yet to be proven whether these alterations are effective enough to reduce plantar pressure at high-pressure areas below the injury threshold, as the relative significance of reductions in PP and PTI for preventing and healing DFU remains uncertain. [71] Another potential approach, is reducing stiffness at both the PP and PTI high-pressure area, to ensure PP as well as PTI reduction in both high-pressure areas.

Although not tested for reproducibility, this study attempted to minimize design inter- and intra-variability through CAD and 3D printing. A fully automatic computerized method was employed to define high-pressure areas, and the designing of offloading insoles was facilitated using CAD. Although user interaction was required during the insole design process, future advancements may allow for increased automation in the design process, minimizing user input, and reducing design variability.

Establishing a reproducible workflow, is essential for conducting a quantitative evaluation, which is crucial for effective DFU prevention and healing treatments[79]. A reproducible methodology allows for the exploration of relationships among various parameters and their influence on DFU healing and DFU development. For example, the IWGDF acknowledged uncertainty regarding the impact of restricting weight-bearing activity on DFU healing, and various health outcomes[9]. A reproducible workflow enables the assessment of weight-bearing activity's influence on DFU healing. Additionally, it facilitates in establishing plantar pressure thresholds for DFU healing and prevention. This emphasizes the relevance of using CAD and 3D printing for the design of customized insoles, as a promising solution to reduce both inter- and intra-variability.[9,90]

Furthermore, the creation of handcrafted offloading devices is a time-consuming and labor-intensive process. CAD technology facilitates designing personalized offloading insoles, ensuring an optimal fit while minimizing production costs and design time.[51] Due to a decreased elasticity and tensile strength in the diabetic foot, joint subluxations or overall stiffening of the foot occurs over time.[91] The use of CAD facilitates the digital storage of designs, and enables accelerated development through partially reusing previous models when a new insole model is needed due to these anatomical changes within the diabetic foot.[52]

Besides, 3D print technology has been subject of interest for various medical applications, due to its suitability for scalability. This makes it well-suited for the manufacturing of offloading insoles.[92] Additionally, using CAD technology with 3D printing enables the customization of both insole shape and stiffness, which are crucial design parameters for creating personalized offloading insoles.[56]

Clinical implications

In summary, our 3D printed insoles are considered effective in reducing plantar pressure at high-pressure areas, without increasing overall plantar pressure. Given the association between PP and PTI reduction and the healing of DFUs, our 3D printed insole exhibits the potential for use in treating patients with DFU. The use of CAD and 3D print technology in the design of offloading insoles, potentially allows for a more reliable and quantitative evaluation of offloading devices, presenting opportunities for improving DFU healthcare.

Limitations

The scope of this study was limited to designing and testing of insoles for a small population, and healthy persons only. Our rationale for this approach was to establish the efficacy of our insoles in a healthy population before testing the 3D printed insoles on individuals who are suffering from a DFU or at higher risk of ulcer development. As patients at risk of DFU generally experience elevated plantar pressure and/or foot deformities, it remains uncertain whether the observed plantar pressure reduction in healthy subjects, will also be achieved in patients with a DFU or a history of DFUs when wearing our 3D printed insoles.

Future directions

While this study shows promising results, there are still several areas that require further exploration. According to the current IWGDF guidelines[9], effective offloading is achieved through the utilization of cushioning materials with suitable stiffness. People with a higher baseline plantar loading need stiffer cushioning materials for maximum offloading than people with a smaller baseline plantar loading.[80] Panagiotis et al.[80] predicted patient-specific optimum cushioning stiffness based on demographic and anthropometric parameters. In this study, we only used two type of lattice structures with porosities of 80% and 90%. To obtain optimized insole cushioning, future studies can focus on customizing insole stiffness, by choosing customized lattice porosity, based on in-shoe plantar pressure distribution.

Insole durability is recognized as key parameter regarding the potential clinical effectiveness of insoles.[65–67] The ability of an insole to retain its soft elasticity over a period of use is critical, as the ability to absorb plantar pressures will change as the device stiffens. The TPU printed insole was not tested for its durability, however TPU is known for its flexibility preventing struts of the lattice from breaking down during compression.[68] Future directions can focus on testing insole durability, in other words, the capability of the offloading insole to maintain its mechanical characteristics. Moreover, the insoles can undergo testing for their offloading effectiveness in patients at risk of DFU. Additionally, their impact on preventing DFU and promoting ulcer healing can be assessed during long term usage. To our knowledge, no studies tested long-term use of 3D printed offloading insoles in terms of comfortability, offloading performance, DFU prevention, and DFU healing.

Incorporating modifications such as a metatarsal bar, a metatarsal dome, an arch support, and replacing the top cover with Plastazote-Poron foam are considered highly effective in offloading or reducing peak plantar pressure (PP) in targeted regions.[93] These design modifications can be incorporated in future designs to further optimize plantar pressure reduction.

Furthermore, the reproducibility of our design workflow remains uncertain. A reproducible workflow facilitates the evaluation of the influence of various parameters on DFU healing and prevention, emphasizing the need for future assessments of reproducibility.

Lastly, the current 3D printed insoles were designed for a Darco shoe, using the insole base that was designed using the contour of the standard flat Darco shoe. The insole base can easily be replaced by another insole base, fitting a different type of offloading shoe. Another possible option is creating a 3D printed insole that is integrated in a total contact cast, as total contact casts have shown best results in healing ulcers.[9]

Conclusion

In this study, promising results were achieved after the implementation of CAD and 3D print technology for the design of personalized offloading insoles. These 3D printed insoles were customized using foot shape, and had adjusted stiffness at identified high-pressure areas. In contrast to wearing a flat insole, the more comfortable 3D printed insoles, effectively reduced plantar pressure at high-pressure areas, without increasing overall plantar pressures in healthy subjects. The use of CAD and 3D print technology in the design of offloading insoles, potentially allows for a more reliable and quantitative evaluation of offloading devices in future.

Attachment A1. Database search

Pubmed(15-06-2023): 202 results

("diabet*"[All Fields]
AND
"ulcer*"[All Fields]
AND
("insole"[All Fields] OR "midsole"[All Fields] OR "shoe"[All Fields] OR "footwear"[All Fields] OR "ortho*"[All Fields] OR "device"[All Fields] OR "heal*"[All Fields] OR "pressure"[All Fields] OR "offload*"[All Fields] OR "off-load"[All Fields] OR "treat"[All Fields])
AND
("3d"[All Fields] OR ("three"[All Fields] AND "dimensional"[All fields]) OR "3-dimensional"[All Fields] OR ("additive"[All Fields] AND "manufacturing"[All fields]) OR ("computer"[All Fields] AND "aided"[All fields]) OR ("finite"[All Fields] AND "element"[All fields])))
OR
("Foot Ulcer"[Mesh]
AND
"Diabetes Mellitus"[Mesh]
AND
("Printing, Three-Dimensional"[Mesh] OR"Finite Element Analysis"[Mesh] OR "Computer-Aided Design"[Mesh])
AND
("Foot Orthoses"[Mesh] OR "Foot Orthoses"[Mesh] OR "Orthotic Devices"[Mesh] OR "Shoes"[Mesh] OR "Pressure"[Mesh] OR "Therapeutics"[Mesh] OR "Patient-Specific Modeling"[Mesh] OR "Rehabilitation"[Mesh] OR "Wound Healing"[Mesh] OR "pressure"[Mesh])))

Embase (26-06-2023): 222 results

("Diabet*"[Title/Abstract] OR "diabetes mellitus"[Mesh])
AND
("ulcer*"[Title/Abstract] OR "Foot Ulcer"[Mesh])
AND
("insole*"[Title/Abstract] OR "midsole*"[Title/Abstract] OR "shoe*"[Title/Abstract] OR "footwear"[Title/Abstract] OR "ortho*"[Title/Abstract] OR "device*"[Title/Abstract] OR "heal*"[Title/Abstract] OR "pressure"[Title/Abstract] OR "offload*"[Title/Abstract] OR "off-load*"[Title/Abstract] OR "treat*"[Title/Abstract] OR "Foot Orthoses"[Mesh] OR "Orthotic Devices"[Mesh] OR "Shoes"[Mesh] OR "Pressure"[Mesh] OR "Therapeutics"[Mesh] OR "Patient-Specific Modeling"[Mesh] OR "Rehabilitation"[Mesh] OR "Wound Healing"[Mesh] OR "pressure"[Mesh])
AND
("3D"[Title/Abstract] OR "three dimension*"[Title/Abstract] OR "3 dimension*"[Title/Abstract] OR "additive manufacturing"[Title/Abstract] OR "computer aided"[Title/Abstract] OR "finite element"[Title/Abstract] OR "Printing, Three-Dimensional"[Mesh] OR "Finite Element Analysis"[Mesh] OR "Computer-Aided Design"[Mesh])

Scopus (21-06-2023): 370 results

(TITLE-ABS-KEY (diabet* AND ulcer*)) AND (TITLE-ABS-KEY (insole OR midsole OR shoe OR footwear OR ortho* OR device OR heal* OR pressure OR offload* OR off-load OR treat*)) AND (TITLE-ABS-KEY (3d OR (three AND dimensional) OR 3-dimensional OR (additive AND manufacturing) OR (computer AND aided) OR (finite AND element)))

Cochrane (23-06-2023): 38 results

1. (Diabet*):ti,ab,kw AND (ulcer*):ti,ab,kw - 3697 results
2. (insole:ti,ab,kw OR (Midsole):ti,ab,kw OR (Shoe):ti,ab,kw OR (Footwear):ti,ab, kw – 31539 results
3. (device):ti,ab,kw OR (heal):ti,ab,kw OR (pressure):ti,ab,kw OR (offload*):ti,ab,kw OR (treat*):ti,ab,kw – 1339890 results
4. (Three dimensional):ti,ab,kw OR (3 dimensional):ti,ab,kw OR (3d):ti,ab,kw OR (additive manufacturing):ti,ab,kw OR (computer aided):ti,ab,kw – 15005 results
5. (finite element):ti,ab,kw – 295 results
6. MeSH descriptor: [Diabetic Foot] explode all trees – 1419 results
7. MeSH descriptor: [Foot Orthoses] explode all trees – 281 results
8. MeSH descriptor: [Pressure] explode all trees – 4239 results
9. MeSH descriptor: [Printing, Three-Dimensional] explode all trees – 190 results
10. MeSH descriptor: [Computer-Aided Design] explode all trees – 542 results
11. MeSH descriptor: [Finite Element Analysis] explode all trees – 94 results
12. (additive manufacturing):ti,ab,kw – 37 results
13. (offload*):ti,ab,kw PR (treat*):ti,ab,kw OR (heal*):ti,ab,kw – 1259673 results
14. #7 OR #8 OR #13 – 1261722 results
15. #9 OR #10 OR #11 OR #12 – 663 results
16. #6 OR #14 OR #15 – 2 results
17. #1 AND (#2 OR #3) AND (#4 OR #5) – 37 results
18. #16 OR #17 – 38 results

Attachment A2. Table of information

The included studies were in silico and in vivo studies. A description on methodology for insole personalization was given, focusing on methodology for stiffness and/or shape optimization. The assessment of insole offloading capability is expressed in terms of in-shoe peak pressure (PP) or in-shoe pressure time integral (PTI). The tables summarizes overall findings and outline any identified limitations.

Table A2.1. In silico studies

Reference	Method of Insole personalization	Results	Conclusion and limitations
Tang et al.*[53] *2021	*Insole stiffness* Finding optimal strut thickness for manually defined high- and low-pressure region using FE modeling	*Stiffness optimization* The optimized lattice insole further reduced PP from 75.6 kPa to 66.5 kPa (in FE model) compared to insole with homogenous lattice structure.	*Conclusion* PP of a patients foot can be further reduced by using a data-driven model to optimize the distribution of elastic modulus using various lattice strut thicknesses. *Limitations* - only static loading condition is considered. - The high and low pressure regions were manually defined,
Jafarzadeh et al.[59] 2021	*Insole stiffness* The optimal Young's modulus for every insole element was found using a FE model, resulting in a variable stiffness *Insole shape* Insole thickness was adjusted until optimal contact pressure was achieved according to a FE model.	*Stiffness optimization* Insole with optimized continuously variable stiffness results in a decrease in PP from 319 kPa to 194 kPa (40%) in a flat insole *Shape optimization* Insole with a stiffness of 74 MPa and optimized for shape, results in a PP reduction from 319 to 240 kPa (25%). *Stiffness and shape optimization* Uniform softening of homogenous insole causes a 30% decrease in PP, and an extra 16% decrease in PP when also optimized for shape.	*Conclusion*: - Maximum plantar pressure occurs at metatarsal and heel areas - Elasticity of footwear is most influential factor on pressure relief. - Most effective model is an insole with soft homogenous material, which is geometrically optimized by proposed optimization method. *Limitations*: - Method was for 1 subject - Only standing position was considered
Geiger et al.[58] 2023	*Insole stiffness* Based on a FE model, plantar pressures were calculated. Lower insole stiffness was assigned to calculated high-pressure areas and higher insole stiffness assigned to calculated low-pressure areas.	*Stiffness optimization* - The use of a young's modulus of 0.5 MPa resulted in largest peak pressure reduction in all areas. - redistribution of pressure towards the medial midfoot region when adjusting young's modulus - *Simulated versus experimental measurements* Deviation between simulated (FE model) and experimental PP was 234 kPa in heel area and 30 kPa in toe area.	*Conclusion* - It is possible to adjust the stiffness of an individually 3D printed insole with parametric FE analysis based on gait measurement. Absolute deviations between experimental and simulated plantar peak pressure were high, but localization of plantar pressure distribution was similar. *Limitations* - FE model is simplification of reality. - Still relatively high pressure in the heel area. Further insole modification could be carried out to minimize this.

Table A2.2. In vivo studies

Reference	Method of Insole personalization	Results	Conclusion and limitations
Hudak et al.[44] 2022	*Insole shape* TCI was designed using a foam box impression *Insole stiffness* - Normal-pressure area: a dense lattice-matched to SoC - Offloading segment: a sparce lattice *Insole designs* - A fully 3D printed TCI insole with - A Hybrid 3D printed TCI insole with upper 4 mm replaced Poron-Plastazote bi-laminate top sheet. *Patient group* 1 diabetic patient without neuropathy or previous ulceration	*PP in offloading region* PP for hybrid (207kPa) and fully 3D printed insole (209 kPa) was 15% lower than standardized footwear (248.8kPa) and the SoC (268.8 kPa) *PP in Adjacent region*: The SoC (161 kPa) had the highest reduction in PP compared to the standardized footwear (186 kPa), the hybrid 3D printed (178 kPa) and the fully 3d (213 kPa). *Durability*: - Hybrid 3D printed insole closely matches durability profile of SoC - Fully 3D printed insole had lower increase in stiffness	*Conclusion* The 3D printed insole successfully offloaded plantar pressure in the desired offloading regions. The hybrid 3D and fully 3D printed were at least as durable as the Soc insole. *Limitation* Sample size of 1
Muir et al.[60] 2022	*Insole shape* TCI was designed using a foam box impression *Insole stiffness* - Normal-pressure area: a dense lattice-matched to SoC - Offloading segment: a sparce lattice *Insole designs* - A fully 3D printed TCI insole with 2 lattice densities. - A Hybrid 3D printed TCI insole with upper 4 mm replaced Poron-Plastazote bi-laminate top sheet and 2 lattice densities. *Patient group* 12 adults without existing ulcer/deformities	*PP in offloading region* - Hybrid insole significantly reduced peak pressure by 50 kPa (20%) compared to SoC - Full insole significantly reduced peak pressure by 32 kPa (14%) compared to the SoC *PP in Adjacent region* - No significant differences were observed in ADJ regions across insole conditions *PTI in offloading region* - Hybrid insole significantly reduced PTI by 14 kPa*s (21%) compared to SoC - Full insole significantly reduced PTI by 10 kPa*s (15%) compared to SoC *PTI in Adjacent region*: - The hybrid insole significantly reduced the PTI 6 kPa*s (10%) compared to full - The SoC significantly reduced PTI by 8 kPa*s (13%) compared to full	*Conclusion* 3D printed in soles reduce plantar pressure more than the standard of care insole, while not significantly increasing pressures in the adjacent regions. It is possible to modify certain offloading regions based on plantar pressure data and a patient personalized metamaterial in a 3D printed insole design. *Limitations* - The PTI of the hybrid and full insoles in the ADJ was slightly higher than in the SoC. - The current insole design has an abort change in stiffness at the end of ROI - Sample size is small
Tang et al.[55] 2019	*Insole shape* Total contact insole was designed using shape of plantar soft tissue FE model *Insole stiffness* FE model was used to determine the Young's modulus of an insole part. Every insole part was filled with a unit structure with a similar Young's modulus. *Insole designs* - Ordinary flat insole - Optimized flat insole - Ordinary TCI - Optimized TCI *Patient group* 1 healthy subject	*Insole stiffness* - Optimized flat insole reduced PP with 20% compared ordinary flat insole. - The young's modulus in the high pressure region was small and the low contact pressure areas had a larger Young's modulus *Insole shape* - Ordinary TCI lowered PP by 18% compared to ordinary flat insoles. *Insole shape & stiffness* - Optimized TCI could reduce peak plantar pressure by 33.67% compared to ordinary flat insole. *Plantar pressures* - Plantar pressures were concentrated in heel region - Experimental results were in good agreement in those predicted using FE analysis.	*Conclusion* A TCI with optimized stiffness, could reduce PP with 33.67% compared to flat insoles that were not optimized for stiffness. *Limitations* - Only a single stance of gait was considered instead of complete gait cycle in the FE model - Geometry was determined using surface morphology of plantar measured in static manner
Telfer et al.[61] 2017	*Insole shape* Forefoot geometry of the insole was modified increasing the height of a metatarsal bar and removing material under each metatarsal head in an iteratively series of simulations using a FE model. *Insole designs* - TCI Milled insole (standard insole) - Virtually optimized milled TCI insole	*Insole shape* - Compared to standard insole, the optimized milled insole showed for 88% of the high-pressure areas a lower peak pressure (41.3 kPa) and the optimized 3D-printed insoles showed for 74% of the high-pressure areas a lower peak pressure (40.5 kPa) - Virtually optimized insoles showed significantly greater forefoot offloading at high-pressure areas than standard insoles	*Conclusion* Virtually optimized insoles (milled & 3D printed) were found to be effective at enhancing the forefoot offloading performance compared to standard milled insoles *Limitations*

	- Virtually optimized 3D printed TCI insole *Patient group* 18 subjects with type 2 diabetes with peripheral neuropathy	- PP increased at midfoot for the virtually optimized insoles (14.1 and 20.6 kPa for milled and 3D printed) - No significant difference in PP between virtually optimized milled and virtually optimized 3D printed insoles	- Assessment was limited to overground walking and no other daily activities - FE model was simplified - Current workflow still requires certain experience and a few days to develop

Attachment B1. Extended methodology for insole design

B1.1. Foam box impression

1. Let the subject sit on a chair with the foot to be scanned directly above the foam box, with the ankle at a 90° angle.
2. Place one hand on the knee and one hand on the foot and push the foot vertically into the foam box (Figure B1).
3. Push the toes in the foam box.
4. The test subject may then remove his/her foot from the foam box (Figure B2).
5. Write a name on the foam box.

Figure B1. Taking a semi-weightbearnig foam box impression while sitting

Figure B2. Foam box impression

B1.2. 3D scanning method

1. Put the regular Darco insole on a black surface or put the foam box on a table.
2. Callibrate the iPad structured sensor pro using the 'calibrator app' and following its instructions.
3. Open the 'Scanner' app and put the settings on 'full' resolution, turn on 'default' and thick the box with 'STSLAMManager' (figure B3).
4. Make sure the insole fits within the square box that is shown on the screen. When the insole gets a red color, press *start scan*.
5. Turn around the insole until the entire insole is scanned and no parts are missing. Press *finish*, when finished (Figure B4).
6. Save the scan.

Figure B3. Setting Ipad

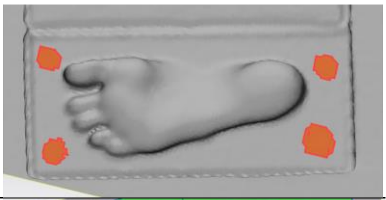
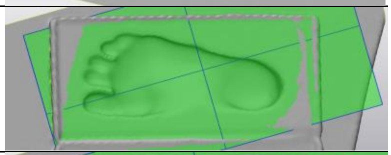
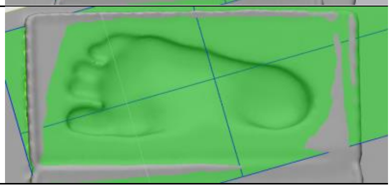
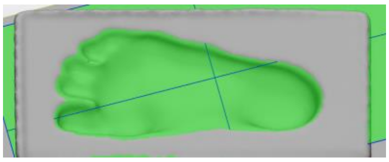
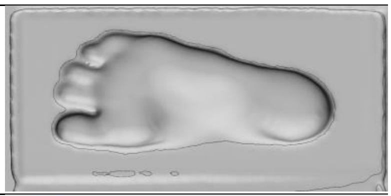
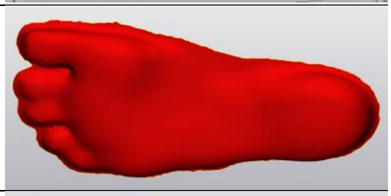
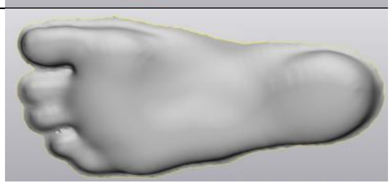
Figure B4. 3D scanned foam box impression.

B1.3. Designing insole using 3-Matic

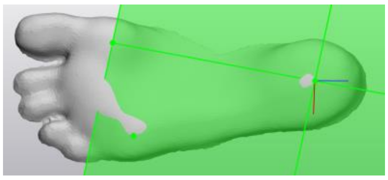
Import 3D scan of foot and of flat insole

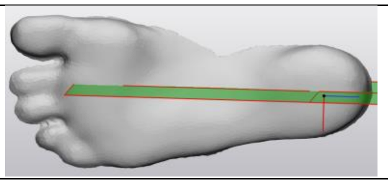
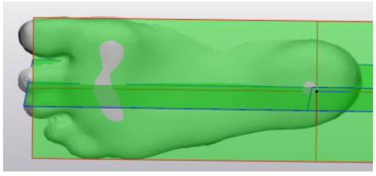
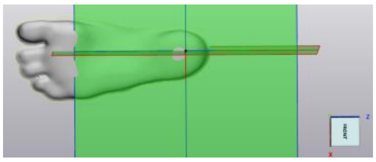
1. import OBJ file
2. Set file units to 1000

Create 3D foot design of 3D foot scan

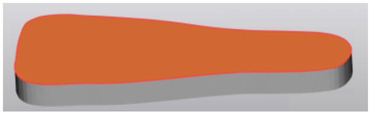
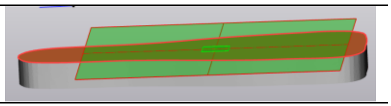
Mark flat surface of foam box scan of *Subject_SWB_R/L*	Mark → Brush Mark → Wave	Brush diameter: 20 Mark all corners (only flat parts)	
Create *Datumplane* of flat surface of foambox	Design → primitive → analytical → fit plane → marked triangles	*'apply'*	
Smooth 3D scan	Fix → Smooth	Entities: *Subject_SWB_R/L* Method: Laplacian (1st order) Smooth factor: 0.5 Number of iterations: 3 Use compensation: on Perform post processing: off	
Translate *Datumplane*	Align → Translate/Rotate	Main entity: *Datumplane* Method: object coordinate system Enable snapping: on Translation step: 2 mm Translate datumplane 2 mm down	
Cut *Subject_SWB_R/L* with datumplane	Design → interactive plane cut	Entities: *Subject_SWB_R/L* Plane: (translated) *Datumplane*	
Keep foot	Mark → Shell	Mark foot, press ´*invert'* and delete all triangles	
If bottom of foot is red: invert normal	Select *'Subject_SWB_R/L'* → Fix → invert normal		

Align Foot with front plane

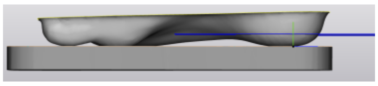
Create Weight bearing plane: *WB_Plane*	Design → Analytical → datumplane → 3 points	Point 1: heel Point 2: first metatarsal Point 3: fifth metatarsal. *'apply'*	

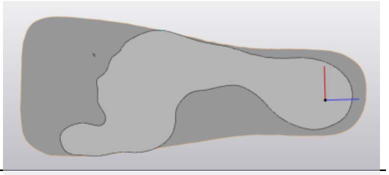
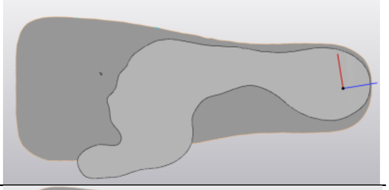
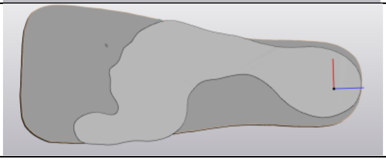
Create Midfoot plane: *Midfoot_plane*	Design → Analytical → datumplane → through 2 points perpedicular to plane	Point 1: heel Point 2: second metatarsal Perpendicular plane: *WB_plane*	
Align *WB_plane* and *Midfoot_plane*	Align → align	Fixed entity: *Midfoot_plane* Moving entity: *WB_plane* Press *'apply'* Fixed part: *Midfoot_plane* X-axis axis Moving part: *WB_plane* Y-axis Align operation: Perpendicular Press *'apply'*	
Align foot with front view	Align → plane to plane	Fixed entity: ZX plane of World Coordinate System Moving entity: *WB_plane* Move along entities: *3Dfoot_model + Midfoot_plane* Method: coincident face to face	

Align flat insole with front plane

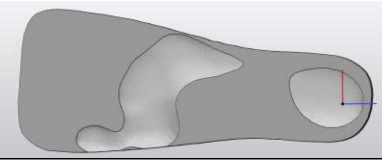
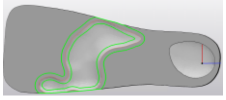
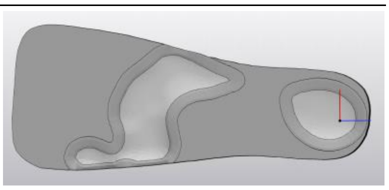
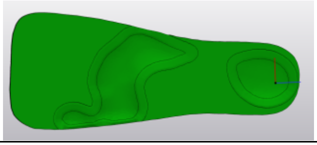
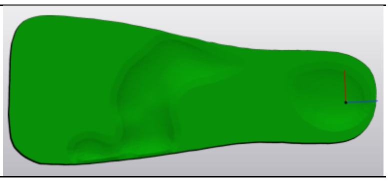
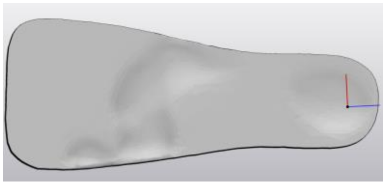
Mark contact surface of *flat_insole*	Mark → plane	Angle deviation: 40 Tolerance: 1 Mark across surfaces *'Mark contact surface'*	
Create datum plane of contact surface: *Surface_flat_insole*	Design → analytical → Datum plane	Method: Fit plane Fitting entities: Marked triangles of *flat_insole*	
Align *Flat_insole* with object coordinate system	Align → update OCS	Entity: *Flat_insole* Method: inertia axes	
Align *surface_flat_insole* with object coordinate system	Align → align	Fixed entity: *Flat_insole* Moving entity: *Surface_flat_insole* Press *'apply'* Fixed part: *Flat_insole X-axis* Moving part: *Surface_flat_insole Z-axis*	
Align *flat_insole* with front view	Align → plane to plane	Fixed entity: ZX plane of World Coordinate System Moving entity: *Surface_flat_insole* Move along entities: *flat_insole* Method: coincident face to face Press *'apply'*	

Align flat insole with 3D foot scan

Align *WB_plane* with *surface_flat_insole*	Align → plane to plane	Fixed entity: *WB_plane* Moving entity: *surface_flat_insole* Move along entity: *Flat_insole* Method: Coincident face to face	
Translate *surface_flat_insole*	Align → Translate/Rotate	Enable snapping: Translation step of 10 mm Move *flat_insole* 10 mm upwards in the positive Y direction	
Cut *3Dfoot_model* with *surface_flat_insole*	Design → interactive plane cut	Entities: *3Dfoot_model* Plane: *Surface_flat_insole* (translated one) *´apply'* Delete the upper part of the foot	

Set view to ‘back’ view	View → default views → Back		
Rotate insole 180 degress	Align → Translate/Rotate	Rotate *Flat_insole* (not *WB_foot!) in ‘back’* view as such, that the back part of the insole overlaps with the heel of the foot.	
Align insole with foot	Align → Translate/Rotate	Move *flat_insole* (Not *WB*_foot) in ‘back’ view until the satisfied. The foot should fit with the insole.	
Translate insole upwards for Boolean substraction	Align → Translate/Rotate	Enable snapping: Translation step of 5 mm Move *flat_insole* 5 mm upwards in the positive Y direction	

Create Total contact insole

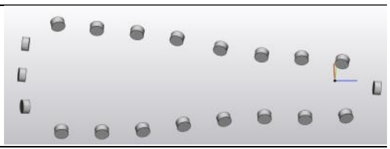
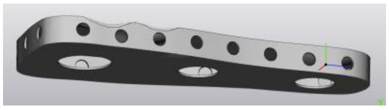
Perform Boolean substraction of *Flat_insole* and *WB_foot* to create total contact insole: *TCI_insole*	Design → Boolean Substract	Entities: *Flat_insole* Substraction entities: *WB_foot* Clearance: 0	
Adaptive remesh	Remesh → adaptive remesh	Select *TCI_insole*	
Smooth edges of depressions	Finish → Smooth edge	Entity: contour of depressions of *TCI_insole*  Influence distance: 5mm Smooth detail: Course	
Merge all surfaces of total contact surface of *TCI_insole*	Select all surfaces	Press right mouse click, and select merge 	
Improve mesh	Fix → enhance → improve mesh	Select *TCI_insole* Shape quality: Medium Maximum geometrical error: 0.05 Maximal edge length: 20.00	
Smooth top surface of *TCI_insole*	Fix → Smooth	Select upper surface of *TCI_insole* (not entire part) Method: Laplacian (1st order) Smooth factor: 0.500 Number of iterations: 3 Use compensation: on Perform post processing: off Save as ‘*Name_L/R_Geometry’*	

Make ‘Name_L/R_Geometry’ Hollow

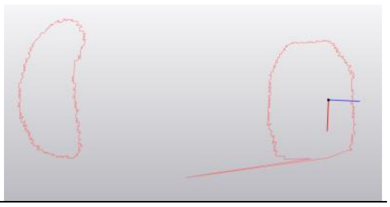
Duplicate *‘Name_L/R_Geometry’*	Right mouse click on *‘Name_L/R_Geometry’* and press duplicate	
Make *‘Name_L/R_Geometry’* Hollow:	Design → Hollow	Select *‘Name_L/R_Geometry’* Hollow type: inside Distance: 1.5 Smallest detail: 0.2

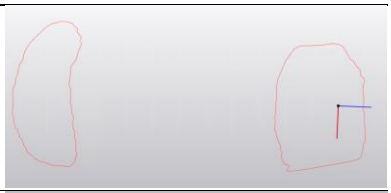
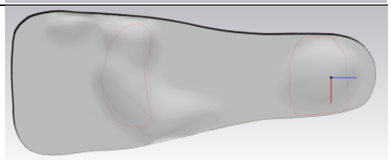
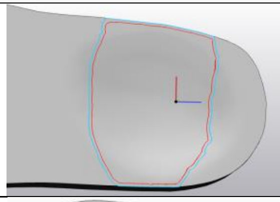
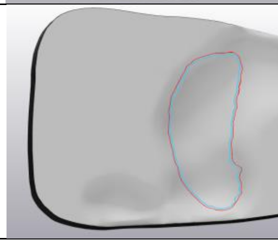
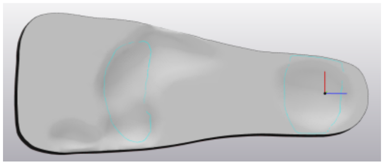
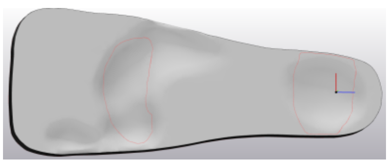
'Name_L/R_Geometry_hollow'		Smooth factor: 0 Reduce: on Remove original: off	
Fill inside of insole with lattice structure: *'Name_L/R_inside'*	Lattice → unit cell based	Entity: *'Name_L/R_Geometry_hollow'* Unit cell: Diamond-Crystal-Lattice (import this from the 3-matic library) Unit cell size: 5 x 5 x 5 Fill: Hollow	
Give lattice a strut thickness of 1mm	Lattice → uniform	Entity: Name_L/R_Inside' Thickness: 1 Accuracy: 0.1 Rename result to: *'Name_L/R_ low_pressures_Lattice'*	
Improve mesh of *'Name_L/R_ inside_Lattice'*	Fix → improve mesh	Select *'Name_L/R_ low_pressures_Lattice'*	

Create holes in insole

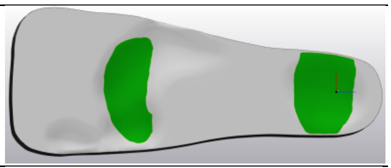
Create/import cylinders to create holes in bottom of insole	Create or import 3 cylinders	Two cylinders with a radius of 15mm and 5 mm thick One cylinders with a radius of 20 mm and 5 mm thick	
Create/import cylinders to create holes at insole sides	Create or import cylinders	Create small cylinders with 10 mm radius and that have a distance of 30 mm from each other (center to center)	
Duplicate cylinders and *'Name_L/R_Geometry_hollow'*	Right mouse click on cylinders and *'Name_L/R_Geometry _hollow' and press duplicate*		
Perform Boolean substraction of *'Name_L/R_Geometry_hollow* and *cylinders* to create holes in the hollow insole	Design → Boolean Substract	Entities: *'Name_L/R_Geometry_hollow'* Substraction entities: *cylinders* Clearance: 0 Rename to *'Name_L/R_Geometry_hollow_cylinders'*	
Improve mesh	Fix → enhance → improve mesh	Select *'Name_L/R_Geometry_hollow_cylinders'* Shape quality: Medium Maximum geometrical error: 0.05 Maximal edge length: 20.00	
Fix *'Name_L/R_Geometry_hollow_cylinders'*	Fix → Fix wizard	Select *'Name_L/R_Geometry_hollow_cylinders'* Press 'apply' and 'Follow advice	

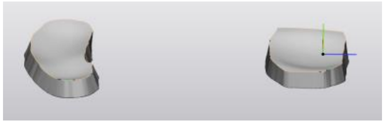
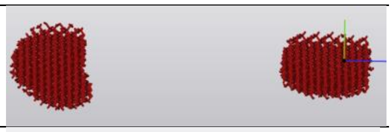
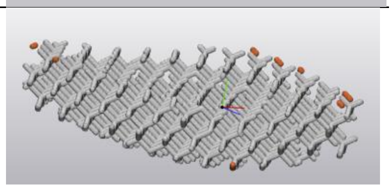
Add contours of high-pressure areas

Select contour of high-pressure areas	Select contours of black part → Separate → copy to part → Create new		

Smooth contours of high-pressure areas	Curve → Smooth	Entities: select curves of high-pressure areas Smoothing factor: 0.5 Number of iterations: 10 Press 'apply'	
Attach curve to *'Name_L/R_Geometry_hollow'*	Curve → Attract Curve	Entities: select curves Target entities: *'Name_L/R_Geometry_hollow'* Distance threshold: 30 Attach curve: on	
Create isocurves within the heel curve	Curve → Create Isocurves	Entities: Curve at heel Interval distance: 1mm Direction: inside Delete previous curve	
Create isocurves outside the other high-pressure areas curves	Curve → Create Isocurves	Entities: Curves other high pressure areas Interval distance: 1mm Direction: inside Delete previous curve	
Smooth contours of high-pressure areas (isocurves created in last step)	Curve → Smooth	Entities: select curves of high-pressure areas (iso curves of previous step) Smoothing factor: 0.5 Number of iterations: 10 Press 'apply'	
Attach isocurves to insole surface	Curve → Attract Curve	Entities: select smoothed iso curves Target entities: *'Name_L/R_Geometry_hollow'* Distance threshold: 30 Attach curve: on *Rename to : 'Name_L/R_PP/PTI_curves*	

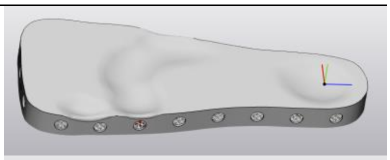
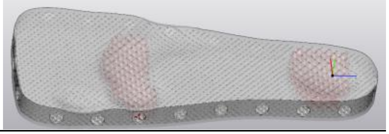
Create lattice of high pressure areas

Duplicate *'Name_L/R_PP/PTI_curves*	Right mouse click on *'Name_L/R_Geometry'* and press duplicate	*Rename to 'Name_L/R_PTI/PP_solid'*	
Split insole surface by curves	Curve → split surface by curves	Entities: *'Name_L/R_PTI/PP_solid'* Split by: 'Selection of curves' Split curves: Select High-pressure area curves	
Remove all surfaces except surfaces of high pressure parts larger than 1 cm^2			
Merge high pressure parts		Merge high-pressure pars of *'Name_L/R_PTI/PP_solid'*	
Translate *'Name_L/R_PTI/PP_solid'*	Align → Translate/Rotate	Main entity: *'Name_L/R_PTI/PP_solid'* Method: object coordinate system Enable snapping: on Translation step: 1.5 mm	

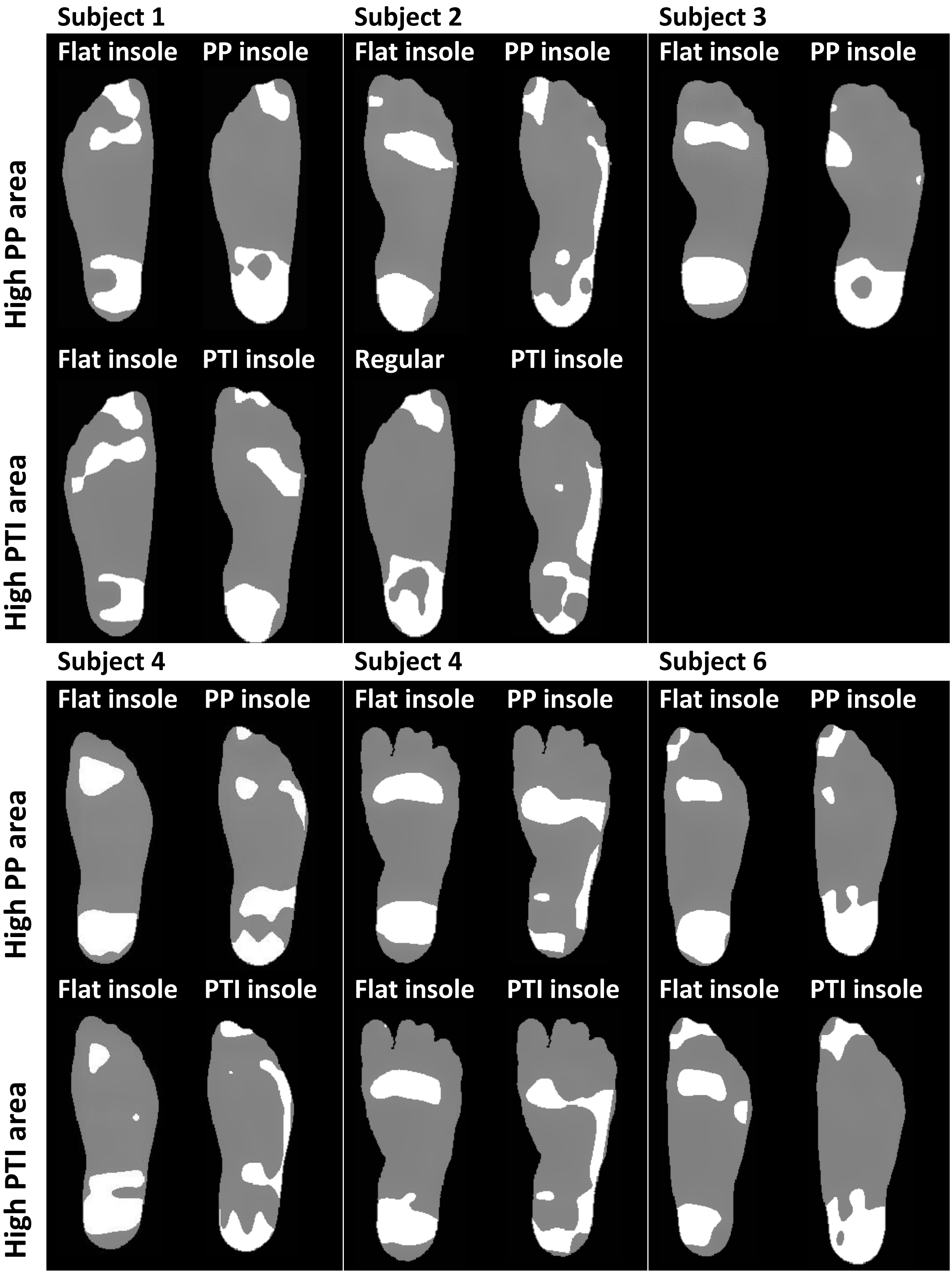
		'Name_L/R_PTI/PP_solid' 1.5 mm down
Adaptive remesh	Remesh → adaptive remesh	Select *'Name_L/R_PTI/PP_solid'*
Uniform internal offset of high-pressure parts	Design → uniform offset	Entities: *'Name_L/R_PTI/PP_solid'* Direction: internal offset Distance; 10 mm Solid: on Press 'apply' 
Improve mesh	Fix → enhance → improve mesh	Select *'Name_L/R_PTI/PP_solid'* Shape quality: Medium Maximum geometrical error: 0.05 Maximal edge length: 20.00
Fix *'Name_L/R_PTI/PP_solid'*	Fix → Fix wizard	Select *'Name_L/R_PTI/PP_solid'* Press 'apply' and 'Follow advice
Fill solid high-pressure areas with lattice structure	Lattice → Unit cell based	Entity: *'Name_L/R_PTI/PP_solid'* Unit cell: Diamond-Crystal-Lattice (import this from the 3-matic library) Unit cell size: 7 x 7 x 7 Fill: Solid 
Give lattice a strut thickness of 1mm	Lattice → uniform	Entity: *'Name_L/R_PTI/PP_solid with graphs'* Thickness: 1 Accuracy: 0.1
Convert lattice of high-pressure areas to mesh	Lattice → Lattice to mesh	Entities: *'Name_L/R_PTI/PP_solid with graphs'* Rename result to: *'Name_L/R_PP_high_pressures_Lattice'*
Improve mesh of *'Name_L/R_ inside_Lattice'*	Fix → enhance → improve mesh	Select *'Name_L/R_PP_high_pressures_Lattice'* Shape quality: Medium Maximum geometrical error: 0.05 Maximal edge length: 20.00
Give lattice of high-pressure area's red colour	Select part → properties → part colour	Select red colour 
Delete all loose struts	Mark → shell →Invert	Mark all high-pressure area's Press 'Invert' Delete all marked loose struts (shown in orange on image) 

Combine all parts

Duplicate *'Name_L/R_PP_high_pressures_Lattice'* , *Name_L/R_ low_pressures_Lattice'* and *'Name_L/R_Geometry_hollow_cylinders'*	Right mouse click on parts and press duplicate	
Reduce lattices	Fix → Enhance → Reduce	Entities: *'Name_L/R_PP_high_pressures_Lattice'* , *Name_L/R_low_pressures_Lattice'* Geometrical error = 0.7 Rename to *'Name_L/R_PP_high_pressures_Lattice_reduced'* , *Name_L/R_low_pressures_Lattice_reduced'*
Improve mesh	Fix → enhance → improve mesh	Select *'Name_L/R_PP_high_pressures_Lattice_reduced'* ,

		Name_L/R_low_pressures_Lattice_reduced' Shape quality: Medium Maximum geometrical error: 0.05 Maximal edge length: 20.00	
Fix *'Name_L/R_PP_high_pressures_Lattice_reduced'* , *Name_L/R_low_pressures_Lattice_reduced'*	Fix → Fix wizard	Select *'Name_L/R_PP_high_pressures_Lattice_reduced'* , *Name_L/R_low_pressures_Lattice_reduced'* Press 'apply' and 'Follow advice	
Merge all parts	Design → Boolean → union	Entities: *'Name_L/R_PP_high_pressures_Lattice_reduced'* , *Name_L/R_low_pressures_Lattice_reduced'* and *'Name_L/R_Geometry_hollow_cylinders'* Rename to '*Final_Name_R/L_PP/PTI'*	 
Improve mesh	Fix → enhance → improve mesh	Select '*Final_Name_R/L_PP/PTI'* Shape quality: Medium Maximum geometrical error: 0.05 Maximal edge length: 20.00	
Fix *'Name_L/R_Geometry_hollow_cylinders'*	Fix → Fix wizard	Select '*Final_Name_R/L_PP/PTI'* Press 'apply' and 'Follow advice	
Export to stl files	Export → STL	Export '*Final_Name_R/L_PP/PTI'* To STL File format: Binary Scaling factor: 1	

Attachment B2. High pressure area masks



Personalized 3D printed offloading insole design

Using a semi-automatic workflow

UMC Utrecht
Department of vascular surgery and 3D Lab

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Background & aim

Current offloading devices are **susceptible for inter-variability**. **Weight-bearing activity** does not impede diabetic foot ulcer healing when adequate offloading is provided. Weight-bearing activity **contributes to managing diabetes** and promotes overall health.

This study aims to create **personalized offloading footwear** with **3D printing** and using a semi-automatic workflow, providing adequate plantar offloading so that **regular weight-bearing activity can be continued.**

Method

Four personalized insoles were designed (Figure 1) for three healthy subjects. Peak pressure while wearing the insoles was measured.

Results

The **pressure-plus-shape-based insoles** showed **higher reduction in peak pressure** compared to the shape-based insoles. The weight-bearing pressure-plus-shape based insole was considered as most suitable design. Peak pressure was on average below 200 kPa, but higher than 200 kPa for some anatomical regions of the plantar surface.

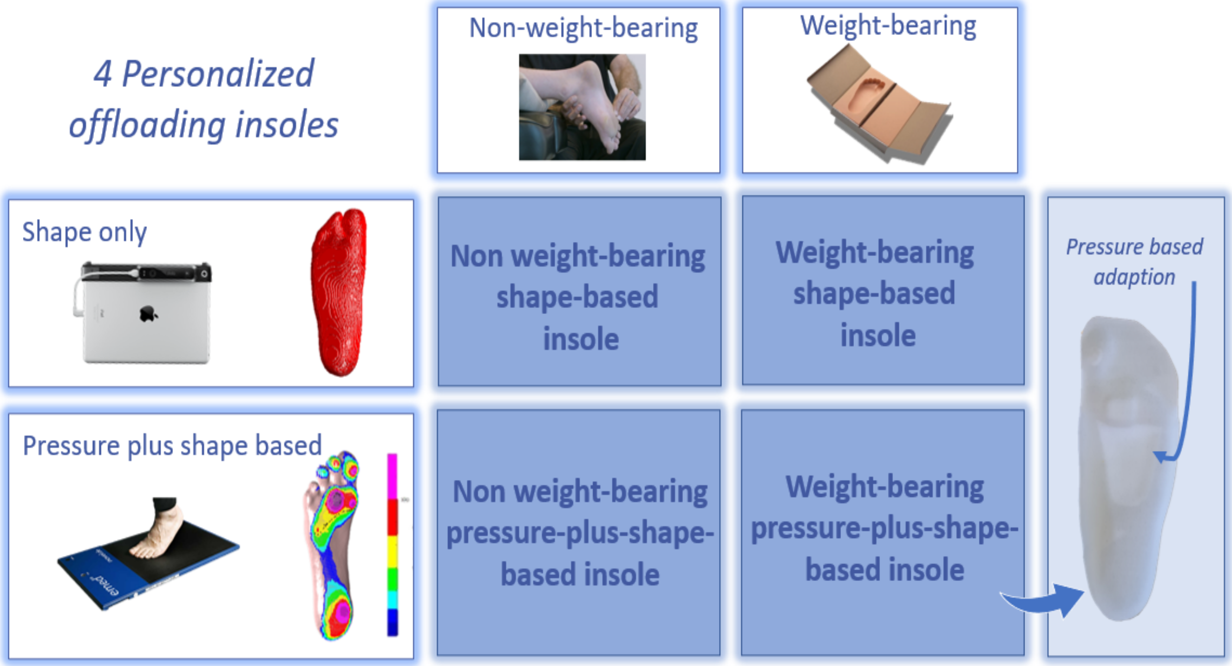

Figure 1: Workflow for designing a pressure-plus-shape based weight-bearing insole. Foot shape of healthy volunteers were obtained by taking a 3D scan of the plantar surface (Non-weight-bearing) or from a foam box impression (Weight-bearing). Peak pressures exerted on the feet while walking barefoot was measured using the Novel EMED X system. The 3D foot scan and pressure measurements were aligned using a semi-automatic script in Matlab and high pressure areas were defined. Four type of personalized insole were designed using 3-Matic. The pressure-plus-shape based insole had depressions at high-pressure areas and a metatarsal bar was included to relieve pressure at the metatarsal heads.

The personalized weight-bearing pressure-plus-shaped based 3D printed offloading insole showed best results in reducing peak plantar pressure. Further research should be conducted to improve the effectivity in pressure distribution and further automate the design process.

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