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Saving Limbs and Lives- Sensing and Monitoring Technologies for the Diabetic Foot

Edited by
Neil D. Reeves and Christopher Nester

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About the Editors

Neil D. Reeves

Professor Neil D. Reeves is a professor of Musculoskeletal Biomechanics and the Director of Research (Associate Dean Research) in Science and Engineering at Manchester Metropolitan University. Prof. Reeves conducts research on clinical movement disorders, with a focus on diabetic foot ulcer prevention and gait impairment in diabetes. His research addresses the underlying mechanisms causing gait impairment and unsteadiness in people with diabetes and tests the effectiveness of therapeutic interventions. He has developed and tested medical devices and novel digital technologies aimed at diabetic foot ulcer prevention and gait improvement. His research utilises other interventions, such as exercise, for reducing diabetic foot ulcer risk and improving gait and balance in people affected by diabetes. He has published 150 papers and has an H-Index of 45. He has led research projects supported by UK and international funding bodies and is currently leading projects supported by the UK Engineering Research Council, the National Institutes of Health (USA), and Diabetes UK.

Christopher Nester

Prof. Dr. Christopher Nester is a Professor of Rehabilitation, School of Allied Health Professions, University of Keele, England. He is a Podiatrist by first degree, has published over 140 journals papers, and had 23 PhD students complete their studies with him. Chris was the first Podiatrist to be appointed to the UK Government "Research Excellence Framework" exercise (REF), which reviews research excellence across all UK Universities.

Chris's research has been supported by funding from the EU, industry, NHS, charities, the National Institute for Health Research, and INNOVATE UK, with 6 "Knowledge Transfer Partnerships" thus far. Chris has been working with CAHPR and HEE on research strategy and led a James Lind Alliance "Priority Setting Partnership" to identify the top 10 foot health research priorities in the UK. He was previously Academic Director of the EPSRC (Engineering and Physical Sciences Research Council) "Centre for Doctoral Training in Prosthetics and Orthotics" at the University of Salford.

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Article

In-Shoe Pressure Measurements in Diabetic Footwear Practice: Success Rate and Facilitators of and Barriers to Implementation

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Abstract: We aimed to assess the success rate and facilitators of and the barriers to the implementation of in-shoe plantar pressure measurements in footwear practice for people with diabetes at high risk of foot ulceration. Eleven Dutch footwear practices were partly supported in purchasing a pressure measurement system. Over a 2.5-year period, trained shoe technicians evaluated 1030 people with diabetes (range: 13 to 156 across practices). The implementation success and associated facilitators and barriers were evaluated quantitatively using completed measurement forms and pressure measurement data obtained during four monitoring sessions and qualitatively through semi-structured interviews with technicians. Across the 11 practices, the primary target group (people with diabetes and a healed plantar foot ulcer) represented 25–90% of all the patients measured. The results showed that three practices were successful, five moderately successful, and three not successful. The facilitators included support by the company management board, collaboration with a prescribing physician, measurement sessions separate from the outpatient clinic, and a (dedicated) shoe technician experiencing a learning effect. The barriers included investment costs, usability aspects, and limited awareness among shoe technicians. In-shoe plantar pressure measurements can be implemented to a moderate to large degree in diabetic footwear practice. The barriers to and facilitators of implementation are organizational, logistical, financial, or technical, and the barriers are modifiable, supporting future implementation.

Keywords: diabetic foot; pressure measurement; custom-made footwear; implementation

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1. Introduction

Foot ulceration is a common complication of diabetes mellitus, with an annual incidence of about 2% in the general diabetes population [1]. After a healed ulcer, 40% of the people have a recurrent ulcer within one year and 60% within three years [2]. Apart from this history of ulceration, the important ulcer risk factors include peripheral neuropathy, peripheral artery disease, foot deformity, amputation, and end-stage renal disease [2–5]. Elevated peak plantar pressure during weight-bearing activity is also an important risk factor for ulceration and its recurrence [2,3,6]. This follows the most common mechanical pathway of foot ulceration, where motor neuropathy and foot deformity lead to biomechanical abnormalities, callus formation from repetitive stress, and eventually skin breakdown [1,2]. To heal and prevent ulcers on the plantar foot surface, the mitigation of this stress is one of the mainstays of treatment in diabetic foot disease [7].

To help prevent plantar foot ulcer recurrence, custom-made footwear is commonly prescribed to high-risk people with diabetes; this footwear mainly aims to reduce plantar peak pressure inside the shoe [8]. This can be achieved by specific design features of the shoe, including a rocker outsole, outsole stiffness, custom-made insole, and different insole elements, such as a metatarsal pad or bar and top cover [9–19]. In-shoe plantar pressure measurement is a tool with which the pressure-relieving capacity of such custom-made footwear and design elements can be evaluated and is widely used in scientific

research [5,20–23]. Additionally, in-shoe plantar pressure measurement has been shown to be valuable as a diagnostic method to identify high-pressure regions and to then guide the modification of footwear with the goal of reducing peak pressure at these locations after footwear delivery [16,20]. This application was first described by Mueller et al. [11] and later elaborated on and protocolized by Bus et al. [21] and Waaijman et al. [20]. Randomized controlled trials show that the use of plantar pressure analysis as a guidance tool to improve pressure relief by footwear significantly reduces the incidence of foot ulcer recurrence in people with diabetes, when the footwear is worn as recommended [24–26]. As a result, international guidelines of the International Working Group on the Diabetic Foot (IWGDF) recommend the use of custom-made footwear with a demonstrated plantar pressure-relieving effect for the prevention of foot ulcer recurrence in people with diabetes who are at high risk of ulceration [8].

Despite the fact that the primary aim of custom-made footwear is to distribute plantar pressure and the available scientific evidence and clinical recommendations for using pressure-driven custom-made footwear designs, in-shoe plantar pressure measurement is not yet widely used in diabetic footwear practice. This may be because custom-made footwear prescription is only slowly changing from a traditional experience- and skills-based approach to a more data- and scientifically driven approach. Furthermore, such measurements require investments in equipment, the training of personnel, and the time to conduct the measurements. When such investments are not (yet) part of reimbursed care, the use of in-shoe plantar pressure measurement relies on the willingness of those prescribing and/or manufacturing footwear to pay for this service. In many countries, including the Netherlands, custom-made footwear is prescribed by physicians and designed and manufactured by technicians (also called pedorthists) of footwear companies that are affiliated with or contracted to outpatient foot clinics within hospitals. Many of these physicians and shoe technicians see the benefit of using in-shoe plantar pressure analysis for evaluating and improving custom-made footwear and are willing to invest in this service, pending contracts for the reimbursement of the service. However, to date, there are no studies that have investigated the feasibility of implementing in-shoe plantar pressure measurements in clinical footwear practice.

Given the clinical benefit of plantar pressure measurement, information on how successfully it can be implemented and what the facilitators of and barriers to such implementation are would help to progress the use of evidence-based pressure-driven footwear design and evaluation in footwear practice. The aim of this study was therefore to assess the success rate and facilitators of and the barriers to using in-shoe plantar pressure measurements in footwear practice for evaluating the custom-made footwear of people with diabetes who are at high risk of foot ulceration.

2. Materials and Methods

2.1. Study Design

This was a prospective observational study monitoring the use of in-shoe pressure measurements in footwear practice over a 2.5-year period. To assess the implementation, the study collected quantitative data through reported measurements and qualitative data through semi-quantitative interviews.

2.2. Participating Companies and Conditions

In the Netherlands, custom-made footwear for people with diabetes is prescribed by physicians and designed and manufactured by shoe technicians working at orthopedic footwear companies that are contracted to outpatient foot clinics within hospitals. Orthopedic footwear companies often have regional or even national coverage and are contracted to more than one hospital. Furthermore, most footwear companies use a workshop within the hospital to modify the shoe when needed and have multiple branches outside of the hospital where patients can have their prescribed footwear fitted, evaluated, and collected.

All the footwear companies that were members of the Dutch branch organization for orthopedic shoe technicians (NVOS-Orthobanda) were contacted by email to inform them about this implementation project, the possibility to participate, and the seminars that would be organized to discuss the project; the requirements for participation were communicated, and the companies were asked to express their willingness to participate. Three seminars were held at locations spread throughout the Netherlands; 42 shoe technicians and managers from 20 footwear companies participated.

The participants in the project had to meet the following preset requirements: (1) a sufficient number of eligible patients for in-shoe pressure measurements to justify support for the purchase and use of an in-shoe pressure measurement system, as judged by the investigators; (2) willingness to purchase, with 50% support in costs through the project grant, a Novel Pedar-X in-shoe pressure measurement system; (3) willingness to adjust business operations to enable measurements; (4) willingness to share collected data anonymously with the investigating team; and (5) the availability of sufficient space to carry out the measurements and an adjacent workshop for immediate footwear adjustments if needed.

The companies could participate as a stand-alone footwear practice, in collaboration with other companies sharing one pressure measurement system, or by outsourcing the pressure measurements to a facility such as a gait laboratory where the pressure measurement equipment is used. After willingness to participate was expressed, the eligibility to participate was assessed based on an intake interview. This project was funded by a grant from the Development Fund for Orthopedic Shoe Companies (OFOM) in the Netherlands.

2.3. Procedures

Prior to the start of the project, the participants were trained by Novel GmbH in the fundamental and technical aspects of plantar pressure measurement and in using the in-shoe pressure measurement system. After the training, the participants were provided with a Pedar-X measurement protocol, which was a simplified version of the protocol used in the gait laboratory of the Amsterdam UMC; the protocol outlined the required steps to conduct a valid and reliable in-shoe pressure measurement with the Pedar-X measurement system. Additionally, the participants were provided with the Amsterdam UMC protocol for the use of in-shoe pressure measurements for footwear evaluation and modification that aims to improve the pressure-relieving capacity of custom-made footwear. Via a flow diagram, this protocol describes the conditions under which shoe modifications should be made and includes two matrices that illustrate the pressure-relieving effect of the (combination of) shoe modifications on a specific region, based on previously published data and schemes from the DIAFOS research project [9,20].

For the duration of the project, the participants were instructed to evaluate every person with diabetes mellitus who had a history of foot ulceration and was provided with some form of custom-made footwear.

In-shoe pressures were measured using the Pedar-X system (Novel, Munich, Germany) during overground walking at a comfortable speed. The Pedar-X system consists of 2 mm thick flexible insoles with 99 capacitance-based sensors that each measure at a 50 Hz sample rate. The system works by inserting the measurement insoles in the shoes and placing them on top of the insoles. A data cable connects the insole to a data logger that is worn around the waist of the subject and that transmits data in real-time via a Bluetooth connection to the computer. A minimum of 12 midgait steps per foot are measured to obtain valid and reliable data for the participant [20]. If the plantar peak pressure at the toes, forefoot, or midfoot was >200 kPa, according to the protocol, the shoe technician was instructed to modify the footwear and reassess the in-shoe plantar pressures until the peak pressures were below an absolute level of 200 kPa or reduced by 25% compared to the baseline assessment [20]. The shoe technician selected the footwear modification and used the evaluation protocol for guidance ad libitum. Multiple modifications could be made at once, and according to protocol, a maximum of two rounds of adjustments and subsequent pressure evaluations were conducted. After each patient measurement session, the participants completed a

form in which they entered demographic, measured pressure, and shoe technical data. The participants were instructed to re-evaluate the in-shoe pressures six months after footwear delivery, using the same protocol.

The participants were instructed to have the Pedar-X measurement system calibrated twice a year. The calibration device of the gait laboratory at Amsterdam UMC was used for this purpose, and the calibration was conducted by gait lab personnel, against payment of a fee commensurate with their time investment.

The primary target group comprised people with diabetes who had a history of plantar foot ulceration and for whom in-shoe plantar measurements are an evidence-based evaluation procedure [24]. Other patient groups could additionally be measured by the participant and could include people with diabetes and a foot ulcer or people with diabetes without a foot ulcer history but with an indication of pressure evaluation based on pressure-related issues with the footwear or present signs of increased pressure such as calluses or red spots. Prior to the start of the measurements, all the patients measured provided written informed consent to have their collected data used for scientific purposes when needed.

2.4. Monitoring and Data Collection

The project had a duration of 2.5 years. Throughout the project, the investigator (JBJZ) conducted four monitoring sessions per participant: three during the project and one final visit after the project's end date. These sessions aimed to collect both quantitative and qualitative data to assess implementation success and to assess the facilitators of and barriers to this implementation. The qualitative data were collected through semi-structured interviews with the person responsible for the measurements at each center. During these interviews, a standard set of closed and open-ended questions were asked, and the answers were synchronously documented in Microsoft Word during the interviews by the investigator (JBZ). The obtained organizational data included (a) the start date, (b) the time investment per patient, (c) the number of footwear branch locations where measurements were conducted, (d) the setting for the measurements, either during an outpatient clinic or in separate sessions, (e) the involvement of a physician, (f) the re-evaluation of in-shoe pressures after 6 months, and (g) the calibration of the measurement system. Additionally, the participants were asked to provide insights into the facilitators of and barriers to the use of the in-shoe pressure measurement system and the impact of conducting these measurements on their professional development (i.e., learning effect and efficiency of footwear adjustments).

The quantitative data were collected through the completed measurement forms and in-shoe pressure data collected per patient. The organizational data included the number of unique patient measurements conducted. The footwear data included (a) type of prescription, (b) footwear design elements, (c) type of modifications, and (d) in-shoe pressure data collected. The patient data included (a) demographic parameters, (b) disease-related parameters, and (c) clinical outcomes over time, if available.

The implementation of in-shoe pressure measurements in footwear practice was classified as fully successful, moderately successful, or not successful. The implementation was considered fully successful when a participant met each of the following four criteria: (1) a minimum of 50 unique patient measurements a year were conducted; (2) more than 60% of the measurements were conducted in the primary target group (i.e., people with diabetes and a healed foot ulcer); (3) in-shoe pressures were re-evaluated every six months; and (4) the measurement system was calibrated at least once a year. The implementation was considered moderately successful when a minimum of 35 unique patient measurements a year were conducted and at least one of the above from criteria 2 to 4 was met. The implementation was considered unsuccessful when none of the four criteria were met or when a participant discontinued the measurements before the end of the study period of 2.5 years.

The footwear design data, in-shoe pressure data, and clinical outcome data were not analyzed for the current study since these data are beyond the scope of this article.

2.5. Data Analysis

The organizational data for the evaluation of implementation success were collated per participant in a table. All the evaluation parameters were analyzed using descriptive statistical analyses in SPSS for Windows (IBM SPSS Statistics version 22, Armonk, NY, USA). All the semi-structured interviews were documented by the first author (JBJZ) and analyzed based on the method of Braun and Clarke [27]. All the statements by those interviewed were coded and grouped into categories to identify the themes regarding facilitators and barriers.

3. Results

The organizational data per participant are presented in Table 1. In total, 17 footwear companies participated in this project. Seven of these companies jointly participated as a footwear practice and purchased and shared one in-shoe pressure measurement system. The remaining ten companies participated independently, and each company purchased an in-shoe pressure measurement system. As a result, the analysis was conducted on 11 footwear practices, and they are named as such in the remainder of the manuscript. The duration of the follow-up varied across practices since not all of them started collecting data at the start of the project for organizational reasons. Six practices started between September and November 2015, three between January and April 2016, and two between September and October 2016.

3.1. Number of Measurements

In-shoe plantar pressures were measured in a total of 1030 people with diabetes, ranging from 13 to 156 across the practices during the project (Table 1). A total 525 measurements (51%) were in the primary target group, and 505 measurements (49%) were in people with diabetes and a foot ulcer or in people with diabetes with no ulcer history but with an indication for pressure evaluation based on pressure-related issues with the footwear or present signs of increased pressure such as calluses or red spots. Three practices measured in-shoe pressures in more than seventy people per year, two in more than fifty people, and three in more than forty people. Two practices measured less than twenty people per year.

3.2. Primary Target Group

The percentage of measurements conducted in the primary target group (i.e., people with diabetes and a healed ulcer) varied between 25% and 90% of the total measured groups across the practices. Two practices had more than 75% of the measurements in the primary target group, four practices between 50% and 75%, and five practices below 50%. The latter five practices conducted the majority of the in-shoe pressure measurements in people with diabetes and a foot ulcer or in those indicated by a pre-ulcer presence or complaint about the footwear.

3.3. Re-Evaluation after 6 Months and Calibration of the Measurement System

Three practices reported that they re-evaluated in-shoe plantar pressures in their patients every six months, as instructed; the other eight did not. Six of the practices had their measurement system calibrated once a year, and five did not. None of the practices calibrated their measurement system twice a year, as was instructed.

Table 1. Organizational data per participant.

Participant (Footwear Practice)	Start Month/Year	Nr. of Branch Locations for Measurement	Measurement Sessions Separate from Clinic	Involvement of Physician	Nr. of People Conducting Measurement + Profession	Footwear Modified By Same Persons Who Measures?	Time Planned per Measurement (min)	Most Measured Patient Group	Total nr. of Unique Patient Measurements	Nr. of Unique Patient Measurements Per Year	% Measurements in Primary Target Group	Re-Evaluation of Footwear after 6 Months	System Calibration	Learning Effect	Plans for Continuation after the Project	Successful Implementation?
1	09/2015	6	Yes	Yes, 3/6	2 OST	Yes	60	PTG	156	78	60%	Yes	Yes	Yes	Optimize + expand	Fully
2	09/2015	2	Yes	Yes	2 OST	Yes	45	PTG	123	55	65%	Yes	Yes	Yes	Optimize	Fully
3	10/2015	3	Yes	No	2 OST	Yes	30–45	PTG	125	58	80%	No	Yes	Yes	Continue as is now	Moderately
4	03/2016	2	Yes	Yes, 1/2	3 POD	No, 3 OST	60	ULC + IND	147	84	35%	Yes	No	Yes	Optimize	Moderately
5	04/2016	1	Yes	Yes	3 LAB	No, 2 OST	30–45	ULC + IND	118	71	25%	No	Yes	Yes	Optimize	Moderately
6	10/2015	5	Yes	Yes, 2/5	2 OSTst	Yes	60	PTG	98	45	65%	No	No	Yes	Optimize + expand	Moderately
7	09/2016	4	Yes	No	4 OSTst	No, 4 OST	60	ULC	59	47	25%	No	Partly	Yes	Optimize + expand	Moderately

Table 1. *Cont.*

Participant (Footwear Practice)	Start Month/Year	Nr. of Branch Locations for Measurement	Measurement Sessions Separate from Clinic	Involvement of Physician	Nr. of People Conducting Measurement + Profession	Footwear Modified By Same Persons Who Measures?	Time Planned per Measurement (min)	Most Measured Patient Group	Total nr. of Unique Patient Measurements	Nr. of Unique Patient Measurements Per Year	% Measurements in Primary Target Group	Re-Evaluation of Footwear after 6 Months	System Calibration	Learning Effect	Plans for Continuation after the Project	Successful Implementation?
8	11/2015	2	No	Yes	2 OST	Yes	60	ULC + IND	77	37	35%	No	Yes	Yes	Expand	Moderately
9	10/2015	4	No	Yes, 1/4	4 OSTst	Yes	60	ULC + IND	86	40	35%	No	No	Yes	Unsure	No
10	01/2016	1	No	No	1 OST	Yes	60	PTG	28	15	90%	No	No	-	No	No
11	10/2016	1	No	No	1 OST	Yes	60	PTG	13	11	75%	No	No	-	No	No

Data are N, or otherwise indicated. OST: orthopedic shoe technician; POD: podiatrist; OSTst: OST student; LAB: lab technician. PTG: primary target group; ULC: ulcer group; IND: on indication. Pressure measurements were conducted 'on indication' when users had a complaint about the footwear or when there were signs of increased pressure such as red spots or calluses. In the column "Involvement of Physician", the fraction mentioned is the number of branch locations of the total in which a physician was involved. "Learning effect" indicates whether technicians reported having a learning curve in optimizing the pressure-reducing properties of the footwear by conducting measurements. "Optimize" indicates that the participant will continue with conducting measurements and aims to make further improvements to the service, such as expanding the number of people measured, increasing the number of measurements within the primary group, or implementing follow-up measurements after six months. "Expand" indicates that the participant intends to extend the in-shoe pressure measurements to additional branch locations of the company. The green cells indicate which of the four criteria for implementation success were met. The last column indicates whether the implementation was successful (green cells), moderately successful (oranges cells) or not successful (red cells).

3.4. Measurement Facilities, Sessions, and Time Slots

The number of facilities (i.e., company branch locations or outpatient foot clinics) where patients were measured for in-shoe pressure varied from one to six across the practices (Table 1). Seven practices organized a standalone session separate from the outpatient clinic to conduct the in-shoe pressure measurements and footwear modifications. The other four conducted measurements during the outpatient clinic. Eight practices planned 60-min time slots to evaluate one patient for pressure measurement and footwear modification, one practice planned 45-min time slots and two practices planned 30- to 45-min time slots.

3.5. Involvement of a Physician

Seven practices had direct collaboration with a physician in an outpatient diabetic foot clinic, where custom-made footwear was prescribed and pressure measurements were ordered. Four practices did not have a physician involved in the procedure.

3.6. Technical Aspects

Some practices experienced technical issues with the measuring system, such as a broken connection cable between the insole and the device and malfunctioning sensors of an insole. In addition, all the practices experienced difficulties measuring people with larger or smaller feet than the available sizes of the measuring insoles and with heavily abnormal foot shapes, such as a Charcot foot or an amputation.

3.7. Implementation Success

Based on the criteria for successful implementation, the implementation of in-shoe pressure measurements was considered fully successful in two practices and moderately successful in six practices (Table 1). In three practices, the implementation was considered unsuccessful; these practices stopped conducting in-shoe pressure measurements before the end of the project, and they did not intend to restart measurements after the project.

3.8. Facilitators and Barriers (Based on Semi-Structured Interviews)

Four themes regarding facilitators were identified: (1) learning effect; (2) support from the management board; (3) patient experience; and (4) collaboration with a prescribing physician. Also, four themes regarding barriers were identified: (1) technical challenges; (2) investment of costs and time; (3) referral to other shoe technicians; and (4) logistical challenges. Regarding the first theme among the facilitators, a positive learning effect among shoe technicians/measurers was reported by 8 of the 11 practices, and a reduction in the required number of footwear modifications over time was also reported by 8 practices. Two practices mentioned that this learning effect translated into a reduction in the time required for a measurement session, and three practices mentioned changes in footwear design based on gained experience in pressure measurement outcomes. Regarding the second theme, in three practices the board reported that the in-shoe pressure measurements contributed to an improvement of quality in footwear care, and in two practices, it was reported that in-shoe pressure measurements could be used to distinguish them from competitors. Regarding the third theme, three practices reported that the evaluated patients were positive regarding the in-shoe pressure measurements and that they appreciated the attention and time devoted to them. Additionally, enhanced patient awareness of the importance of appropriate footwear due to the visualization of pressure outcomes was reported by two practices. Regarding the fourth theme, two practices reported that they used the pressure measurements as evidence in discussions with the physician in cases where there was debate about whether a problem was footwear-related or related to the non-adherence of the user.

Among the barriers, within the first theme, 10 of 11 practices highlighted the complexity and friendliness of using the in-shoe pressure measurement system. System vulnerabilities, including Bluetooth connection problems and defects in sensors, cables, insoles, or

batteries were reported by eight practices. Furthermore, four practices reported constraints related to the number and available sizes of measuring insoles and difficulties in measuring heavily deformed feet (n = 4). Regarding the second theme, five practices reported that the pressure measurement and footwear adjustment process was time-consuming, and four reported that the investment costs were high. Regarding the third theme, six practices reported having a limited awareness of the referral patients for a pressure measurement session, and four reported a resistance due to the concern that their manufactured shoes were being evaluated and (sometimes) adjusted by colleagues. Regarding the fourth theme, two practices reported logistical difficulties with conducting measurements with one system at multiple branch locations and with the availability of the system due to its rotation between branch locations. Additionally, the scheduling of patients who had been referred by other branch locations was reported as challenging by these practices.

4. Discussion

This is the first study that investigated the success and facilitators of and barriers to the implementation of in-shoe plantar pressure measurements in footwear practice for people with diabetic foot disease. The implementation of in-shoe pressure measurements was considered a full success or a moderate success in 8 of 11 footwear practices and as unsuccessful in the other 3. Several barriers to and facilitators of successful implementation are present and are discussed below.

The in-shoe plantar pressures were measured during the 2.5-year project duration in 1030 individuals with diabetes, with a large range of 13 to 156 in the number of patients measured per practice. The low numbers in this range, i.e., those up to a total of 100 patients seen in 6 of 11 practices, may be attributed to practices overestimating the number of eligible patients for in-shoe pressure measurements. Additionally, a low awareness (or resistance) of shoe technicians regarding the measurement of patients may explain this outcome. Some practices did not measure all the eligible patients due to logistical challenges, such as the sharing of the system between branch locations of the same company or the scheduling of footwear deliveries at moments or locations where the system or a technician was not available for measuring the in-shoe plantar pressure.

These findings indicate that only one to a few measurements per week were conducted with one measurement system, meaning that the system remained idle for most of the week. The efficiency of use was therefore low, giving a limited return on purchase, maintenance, and training costs. Furthermore, there is a risk of not building up sufficient experience in measuring in-shoe plantar pressures, particularly when more than one technician per practice is involved in conducting the measurements. A possible solution to this could be to setup a scheme whereby the measurement system is used within more branch locations of the company so that more people are measured. Another option may be to assign one or two technicians within the company to be responsible for the measurements, who then rotate between the different branch locations. Yet another option could be to refer patients to a geographically centrally located branch of the company to have their in-shoe pressures measured. This last option has the disadvantage that patients may need to travel a relatively long distance and that if any footwear modifications are necessary, they will not be conducted by the patient's own shoe technician. Creative solutions are needed here to increase the efficiency of use of the in-shoe pressure measurement system.

The percentage of measurements conducted in the primary target group of people with a healed plantar foot ulcer ranged substantially across practices between 25% and 90% and was on average 51%. Five practices mostly measured people with diabetes who had a foot ulcer or those who had a pre-ulcer present or had a complaint about their footwear. Although in-shoe plantar pressure measurements in these groups may be highly valuable, this is not evidence-based. Additionally, while a peak pressure target level of 200 kPa is used as an evidence-based threshold for ulcer prevention in the primary target group [21,28], such a level may not apply to other groups measured. In patients with a

foot ulcer, for example, a lower target pressure threshold is likely to apply. This awareness appears to be insufficiently present among shoe technicians and prescribing physicians.

Only 3 of the 11 footwear practices reassessed in-shoe plantar pressures after 6 months; most practices only measured at footwear delivery. As a result, changes in the pressure-relieving properties of the footwear over time remained unnoticed. The DIAFOS study showed that the pressure-relieving properties of the footwear change over time, even within 3 months, which is likely due to the wear of the materials, emphasizing the need for timely re-evaluation of in-shoe plantar pressure [24]. As a possible explanation, most practices reported that the re-evaluation of in-shoe plantar pressures is not integrated into their routine practice, where they usually only see the patient return for monitoring of their footwear when the patient develops a foot problem or has a complaint about the footwear. Implementing a standard procedure of scheduling re-evaluations over the lifetime of the prescribed footwear at footwear delivery may help to improve the re-evaluations. Additionally, re-evaluating the footwear every six months requires extra time and costs, which may even be doubled or tripled compared to those of the single measurement. Shoe companies seem reluctant to invest in such measurements over time if they do not receive compensation through the reimbursement system, despite the fact that a positive effect of such reassessments is that the efficiency of using the system is improved. Having such reimbursement implemented will also improve the re-evaluations of the footwear.

A technical aspect that received very little attention from the footwear practices is the calibration of the measuring system. The Amsterdam UMC has a calibration device for the Pedar-X system, and the footwear practices had the option to have their measurement system checked and calibrated against payment of a fee. Despite the recommendation in the project to calibrate the system every six months, none of the practices followed this recommendation, and only six practices calibrated their systems once per year. The other five did not calibrate their systems at all. A potential explanation may be that the practices do not perceive the necessity to calibrate such a system, as they may not be aware of the importance of calibration, compared for example with researchers or lab personnel. This may also explain why none of the practices purchased their own calibration system. Additionally, the necessity to send their Pedar-X system to Amsterdam UMC for calibration, causing temporary unavailability and a fee payment, may have made the practices reluctant to have the system calibrated. Such calibration is not specific to the Pedar-X system used in the project, as all measurement systems must be calibrated at some point to ensure accurate and reliable outcomes. Further stressing to users that calibration will help to maintain accurate outcomes is probably needed to improve calibration. Additionally, the participants purchasing and using their own calibration systems or automatic reminders to conduct a pressure system calibration every several months may help.

Most of the practices scheduled sessions for in-shoe pressure evaluation and footwear modification that were separate from the often busy outpatient foot clinics. An important finding of this project is that almost all of the successful and moderately successful practices used separate measurement sessions; the ones that were not successful all performed the measurements in outpatient foot clinics. While such a setup probably requires patients to make an extra visit for footwear evaluation, the results suggest that this is necessary for successful implementation.

Furthermore, all but one of the successful or moderately successful practices collaborated directly with a prescribing physician in the clinic that they were affiliated with, which likely facilitated implementation. Still, in most cases, the shoe technician requested and scheduled the pressure measurements, not the prescribing physician, who ordered the pressure measurements in only a few cases. Given the clinical implications and the responsibilities involved with evaluating and improving footwear, it is desirable that in-shoe plantar pressure measurements are performed in close collaboration between the physician and technician.

4.1. Facilitators of and Barriers to Implementation

Based on the analysis of the quantitative findings, implementation seems facilitated by the use of sessions for in-shoe pressure measurement and footwear modification, which are separate from the normally busy outpatient clinics, are preferably at a fixed time during the week, and use 45–60 min time slots per patient. Having multiple patients scheduled per session facilitates efficiency in the use of the system. Using the measurement system across branch locations, such as by rotating the system or by rotating technicians between locations, helps to measure more eligible patients and to increase efficiency.

The quantitative and qualitative data seem to show that close collaboration and shared decision making between the prescribing physician and the shoe technician also facilitates implementation and helps to increase the percentage of eligible patients being measured.

The support of the company's management board for the use of such a service is also an important facilitator.

The qualitative analysis shows that a positive learning effect and positive patient experience seem to facilitate implementation. Improved skills in measuring and adjusting footwear over time increases efficiency and reduces the time required for a measurement session. This may enhance the feasibility of using in-shoe pressure measurements in footwear practice and the efficacy of the footwear provided.

A barrier to implementation is the usability of the pressure measurement system perceived by the involved shoe technicians. These pressure measurement systems were originally developed primarily for research purposes and used by highly qualified and trained scientists and lab personnel. Their use by less trained shoe technicians may require an adaptation of the system. The reported technical issues, including system malfunctions and constraints related to the number and available sizes of measuring soles, limit the number of people that can be measured (in the time available). Measuring people with abnormal foot shape due to Charcot deformity or amputation may require further investments in measurement insoles for these cases.

Another barrier to implementation is the required investments in costs and time for conducting the in-shoe pressure measurements. A solution to this barrier would be to have the costs for the service reimbursed or otherwise paid for. A cost-effectiveness analysis of the outcomes of the DIAFOS trial shows that custom-made footwear that is evaluated and, if needed, modified at intervals of 3 months using in-shoe plantar pressure analysis is more cost-effective than the usual care [29]. Such findings can hopefully help to engage the users and potential funders of this service in discussions regarding reimbursement.

As a barrier, the limited awareness or resistance of shoe technicians regarding measuring patients or referring patients for an in-shoe pressure measurement indicates the importance of finding a solution for the integration of the service into the standard workflow of shoe technicians.

4.2. Study Limitations

Firstly, the implementation was partially facilitated by compensating half of the purchase costs for the pressure measurement system through the study grant. While this may reflect how footwear companies see this service. i.e., as a reimbursed option, it may affect participation and motivation and, consequently, the implementation outcomes. A second limitation is the limited number of practices in two of the three participating setups, i.e., the sharing of a system between companies in one footwear practice and the outsourcing of the measurements, e.g., to a gait laboratory. For a better comparison between setups, more practices per setup would be needed. A third limitation is the inherent subjectivity present in much of the data collection, such as in the classifying of implementation success and the experiences from footwear practices. Lastly, the outcomes may be specific to the Dutch context and may have limited generalizability to footwear settings in other countries, where the system for providing footwear for people with diabetes may be different regarding healthcare policies, reimbursement, available resources, and the organization of foot care and footwear services.

5. Conclusions

In-shoe plantar pressure measurements can be implemented to a moderate to full degree in footwear practice for people with diabetes. Implementation success largely depends on organizational/logistical, financial, and technical factors, most of which are modifiable. While implementation was not fully successful across practices, the modifiable barriers highlight the potential for the implementation of this service for the evaluation of custom-made footwear for people with diabetes.

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Data Availability Statement: The data of this study are all contained within the manuscript and also available upon request to the corresponding author.

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Article

Habitual Physical Activity of People with or at Risk of Diabetes-Related Foot Complications

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Abstract: Regular physical activity is an important component of diabetes management. However, there are limited data on the habitual physical activity of people with or at risk of diabetes-related foot complications. The aim of this study was to describe the habitual physical activity of people with or at risk of diabetes-related foot complications in regional Australia. Twenty-three participants with diabetes from regional Australia were recruited with twenty-two participants included in subsequent analyses: no history of ulcer (N = 11) and history of ulcer (N = 11). Each participant wore a triaxial accelerometer (GT3X+; ActiGraph LLC, Pensacola, FL, USA) on their non-dominant wrist for 14 days. There were no significant differences between groups according to both participant characteristics and physical activity outcomes. Median minutes per day of moderate-to-vigorous physical activity (MVPA) were 9.7 (IQR: 1.6–15.7) while participants recorded an average of 280 ± 78 min of low-intensity physical activity and 689 ± 114 min of sedentary behaviour. The sample accumulated on average 30 min of slow walking and 2 min of fast walking per day, respectively. Overall, participants spent very little time performing MVPA and were largely sedentary. It is important that strategies are put in place for people with or at risk of diabetes-related foot complications in order that they increase their physical activity significantly in accordance with established guidelines.

Keywords: diabetes; diabetic foot; peripheral neuropathy; physical activity; exercise

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1. Introduction

People with diabetes are at risk of developing lower-extremity complications, such as peripheral neuropathy and peripheral artery disease, which can lead to foot ulceration and lower-extremity amputation [1]. Diabetes-related foot complications are a large and growing contributor to the disability burden worldwide, globally accounting for an estimated 59% of all diabetes-related years lived with disability [2]. Diabetes-related foot complications are hard to manage and often recur [3], negatively influence quality of life [4], and are disproportionately represented in socially disadvantaged populations and in regional and rural geographic areas [5,6].

The American Diabetes Association guidelines recommend that adults with diabetes should engage in 150 min or more of moderate-to-vigorous physical activity per week [7]. People who participate in diabetes lifestyle interventions that increase physical activity can reduce reliance on medications through a range of metabolic benefits (e.g., body mass control, reduced blood pressure, enhanced insulin sensitivity, improved lipoprotein balance) as well as enhancing musculoskeletal function [8]. The positive effects of exercise training on glucose control, physical function, and the signs and symptoms of peripheral

neuropathy have been confirmed via meta-analyses of studies on people with existing neuropathy [9]. Furthermore, with adequate baseline screening and participant selection adverse events are unlikely, and the risk of further ulceration in response to exercise is low [9–11].

Early research investigating daily activity patterns in patients with diabetic foot complications indicated that people with diabetes and peripheral neuropathy take fewer steps, but with more variation in step counts (or "spikes"), and that more steps are taken indoors than outdoors [12,13]. One Australian group has reported that people with current active diabetes-related ulceration take fewer steps but expend more energy than those without ulceration [14]. People with diabetes have been reported to undertake more steps indoors than outdoors, but the authors of a recent review concluded that future research using technology to investigate a variety of outcomes related to physical activity such as standing/sedentary time and bouts of activity in different settings is needed [15].

It is currently unclear if people with or at risk of diabetes-related foot complications in regional and rural populations in Australia are meeting physical activity guidelines. A better understanding of the habitual activity patterns in this population has the potential to inform effective activity-based preventative health interventions for both primary and secondary prevention that could reduce the health burden of people with diabetes in regional and rural Australia. Thus, the aim of this study was to describe the habitual physical activity of people with or at risk of diabetes-related foot complications in regional Australia.

2. Materials and Methods

This observational study recruited participants from a high-risk foot service in regional Australia. Inclusion criteria were diagnosis of type 2 diabetes. Exclusion criteria were less than 18 years old, an active skin ulceration on the foot, and inability to provide informed consent. Potentially eligible participants from a high-risk foot service in regional Victoria were invited to participate in the study. The podiatry-led high-risk foot service is a multi-disciplinary service and accepts referrals for people with diabetes across the entire spectrum of diabetes-related foot disease. Referral and prioritising systems in place ensure people at high risk of or with active foot morbidity are managed by the tertiary high-risk foot service, with maintenance and prevention services undertaken by affiliated community health services. Ethical clearance was provided by institution ethics committees (LNR/14/BHSSJOG/24), and informed consent was provided by all participants.

General participant characteristics were measured and included age, sex, body mass index (BMI), diabetes history (diabetes type, diabetes duration, and method of diabetes control), and foot morbidity (foot deformity, presence of peripheral neuropathy, history of ulceration, and history of amputation). To measure physical activity outcomes, each participant wore a triaxial accelerometer (GT3X+; ActiGraph LLC, Pensacola, FL, USA) calibrated and synchronised to record triaxial accelerations at 100 Hz on their non-dominant wrist for 14 days, 24 h per day, except when they were likely to submerge the accelerometer underwater. ActiLife software (version 7.0; ActiLife Corp., Pensacola, FL, USA) was used to obtain the raw triaxial acceleration data, which was downloaded in epoch lengths of 60 s. Non-wear time was determined using the Choi wear time validation algorithm [16], while sleep time was differentiated from wake time using the Cole–Kripke sleep algorithm [17]. Periods classified as non-wear and/or sleep were removed from the dataset prior to the export of raw triaxial acceleration data. To be included in the analysis, two valid weeks of data were required where a valid week was defined as $\geq$10 h per day of wear time on at least five days including one weekend day [18].

In line with recent research demonstrating the unfavourable performance of linear regression-based predictive models and traditional machine learning-based predictive models to estimate the intensity of physical activity in wrist-worn accelerometers in free-living conditions [19], a Convolutional Neural Network (CNN) variant of a deep learning algorithm was used to predict energy expenditure and the intensity of physical activity [20]. The CNN deep learning method has been shown to closely predict activity intensity

(83.7%, 95% CI: 80.9–86.5%) and has recently demonstrated a strong correlation with energy expenditure predictions (r = 0.86, 95% CI: 0.84–0.87) with a reference hip-specific method (modified Freedson VM3 Combination equation) [20]. Daily physical activity outcomes predicted by the CNN models were energy expenditure (kJ); average metabolic equivalents (METs); and minutes spent in sedentary activity, low-intensity physical activity (LPA), and moderate-to-vigorous physical activity (MVPA). Additionally, non-wear time (minutes) and the sleep-related measures of average sleep duration (minutes) and sleep efficiency (%) were also measured.

In addition to these commonly reported measures of physical activity, MX metrics were also extracted. MX is a novel accelerometer metric that captures the intensity (acceleration) during a person's most active period of the day [21]. MX metrics are translational metrics that facilitate meaningful public-health messages due to their ability to be described in terms of activities (e.g., fast walking) or intensity (e.g., moderate-to-vigorous physical activity). MX metrics were reported as the average magnitude of dynamic acceleration (corrected for gravity) averaged over 5 s epochs and expressed as milligravitational units (m*g*) [21,22]. MX metrics have previously been used to report physical activity and chronotype in people with type 2 diabetes [23]. The most active 480 min or third of a day (M480), 120 min (M120), 60 min (M60), 30 min (M30), 10 min (M10), 5 min (M5), and 2 min (M2) were recorded and compared to approximate accelerations associated with a slow (100 m*g*) and fast (200 m*g*) walk [20,21,24].

Signal processing to process multi-day raw accelerometer data for physical activity and sleep research included autocalibration using local gravity as a reference [25]; detection of sustained abnormally high values; detection of non-wear; and calculation of the average magnitude of dynamic acceleration, corrected for gravity averaged over 5 s epochs and expressed in milligravitational units (m*g*). Participants were excluded if their accelerometer files showed a post-calibration error greater than 0.01 g (10 m*g*), if they had fewer than 3 days of valid wear (defined as >16 h per day), or if wear data were not present for each 15 min period of the 24 h cycle [26,27]. The default non-wear setting was used whereby invalid data were imputed via the average at similar time-points on different days of the week. The average of all valid days was used for all outcome variables.

For the CNN modelling, inputs for predictive model development were the raw 100 Hz accelerometer files extracted from ActiLife with models developed using Python programming language (Python Software Foundation, https://www.python.org/; accessed on 23 January 2023). To extract and visually represent MX metrics, the raw GT3X files exported from ActiLife were processed using the R-package GGIR (version 2.8–2; http://cran.r-project.org; accessed on 23 January 2023) [21].

Physical activity was analysed for the entire sample. As the risk for a future ulceration is extremely high for people with a previous ulceration, secondary between-groups analysis was undertaken for participants who had a history of diabetes-related foot ulceration compared those who had not. Final data analysis was undertaken using IBM SPSS Statistics for Windows (version 24.0; IBM Corp., Armonk, NY, USA). For continuous variables with normal distributions, means and standard deviations were reported with differences between groups assessed using independent samples' *t*-tests. Continuous variables that did not conform to the assumptions of normal distributions were presented as medians and interquartile ranges (IQR), and differences between groups were assessed using the Mann–Whitney U-test. For categorical variables, proportions were reported, and differences between groups were tested using chi-squared with continuity correction. Statistical significance was set at $p < 0.05$.

3. Results

Twenty-three participants were recruited for this study. One participant was excluded due to mechanical failure of the accelerometer. Therefore, 22 participants were included in subsequent analyses, with 11 participants having a history of ulceration and 11 who did not have a history of ulceration.

There were no significant differences between those with history of ulcer when compared to those without a history of ulcer according to both participant characteristics (Table 1) and physical activity or sleep outcomes (Table 2).

Table 1. Participant characteristics.

Characteristic	Total (n = 22)	History of Ulcer (n = 11)	No History of Ulcer (n = 11)	p-Value
Diabetes type				0.534
Type 1	3 (13.6%)	2 (18.2%)	1 (9.1%)	
Type 2	19 (86.4%)	9 (81.8%)	10 (90.9%)	
Male sex	12 (54.5%)	7 (63.6%)	5 (45.4%)	0.669
Age (years)	65 ± 10	61 ± 7	69 ± 11	0.076
Body mass index	33.0 ± 7.0	34.9 ± 8.2	30.7 ± 6.0	0.186
Diabetes duration (years)	18 ± 10	20 ± 9	15 ± 11	0.348
Previous amputation	3 (13.6%)	3 (27.3%)	0 (0.0%)	0.062
Presence of peripheral neuropathy	15 (68.2%)	11 (100%)	4 (36.4%)	0.001
Foot deformity	11 (50.0%)	7 (63.6%)	4 (36.4%)	0.394
Method of diabetes control				0.873
Insulin	12 (57.1%)	6 (54.5%)	6 (54.5%)	
Oral hypoglycaemics	7 (33.3%)	2 (18.2%)	5 (45.5%)	
Combination	2 (9.5%)	2 (18.2%)	0 (0.0%)	

Note: due to data collection error, the reporting of variables for diabetes duration and diabetes control is based on 21 participants only. Data presented as number (%) or mean ± SD.

Table 2. Daily physical activity and sleep outcomes.

Daily Activity Outcomes	Total (n = 22)	History of Ulcer (n = 11)	No History of Ulcer (n = 11)	p-Value
METs	1.5 ± 0.1	1.5 ± 0.1	1.4 ± 0.7	0.246
Energy expenditure (kJ) ^	14,262 (1164–18,797)	16,787 (11,465–20,707)	13,189 (11,700–14,539)	0.101
Sedentary behaviour (minutes)	689 ± 114	676 ± 105	702 ± 125	0.664
LPA (minutes)	280 ± 78	286 ± 82	274 ± 77	0.816
MVPA (minutes) ^	9.7 (1.6–15.7)	10.8 (1.6–15.8)	4.6 (1.1–15.7)	0.478
Sleep duration (hours)	5.6 ± 1.7	5.3 ± 1.5	6.0 ± 1.9	0.149
Sleep efficiency (%) *	92.7 ± 3.8	92.1 ± 4.7	93.3 ± 2.7	0.471
Accelerometer non-wear time (minutes) ^	96 (44–198)	105 (5–223)	74 (17–172)	0.236

Data reported mean ± SD unless otherwise stated. * Proportion of time asleep while in bed. ^ Median (interquartile range, IQR). MET, metabolic equivalent of tasks; kJ, kilojoules; LPA, low-intensity physical activity; MVPA, moderate-to-vigorous physical activity.

The median accelerations of the most active continuous 2, 5, 10, 30, 60, 120, and 480 min were 223 mg (IQR 182-276 mg), 179 mg (IQR 146-223 mg), 151 mg (IQR 122–182 mg), 102 mg (IQR 89–125 mg), 79 mg (IQR 70–97 mg), 54 mg (IQR 50–71 mg), and 18 mg (IQR 16–23 mg), respectively. Figure 1 presents a radar plot illustrating continuous MX metrics. The dashed circles reflect accelerations that are associated with a slow (blue) and a fast (red) walk [22]. The sample achieved on average 30 min of slow walking and 2 min of fast walking per day (Figure 1).

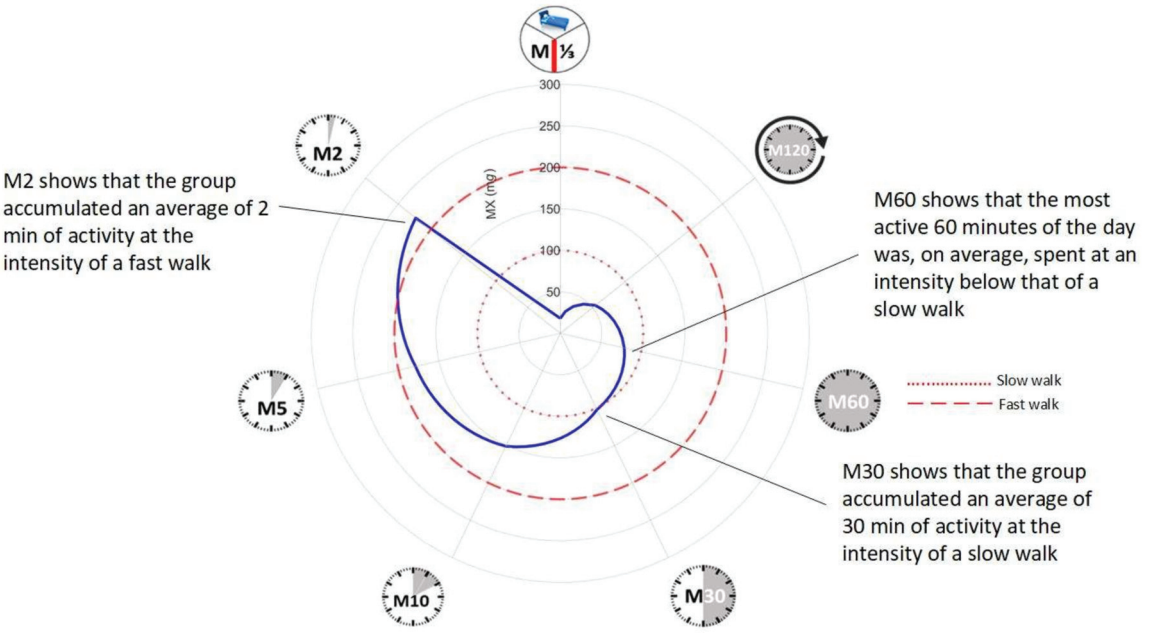

Figure 1. Radar plot illustrating mean MX metrics for the sample (clockwise) for the most active 8 h of the day (M1/3DAY), 120 min (M120), 60 min (M60), 30 min (M30), 10 min (M15), 5 min (M5), and 2 min (M2). The dashed red lines represent indicative values for: slow walking (.....) and fast walking (---) [24].

4. Discussion

This study describes the habitual physical activity and sleep characteristics of people with or at risk of diabetes-related foot complications in a regional Australian population. The results showed that the participants were insufficiently active with high amounts of sedentary behaviours, and they slept for shorter durations than recommended.

The American Diabetes Association guidelines recommend that adults with diabetes should engage in 150 min or more of moderate-to-vigorous activity per week, undertake daily exercise (with no more than two consecutive days without activity) including both aerobic and resistance exercises, and reduce sedentary behaviour [7]. The participants in this study performed less than half the recommended weekly MVPA, mean METs indicated daily intensity of activity was equivalent only to sitting [28,29], and MX metrics indicated that that participants failed to engage in daily physical activity at an intensity above that of a slow walk for 60 continuous minutes. This in contrast to (pre COVID-19 pandemic) Australian census data showing that 26.1% of adults 65 years and over engaged in 30 min of exercise on 5 or more days [30]. These findings are concerning. Physical activity has many benefits for people with diabetes, including those with or at risk of diabetes-related foot complications; benefits include weight reduction, enhanced blood glucose control, reduced cardiovascular risk factors, improved balance, and likely also improved peripheral nerve function [7,9,31]. Additionally, high sedentary time has been found to be an independent predictor of the development of diabetes-related ulceration in people with peripheral neuropathy [32], and it is also associated with an increased risk for metabolic syndrome, cardiovascular disease, and all-cause mortality [33,34].

It is clear that there are positive health benefits of exercise for people with or at risk of diabetes-related foot complications [9,35]. There is also consolidated information about the recommended types of exercise, as well as frequency and duration. The American Diabetes Association position statement on exercise and type 2 diabetes recommends that

all adults with type 2 diabetes reduce sedentary time and that a combination of aerobic and resistance exercise training is required for optimal glycaemic and health outcomes [7]. For most adults, this includes 150 min or more of moderate-to-vigorous activity weekly, and 2–3 sessions/week of resistance exercise [7]. The ADA also recommends supervised training over non-supervised training [7]. More recently, Streckman et al. published findings from meta-analyses investigating exercise interventions for people with diabetes-related peripheral neuropathy in order to derive evidence-based recommendations [9]. A total of 27 randomised controlled trials were included in the review, and results showed that aerobic training of at least moderate intensity (40–70% heart rate reserve) 3–6 times per week for 12 weeks improves glucose control and may improve peripheral nerve conduction. Sensorimotor training was also identified to improve static balance, playing a role in targeting balance control and sensory and motor signs and symptoms of peripheral neuropathy [9].

There are challenges to facilitating increased physical activity, and a variety of individual and social factors have been shown to influence physical activity uptake in adults such as age, income, rurality, and social support, and the relatively low physical activity and sleep duration reported in this study are consistent with non-urban, older populations [36–38]. These factors may contribute to the gap that exists between intent and actual behaviour, with as many as 46% of individuals failing to follow through with their long-term intentions regarding physical activity [39]. Data from this aforementioned meta-analysis indicate that motivation, self-regulation, and habit/automaticity are also likely to be influential psychological constructs [39]. Further challenges in the sub-population include a reluctance from health professionals to facilitate increased weight-bearing physical activity through a perceived concern of skin trauma and subsequent ulceration. Current national Australian recommendations from Diabetes Feet Australia do not provide information about exercise, apart from cautioning that an increase in physical activity should be gradual [40]. However, as early as 2008 evidence emerged that weight-bearing activity for this population does not increase the rate of foot ulcers, and there is a call for a paradigm shift towards maintaining and increasing physical activity [41,42]. Results from subsequent studies have consistently demonstrated that with adequate baseline screening, participant selection, and appropriate footwear, the risk of further ulceration in response to activity is low [9–11]. The European Wound Management Association has investigated the exercise interventions in people with current ulceration and suggests that some weightbearing is not detrimental to ulcer healing (if appropriate footwear is ensured) [43]. Better mechanisms are needed to assist health professionals and people with diabetes to increase their physical activity in accordance with guidelines and their particular circumstances. This should include access to affordable health professional support. In Australia, this could include better utilisation of government funding sources to enable engagement of an exercise physiologist for appropriate assessment and subsequent design of an exercise program, which can include group exercise programs [11,44].

Total MVPA time is lower than previously reported in a metropolitan Australian setting. Lee at al. reported that participants with diabetes with or at risk of diabetes-related foot morbidity performed $\geq$30 min of MVPA most days of the week, although the MVPA was accumulated in short durations rather than meeting the criteria of an exercise bout and therefore was likely to be incidental [45]. It is also possible that the discrepancy in findings can be attributed to differences in the micro-technology and algorithms used to estimate physical activity intensities [18,46]. The previous Australian research reported daily physical activity outcomes from data derived from the SenseWear Armband (BodyMedia Inc.; Pittsburgh, PA, USA) in a similar population to the current study [14,45], and caution is required when making comparisons [19]. The sedentary time of over eleven hours each day is similar to previous studies using accelerometry [14], and the self-reported Physical Activity Scale [32] data to measure physical activity. The MX metrics findings are comparable to those reported by authors of a relatively large observational trial of people

with type 2 diabetes who also failed to meet or just met 60 min of continuous activity at or above an intensity reflective of a slow walk [23,47].

Recommended sleep duration for adults up to 64 years is 7–9 h per day, and for those over 64 years is 7–8 h per day [48]. The sample reported a shorter sleep duration than these recommendations, and shorter sleep duration than a representative sample from the general population of people aged over 64 years [49]. For people with diabetes, a short duration of sleep has been shown in a meta-analysis to be associated with worse glycaemic control [50]. Restricted sleep is thought to effect hormonal regulation of appetite, leading to elevated appetite that could lead to an increase in body mass index and insulin resistance [50,51], and a recent cohort study has shown that people with diabetes with inadequate sleep duration have a higher risk of coronary heart disease and all-cause mortality [52]. For a person with diabetes, reduced sleep can also impact the inclination to undertake self-care behaviours and exercise [53]. Specific data on sleep in people with or at risk of diabetes-related foot complications is limited, with a recent scoping review identifying 12 heterogeneous observational studies that investigated a variety of foot health and sleep outcomes [54]. The authors suggest a possible association between obstructive sleep apnea and the presence or history of diabetes-related foot ulceration, but high-quality research is needed to understand the role sleep duration and quality has on the prevention or treatment of diabetes-related foot complications.

Although the between-groups analysis did not find a statistically significant difference in physical activity or sleep outcomes between participants with no history of ulcer and those with history of ulcers, there was a trend for the history of ulcer (i.e., higher-risk) group to exhibit increased energy expenditure in comparison to the group with no ulcer history. Increased energy expenditure has also been observed in worse foot morbidity groups such as those with a current diabetes-related foot ulcer [14]. For those with an active ulcer or peripheral neuropathy, it is possible that increased energy expenditure is due to wound healing and the adoption of an inefficient gait pattern [14,55], but research into possible energy imbalance across people with different levels of foot morbidity is required [14].

The results of the study need to be interpreted considering some limitations. The sample size is small, and from a regional area of Australia. The findings might not be generalisable to other populations from different geographical areas, and the between-groups analysis may be underpowered to make definitive conclusions. The descriptive nature of the study did not allow detailed assessment of broad factors associated with undertaking physical activity or sleep patterns. However, this is the first time that data from a regional Australian population has been reported, which has extended previous Australian research [14,45]. Wear time from participants indicated excellent participant adherence to the 14-day data collection period of continual 24 h accelerometer wear, similar to the previous Australian studies [14,45]. This is consistent with emerging evidence that people with or at risk of diabetes-related foot complications have a positive attitude and high self-efficacy towards using technology to monitor foot health [56]. Wearable devices, such as accelerometer-based motion sensors, can capture a variety of physical activity outcomes and have gained popularity due to their ease of use, availability, and objective measurement of physical activity [46]. However, large variances can exist in predicted physical activity according to the type of accelerometer, where the device is worn (e.g., wrist or waist), and analysis technique [18,19,46]. To overcome some of these challenges, the ActiGraph triaxial accelerometer used in this study (GT3X+; ActiGraph LLC, Penascola, FL, USA) has been shown to be reliable and valid for older adults with type 2 diabetes [57], and to overcome the limitations of traditional linear-regression-based predictive analysis of physical activity, a CNN deep learning algorithm was used to estimate energy expenditure in this population [20]. The MX metrics, reported for the first time for this population, provide practical ways to conceptualise patterns of physical activity.

5. Conclusions

This is the first study of habitual physical activity patterns and sleep duration of people with or at risk of diabetes-related foot complications in a regional Australian population. A variety of novel validated measures of physical activity and sleep were used for this population. Participant engagement with the monitoring was excellent. By all measures, the results showed that people with or at risk of diabetes-related foot complications are not meeting physical activity or sleep duration guidelines, undertake insufficient MVPA, and are largely sedentary. The novel MX metric data suggest that the most active 60 min of each day are undertaken at an intensity lower than a slow walk. It is important that health professionals seek ways to facilitate significantly increased habitual physical activity in this population in accordance with established guidelines.

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The Validity and Reliability of Self-Reported Adherence to Using Offloading Treatment in People with Diabetes-Related Foot Ulcers

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Abstract: Adherence to using offloading treatment is crucial to healing diabetes-related foot ulcers (DFUs). Offloading adherence is recommended to be measured using objective monitors. However, self-reported adherence is commonly used and has unknown validity and reliability. This study aimed to assess the validity and reliability of self-reported adherence to using removable cast walker (RCW) offloading treatment among people with DFUs. Fifty-three participants with DFUs using RCWs were included. Each participant self-reported their percentage adherence to using their RCW of total daily steps. Participants also had adherence objectively measured using dual activity monitors. After one week, a subset of 19 participants again self-reported their percentage adherence to investigate test–retest reliability. Validity was tested using Pearson's r and Bland–Altman tests, and reliability using Cohen's kappa. Median (IQR) self-reported adherence was greater than objectively measured adherence (90% (60–100) vs. 35% (19–47), $p < 0.01$). There was fair agreement (r = 0.46; $p < 0.01$) and large 95% limits of agreement with significant proportional bias ($\beta = 0.46$, $p < 0.01$) for validity, and minimal agreement for test–retest reliability (K = 0.36; $p < 0.01$). The validity and reliability of self-reported offloading adherence in people with DFU are fair at best. People with DFU significantly overestimate their offloading adherence. Clinicians and researchers should instead use objective adherence measures.

Keywords: adherence; diabetic foot; foot ulcer; offloading; self-report

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1. Introduction

Diabetes-related foot ulcers (DFUs) affect around 20 million people globally [1,2] and are responsible for high incidences of hospitalisations, amputations, disability, treatment costs, and premature death [1,3–6]. DFUs are typically caused by high plantar pressure in people with a loss of foot sensation from diabetes-related peripheral neuropathy [2].

International DFU guidelines have long concluded that offloading high plantar pressure from DFUs is crucial to healing people with DFU [7]. Non-removable offloading devices are recommended as the gold standard offloading treatment for people with DFU [8,9]. However, implementing non-removable offloading devices in clinical practice has been

found to be challenging due to the technical skills required to customise non-removable offloading treatments, such as total contact casts [10–13], and people's preferences for not using offloading devices all the time, such as when not bearing weight [10,12]. The second-choice recommended offloading treatments are removable offloading devices, such as removable cast walkers, which are more commonly used in clinical practice and offer very similar plantar pressure reductions to non-removable offloading devices [14]. However, although removable offloading devices offer similar plantar pressure reductions, they have been found to be much less effective at healing DFU due to people's low adherence to using these removable devices [8,15,16]. Thus, adherence to using removable offloading devices has been highlighted in the latest international DFU guidelines as an important topic for future research [7].

Guidelines recommend using objective measures to assess adherence to offloading treatment in patients with DFU [7,17]. Examples of such measures include wearable activity monitors to measure the proportion of adherence to total weight-bearing activity [17,18], or temperature monitors to measure the proportion of adherence of total treatment time [19]. However, there are barriers to using these objective monitors, such as costs of monitors [20], privacy concerns [20,21], technical skills required to use [15,22], and limited battery power to use over long periods [23]. On the other hand, people's self-reported adherence is more commonly used in clinical practice and research, as it has been shown to be quick, affordable, and easy to implement [24]. However, self-reported adherence measures have been shown to be unreliable compared to objectively measured adherence in other similar treatments, such as brace treatments for clubfoot or scoliosis [25–27].

To our knowledge, people's self-reported adherence to offloading treatment among people with DFU has not been tested for validity or reliability. The assessment of validity and reliability of self-reported scales of offloading adherence should guide researchers to know whether they can rely on using self-reporting measures and potentially overcome the aforementioned challenges associated with objective measures of adherence. Furthermore, clinicians should be informed if they can use their patients' self-reports of adherence as a valid source of assessing adherence to prescribed offloading treatments in clinical practice. Thus, this study aimed to assess the validity and reliability of self-reported adherence to using removable cast walker (RCW) offloading among people with DFUs.

2. Materials and Methods

2.1. Study Design and Settings

This was a secondary analysis of a larger multi-centre study with a cross-sectional design that aimed to examine adherence to wearing removable cast walkers (RCWs) [16]. Data were collected from three main referral diabetes-related foot clinics in Amman, Jordan, including (i) the National Centre for Diabetes, Endocrinology, and Genetics; (ii) Jordanian Royal Medical Services; and (iii) the Prince Hamza Hospital.

2.2. Participants

Eligible participants were adults (>18 years) with diabetes (type 1 or 2) and a plantar DFU, and had been using an RCW for at least four weeks prior to recruitment. A plantar DFU was defined as a full-thickness wound on the plantar surface of the foot in a person with diabetes [16,28]. Removable cast walkers were defined as prefabricated knee-high offloading devices that could be removed by the patient [7,16]. Participants were required to have used RCW for at least four weeks prior, to reduce any effect of initially elevated RCW adherence after receiving offloading treatment as previously identified [29]. Participants who were managed by non-removable offloading devices, unable to ambulate without a walking aid, or had cognitive impairment or illiteracy were excluded [16]. We used data from 53 eligible participants from a larger study who both self-reported adherence and had their adherence objectively measured to test validity [16,30]. The sample size calculation of the larger study was based on five factors, including a final multiple linear regression model with a minimum of 10 participants needed for each included factor and accounting

for a 5–10% drop out rate (16). The original sample was considered large enough for this validity study, and a subset of 20 participants were asked to self-report adherence again at a second visit to test reliability based on sample size needed for appropriate interval estimation for Cohen's kappa [31].

2.3. Variables Collected

The definitions for all variables collected have been previously detailed elsewhere [16]. Sociodemographic variables included age, gender, living arrangement, highest education level achieved, employment, and family income (in Jordanian Dinar (JOD)) [16,30]. Medical variables [16,30] included diabetes type, diabetes duration, body mass index (BMI), previous DFU history, current DFU duration, duration of offloading device use [32], peripheral neuropathy [28], peripheral artery disease (PAD) [28], foot deformities, amputations [28,33], DFU area [32], DFU infection, and DFU grade [34].

2.4. Outcome Measures

2.4.1. Self-Reported Adherence

Self-reported adherence to using RCW was measured by asking participants to estimate their adherence to using their RCW during total weight-bearing steps on a typical average day, by completing a 10-point visual analogue scale (VAS) converted to a percentage of adherence (0–100%) [30,35,36]. This self-reported adherence measure had been developed, tested for face validity, and translated into the Arabic language as previously detailed elsewhere [30] (see Supplementary Material File S1 for Arabic and English versions of the self-reported adherence measure).

2.4.2. Objective Adherence (Criterion Measure)

Objectively measured adherence to using RCW was measured using a validated dual-activity monitor method over one week [15]. Fitbit Flex© activity monitors were used, which have been shown to be valid and reliable among elderly populations to measure steps [37–40]. One Fitbit monitor was attached to the RCW to measure the steps when the RCW was used, and the other monitor was worn on the wrist by the study participants to measure their total steps [16]. Participants were instructed to wear wrist monitors at all times for the seven-day period, of which they were reminded daily via text or audio messaging [16]. Participants were concealed from the aim of the measurement to avoid biasing their natural adherence behaviour [17], and otherwise, they received usual adherence instructions from their treating clinicians [16]. After 1 week, monitors were returned, and the steps data were synchronised into 15 min activity units. Adherence to an activity unit was deemed when the activity monitor attached to the RCW recorded at least 50% of the steps recorded by the wrist monitor in the 15 min activity unit [15–17,41]. Objective adherence was then reported as the percentage of adherent activity units in the total activity units [15,16,41].

2.5. Procedure

At the initial study visit (baseline), all demographic and medical variables were collected, along with participants' self-reported adherence. The activity monitors were then installed on participants to objectively measure adherence for the one-week period. The activity monitors were returned after one week at a second study visit during regular wound care follow up. At this second visit, the subset of 20 participants was selected by asking every 3rd participant to again self-report their adherence by completing the same aforementioned scale [16,30].

2.6. Statistical Analysis

Data analysis was conducted using SPSS 23.0 for Windows (IBM Corp, Armonk, NY, USA). Descriptive analysis included frequencies (proportions), mean (standard deviation (SD)), and median (interquartile range (IQR)). Wilcoxon signed ranks test was used to test the difference between nonparametric adherence outcomes. Pearson's correlation (r) was used to test the strength of agreement for validity between self-reported adherence and objectively measured adherence outcomes, in which $r > 0.75$ was considered excellent; $r = 0.50–0.75$ was good; $r = 0.25–0.49$ was fair; and $r < 0.25$ was no agreement [42]. Bland–Altman plots were also used for validity to estimate if the differences between both measurements of adherence led to large mean and 95% limits of agreement and if there was any estimation bias during reporting different levels of adherence. Linear regression was further used to test the significance of the potential proportional bias between the mean difference between self-reported adherence and objective adherence and the mean of these two measurements [43]. Cohen's kappa was used to reflect the self-reported test–retest reliability agreement in the subset. The Kappa values were considered no agreement in the range 0–0.20; minimal agreement 0.21–0.39; weak agreement 0.40–0.59; moderate agreement 0.60–0.79; strong agreement 0.80–0.90; and almost perfect agreement >0.90 [44].

3. Results

3.1. Characteristics

Table 1 displays the sociodemographic and medical characteristics of the 53 participants, including a mean (SD) age of 55 (10) years, 77% were male, 94% had type 2 diabetes, 91% had peripheral neuropathy, 26% had PAD, 30% had minor amputation(s), 51% had infected DFU, and 42% had deep DFU, and there was a median (IQR) duration of prior RCW use of 12 (4–32) weeks. Of the 20 participants selected in the subset and asked to test–retest self-reported adherence, 19 completed the self-reported adherence scale at the second visit (retest) and one missed completing the scale.

Table 1. Participant sociodemographic and medical characteristics (number (%) or mean ± SD unless otherwise stated^).

Characteristics	Total
Numbers	**53**
Age (years)	55.3 (9.9)
Males	41 (77.4%)
Living with family	49 (92.5%)
Secondary school education	24 (45.3%)
Retired	17 (32.1%)
Family income (JD) ^	400 (300–712.5)
Type 2 DM	50 (94.3%)
Duration of diabetes (years)	17.7 (7.0)
HbA1c (%, mmol/L)	8.9 (2.1)
BMI	31 (6.5)
Daily steps (wrist activity monitor) ^	2758.4 (1729–4676)
Neuropathy	48 (90.6%)
PAD	14 (26.4%)
Foot deformities	38 (71.7%)
Minor amputations	16 (30.2%)
Major amputations	0 (0%)
History of previous ulceration	35 (67.3%)
Duration of ulcer (weeks) ^	16 (5.0–38)
Ulcer size (cm^2) ^	1.5 (0.5–6.0)

Table 1. *Cont.*

Characteristics	Total
Numbers	**53**
Deep ulcer (UTWCS Grade 2 or 3)	22 (41.5%)
Ulcer infection	27 (50.9%)
Duration of RCW (weeks) ^	12 (4.0–32.0)

^ Displayed as median (IQR). Abbreviations: BMI: body mass index, CM: centimetre, DM: diabetes mellitus, JD: Jordanian Dinar (JOD), PAD: peripheral artery disease, RCW: removable cast walker, SD: standard deviation, UTWCS: University of Texas Wound Classification System.

3.2. Adherence

Participants' median (IQR) self-reported adherence at a baseline of 90% (60–100) was significantly higher than the objectively measured adherence of 35% (19–48) ($z = 6.19$, $p < 001$). There was no statistical difference between the median (IQR) self-reported adherence reported at the baseline visit (90% (60–100)) and the second visit in the subset of $n = 19$ participants (80% (70–100)) ($z = -0.26$, $p = 0.80$).

3.3. Validity

The self-reported adherence demonstrated only fair agreement with objectively measured adherence ($r = 0.46$; $p < 0.05$). Figure 1 displays a lower right skewing of self-reported adherence data when plotted against the objective adherence data, indicating an overestimation of self-reported adherence. Figure 2 displays a mean difference (95% limits of agreement) of 43.0% (3.6–89.6) between the self-reported and the objective adherence in the Bland–Altman plots, indicating large differences between self-reported and objective adherence. The linear regression model also identified a significant proportional bias for self-reported adherence ($\beta = 0.46$, $p < 0.01$), indicating a significant and systematic overestimation of the self-reported adherence to using RCW.

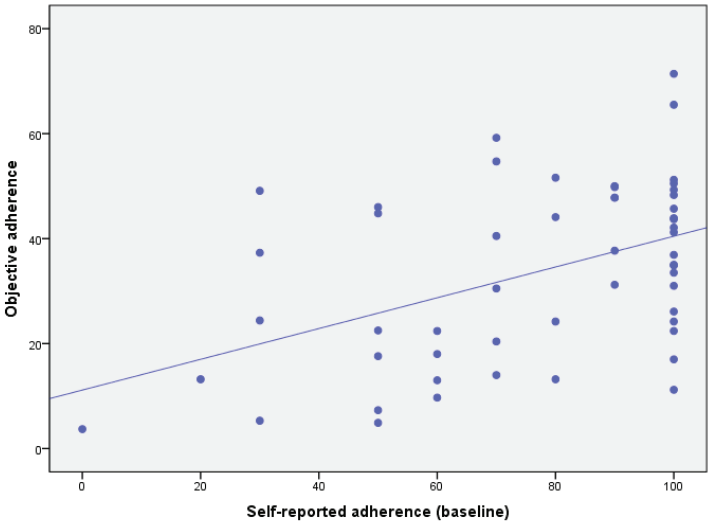

Figure 1. Scatter plots depicting self-reported adherence percentage compared to the objectively measured adherence percentage to using RCW.

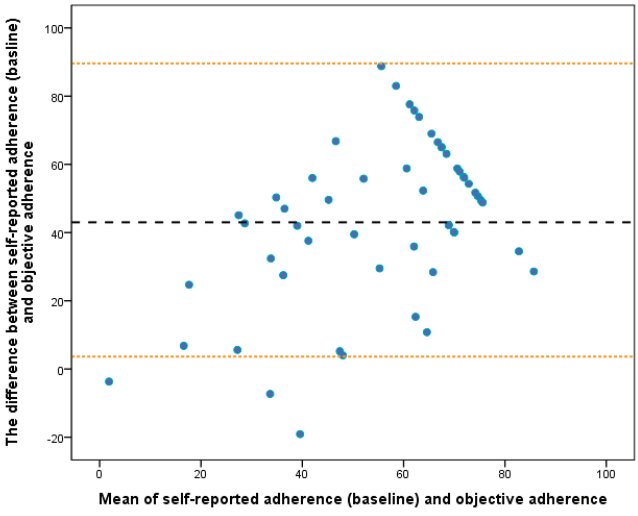

Figure 2. Bland–Altman plot depicting the agreement between the self-reported and objectively measured adherence to wearing RCW using activity monitors. The dashed black line represents the mean difference between self-reported and objective adherence, and the orange dashed lines represent the upper and lower limits of agreement.

3.4. Reliability

The self-reported test–retest adherence measured at the first baseline visit and second visit in the subset of participants also demonstrated only minimal agreement (Kappa (SE) = 0.36 (0.12); $p < 0.01$).

4. Discussion

We tested the validity and reliability of self-reported adherence to using removable offloading treatment (RCW) among people with DFUs. We found a median self-reported adherence of 90% of daily steps, which was a significant overestimation in comparison to the 35% objectively measured adherence using dual-activity monitors. For validity, we found only fair agreement between self-reported adherence and objective measures and noticed a systematic bias towards higher self-reporting of adherence. The bias increased when reporting higher levels of adherence. This indicates that patients with DFUs are not able to accurately assess their offloading adherence. For test–retest reliability, we found minimal agreement between two self-reported adherence measures one week apart, indicating limited stability when patients self-report adherence. These findings suggest that current methods of self-reporting of offloading adherence by patients with DFUs have limited validity and reliability.

Our findings of a significant overestimation of adherence aligns with previous adherence studies in other conditions that compared self-reported and objective measurements, such as in clubfoot, cystic fibrosis, idiopathic scoliosis, and chronic knee pain [25–27,45,46]. Studies suggest that patients may overestimate their adherence to avoid conflicts with their clinicians [47], to be socially desirable (i.e., people like to be seen as "good people") [48], due to memory bias [24], or due to a distorted perception of adherence itself [49]. In the context of adherence to offloading treatment in people with DFU, a recent qualitative investigation by our group found that patients may overestimate their adherence due to a distorted perception of offloading adherence [30]. Patients considered that adherence to using offloading treatment was only required for weight-bearing activity outside the house or during the daytime, whereas they perceived using their offloading devices inside the house or during night-time when weight-bearing as not being part of adherence require-

ments [30]. Moreover, a recent qualitative meta-analysis demonstrated that patients with DFUs might not have adequate understandings regarding causation, timelines, and related consequences of DFUs, and this may also lead to a distorted perception of adherence, which may result in inaccurate estimation [50]. We recommend clinicians clarify with patients that total adherence means using their offloading treatment during any weight-bearing activity, outside or inside the house, especially as studies have shown that most weight-bearing activity in this population is performed inside the house [51]. However, while this hypothesis is plausible, further studies are needed to confirm if patients do have a distorted perception of adherence to using offloading or if other factors may be impacting their significant overestimation of adherence to offloading treatment.

Overall, estimating self-reported adherence to using the offloading device may be a challenging task for patients with DFU. The significant overestimation by patients found in this study is likely to mislead patients and clinicians as to the effectiveness of removable offloading treatments to heal DFUs. Therefore, when measuring adherence, we recommend clinicians and researchers do not use the current self-reported measures, and instead use recommended objective measures of offloading adherence [17,23], such as dual-activity monitors to measure adherence during weight-bearing activity [20] or the in-device temperature monitors to measure adherence during treatment time [19]. Furthermore, the recent incorporation of objective self-monitoring adherence technology within offloading devices ("smart offloading boots") seems a promising option to provide patients and clinicians with objective real-time monitoring of adherence in the future [18]. This may result in adherence enforcement to using offloading treatment, which may positively contribute to enhanced adherence and in turn improved healing rates similar to those found in non-removable offloading devices. Such self-monitoring technology may also help researchers to examine other factors associated with adherence to offloading treatment among patients with DFUs. Otherwise, developing demonstrated valid and reliable self-reported measures of adherence to offloading treatment in the future would still be a valuable addition to the field, as self-reported measures have been found quick, affordable, and easy to implement.

Strengths and Limitations

The strengths of this study included comparing a self-reported method of reporting adherence typically used in clinical practice and research against a recommended validated objective dual activity monitor method in an appropriate sample to test validity and reliability. In addition, we used a minimum of four weeks' prior experience of using RCW as an inclusion criterion to be more representative of the typical adherence behaviour patterns of patients with DFU [29]. However, the limitations of this study also need to be considered. First, there was a slight difference in the units of measurement used for the self-reported and objective adherence measures. The self-reported measure used the percentage of daily steps, while the objective measure used the percentage of daily activity units as recommended for objective adherence measures [15,17]. However, we consider that these slight differences in units should not have had any major impact on findings, as activity units are also made up of the percentage of steps using the offloading device per 15 min period, and as such, are a similar measure to the percentage of daily steps. Furthermore, it would be challenging for patients to understand and self-report adherence for daily activity units. Second, participants were asked to self-report their adherence for an average typical day, whereas the objective measure captured percentage adherence for a set one-week period. However, we included participants with at least four weeks of prior use of RCW treatment [29], and we chose the one-week period because four weekdays and one weekend day have been shown to be representative of average daily activity in physical activity studies [16,17,52–54], and thus we should have a representative sample of the true daily activity of a DFU population. Third, the sample size was based on the sample size calculations of our main study that used regression and not specifically for this analysis of validity and reliability [16]. Sample size calculations and potentially larger sample sizes are recommended for similar studies in the future. Last, there was a possibility of not wearing

the wrist activity monitors; however, we attempted to minimise non-adherence of wearing wrist trackers via daily reminders to participants [16,30].

5. Conclusions

This study suggests that people with DFUs substantially overestimate their adherence to using offloading treatment compared to objective measures. In addition, we found only fair agreement at best to support the validity and reliability of self-reported adherence and significant proportional bias. Thus, it seems that self-reported adherence is not an accurate or reliable measure of actual adherence. We recommend that clinicians and researchers adopt objective measures to avoid misleading measurements of removable offloading adherence until improved self-reported measures are developed and tested in the future.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/s23094423/s1, Supplementary File S1 contains the Arabic and English versions of the self-reported adherence measure.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data available on request due to privacy restrictions. The data presented in this study are available on request from the corresponding author.

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Conflicts of Interest: A.A. had worked as a clinician at the NCDEG and this may be regarded as a potential conflict of interest. Otherwise, the authors declare no other relevant conflicts of interest.

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sensors

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Article

A Wearable Insole System to Measure Plantar Pressure and Shear for People with Diabetes

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Abstract: Pressure coupled with shear stresses are the critical external factors for diabetic foot ulceration assessment and prevention. To date, a wearable system capable of measuring in-shoe multi-directional stresses for out-of-lab analysis has been elusive. The lack of an insole system capable of measuring plantar pressure and shear hinders the development of an effective foot ulcer prevention solution that could be potentially used in a daily living environment. This study reports the development of a first-of-its-kind sensorised insole system and its evaluation in laboratory settings and on human participants, indicating its potential as a wearable technology to be used in real-world applications. Laboratory evaluation revealed that the linearity error and accuracy error of the sensorised insole system were up to 3% and 5%, respectively. When evaluated on a healthy participant, change in footwear resulted in approximately 20%, 75% and 82% change in pressure, medial–lateral and anterior–posterior shear stress, respectively. When evaluated on diabetic participants, no notable difference in peak plantar pressure, as a result of wearing the sensorised insole, was measured. The preliminary results showed that the performance of the sensorised insole system is comparable to previously reported research devices. The system has adequate sensitivity to assist footwear assessment relevant to foot ulcer prevention and is safe to use for people with diabetes. The reported insole system presents the potential to help assess diabetic foot ulceration risk in a daily living environment underpinned by wearable pressure and shear sensing technologies.

Keywords: diabetic foot ulcer; pressure; shear; insole system; plantar stress

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1. Introduction

Approximately one in three people with diabetes develop a diabetic foot ulcer (DFU), and among them, one in four of them will progress to lower limb amputation [1,2]. The management of DFU is challenging as the risk of re-ulceration is 40% within the first year and 65% over five years [1]. The five-year survival rate after diabetes-related amputation is up to 50%, which is worse than breast and prostate cancers [3]. This evidence suggests that the current DFU prevention strategy, involving education, screening and foot care, in the UK National Health Service (NHS) is not fully effective and remains elusive. It is also well-recognised that a research-led solution is one of the key solutions to help address this issue [1,4,5]. Wearable devices adopting a user-centered design and using IoT technologies to monitor health conditions may offer a way to improve outcomes [6].

The development of DFU is a complex process, especially for people with combinations of peripheral neuropathy, peripheral arterial disease, and foot deformity. Neuropathy results in the loss of protective sensation, which in combination with a foot deformity or insufficient blood flow, leads to localised tissue injury and tissue death [7]. The load acting upon the foot includes pressure acting perpendicular and shear acting parallel to the

surface of plantar tissue. Pressure is known to be one of the key external causes of DFU, and a threshold of 200 kPa has been advised as a target for pressure-relieving footwear and orthotic interventions for those who have previously ulcerated (measured under clinical conditions) [8]. Long-term and daily monitoring of pressure and providing alerts to patients when excessive pressure is identified have been shown to reduce ulceration risk [9]. However, The National Pressure Ulcer Advisory Panel et al. [10] reported that the combination of pressure and shear is responsible for ulceration. Bader et al. [11] reported that both pressure and shear exerted on the skin could cause internal shear stresses in the underlying tissues, which act to distort tissues, pinch and occlude capillaries crossing tissue planes, reduce blood and lymphatic flow and cause physical disruption of tissues and contribute to diabetic foot ulceration. Plantar tissue for people with diabetes also tends to have a reduced tolerance to external loading and, when coupled with bony prominences such as heel, metatarsal heads and hallux, further exacerbates ulceration risk. The IWGDF [12] has also long recognised that pressure is coupled with shear stress, and both have an impact on cell and tissue integrity. Both shear and pressure are therefore important for DFU risk assessment, and indeed, elevated shear stress has been reported at key sites at risk of plantar ulceration during walking under controlled laboratory conditions [13] but never in real-world conditions.

Insole systems that are sensitive to pressure but not shear have previously been developed for laboratory research purposes [14–16] as well as for the purpose of monitoring foot pressure in real-world living conditions. This includes the F-Scan System (Tekscan, Inc., Norwood, MA, USA), pedar (novel GmbH, München, Germany), XSENSOR (XSENSOR® Technology Corporation, Calgary, AB, Canada) and Orpyx SI (Orpyx Medical Technologies Inc., Calgary, AB, Canada). However, none of these can measure shear forces at the same time when pressure is measured. To provide comprehensive assessment of plantar loading, tools were reported to measure multi-directional plantar forces but only in laboratory settings [13,17,18]. These include a strain gauge-based pressure and shear sensing platform which was designed only for barefoot conditions [13] and thus is not a wearable solution. Wang et al. [17] developed an inductive-based insole sensing system, which requires specific footwear modification and strapping electronic devices on the shank, limiting its adaptation to common footwear. Takano et al. [19] developed a system consisting of a combined shear force sensor and F-Scan pressure sensor; however, it requires a specialised insole, an electronic box to be worn and a wired connection to a computer, which again is not wearable in everyday living. Amemiya et al. [18] directly attached piezoelectric-based sensors to the metatarsal heads, and it is not a wearable system that could be worn by patients outside the lab. The motivation of this study is to develop a sensorised insole system that is capable of measuring both pressure and shear stress but also can be adapted to a range of footwear without modification. Such a wearable system could underpin a diabetic foot ulcer prevention solution based on comprehensive plantar pressure and shear monitoring during daily living activities. Based on a previously reported tri-axial pressure and shear (TRIPS) sensing system [20], a sensorised insole system capable of measuring both pressure and shear simultaneously has been developed. The TRIPS sensors are thin and flexible and have previously been applied at the residuum/socket interface of lower limb amputees to measure real-time kinetic residuum and socket interactions [20,21]. In this work, we focus on reporting the design, development and evaluation of the sensorised insole system which incorporates TRIPS sensing technology. The insole with sensor integration was evaluated using both laboratory-based and human participants tests. The potential of using this wearable insole system for future DFU prevention is discussed.

2. Development of the Sensorised Insole System

The TRIPS sensors' working mechanism, design and development have been detailed in our previous publications [22]. In brief, a capacitive sensing mechanism was adopted to measure pressure and shear stresses (in two orthogonal directions) simultaneously as a function of time. Each sensor had an approximate dimension of 20 mm by 20 mm by

1 mm and was flexible. In this work, we focus on reporting the novel development of the sensorised insole system, which integrates these sensors ready for measuring pressure and shear across different plantar sites in real-time. Building upon a previously reported [20] single-sensor system, a bespoke electronic system was designed to incorporate multiple sensors, which requires additional power management, data storage and a system status indication module with a view to improving its usability in the daily living environment.

2.1. Sensor Locations

The sensorised insole contains four TRIPS sensors, with the same dimensions (20 mm × 20 mm × 1 mm) and design, positioned at the heel, 5th metatarsal head (5MH), 1st metatarsal head (1MH) and hallux (Figure 1a). These locations were chosen as they represent the locations of the high occurrence of DFU and enable key gait events to be detected, for example, start and end of stance, heel-only and forefoot-only loading periods [23].

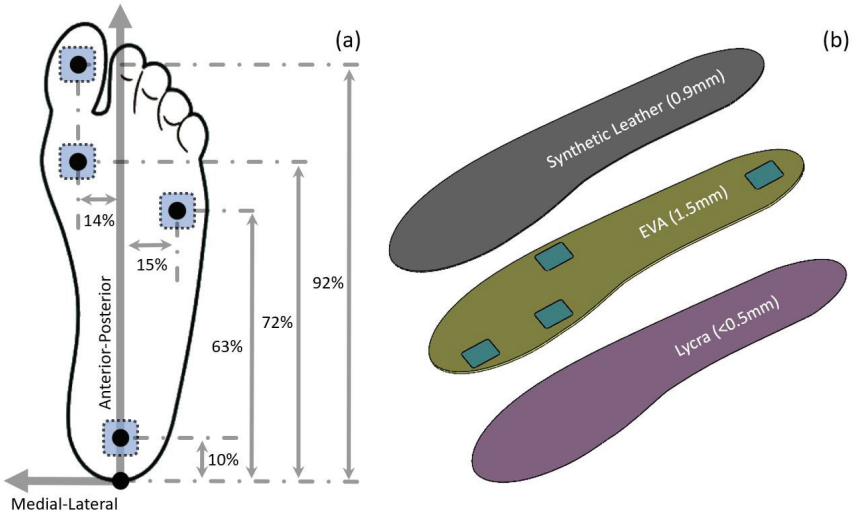

Figure 1. (**a**) Location of the sensors as a percentage of foot length and width. (**b**) Layered sensorised insole construction. The black dots represent the geometrical centre of the sensors.

In the anterior–posterior direction, heel, 5MH, 1MH and hallux sensors were located at approximately 10%, 63%, 72% and 92% of the foot length measured from the posterior-most point. These percentages, in the anterior–posterior direction, were determined based on a foot morphological study [24] and a plantar pressure study [25]. In the medial–lateral direction of the heel, 5MH, 1MH and hallux sensors were located at approximately 0%, 15%, 14% and 15% of the foot width, measured from the long axis of the foot. These percentages, in the medial–lateral direction, were determined using plantar pressure distribution reported in previous studies [26,27].

2.2. Insole Construction

The sensorised insole (Figure 1b) consists of three layers of material, i.e., Ethylene-vinyl acetate or EVA (nora® Lunacell, nora systems GmbH, Weinheim, Germany), synthetic leather (Yampi, A. Algeo Ltd., Liverpool, UK) and Lycra. These are the typical materials used for constructing a layered orthotic insole, as they demonstrate suitability for appropriate biocompatibility, durability and shock absorption against industry standards [28,29]. Sensors were embedded in the middle EVA layer. Four square cut-outs were made to the middle layer such that the sensor could be placed at the corresponding anatomical locations without protrusion. Subsequently, a layer of synthetic leather and a layer of Lycra material were adhered to the top and bottom surfaces of the middle layer, respectively. This was

to ensure there no direct contact between the skin and the sensor to avoid elevated stress introduced by the sensors. The overall thickness of the insole was less than 3 mm and, therefore, could be used as a standalone insole or adhered to a prescribed insole to ensure its wider clinical application.

The sensorised insole was connected to a signal processing and data collection hub via a thin and flexible cable, exiting from the posterior–lateral side of the insole, as shown in Figure 2a. The posterior–lateral exit was chosen for the flexible cable to avoid contact at the navicular region where the tissue is prone to injury. The hub can be attached to the lateral collar of the footwear with no modification required on users' footwear to ensure the device is wearable in a daily living environment, which is critical for monitoring the risk of DFU.

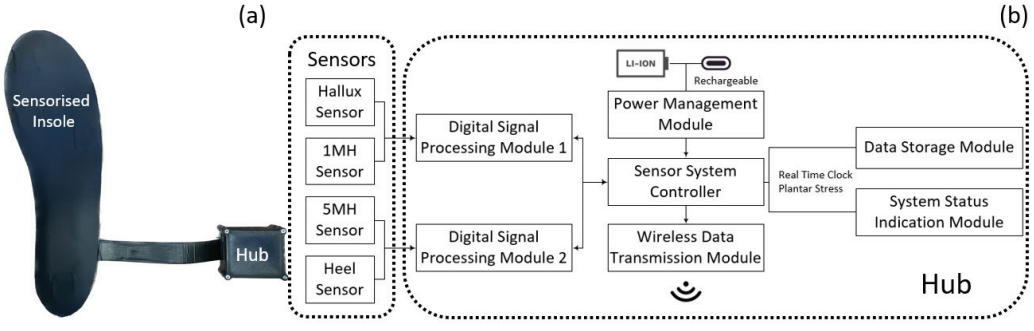

Figure 2. (**a**) A photo of the sensorised insole system and (**b**) a diagram illustrating key function modules within the hub.

2.3. Sensorised Insole System

Figure 2b illustrates the functional diagrams of the electronic system within the hub, formed by key sub-modules. The sensorised insole system consists of a sensorised insole and a hub containing an electronic system for data acquisition and processing. Four sensors were incorporated within an insole, forming a sensorised insole. The operating mechanism of the hub is detailed in a previous publication [20]. In brief, the main functionalities of the electronic hub system are controlled by a 32-bit microcontroller loaded with a real-time operating system which runs multi-threaded applications to manage tasks for each module, as shown in Figure 2b. Signals from the sensorised insole are processed by the digital signal processing module, containing capacitance-to-digital converters, at 100 Hz operating frequency. The digitised sensor signals are then communicated with the sensor system controller via the serial–peripheral interface. The sensor system controller subsequently sends both plantar stress data and real-time clock data to an onboard data storage module via the secure-digital input–output interface for data storage purposes. This provides the capability that plantar stress can be studied as a function of real-time in a year–month–day–hour–minutes format. The hub also provides a wireless data transfer function, so the data can be communicated wirelessly with an external device, such as a mobile phone. From a user perspective, a USB type-C connector is available on the hub for charging purposes, and a simple LED light, controlled by the system status indication module, is provided to the user for hub system status indication.

3. Laboratory Evaluation of the Sensorised Insole System

3.1. Experimental Setup and Test Method

A uniaxial mechanical test machine (E1000, Instron, High Wycombe, UK) with a load cell capacity of ±1 kN was used to evaluate the performance of the insole system. Aluminium platens were designed, manufactured and attached to the test machine with a view of applying known pressure (Figure 3a) and shear stresses (Figure 3b) to the specified

sensor location of the sensorised insole. Static and dynamic loading profiles were designed, and the test machine was programmed to convert the design loading profile to actuator movements. The known applied load from the test machine was then compared with the outputs of our sensorised insole system.

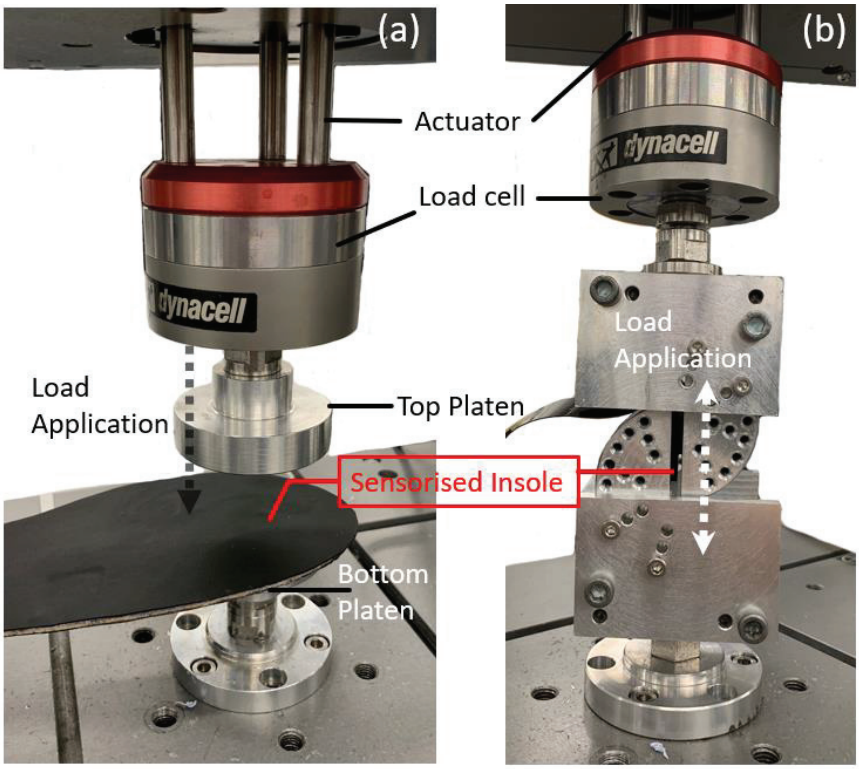

Figure 3. Experimental setup for evaluating (**a**) pressure and (**b**) shear stress measurement from the insole system.

3.2. Pressure

A step loading profile (Figure 4a), incorporating 20 loading and unloading steps with 10 kPa pressure per step, was designed to characterise static pressure measurement from the insole system. In static conditions, a linearity error of 2% was estimated in a measurement range between 0 kPa and 300 kPa (Figure 4b). The cyclic loading profile was designed to evaluate the insole system performance in a controlled laboratory environment by applying representative load experienced during walking. The profile consists of a half sinusoidal wave with a loading amplitude of 250 kPa and a frequency of 1 Hz, followed by an unloading period of approximately 0.5 s. Accuracy error, the estimated percentage of the peak value, is approximately 4% of the full scale in both static and dynamic test conditions.

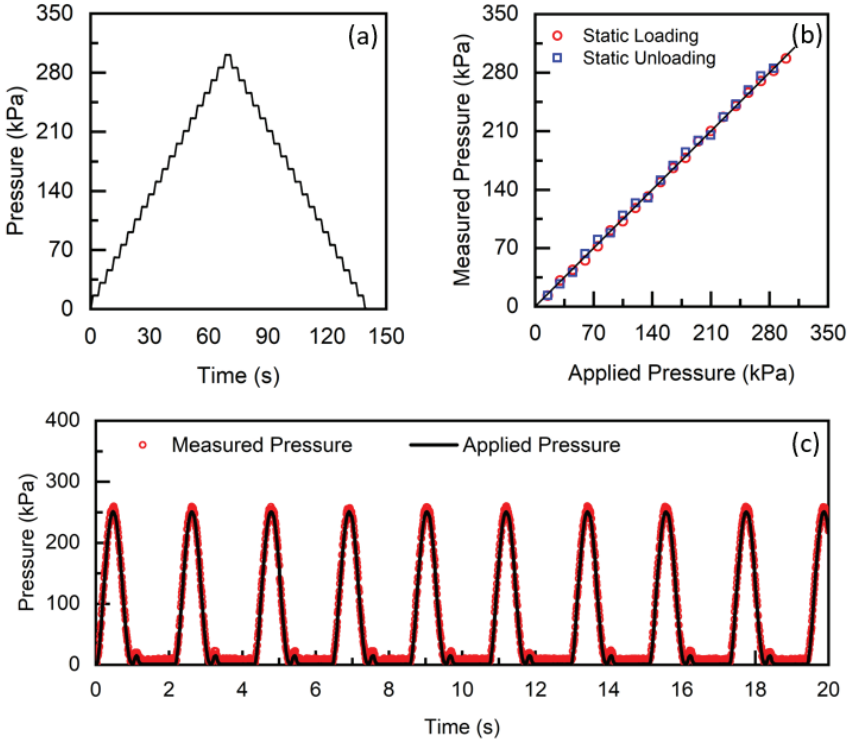

Figure 4. (**a**) Applied static pressure from the Instron mechanical test machine as a function of time. Measured pressure from the insole system and applied pressure from the test machine, obtained from the (**b**) static and (**c**) dynamic pressure test.

3.3. Shear Stress

Similar step-loading profiles were designed to evaluate shear stress measurement from the insole system in a static condition. The step profile consists of 10 loading and unloading steps in both positive and negative directions (Figure 5a). Each loading step corresponds to 9 kPa of shear stress increment. In static conditions, a linearity error of up to 3% was estimated in a measurement range between −90 kPa and 90 kPa. A dynamic shear stress profile was designed such that a half-sinusoidal loading profile was applied with an amplitude of 50 kPa in both positive and negative directions at 1 Hz loading frequency. Followed by the dynamic load phase, an unloading phase of up to 0.5 s was also incorporated. In dynamic conditions, the accuracy error is estimated to be 5% of the full scale.

Stress measurements from the insole system were evaluated in this study. Low linearity errors of up to 3% were revealed in both pressure and shear measurement. The accuracy error (up to 5% of full scale in both pressure and shear) of the insole system reported in this study is equivalent to a recently reported SLIPS system [17], as well as a commercial pressure-only system [30].

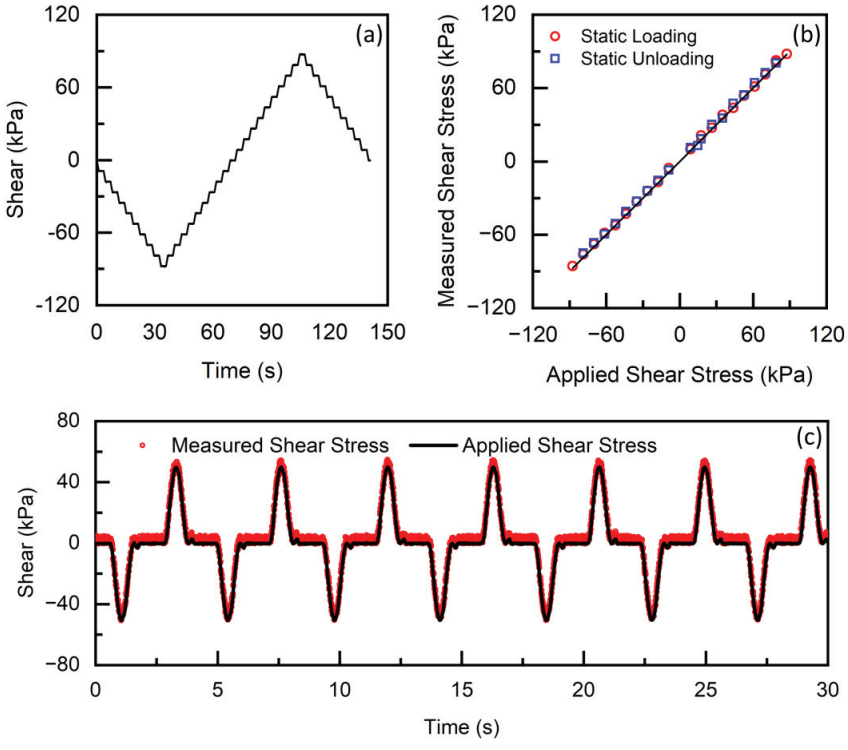

Figure 5. (**a**) Applied static shear stress from the mechanical test machine as a function of time. Measured shear stress from the insole system and applied shear stress from the test machine, obtained from the (**b**) static and (**c**) dynamic shear test.

4. Evaluation of the Sensorised Insole System on a Human Participant

4.1. Test Protocol

One healthy male participant (age 32 years, body mass 97 kg, height 177 cm, UK shoe size 8) with no lower limb injury, or known walking dysfunctions, was recruited for walking tests. The participant was asked to change into a pair of standard socks and trainers (React Miler 3, Nike Inc., Beaverton, OR, USA). The original insole in the trainer was removed and replaced with the sensorised insole. The participant walked for at least five minutes to ensure comfort at the start. Subsequently, he was asked to perform level walking along a 28 m corridor (Figure 6) at a self-selected speed. Walking cadence was recorded by counting the number of steps covered in 30 s and used to define self-selected walking cadence.

The level walking test was repeated with two additional types of footwear (Figure 7). Plimsolls (Figure 7a) and therapeutic footwear (Figure 7c). The plimsoll has a flat outsole, representing typical retail footwear that would not be advised for people with diabetes due to the lack of sole thickness and inadequate upper support. The therapeutic footwear (Omar 11, fisio duna) was designed for people with diabetes [31] and had a forefoot rocker angle of 20°. The self-selected walking cadence was controlled by a digital metronome to minimise the effect of walking speed on plantar pressure and shear measurement.

Figure 6. A photo showing level walking along a 28 m indoor corridor with the device attached to the footwear.

Figure 7. (**a**) Plimsoll with a flat sole, (**b**) trainer as a standard type of footwear used in the experiment and (**c**) therapeutic footwear with rocker features.

4.2. Temporal Pressure and Shear Stress Profile during Level Walking

Figure 8 shows the typical pressure, medial–lateral and anterior–posterior shear stress obtained from a healthy participant as a function of time when wearing a pair of everyday trainers. Peak pressure of up to 200 kPa was obtained across the four locations (Figure 8a). Within the stance phase, four distinctive peaks were revealed, with peak pressure at the heel revealed first in the initial contact phase of the gait and peak pressure at the hallux revealed at last at the hallux location, representing the push-off phase of the gait. These sequence-related peak events, as well as the timing between each of the two peaks, could be metrics of the roll-over characteristics of the foot, important as people with diabetes can experience loss of ankle range of motion and impaired gait as a result [32]. It is also important to note that in-shoe pressure of 200 kPa has been previously recommended by

IWGDF as an indicative threshold to help prevent recurrent foot ulceration risk for people with diabetes. The real-time pressure and corresponding plantar sites reported here could also be potentially explored to facilitate the assessment.

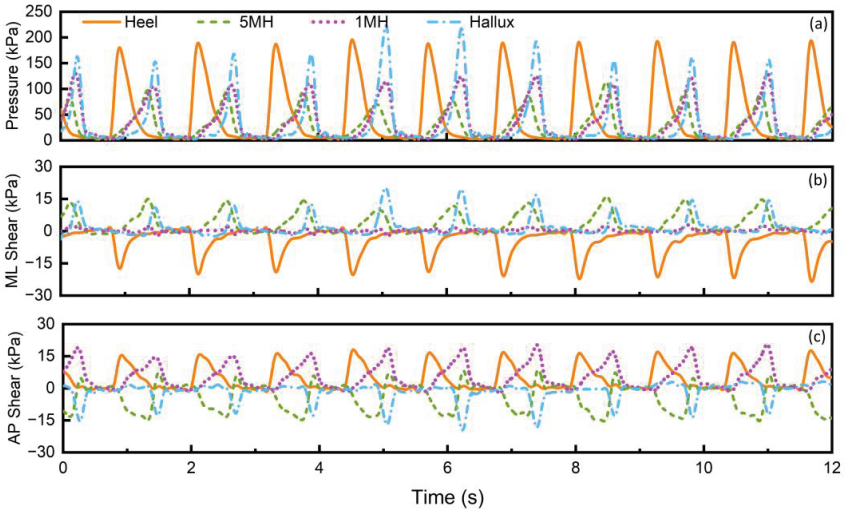

Figure 8. (**a**) Pressure, (**b**) medial–lateral (ML) shear and (**c**) anterior–posterior (AP) shear stress as a function of time from the healthy participant wearing a trainer.

Figure 8b,c illustrates the shear stress in the medial–lateral direction and anterior–posterior direction, respectively. Up to 18 kPa and 16 kPa of peak shear stress were measured in the medial–lateral and anterior–posterior directions across the four locations, respectively. The peak shear stress reported in this study is lower than that measured barefoot, highlighting the difference between in-shoe and barefoot results [33]. It is also worth noting that the peak shear stress was significantly lower than peak pressure, which is consistent with previous studies [13,17]. To our best knowledge, this is the first study that reports in-shoe real-time shear stress in two orthogonal directions, which could be potentially used to study balance in the medial–lateral direction as well as braking and propulsive impulses during gait [34]. These are critical parameters as understanding balance may help better manage the risks of loading asymmetry due to loss of movement control and localised stress distributions, all of which may lead to ulceration [35].

4.3. Effect of Footwear on Plantar Pressure and Shear Stresses

Figure 9a illustrates the mean peak pressure (MPP) obtained at the four locations when wearing three types of footwear. Regardless of the footwear, higher pressures were obtained at the heel (up to 215 kPa) and hallux (up to 243 kPa) compared to the other two metatarsal locations. At all locations, the lowest pressures were obtained when wearing trainers compared to the value obtained with therapeutic and flat-sole footwear. The reduction in peak pressure of up to 20% in all four locations, when wearing trainers may be attributed to the mechanical property, e.g., Young's Modulus, as well as the microstructure of the material used for the footwear construction to achieve shock absorptions. The plimsoll and therapeutic footwear featured thin and rigid outsoles, respectively, which may have reduced the shock absorption capability.

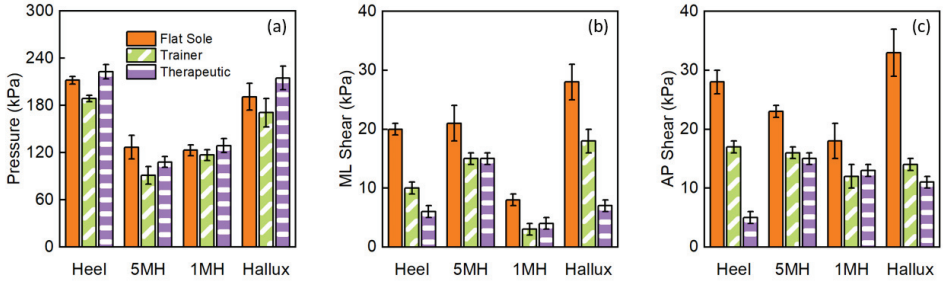

Figure 9. (**a**) Mean peak pressure and (**b**) medial–lateral (ML) and (**c**) anterior–posterior (AP) shear stress obtained over gait cycles with three types of footwear.

Among the four locations, the highest shear stress of up to 28 kPa and 33 kPa was revealed at the hallux location when wearing plimsolls, in medial–lateral and anterior–posterior directions, respectively. At all four locations, reductions of up to 75% medial–lateral shear and 82% anterior–posterior shear were evident when wearing therapeutic footwear compared to the plimsolls. This may be explained by the rocker sole (Figure 7c) incorporated in the therapeutic footwear design. In the early stance phase, the heel rocker assists the foot lowering to achieve foot flat in the midstance phase. In the terminal stance phase, the forefoot rocker helps transfer the load from the hindfoot to the forefoot and thereby achieve foot 'roll-over'. Both these footwear features were absent in the plimsolls, requiring the activation of muscle forces to assist load transfer under the foot, generating different shear stresses at the plantar interface. In addition, up to 40% and 61% reduction in medial–lateral shear was revealed when wearing the therapeutic footwear compared to that obtained for the trainer at the heel and hallux, respectively. Similar shear stress reduction was also revealed in the anterior–posterior direction, where reductions of up to 71% and 21% were measured at the heel and hallux, respectively. This indicates that the reported insole system has adequate sensitivity and could detect expected differences in the effects of the trainer and therapeutic footwear, which have similar footwear construction features.

The combined pressure and shear assessment may be used to offer insights to understand the effect of the design of footwear on loading characteristics at critical anatomical locations. This preliminary case study shows that pressure alone is not adequate to provide a comprehensive assessment of loading characteristics as a function of footwear design and choice. The significant difference in shear stress revealed when wearing therapeutic footwear may be potentially used as quantitative evidence to assist the design of footwear for DFU prevention.

5. Safety Evaluation for Use in Shoes by Patients with Diabetes

5.1. Test Protocol

Five participants, including three males and two females with diabetes at risk of ulceration, were recruited to participate in a walking evaluation. The primary aim was to detect whether the usage of the sensorised insole would induce notable changes in pressure for people with diabetes. Participants had a mean age of 67.2 years (range: 40–85 years) and UK shoe size between 8 and 9 with known diabetes duration 10.8 years (range: 2–22 years). The risk of foot ulceration was assessed on all participants based on IWGDF guidelines, resulting in four participants with moderate and one with a high risk of DFU. Participants completed walking at a self-selected pace along a 50 m walkway whilst wearing standardised therapeutic footwear (Omar 11, fisio duna) with and without the sensorised insole.

Plantar pressure data were collected using the XSENSOR system (Foot and Gait v4, XSENSOR® Technology Corporation, Calgary, AB, Canada) at 50 Hz. To evaluate the safety of wearing the new insole system, the difference in MPP over 10 mid-gait steps was calculated [36] (Table 1); this represents a known marker for risk in the diabetic foot [12].

This was evaluated for regions of interest defined based on sensor locations stated in Figure 1a, with an additional boundary of 10% in each direction to accommodate for misalignment (Figure 10). The group mean differences were then calculated.

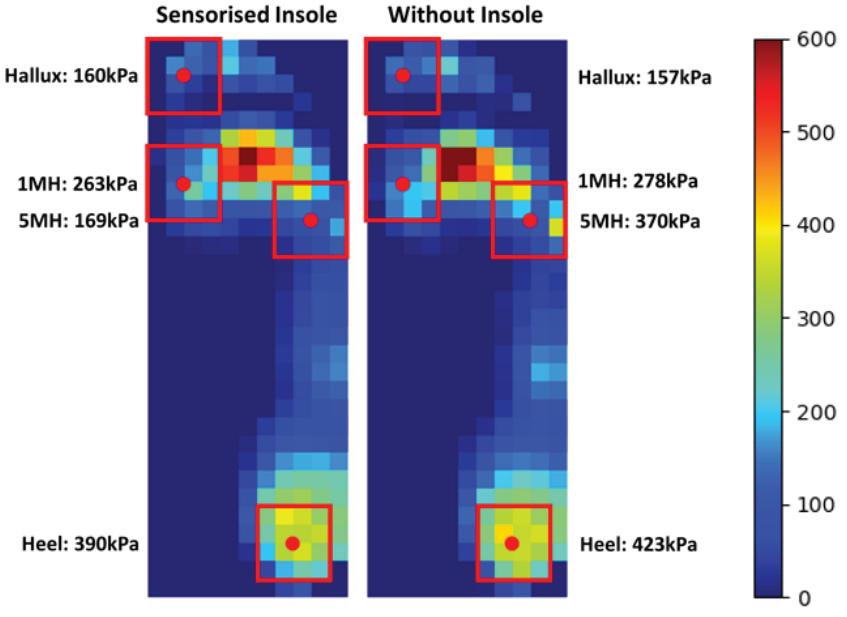

Figure 10. Mean peak plantar pressure distribution during walking obtained using the XSENSOR system with and without the sensorised insole. The four sensing locations are highlighted to allow regional peak pressure value comparison. The red dots represent the geometrical centre of each sensor.

Table 1. Peak pressure safety evaluation for 5 participants with diabetes. MPP: Mean peak pressure values for each participant represent the average of 10 mid-gait steps. Effect calculated as absolute pressure with sensorised insole MPP minus without insole MPP (S − W).

	Sensorised Insole	**Without Insole**	**Effect**		
D_01	Mean ± SD	Mean ± SD	S − W	% Diff	
Heel	119.46 ± 10.98	118.90 ± 11.57	0.57	0%	-
5MH	46.83 ± 3.30	31.58 ± 4.06	15.25	33%	/\
1MH	74.60 ± 3.88	85.68 ± 10.43	−11.08	−15%	\/
Hallux	171.45 ± 28.71	208.02 ± 15.54	−36.57	−21%	\/
D_02	Mean ± SD	Mean ± SD	S − W	% Diff	
Heel	178.25 ± 20.56	211.37 ± 16.04	−33.12	−19%	\/
5MH	92.84 ± 14.69	154.44 ± 34.51	−61.59	−66%	\/
1MH	284.38 ± 28.62	308.89 ± 61.47	−24.51	−9%	\/
Hallux	123.94 ± 20.11	172.68 ± 26.08	−48.74	−39%	\/
D_03	Mean ± SD	Mean ± SD	S − W	% Diff	
Heel	197.75 ± 26.18	185.24 ± 19.99	12.51	6%	/\
5MH	94.45 ± 19.25	82.94 ± 10.74	11.51	12%	/\
1MH	187.31 ± 53.43	257.36 ± 42.90	−70.05	−37%	\/
Hallux	244.82 ± 15.83	253.46 ± 27.35	−8.65	−4%	\/

Table 1. *Cont.*

	Sensorised Insole	**Without Insole**	**Effect**		
D_04	Mean ± SD	Mean ± SD	S − W	% Diff	
Heel	389.68 ± 19.89	422.73 ± 20.10	−33.05	−8%	\/
5MH	168.99 ± 28.70	370.31 ± 62.10	−201.32	−119%	\/
1MH	262.58 ± 53.02	277.80 ± 11.28	−15.22	−6%	\/
Hallux	159.82 ± 14.16	156.85 ± 7.61	2.97	2%	/\
D_05	Mean ± SD	Mean ± SD	S − W	% Diff	
Heel	319.48 ± 9.26	397.56 ± 33.17	−78.07	−24%	\/
5MH	168.76 ± 14.50	273.22 ± 41.83	−104.46	−62%	\/
1MH	333.30 ± 53.14	381.77 ± 46.23	−48.46	−15%	\/
Hallux	304.76 ± 49.74	277.67 ± 39.40	27.09	9%	/\

5.2. Safety Evaluation on People with Diabetes

Figure 10 illustrates the comparison of regions of interest for the peak pressure distribution map with and without the sensorised insole. Table 1 presents the MPP outcomes for each participant. The incorporation of the sensor within the insole resulted in −9%, −41%, −16% and −11% group mean percentage difference in peak pressure during walking at the heel, 5MH, 1MH and hallux, respectively. The 5MH region may also be affected by the raised lateral border of the XSENSOR measurement insole [30]. Due to the slight padding of the sensorised insole's middle EVA layer, some reduction in pressure was observed across regions. The effect within individuals and at individual regions varied, with changes in pressure affected by proximity to other loaded sites and variation within the gait. The use of small and fixed pressure masking associated with sensor locations may have influenced the step-to-step variability. For sites which demonstrated increased pressure, the resulting change in pressure magnitude was less than or similar to the between-step standard deviation suggesting this may be underpinned by step-to-step variation. These changes are, therefore, beneficial or negligible and show that the sensorised insole introduced almost no risk to user comfort and tissue injury.

6. Discussion

This paper presents an insole system that can measure real-time pressure and shear stresses under the foot. The design included all the elements required for a practical at-home solution, including a data storage interface, battery charging and mounting to footwear. The system is suitable for the assessment of the complex loading characteristics of people with diabetes and may inform guidance and management to underpin DFU prevention. In addition, the two-directional shear stresses, coupled with pressure, can be exploited to study balance in both sagittal and coronal planes, braking and propulsive impulses in people with diabetes and others affected by difficulties of movement control. Further work should seek to understand these kinetic parameters coupled with lower limb kinematics to provide a comprehensive biomechanical assessment of the foot in real-world settings of people's daily lives and activities.

The sensorised insole can be used in footwear with no modification or customisation required, assuming suitable footwear is chosen. This supports its use in daily living environments as a monitoring tool to provide warning to patients and health professionals when pressure and shear-related elevated DFU risks are detected. The insole presented in this study offers a significant advantage compared to other devices [17,18], where footwear modification is required, or over-sized device electronics are required to be attached to other parts of the lower limb, which may affect normal walking and also impact adherence and usage. These factors were subjected to further study as part of this project.

The footwear used in this study represents the range of footwear available, including those offered for patients who have diabetes and are classified as at-risk of ulceration [37].

While therapeutic footwear is the recommended footwear for patients at high risk of ulceration [12], this is not standard provision across patients of lower risk. So, understanding the use of the insole system in a range of footwear and what changes to pressure and shear might occur due to different footwear is an important next step in research. Pressure values do not demonstrate large changes even across this known range of footwear; however, shear data presented in Figure 9 show potential for modification by footwear intervention and warrants further investigation.

While initial work has highlighted the importance of activity type in plantar pressure assessment [38], it is unknown how these varied activities of daily living generate potential risk from shear loading for people with diabetes. Further, the sensorised insole presented here will enable measurements relevant to individual patients' activity profiles, allowing for a more personalised monitoring and risk evaluation in a real-world setting. To facilitate these future studies, further work in assessing the performance of the sensorised insole in real-world conditions such as weather, different ground surfaces and terrains will be conducted.

7. Conclusions

A first-of-its-kind sensorised insole system was reported, which is capable of measuring real-time plantar pressure and shear stress that could be potentially used by people with diabetes to help monitor and assess the risk of DFU. The technical performance of the system was validated through a combination of lab testing and initial walking trials. The insole and the wireless electronic hub were designed to be used with a range of existing footwear without the need for modifications. This is a significant improvement over any other existing devices reported in this field. These important wearability features and the comprehensive in-shoe pressure and shear measurement capability are essential for DFU prevention in the daily living environment. Preliminary results involving a healthy participant revealed such a wearable system is also sensitive to investigating the effect of different footwear on plantar loading. The safety of the device was further evaluated in diabetic participants. The result suggests that the inclusion of the sensorised insole itself does not elevate the plantar pressure and thus introduces no risk to user comfort and plantar tissue injury. Overall, our initial results reported here demonstrated the significant potential for the use of the sensorised insole in everyday living for DFU risk monitoring and prevention.

8. Future Work

Future work should involve recruiting people with diabetes with different levels of DFU risks to investigate the association between the plantar loading profile and the formation of DFU. Data from one participant (UK shoe size 8) were reported here to underpin the technological development and potential suitability for people with diabetes. Sensorised insoles of different sizes should be designed to accommodate the need of an expanded population, and subsequently, device durability tests must be conducted. The potential acceptance of the device by a large population would also help drive the unit cost down.

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sensors

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Article

Taking a Load Off: User Perceptions of Smart Offloading Walkers for Diabetic Foot Ulcers Using the Technology Acceptance Model

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Abstract: People with diabetic foot ulcers (DFUs) are commonly prescribed offloading walkers, but inadequate adherence to prescribed use can be a barrier to ulcer healing. This study examined user perspectives of offloading walkers to provide insight on ways to help promote adherence. Participants were randomized to wear: (1) irremovable, (2) removable, or (3) smart removable walkers (smart boot) that provided feedback on adherence and daily walking. Participants completed a 15-item questionnaire based on the Technology Acceptance Model (TAM). Spearman correlations assessed associations between TAM ratings with participant characteristics. Chi-squared tests compared TAM ratings between ethnicities, as well as 12-month retrospective fall status. A total of 21 adults with DFU (age 61.5 ± 11.8 years) participated. Smart boot users reported that learning how to use the boot was easy ($\rho = -0.82$, $p \leq 0.001$). Regardless of group, people who identified as Hispanic or Latino, compared to those who did not, reported they liked using the smart boot ($p = 0.05$) and would use it in the future ($p = 0.04$). Non-fallers, compared to fallers, reported the design of the smart boot made them want to wear it longer ($p = 0.04$) and it was easy to take on and off ($p = 0.04$). Our findings can help inform considerations for patient education and design of offloading walkers for DFUs.

Keywords: diabetic foot; smart offloading; remote patient monitoring; adherence; foot care; foot ulcer; wearable; digital health; telehealth

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1. Introduction

Of the estimated 30 million people in the US with diabetes, 34% will develop a diabetic foot ulcer (DFU) in their lifetime [1]. DFUs, which precede 80% of amputation in people with diabetes, are associated with impaired physical function, reduced quality of life, and increased risk of death [2]. Ulcers requiring acute care can result in treatment costs of up to USD 70,000 per event, varying with the severity of the wound [3]. The annual direct cost related to DFUs in the US is almost USD 40 million, despite being a preventable complication of diabetes [4,5]. The standard of care for DFU management is protective offloading with either an irremovable or removable offloading boot, which allows the wound to heal while the person remains ambulatory [6–9].

However, inadequate adherence to the prescribed use of offloading devices could be a potential barrier to ulcer healing. Irremovable knee-high offloading devices are recommended for offloading intervention [10]. Removable offloading devices are recommended as a second option but are often more frequently prescribed than irremovable devices due to cost and healthcare team expectations of increased patient adherence [11]. People who wore offloading devices for 90 days had significantly higher acceptance of removable boots, compared to irremovable walkers or contact casts [12]. Despite higher rates of healing in irremovable devices [13,14], time to healing and amputation rates in removable walkers were

comparable to the irremovable device literature [15]. Further, people who used removable walkers showed significantly more activity beginning at week 4, suggesting changes in adherence [15].

Despite adherence being a barrier to ulcer healing, few studies have investigated patient perceptions of offloading devices to help inform ways to improve adherence [16]. Several factors have been associated with low adherence to removable walkers, such as being male, a longer time with diabetes, not having peripheral arterial disease and higher perceived walker heaviness, as well as low wound healing and postural instability [17,18]. Additionally, a thematic analysis of people who wore a removable walker for anywhere between 1 week to 3 years found that although people reported they understood the benefits of the device, they also felt pressure from managers/coworkers not to wear it at work, did not like the height imbalance, and stated that the device felt heavy [19]. While studies have examined perceptions of offloading devices, no literature has examined perceptions surrounding the addition of technology offloading devices.

With advances in wearables, digital health, and remote patient monitoring technology, new solutions have emerged to help actively engage patients in caring for their wound, rather being passive recipients of wound care. However, patients' acceptance of these solutions, as well as factors that may influence perceptions, are still unknown. Park et al. proposed the concept of smart offloading to reinforce adherence in using offloading devices and tested its proof of concept validity, comfort level, and ease of use in healthy adults without DFUs [20]. Further, Najafi et al. proposed the concept of smart insoles in people with a history of DFU and found users who received one alert every two hours were significantly more adherent to use their prescribed footwear [21]. To our knowledge, no prospective study has examined the acceptability and factors affecting adherence to smart-offloading devices for people with active DFUs. Thus, additional literature on perspectives of offloading devices with and without technology could help inform ways to promote adherence in people with DFUs. This knowledge could help inform factors that may be associated with the acceptance of smart offloading, particularly in older adults with diabetic foot syndrome.

This study is the first to explore perceptions surrounding smart offloading with real-time feedback in people with DFUs, and what participant characteristics may be associated with acceptability. The objective of this study was to examine user perspectives of irremovable, removable, and sensorized offloading walkers to provide insight on ways to help promote adherence. This study also sought to gain insight about factors associated with the acceptance of a smart offloading device with a remote patient monitoring component. Research outcomes were user perspectives on offloading boots, which were expressed through a questionnaire based on the Technology Acceptance Model.

2. Materials and Methods

This manuscript presents preliminary qualitative findings from an ongoing parallel randomized control trial (ClinicalTrials.gov Identifier: NCT04460573) to investigate the influence of a sensorized offloading walker on health outcomes in people with DFUs, termed Smart Monitoring of patient Activity via Remote Technologies for Best Optimizing Offloading Therapy (SMARTBOOT). All participants signed an approved consent form before enrolling in this study. The study protocol and consent form were approved by the University of Southern California Institutional Review Board (protocol number: HS-20-00526). A computer-generated list (MATLAB software) randomly assigned participants in a 1:1:1 ratio to one of three offloading device groups: (1) irremovable cast walker (iRCW, reference group), (2) original removable cast walker (oRCW, control group), or (3) smart removable cast walker (sRCW, intervention group). The offloading component was identical between groups and only the method for managing adherence was different. All participants wore their offloading device for 12 weeks, or until their ulcer was deemed healed by a physician.

Participants were recruited from the Keck School of Medicine (Los Angeles Metropolitan, CA, USA). To be included in the study, individuals had to be over 18 years of age, have diabetes mellitus, have a plantar ulcer, have evidence of peripheral neuropathy, and be ambulatory at home with or without assistance, and be willing and able to provide informed consent. Individuals were excluded from participating in the study if they had major foot deformity so that the patient could not fit to standard offloading (e.g., Charcot neuroarthropathy), active infection, major lower limb amputation, changes in psychotropic or sleep medication in the last 6 weeks, any clinically significant medical or psychiatric condition, severe cognitive impairment, or laboratory abnormality that would interfere with the ability to participate in the study. Additionally, individuals were excluded from participating in the study if they were being considered for revascularization during the study, concurrently participating in exercise training, or unable or unwilling to attend prescribed clinic visits or comply with protocol. Only participants who completed all self-report data (TAM and all participant characteristics reported in this manuscript) were included in the analysis. Figure 1 depicts the number of participants assessed for eligibility, and those who were excluded or included. After providing informed consent, demographics were collected, which included age, sex, weight, height, and number of 12-month self-reported retrospective falls.

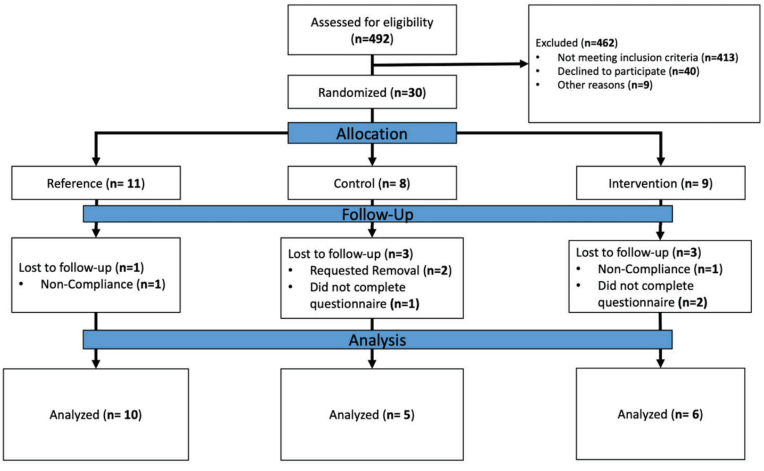

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram for inclusion and exclusion of participants.

Study groups are depicted in Figure 2. The iRCW was sealed with patches of leather, so participants could not readily remove the boot, the oRCW was off-the-shelf with no additional modifications, and the sRCW had a sensor-based system that was designed to provide feedback on adherence.

The sRCW and its validity were described in detail in our prior publication on healthy controls [20]. In summary, sRCW includes an identical offloading as iRCW and oRCW, however it uses a six-degree-of-freedom inertial measurement unit (Sensoria Health, Seattle, WA, USA, Figure 3) attached on the strut of offloading, enabling real-time measurement of adherence, walking steps, and walking cadence. Participants received real-time feedback about adherence and walking steps using a smartwatch with a dedicated patient monitoring app. The Bluetooth Low Energy module enabled real-time communicate of parameters of interest with the smartwatch. The microcontroller in the smartwatch processed the data and showed real-time (with maximum 5 s lag time) boot condition (boot on or boot off), activity condition (active or resting), step count, and notifications. Additionally, data were streamed to a secured cloud-based system for a remote patient monitoring solution, via a 4G LTE

Internet of Things (sim card enabled). This allowed the remote monitoring of parameters of interest (e.g., adherence, daily steps with and without adherence, and cadence), which could be used by clinicians to personalize patient education during weekly visits. Participants received real-time notifications from their smartwatch to encourage adherence via visual (e.g., happy face for good adherence, sad face for poor adherence) and vibration/audio feedback (walking while not wearing offloading). Additionally, participants had a daily comprehensive report via watch interface about level of adherence and daily steps.

Figure 2. Participants were randomized to wear (1) an irremovable cast walker (iRCW), (2) an original removable cast walker that is standard of care (oRCW; OG indicates original gadget), or (3) a smart removable cast walker designed to provide feedback on adherence via a sensor and smartwatch (sRCW).

Figure 3. The overall smart offloading system, used by participants assigned to use the smart removable cast walker (sRCW). The system consists of a sensor that attaches to the cast walker, as well as a watch that provides the participant notifications regarding their adherence.

Participants completed the following patient-reported outcomes: the Montreal Cognitive Assessment (MoCA) to assess cognition [22], the Falls Efficacy Scale International (FES-I) to assess falls efficacy [23], and the Patient Reported Outcomes Measurement Information System (PROMIS-29) to assess quality of life [24].

To assess perspectives on device acceptability, participants also completed a 15-item questionnaire based on the Technology Acceptance Model (TAM) [25], with a 5-point Likert scale, with the following options: strongly disagree, disagree, neutral, agree, and strongly agree. The 15 items are listed in Figure 4.

Technology Acceptance Model (TAM) Items	Parameters with significant correlations of $p \leq 0.05$				Parameters with significant correlations of $p \leq 0.001$					
	PROMIS Fatigue	Ulcer Width	Wagner	FES-I	PROMIS Pain Interf.	Group	Cadence	Ulcer Depth	# Retro. Falls	Ethnicity
Using the boot can improve my quality of life	-0.308	-0.026	-0.140	0.103	0.343	-0.309	0.478	-0.088	-0.378	0.088
The boot helped me in doing my daily activities	-0.310	0.107	-0.264	-0.116	.575*	-0.266	.656*	-0.336	0.324	**-.589****
The boot helped me follow the doctor's instructions	-.609*	-.440*	-.477*	-0.239	0.321	0.044	**.740****	**-.551****	-0.027	-0.391
The boot encouraged me to monitor how much I walk	-0.241	-0.161	-0.222	0.019	0.386	-0.415	0.397	-.438*	-0.216	-0.163
The design of the boot made me want to wear it longer	0.063	-0.113	-0.004	0.249	0.184	-0.001	0.089	-0.194	**.646****	-0.422
I feel more connected to my care provider	-0.260	-0.085	-0.179	-0.135	**.662****	-0.333	0.227	-.530*	0.110	-.525*
The boot is comfortable	-0.239	-0.153	-0.007	0.112	0.132	-0.231	0.216	-0.295	.538*	-.484*
Learning how to use the boot was easy	0.172	0.158	0.120	.491*	0.381	**-.815****	-0.039	-0.184	-0.063	0.082
Using the boot is easy	-0.349	-0.302	-.486*	-0.070	0.196	-0.083	0.176	-0.336	-0.089	0.138
The boot is easy to take on and off	-0.211	-0.306	-0.108	-0.067	0.237	-0.093	0.053	-0.361	0.302	-.453*
The boot looks good	0.213	-0.422	0.024	.444*	0.123	-0.150	0.072	-0.167	.520*	**-.565****
I like using the boot	-0.095	-0.118	-0.036	0.102	0.357	-0.207	0.206	-0.303	**.551****	-.486*
I think the boot is a good idea	-0.041	-0.044	-0.117	0.115	0.366	-0.163	0.139	0.079	-0.080	0.218
I would like to use the boot in the future	-0.123	0.038	-0.087	-0.121	0.266	0.109	0.375	-0.160	**.549****	-.540*
I would recommend the boot to my friends	-0.247	0.029	-0.249	-0.260	.586*	-0.170	0.486	-0.285	-0.037	-0.279

Figure 4. Significant Spearman correlations between participant ratings on Technology Acceptance Model (TAM) Questionnaire items and participant characteristics. Ratings were coded as 1= strongly agree, 2 = agree, 3 = neutral, 4 = disagree, and 5 = strongly disagree. Significance was considered $p \leq 0.05$. *p*-values with asterisks (*) and dark blue shading denotes significance of $p \leq 0.05$. Bold text with two asterisks (**) and light blue shading denotes significance of $p \leq 0.001$, which are discussed in the main text. Non-significant correlations are listed in Supplementary Table S1. Abbreviations: MoCA = Montreal Cognitive Assessment, PROMIS = Patient-Reported Outcome Measurement Information System, FES-I = Falls Efficacy Scale International.

Participants who reported identifying as Hispanic or Latino were classified as Hispanic or Latino, while those who did not were classified as Non-Hispanic or Latino. Additionally, participants who reported experiencing at least one fall in the past 12 months were categorized as fallers, while those who did not report experiencing any falls in the past 12 months were categorized as non-fallers.

Spearman correlations were performed to determine associations between participant characteristics and TAM ratings. Chi-squared tests of independence were performed to examine the relationship between TAM ratings with ethnicity (Hispanic or Latino, Non-Hispanic or Latino), as well as TAM ratings with 12-month retrospective fall status (faller, non-faller). All statistical analyses were performed using IBM SPSS Statistics 25 (IBM, Chicago, IL, USA). Statistical significance in all tests was considered to be a 2-sided *p*-value of $p \leq 0.05$.

3. Results

A total of 21 adults with DFUs (age 61.5 $\pm$ 11.8 years; 85.7% male) were randomized to use an iRCW (n = 10), oRCW (n = 6), or sRCW (n = 5). Participant characteristics by ethnicity and fall status are depicted in Table 1. People who identified as Hispanic or Latino, compared to those who did not, had significantly higher cadence (Table 1). Fallers, compared to non-fallers, had significantly higher T-scores on PROMIS-Cognitive Function and PROMIS-Depression items, which is interpreted as having higher indications of cognitive function and depression (Table 1).

Table 1. Participant Characteristics by Ethnicity and Fall Status.

	Hispanic or Latino (n = 14)	**Non-Hispanic or Latino (n = 7)**	***p*-Value**	**Fallers (n = 8)**	**Non-Fallers (n = 13)**	***p*-Value**
Randomized Group	50% iRCW, 21.4% oRCW, 28.6% sRCW	42.9% iRCW, 14.3% oRCW, 14.3% sRCW	0.675	12.5% iRCW, 50% oRCW, 37.5% sRCW	69.2% iRCW, 7.1% oRCW, 23.1% sRCW	0.057
Age (years)	60.7 ± 13.3	60.1 ± 12.7	0.693	59.2 ± 16.8	60.5 ± 10.3	0.901
BMI (kg/m^2)	27.3 ± 5.4	58.9 ± 17.7	0.155	32.2 ± 14.8	29.0 ± 5.7	0.570
Ethnicity (% Hispanic or Latino)	100	0	**0.001** *	100	0	0.252
Sex (% Male)	92.9	85.7	0.400	90.5%	87.5%	**0.001** *
#12-month retrospective falls	0.4 ± 0.9	2.3 ± 3.1	0.200	1.1 ± 2.0	0.0 ± 0.0	**0.001** *
Healing time (weeks)	7.1 ± 4.5	7.5 ± 4.2	0.482	7.2 ± 4.2	5.9 ± 4.3	0.770
Cadence (steps/min)	66.8 ± 30.0	47.8± 43.5	**0.015** *	62.7 ± 32.4	68.0 ± 38.3	0.121
HbA1C (%)	6.7 ± 3.1	8.0 ± 0.9	0.194	7.1 ± 2.7	6.5 ± 3.0	0.095
MoCA Score	10.5 ± 5.9	12.0 ± 8.8	0.610	11.0 ± 6.8	10.3 ± 5.9	0.601
FES-I Score	24.5 ± 18.5	31.4 ± 24.4	0.295	26.9 ± 20.4	27.0 ± 20.1	0.288
Wagner Score	1.7 ± 1.2	1.6 ± 0.8	0.833	1.7 ± 1.1	1.6 ± 1.2	0.771
Ulcer Characteristics						
Length (cm)	1.4 ± 1.5	1.1 ± 0.4	0.357	1.3 ± 1.2	1.4 ± 1.5	0.560
Depth (cm)	0.2 ± 0.3	0.1 ± 0.1	0.078	0.8 ± 0.2	0.2 ± 0.3	0.933
Width (cm)	1.8 ± 1.8	1.0 ± 0.7	0.154	1.6 ± 1.5	1.7 ± 1.9	0.459
Area (cm^2)	3.1 ± 5.6	1.0 ± 0.9	0.174	2.4 ± 4.7	3.1 ± 5.8	0.295
PROMIS T-Scores						
Pain Interference	53.5 ± 13.9	58.6 ± 10.1	0.221	55.4 ± 12.6	55.2 ± 13.5	0.805
Cognitive Function	34.2 ± 5.8	36.1 ± 7.5	0.568	34.9 ± 6.3	32.5 ± 4.8	**0.035** *
Depression	47.3 ± 7.4	51.0 ± 11.1	0.220	48.6 ± 8.9	45.4 ± 7.2	**0.039** *
Social Function	48.2 ± 13.1	47.8 ± 16.0	0.373	48.1 ± 13.8	50.1 ± 13.4	0.245
Anxiety/Fear	47.7 ± 10.5	47.0 ± 11.4	0.869	47.5 ± 10.5	46.0 ± 10.2	0.312
Fatigue	42.9 ± 14.3	48.6 ± 12.3	0.168	45.0 ± 13.5	43.3 ± 13.9	0.556
Physical Function	32.9 ± 10.8	31.9 ± 9.1	0.200	32.5 ± 10.0	32.5 ± 11.1	0.766
Sleep Disturbance	54.5 ± 3.1	50.7 ± 5.2	0.223	53.1 ± 4.3	53.5 ± 2.8	0.578

Table 1: Participant characteristics by ethnicity (Hispanic or Latino, Non-Hispanic or Latino) and fall status (fallers, non-fallers). Kruskal–Wallis (randomized study group), Chi-squared (ethnicity, sex) and Mann–Whitney U tests (all other items) were used to determine statistical significance. 2-sided *p*-values of $p \leq 0.05$ were considered significant. Bolded *p*-values with asterisks (*) denote significance.

The majority of participant characteristics had no significant correlations with any of their self-reported TAM ratings, which are presented in Supplementary Table S1. Correlations with significance are depicted in Figure 4. Due to the high number of correlations with a *p*-value of $p \leq 0.05$, only those with a *p*-value of $p \leq 0.001$ are discussed. Participants who used the smart boot ($\rho = -0.82$, $p < 0.001$) reported that learning how to use the boot was easy (Figure 4). Participants who had lower cadence ($\rho = 0.74$, $p < 0.001$) or deeper ulcers ($\rho = -0.55$, $p < 0.001$) reported that the boot helped them follow physician orders (Figure 4). Participants with lower T-scores on the PROMIS-Pain Interference, indicating less pain, reported feeling more connected to their care provider ($\rho = 0.66$, $p < 0.001$) (Figure 4).

Chi-squared results by ethnicity and fall status are depicted in Table 2. Individuals who identified as Hispanic or Latino reported the boot helped with their daily activities ($\rho = -0.59$, $p < 0.001$) and looked good ($\rho = -0.57$, $p < 0.001$). Individuals who identified as Hispanic or Latino, compared to those who did not, reported they liked using the boot ($p = 0.05$) and would like to use it in the future ($p = 0.04$). Individuals with fewer retrospective falls reported the boot's design made them want to wear it longer ($\rho = 0.65$), they liked using it ($\rho = 0.55$), and would like to use it more in the future ($\rho = 0.55$) (all $p < 0.001$). Non-fallers, compared to fallers, reported the design of the boot made them want to wear it longer ($p = 0.04$) and it was easy to take on and off ($p = 0.04$).

Table 2. Chi-Squared Results by Ethnicity and Fall Status.

TAM Questionnaire Items	Hispanic or Latino (n = 13) SA/A/N/D/SD	Non-Hispanic or Latino (n = 8) SA/A/N/D/SD	$\chi 2$	*p*-Value	Fallers (n= 8) SA/A/N/D/SD	Non-fallers (n = 13) SA/A/N/D/SD	$\chi 2$	*p*-Value
Using the boot can improve my quality of life	8/5/0/0/0	6/1/1/0/0	2.928	0.231	7/1/0/0/0	7/5/1/0/0	2.625	0.269
The boot helped me in doing my daily activities	7/4/1/1/0	1/1/2/1/3	8.950	0.062	3/0/1/1/3	5/5/2/1/0	8.102	0.088
The boot helped me follow the doctor's instructions	9/2/2/0/0	2/4/1/1/0	5.580	0.134	4/3/0/1/0	7/3/3/0/0	3.846	0.279
The boot encouraged me to monitor how much I walk	6/3/4/0/0	2/3/3/0/0	1.010	0.604	4/3/1/0/0	4/3/6/0/0	2.524	0.283
The design of the boot made me want to wear it longer	2/5/3/2/1	1/0/2/2/3	5.664	0.226	0/1/1/2/4	3/4/4/2/0	9.975	**0.041** *
I feel more connected to my care provider	6/4/3/0/0	1/1/4/2/0	6.704	0.082	3/1/2/2/0	4/4/5/0/0	4.281	0.233
The boot is comfortable	2/7/1/2/1	1/0/1/3/3	7.784	0.100	0/1/1/3/3	3/6/1/2/1	6.976	0.137
Learning how to use the boot was easy	7/2/4/0/0	5/1/2/0/0	0.151	0.927	5/2/1/0/0	7/1/5/0/0	2.272	0.321
Using the boot is easy	4/6/2/1/0	4/2/2/0/0	1.918	**0.049** *	3/4/1/0/0	5/4/3/1/0	1.388	0.708
The boot is easy to take on and off	5/5/2/1/0	1/2/1/3/1	5.401	0.249	1/3/0/4/0	5/4/3/0/1	10.197	**0.037** *
The boot looks good	1/6/5/0/1	0/0/5/1/2	7.572	0.109	0/1/4/0/3	1/5/6/1/0	7.289	0.121
I like using the boot	2/7/2/1/1	1/0/1/5/1	9.692	**0.046** *	0/2/0/4/2	3/5/3/2/0	9.288	0.054
I think the boot is a good idea	9/3/1/0/0	7/1/0/0/0	1.123	0.570	6/2/0/0/0	10/2/1/0/0	0.858	0.651
I would like to use the boot in the future	4/5/2/2/0	1/1/0/2/4	9.834	**0.043***	0/2/0/3/3	5/4/2/1/1	8.986	0.061
I would recommend the boot to my friends	7/4/2/0/0	2/4/1/0/1	3.096	0.377	4/2/1/0/1	5/6/2/0/0	2.389	0.496

Table 2: Rating counts of participants who selected strongly agree (SA)/agree (A)/neutral (N)/disagree (D)/strongly disagree (SD) on the Technology Acceptance Model (TAM) questionnaire items. Chi-squared tests of independence were performed to assess significant differences between ethnicity (Hispanic or Latino, Non-Hispanic or Latino) and fall status (fallers, non-fallers). Chi-squared values ($\chi 2$) are depicted. 2-sided *p*-values of $p \leq 0.05$ were considered significant. Bolded *p*-values with asterisks (*) denote significance.

4. Discussion

This study sought to examine user perspectives of irremovable, removable, and sensorized offloading boots (smart boot) to provide insight on ways to help promote adherence and gain insight about factors associated with the acceptance of a smart offloading device with a remote patient monitoring component. Correlation results suggest smart offloading may ultimately help promote adherence, since sensorized boot users were more inclined to report that learning how to use the boot was easy. Additionally, participants with lower cadence or deeper ulcers tended to report that the boot helped them follow physician instructions, regardless of group. Chi-squared results suggest that participants who identified as Hispanic or Latino, as well as those who had fewer or no retrospective falls, tended to rate their offloading boot more favorably regardless of group. These findings provide

supporting evidence that older adults could find a sensorized offloading boot easy to use for DFU management. Further, people who do not identify as Hispanic or Latino, report falling in the past 12 months, or report less severe symptoms (e.g., higher cadence, shallower ulcer) may need additional targeted patient education to promote adherence.

Age, dropout from the study, group assignment, fear of falling, or cognition did not show significant associations with TAM ratings. Based on previous work that has indicated people prefer lower-profile walkers that are removable [12], we expected TAM ratings would differ by group assignment. However, participants only wore and rated the one walker they were assigned. Future research could examine preferences after using multiple walker types. Additionally, we expected cognition and age would be associated with perceptions on ease of use and the adoption of technology (e.g., impaired eyesight, dexterity, ability self-care) [26–28]. Future work could focus on examining if age or cognition influences perceptions of sensorized boot use or adherence.

In previous research, people with diabetes who identify as Hispanic or Latino have been shown to experience higher rates of foot ulcers and subsequent amputations, be more likely to develop chronic foot wounds despite receiving regular care, and be less likely to receive diabetic foot care and attempted limb salvage [29–32]. In this study, findings indicated that people who identified as Hispanic or Latino tended to report the offloading boots more favorably, regardless of group. This suggests the overall design of the boot, regardless of the modifications to the boot in each of the three groups, may help reduce ethnicity-related health disparities in DFU management. Higher cadence may also influence more favorable perceptions, since people who identified as Hispanic or Latino also had significantly higher cadence compared to those who did not identify as Hispanic or Latino. To help determine this, future work could examine open-ended perceptions of participants to determine what aspects of the boot they thought "looked good" or "helped with their daily activities" when rating those items favorably.

Participants who reported having fewer falls in the past 12 months (correlation results) or were non-fallers (Chi-squared results) tended to report more favorable perceptions, particularly regarding the design and ease of taking the device on and off. This appears to be aligned with prior work that found postural instability was a factor associated with low adherence to boot use [18]. However, no significant relationship of $p < 0.001$ was found between fear of falling and TAM ratings. This suggests that self-reported number of 12-month falls may be a better indicator of boot acceptability than fear of falling. Fallers also had significantly higher indications of cognitive function (better) and depression (worse) compared to non-fallers, which may have also influenced perceptions. More work is needed to directly examine these relationships.

This study had a limited sample size of 21 participants, and acceptability was determined by a single questionnaire. Our findings could help inform directions for a thematic analysis, which would provide more detailed user perceptions on specific factors to help promote adherence. While this study focused on patient factors, the WHO recommends four other dimensions of factors (social/economic, therapy-related, condition-related, and health-system related) that should also be considered [33]. For example, participant hygiene or exposure to physical therapy could also influence acceptability.

5. Conclusions

Overall, findings from this study suggest that smart offloading with a remote patient monitoring solution may help promote adherence among older adults to wear offloading boots prescribed for DFUs. The design of the particular walker that was used in this study, regardless of being irremovable or removable, was better accepted among people who identified as Hispanic or Latino. Further, findings suggest clinicians could provide additional patient education for people who report experiencing at least one fall over the previous 12 months, particularly in putting on and taking off the walker. Manufacturers could also consider designs that improve perceptions of stability and appearance of the walker.

Ultimately, smart technology and considerations surrounding ethnicity and fall status may help improve adherence in older adults with DFUs who are prescribed offloading walkers.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/s23052768/s1, Table S1: Correlations between TAM ratings and participant characteristics that were non-significant.

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Self-Monitoring Diabetes-Related Foot Ulcers with the MyFootCare App: A Mixed Methods Study

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Abstract: People with diabetes-related foot ulcers (DFUs) need to perform self-care consistently over many months to promote healing and to mitigate risks of hospitalisation and amputation. However, during that time, improvement in their DFU can be hard to detect. Hence, there is a need for an accessible method to self-monitor DFUs at home. We developed a new mobile phone app, "MyFootCare", to self-monitor DFU healing progression from photos of the foot. The aim of this study is to evaluate the engagement and perceived value of MyFootCare for people with a plantar DFU over 3 months' duration. Data are collected through app log data and semi-structured interviews (weeks 0, 3, and 12) and analysed through descriptive statistics and thematic analysis. Ten out of 12 participants perceive MyFootCare as valuable to monitor progress and to reflect on events that affected self-care, and seven participants see it as potentially valuable to enhance consultations. Three app engagement patterns emerge: continuous, temporary, and failed engagement. These patterns highlight enablers for self-monitoring (such as having MyFootCare installed on the participant's phone) and barriers (such as usability issues and lack of healing progress). We conclude that while many people with DFUs perceive app-based self-monitoring as valuable, actual engagement can be achieved for some but not for all people because of various facilitators and barriers. Further research should target improving usability, accuracy and sharing with healthcare professionals and test clinical outcomes when using the app.

Keywords: mobile health; patient generated health data; medical selfie; augmented reality; foot ulcer; diabetic; self-care (rehabilitation); therapeutic adherence and compliance; patient engagement; podiatry

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1. Introduction

Diabetes-related foot ulcers (DFUs) are a leading cause of morbidity, mortality, and healthcare cost burdens globally [1,2]. In Australia alone each day, 50,000 people live with a DFU, 1000 are in hospital, 12 have an amputation, and 4 die because of a DFU, at an estimated annual direct cost of AUD 1.6 billion [3,4]. Best-practice treatment of people with DFU requires multidisciplinary team treatment in specialised DFU clinics, with various clinicians working together typically (bi-)weekly over several months to provide effective clinical care to heal the DFU [5]. However, the majority of DFU care performed is by the patients themselves or their carers away from the clinic, as self-care. Recommended DFU self-care typically includes patients regularly changing wound dressings, checking their DFU for changes and infection, and wearing offloading devices to relieve pressure and protect the ulcer [5]. Such recommendations are typically implemented in consulta-

tion between patients, carers, and clinicians to fit within the personal circumstances of the patient.

Self-monitoring is a key component of self-care [6]. For people with DFUs, self-monitoring holds potential to offer awareness of DFU healing and the impact of daily behaviours and self-care. Self-monitoring can also provide information to recognise complications and mitigate risks such as hospitalisation and amputation. This is important because patients often have a limited understanding of DFUs and the significance of self-care on DFU healing [7]. Poor mobility combined with the location of their DFU (most often on the plantar surface of their foot) also means that patients can find it difficult to see, reach, and care for the DFU themselves [8]. Perhaps most importantly, patients need to be able to perform self-care consistently over many months of DFU treatment [9], and during that time DFU healing changes can be hard to detect on a daily basis, which can be demoralising [8]. Hence, experts recommend that there is a need for simple and accessible methods for patients and carers to monitor DFUs at home [10].

To address this need, we created a new mobile phone app, "MyFootCare", for patients and carers to monitor DFUs in their own homes and to receive encouraging feedback. MyFootCare encourages people to use their smartphone camera to take a digital photo of their foot. It uses visual analytics to help patients extract and monitor DFU size from their foot photo to track their healing progress more objectively. Similar mobile apps for monitoring DFU healing have been developed for use in healthcare services [11,12], with clinicians stating that such an app could potentially aid people with diabetes in checking their feet at home [11]. A study based on an imagined app showed that DFU patients also see potential in using photos for DFU self-monitoring [13]. Several systems have been developed to monitor feet at home [12,14–16], but these systems were largely used by people at risk of developing DFU, who had their photos assessed remotely by healthcare professionals. Contrary to these, MyFootCare was designed for people who already have a DFU to help them see, monitor, and care for a plantar DFU.

The specific aims of this mixed methods, but predominantly qualitative, study were to investigate (1) the value of MyFootCare perceived by patients and (2) the enablers and barriers for engaging with MyFootCare in naturalistic conditions over extended periods of time.

2. Materials and Methods

2.1. MyFootCare Design

MyFootCare was created by the investigator team through a user-centred design process with patients to identify self-care challenges [8] and to trial app prototypes [17,18], which have been described in detail elsewhere. In brief, three workshops with 14 podiatrists were conducted to further develop design ideas, conduct usability tests, and to obtain their support for this study.

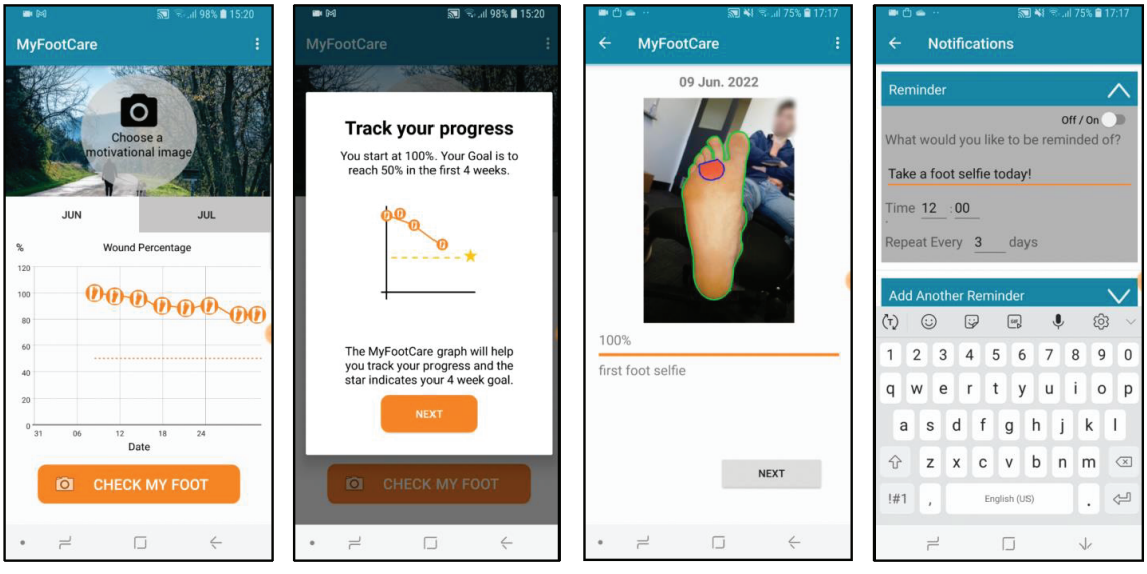
MyFootCare was implemented as a fully functional Android app, based on Java frameworks and OpenCV [19], a free real-time computer vision development library. To measure the DFU size from foot images, the app uses a morphological watershed algorithm [20] provided by OpenCV to segment the foot from the image background and then the ulcer from the foot. The app relies on the surface area of the foot as a scale to measure DFU size. This approach was taken for usability reasons, so that users did not need to provide a reference point (like a ruler or a sticker on the foot) when taking a foot photo. As a result, the ulcer size was not measured as an exact cm^2 measurement but as a percentage of the ulcer size from the first foot photo taken. The mobile phone flash was used to evenly illuminate the foot and keep the background dark. The prototype was developed and evaluated on a Samsung Galaxy S8 mobile phone.

MyFootCare offers the following features:

- **Progress graph**: users can monitor DFU size over time through a graph on the home screen (Figure 1a). The graph starts at 100% based on the DFU size from the first photo taken. A star on the graph visualises the goal to reach a 50% reduction within 4 weeks

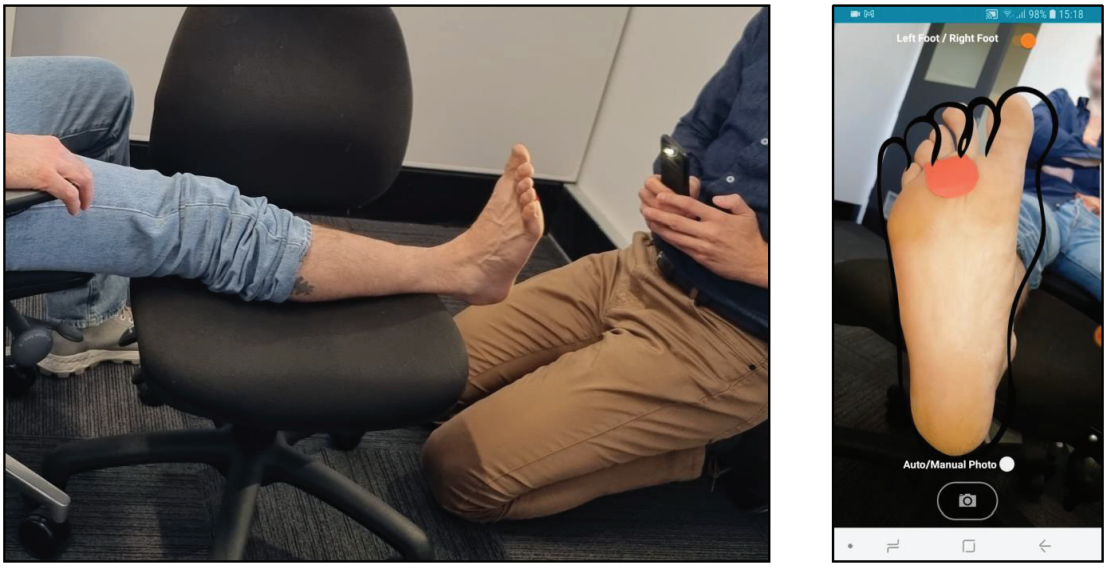
(Figure 1b). Reaching this goal can predict complete wound healing over an extended 12-week period [21].

- **Foot check**: to monitor the DFU size, users need to have a photo taken of their foot by another person, such as a relative or carer (Figure 2). Next, users need to manually analyse the photo by drawing lines to assist the app in segmenting the ulcer from the foot and the background (Figure 3). Users can review the foot image to identify changes and complications (e.g., infection) and add notes for discussion with their podiatrist or general practitioner. Finally, users receive feedback on their ulcer size, quantified as a percentage of the ulcer size from the first foot check (Figure 3d). Feedback messages and badges are customised to provide encouraging feedback tailored to their progress (e.g., "You've Reached Your Goal!"; see Appendix A for all messages).
- **Photo gallery**: users can review all their foot checks (image, progress, and notes) and show them to healthcare professionals via their gallery (Figure 1c).
- **Motivational image**: the upper half of the home screen shows an image that visualises a goal that users wish to achieve when their DFU has healed (e.g., be able to walk the dog, Figure 1a). Users could choose from 10 different images or upload their own photo. This is important because setting a realistic goal based on something that people want to achieve (rather than avoid) is typically one of the first steps in establishing a self-care plan [22,23].
- **Notifications**: users receive reminders to take a foot selfie. The timing and message of reminders can be tailored to fit with the time of their dressing changes (Figure 1d).



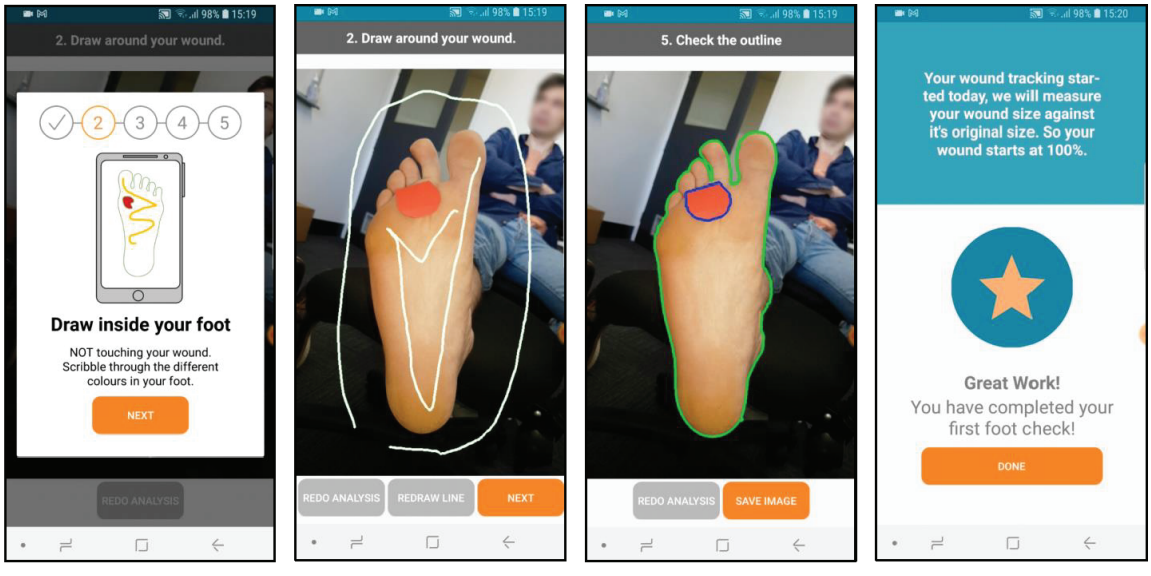
(**a**) (**b**) (**c**) (**d**)

Figure 1. MyFootCare features. (**a**) A motivational image on the top of the home screen visualises a person's goals (e.g., to go for a walk). A progress graph shows changes in DFU size over time. (**b**) A star on the graph visualises the goal to reach a 50% reduction within 4 weeks. (**c**) Patients can review all foot checks through a gallery. (**d**) Notifications to take foot selfies can be tailored under settings.



(**a**) (**b**)

Figure 2. (**a**) Taking photos for a foot check requires the person with the DFU to rest their foot on a chair while another person takes a photo. (**b**) A silhouette supports photographers in taking photos at a consistent distance.



(**a**) (**b**) (**c**) (**d**)

Figure 3. Foot checks involve a five-step process to segment the ulcer from the rest of the foot and the background: (**a**,**b**) users need to draw a line around the foot, draw inside the foot, zoom in on wound, draw inside the wound, and (**c**) check the outlines around the ulcer and around the foot. If the outlines are inaccurate, users can redraw the lines to get a more accurate result. (**d**) Users receive tailored feedback to encourage monitoring.

2.2. Trial Study

2.2.1. Study Design

The study was designed as a mixed methods prospective 3-month cohort study, as this period is the typical DFU healing duration and recommended by international criteria for clinical studies [24]. The study was predominantly qualitative, based on semi-structured interviews. Quantitative measures were created from app log data and ratings of app features. Ethics approval was obtained from the Prince Charles Hospital (#HREC/18/QPCH/185), and the study was registered before commencement (ACTRN12618001276246).

2.2.2. Participant Recruitment

Eligible participants were people with a DFU on the plantar surface of the foot who were treated at a diabetic foot clinic, who owned a smartphone and who were assisted in their DFU management by a carer (e.g., a spouse, or home care nurse). DFUs were defined as a full thickness wound on the foot (i.e., below the malleoli) of a person with diagnosed type 1 or type 2 diabetes mellitus [1]. A smartphone was defined as an internet-enabled mobile phone and was a requirement so participants would have some familiarity with mobile applications.

Participants were recruited through three clinics in Brisbane, Australia. Eligible patient participants and their carers were invited to participate by their treating clinician. As a further incentive, participants were offered an AUD 50 voucher at the start of the study and another AUD 50 voucher if they completed the study. During the entire study period, participants continued to receive standard care from their clinic.

The recruitment target of 12 patients was based on our prior experience with reaching data saturation in similar studies. Prior research also shows that data saturation often occurs after 12 interviewees [25]. A total of 12 participants is also the most common sample size in human–computer interaction studies as it is seen to provide a balance between cost and return on significant insights on user engagement digital technology [26].

2.2.3. Data Collection

Demographics and DFU information were recorded by their podiatrist in the validated Queensland High Risk Foot Form clinical record [27].

Semi-structured interviews were conducted at weeks 0, 3, and 12 in person at the participant's clinic by one of the investigators (DC, BP) based on an interview guide (Supplementary Materials). Interviews were audio-recorded and transcribed verbatim. Interactions with MyFootCare during the interviews were screen-recorded.

Before interview 1, the investigators used MyFootCare to take a high-quality foot photo during the participant's consultation. This photo served as a baseline (100%) for further foot checks.

Interview 1 (day 0, 60 min) focused on understanding the participant's background and on introducing MyFootCare. First, we discussed the participant's DFU and diabetes history, self-care practices at home and their impact on their everyday life, and their smartphone use. Second, we showed participants all features of the MyFootCare app and we used a think-aloud technique [28] to gain their initial impressions and questions about each app feature. Finally, participants rated the perceived usefulness of each app feature on a scale from 1 (not useful) to 10 (very useful) and explained their rating.

During interview 1, participants either received a smartphone (Samsung S8) for the study duration with MyFootCare installed on it, or we installed MyFootCare on their personal phones if the participants preferred and it was a similar phone model. Participants were asked to use MyFootCare each time they changed their wound dressing away from the clinic. They also received a stylus and a printed guide to assist with their foot checks.

After 10 days, participants received a phone call from one of the investigators to check if they had questions or needed technical assistance.

Interview 2 (week 3, 45 min) focused on understanding the participant's initial app engagement. First, participants were asked to reflect on their progress. Second, participants

were asked to open their MyFootCare app and show the investigators how they used the app and to raise any usability issues they may have experienced. Finally, participants rated the perceived usefulness of each app feature using the same scale as in interview 1, having now used the app for several weeks.

Interview 3 (week 12, 60 min) focused on understanding the participant's ongoing app engagement and perceived value of MyFootCare for self-care. First, participants were asked to reflect on the progress of their DFU and self-care. Second, participants were asked to open their MyFootCare app and tell the investigators about their app data (graph and photo gallery), their experiences with taking photos and analysing them, and their reflections on factors that may have supported or impeded their progress and app use. Finally, participants rated the perceived usefulness of each app feature again and reflected on the value provided.

Quantitative data on MyFootCare engagement were automatically collected on the participant's phone by the app. MyFootCare automatically logged each interaction with the app with timestamps in a log file and all foot images taken were stored on the phone. A second log file contained the time stamp and wound size for each foot check. Log files were exported at the end of interview 3.

2.2.4. Data Analysis

We analysed the data based on the principles of a reflexive thematic analysis approach [29,30]. In contrast to positivist thematic analysis, a reflexive approach highlights that themes are not discovered but generated by the researcher [30]. The researcher plays an active role in the thematic analysis, and their interpretation of the data and the themes generated are shaped by their background and by theoretical frameworks [29]. In this project, the analysis was led by the first two authors—a human–computer interaction researcher (BP) and a podiatrist (DC). The following frameworks guided our analysis:

- Self-care, which the WHO defines as "the ability of individuals, families, and communities to promote, maintain health, prevent disease, and to cope with illness with or without the support of a health-care provider" [31].
- Perceived value of patient-generated health data [32,33] for patients, which is defined as functional (to support health outcomes), emotional (understand and regulate emotions), social (share experience and support with peers), transactional (enrich consultations with health professionals), efficiency (eliminate unnecessary appointments), and self-determination value (empower patients).
- User engagement, which is defined as the process of how people start and continue to use technology for a certain purpose [34], which can be cyclical and include phases of disengagement and re-engagement [35]. Engagement is different from adherence, in that it is more dynamic and shaped by subjective factors such as a person's goal, challenge, and experience with technology [36].

Our reflexive thematic analysis consisted of:

1. Familiarisation: all interviews were transcribed verbatim by a professional transcription service. Immediately after each interview, we created notes with initial observations about the value and engagement with MyFootCare.
2. Generating initial codes: coding started after completing the interviews. We created inductive codes both deductively (e.g., perceived functional value) and inductively to create more specific codes for our particular context (e.g., functional value from seeing the plantar side of the foot). The qualitative data analysis software NVivo was used to code all transcripts.
3. Constructing themes: our research aims were used to construct themes that provide a coherent and insightful account of how patients engage and the value they perceive. Crosstab queries in NVivo allowed us to compare the frequency of codes between participants with different engagement levels.
4. Reviewing and defining themes and producing the report: these three phases were intertwined and iterative. Themes were reviewed through regular meetings with all

authors. Definitions were created and refined throughout the writing of the report and reviewed with all authors until consensus was reached.

All quantitative data were analysed using Microsoft Excel for Mac 16. Descriptive statistics used to display variables included frequencies (proportions), mean (standard deviation (SD)), and median (interquartile range (IQR)).

3. Results

3.1. Participants

All participant characteristics are displayed in Table 1. In total, we recruited 12 participants; 9 (75%) were male, median (IQR) age 53 (46–65) years, and 10 (83%) had type 2 diabetes. Three (25%) participants had MyFootCare installed on their personal Android phone and nine (75%) received a Samsung S8 smartphone with MyFootCare installed for the study duration. All 12 participants completed the study with a third and final interview at week 12. Only P02 asked to conduct his final interview earlier at week 7 because of a health concern.

Table 1. Participant characteristics (number (%) or median (IQR), unless otherwise stated).

Characteristics	Total
Numbers	12
Age (years)	53 [46; 65]
Males	9 (75%)
Type 2 Diabetes	10 (83.3%)
Occupation	
Employed	3 (25%)
Unemployed	4 (33.3%)
Retired	5 (41.7%)
Smartphone owned	
Android	9 (75%)
iOS	3 (25%)
MyFootCare access on	
Study phone	9 (75%)
Personal phone	3 (25%)
Ulcer duration history (months)	6 [5; 12]
Ulcer location	
Digit/toe	2 (16.7%)
Forefoot	8 (66.7%)
Midfoot	1 (8.3%)
Heel	1 (8.3%)
Ulcer healing status at week 12	
Healed	1 (8.3%)
Decreased in size	5 (41.7%)
Increased in size	6 (50%)

3.2. Value from Digital DFU Self-Care

Table 2 shows participants' ratings of the perceived usefulness of MyFootCare at weeks 0, 3, and 12. The median (IQR) rating of the overall MyFootCare app was 10 (10, 10) ("very useful") from a 10-point Likert scale at week 0, and this did not change at week 3 and week 12. Of the individual app features, participants also rated as very useful the ability to track progress through a graph (10 (8,10)), see wound photos in the gallery (10 (10,10)), and share data with health professionals (10 (3,10)) throughout the study, whereas participants rated the reminder notifications (8 (5,10)) and motivational image (6 (4,9)) features lower and these scores decreased throughout the study.

Table 2. Participant ratings of MyFootCare app usefulness, reported as median (IQR).

App Feature *	Week 0 (n = 12)	Week 3 (n = 12)	Week 12 (n = 11 ^)
MyFootCare app overall	10 [10; 10]	10 [7; 10]	10 [8; 10]
Motivational image	6 [4; 9]	6.5 [3; 10]	5 [3; 9]
Notifications	8 [5; 10]	6 [4; 10]	3 [2; 9]
Progress graph	10 [8; 10]	10 [9; 10]	8 [8; 10]
Photo gallery	10 [10; 10]	10 [8; 10]	10 [10; 10]
Share data with a health professional	10 [9; 10]	9.5 [9; 10]	10 [8; 10]

* Reponses to questions/items of 'how useful are the different app features/app as a whole for you?' (1 = not useful; 10 very useful). ^ Only 11 participants reported, as 1 participant reported open-ended feedback without a rating.

The qualitative data presented below provides the reasons behind the ratings and the value that participants perceived (based on [32]). Participants with limited app engagement sometimes rated the app's potential rather than the value that materialised for them.

3.2.1. Functional Value: Monitoring Progress through Graph and Photo Gallery Features

Performing digital foot checks with MyFootCare provided clear value to DFU care. Ten participants reported that MyFootCare supported their health outcomes (functional value) because it allowed them to see the progress of their ulcer with their own eyes.

> *"I think it's a necessity. If you involve the patient, like I was involved with it, so of course I was keen to see it, and you're obviously keen to see it go down."* (P09)

> *"I think that's fantastic. Yes, I'd give that a 10, because you know what's going on. Because how are you to know if you don't see it?"* (P08)

3.2.2. Functional Value: Reflection on Care and Health Decisions

Participants valued MyFootCare because it allowed them to reflect on events that affected their care and to aid with health decisions. During interviews, all participants used the graph to reflect on the reasons for changes in their wound size, for example, because they were more active on their feet. Five participants reported that reflection on MyFootCare data played a role in care decisions.

> *"I did write something on it [added a note to the photo]. Tinge of green. Well, the smell. The sign of infection."* (P10)

> *"It aided in the decision to stop work and improve."* (P02)

3.2.3. Transactional Value: Enhancing Consultations with Healthcare Professionals

The participants saw clear potential value in sharing MyFootCare data with a health professional to aid with clinical consultations. Seven participants reported that they intend to show MyFootCare to their health professional (GP, endocrinologist, and surgeon) to review the ulcer progress without having to take off and re-dress the bandage. These health professionals lacked equipment to re-dress their ulcers, and hence participants were reluctant to take off their dressing during consultations. Three participants also wished to share MyFootCare data electronically, e.g., by sending an email.

> *"But yeah, I think it's a good idea, because when I do go to my GP, I can show her the photos and how I've progressed, and now it's healed."* (P03)

> *"If people think that there might be an infection, instead of ringing up and making an appointment maybe send a photo through and the nurse or the doctor could have a look at that and be like, 'Oh, yeah, maybe you should come in,' or at least put their mind at ease and say, 'No, that can wait for our appointment.'"* (P04)

In practice, participants often did not share their photos because healthcare professionals appeared busy and did not prompt patients to show photos or because they were taking their own photos.

> *"From what I've seen with the GPs they seem to rush through. So I don't know whether they would sit down and talk about it."* (P02)

> *"They [podiatrists] took their own photos on the camera that they provided. They are not really that interested. Yeah."* (P01)

It is important to note that the value for consultations is not purely hypothetical because three participants shared foot photos with a healthcare professional during the trial study.

> *"We'll be going to our diabetic man this week and he'll be interested to know how [P10]'s feet are going, and he used to say to us, can I have a look, and we'd say, no—because he has absolutely nothing there that he could possibly put it—bandage it up or anything."* (Carer of P10)

3.3. Engagement with MyFootCare

Figure 4 displays the log data over the 12-week duration of the study. Overall, participants used MyFootCare a mean (SD) 16 (11.5) times over the 12-week duration or 1.4 (1) times per week. Three different usage sub-groups emerged with four (33%) participants "continually" using (28 (11.3) over 12 weeks; ≥20 digital foot checks overall), four (33%) others "temporarily" using (16 (2.5) over 12 weeks; ≥10 and <19 foot checks), and the other four (33%) "failing" to use MyFootCare after the first few weeks (5 (1.4) over 12 weeks; <10 digital foot checks).

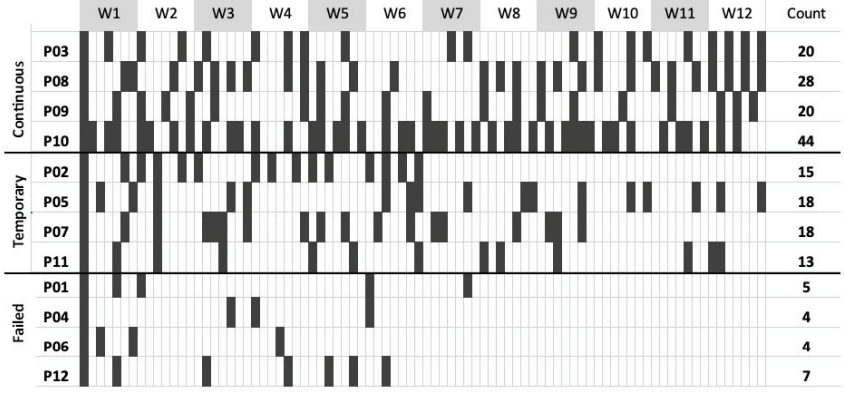


Figure 4. MyFootCare usage log data, showing the foot checks (photo and analysis) performed for each participant throughout the study period. Participants are clustered into three groups: continuous, temporary, and failed engagement.

Our qualitative findings seemed to confirm and further tease out the three distinct patterns identified in the quantitative findings. Enablers and barriers to engagement for each group are described below. The engagement level of each participant is indicated through a "C", "T", or "F", e.g., "P03C" for continuous engagement of participant 3.

3.3.1. Enablers for Continuous Engagement

Participants who continuously engaged with MyFootCare were also dedicated to diabetes and DFU self-care. The following enablers allowed them to integrate MyFootCare with their self-care routines, although we noted some enablers were also identified by other participants.

MyFootCare installed on personal phone: all three participants who had MyFootCare installed on their personal phone were continuous users. This enabled them, as they had MyFootCare with them all the time. For example, P03C even took photos during her stay in hospital, which also meant she could show photos to the surgeon. It also meant that other features, such as reminder notifications and the motivational image, were more accessible.

> *"I think it's very useful, because you can show your doctor or the surgeon the progress of what's been going on with your foot."* (P03C)

Familiarity with foot selfies: six participants already had photos of their own foot ulcer on their personal phone. They were used to reviewing these photos and to reflecting on the reasons that promoted or inhibited healing. However, prior to using MyFootCare, foot photos were usually mixed in with all their personal photos and difficult to retrieve.

> *"I have all of them [on the phone]. They're taken for other medical viewing by doctors, and whatever."* (P10C)

Dedicated caregivers who take high-quality photos: it took time for carers to learn how to take a good photo and to understand how this impacts the accuracy of the analysis. We saw that all four continuous users had caregivers who put in considerable effort to ensure they produced high-quality photos. For example:

> *"See, the boys got down on their knees and took it straight on, which you need to do to get that exact outline."* (P03C)

3.3.2. Barriers Leading to Temporary Disengagement

Four participants engaged with MyFootCare for parts of the trial study (Figure 4). The following barriers were not directly related to MyFootCare, yet they were stated as the main reasons for pausing their engagement.

Work commitments: a main barrier was the tension between (paid and unpaid) work commitments and the need to care for and rest the foot. For example, one participant described the tension between having to work to support his family and needing to rest to heal the ulcer as a "Catch-22".

> *"I'm in a real Catch-22 now. I know health's more important, but so is your family. So it's a really sticky situation. I mean, I'm not a rich person. Obviously, if I was, I'd take the time off and sit at my house for three months and not do anything. Which is probably what I need to do. But I just can't afford to do that."* (P11T)

Health disruptions: a second barrier for engagement were health disruptions. For example, one participant permanently disengaged from MyFootCare when he was hospitalised because of complications arising from cancer, followed by almost daily health appointments. The MyFootCare app was secondary to these needs during that time.

> *"I spent nine days in hospital and quite a bit of other stuff. And then like with the prostate cancer and I got—every day of the week we were at the doctors giving blood, at the hospital, podiatrist. It's just been full on, absolutely full on."* (P07T)

3.3.3. Barriers Leading to Failed Engagement

Four participants failed to engage with MyFootCare: they used the app occasionally at the start of the study but generally stopped using MyFootCare after a few weeks (Figure 4). These participants highlighted barriers related to their health, as well as barriers related to the usability of MyFootCare.

Frustration with lack of healing progress: three participants reported frustration with the lack of progress on their ulcer, which also affected their engagement with MyFootCare as they could not see any progress on the graph.

> *"To be honest, I'm at the point where I just want my foot cut off. It has made a huge impact on my life."* (P04F)

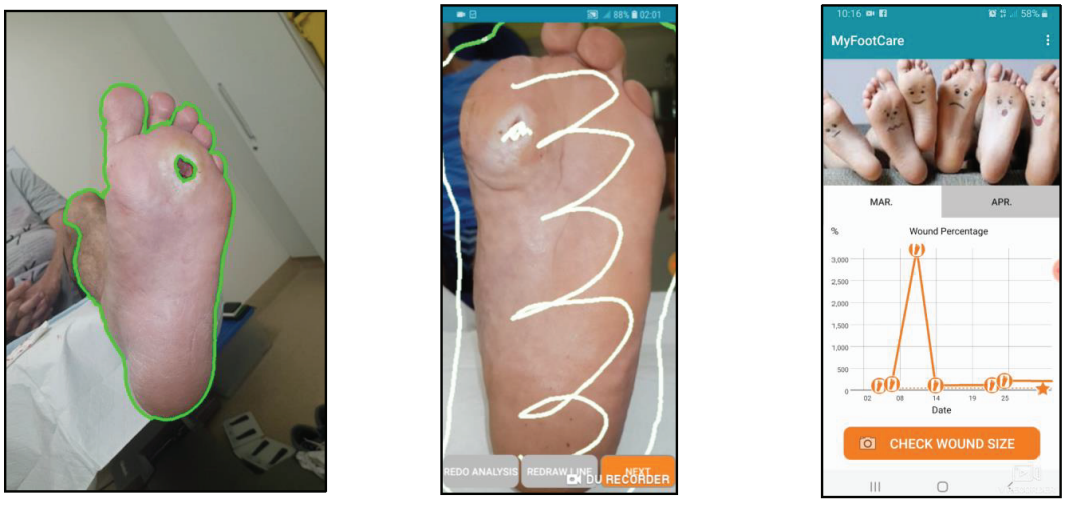
Lack of confidence using smartphones: during the interviews, we observed that the skills and confidence with which participants used smartphones varied considerably. Participants with lower confidence reported using their own phone primarily for communication and rarely for apps or to take photos. We observed that some participants navigated MyFootCare with difficulty because they were not used to the shape and operating system of the study phone, or they found it difficult to read information.

> *"Without my glasses I can see the graph, but I can't really see the numbers."* (P04F)

Frustration with having to re-do foot checks: having to retake the photo or repeat the analysis was a major source of frustration, which we also witnessed during some of our interviews when we analysed photos together with participants.

> *"The greatest bother was if I put my finger in one spot and started the outline, and I noticed it was a bit close, then having to go back and then having to do all of the outlines again. . . . To me, it was kind of annoying, sorry to say."* (P04F)

The main reason for having to redo foot checks were poorly taken photos. This was the case when photos were taken from above rather than parallel to the foot, when they did not show the whole foot, or when they contained background distractions like bright lights or the skin of the leg and arm (Figure 5a). A second reason was that the lines drawn during the analysis to separate the background, foot, and ulcer were poorly drawn. Instead of drawing around the foot and staying away from the edge, we observed how participants tried to cut as close to the edge as possible, similar to cutting out a picture. Some participants drew too many lines and thereby cut across edges, like when trying to colour in an area (see Figure 5b). Participants also struggled with the last step of the analysis, where they needed to tap the wound without touching the edge or outside of the wound. We provided a stylus to assist them with this step. However, images with small wounds or wounds close to the edge of the foot remained a challenge.



(**a**) (**b**) (**c**)

Figure 5. Examples of problems. (**a**) Background distractions such as skin of the leg and arm led to poor analysis results, with the green outline of the foot also covering the leg (P01F). (**b**) The white lines show the lines drawn by P12F during the analysis. The scribble drawn to indicate the ulcer cuts across the edge of the ulcer, and therefore, the analysis did not work. (**c**) Outliers in the data that were due to analysis problems changed the scale of the graph and made the progress difficult to see.

Lack of accuracy and reliability: inaccurate foot check results and limited reliability between different foot checks performed by the same participant were also a major barrier.

This was largely a consequence of the limitations of MyFootCare (limited camera resolution and non-standardised photos) and of problems associated with the manual analysis process (when participants had enough of redoing foot checks and accepted inaccurate outlines of the foot and wound, as described above). In addition, occasional analysis errors made the graph difficult to read because these outliers changed the scale of the graph and minimised the actual progress (see Figure 5c).

> *"Yeah, I don't know, sort of, because it's saying, like, 800–8000 percent bigger and, and 2000-something percent bigger. It's just—you probably see—it doesn't really do jack shit, in other words."* (P01F)

4. Discussion

4.1. Principal Results

The majority of participants perceived self-monitoring DFUs with MyFootCare as valuable for their self-care, in particular to see ulcer healing progress from the foot check feature (photos and graph). Similar to previous studies [14–16], we found that the majority of people perceived foot photos as valuable for self-monitoring at home. Additionally, MyFootCare provided a progress graph to provide objective DFU size information. While such a feature has been mentioned as potentially useful in previous studies by clinicians [11] and by patients imagining such an app [13], the current study presents experiences from patients actually using progress data in their daily lives. The results showed that most patients valued such data to verify subjective observations from the photos, even though they recognised that the accuracy of the progress graph was limited. Furthermore, the timeline of the graph encouraged many participants to reflect on actions and events that affected their self-care and healing progress. Such personal reflection is important because it can lead to patients feeling a higher degree of control in their health care, congruent with psychological empowerment [37].

Participants saw potential value in sharing MyFootCare data with healthcare professionals who typically do not treat or view the ulcer during consultations, such as their general practitioner. Thus, capturing photos can help patients to prepare for consultations and take on a more active role in their interactions with healthcare professionals, as found in other studies, e.g., by recalling information and health decisions [38,39]. Reviewing photos during consultation also benefits healthcare professionals because it prompts discussion about health experiences [40], adherence to treatment plans [41], and the broader lives of patients [42]. Unfortunately, such sharing rarely occurred in this study because participants perceived healthcare professionals as too busy and not interested in their observations. This observation also aligns with recent studies that show that patients rarely share their data unless they get asked by the clinician [43], and clinicians spend little to no time asking patients [44]. This seems a missed opportunity, and in Section 4.2, we recommend several practical implications that may improve this in future.

We identified and then explored three distinct engagement patterns with MyFootCare from participants: continuous, temporary, or failed engagement. Understanding these patterns is important because they reflect the reality of digital health interventions, where many systems are seen as valuable but have mixed uptake because of challenges with accessibility, privacy, and accuracy [33]. The patterns in this study were comparable to similar studies of digital systems for DFU self-care. An 8-week trial by Anthony et al. [16] showed that 77% of users were willing to take regular foot photos once a week, which is similar to the 66% (continuous or temporary) users in our study who took on average at least one photo per week. A 6-month trial of the "Foot Selfie" system [14] showed that 93% of participants were imaging their feet at least every other day. However, in both studies, photos were taken primarily to screen the foot for ulcers. In contrast, the participants in our study used MyFootCare as part of their self-care routine when they changed wound dressings. They used MyFootCare more continuously when it was on their own phone, when they were familiar with foot selfies, and when they had a dedicated carer to take high-quality photos.

In examining the barriers to engagement, we found that participants took breaks from using MyFootCare when they experienced health disruptions, e.g., when they received care in hospitals. As predicted by technology engagement frameworks [34,35], we found that participants re-engaged when they were back at home.

Participants stopped using MyFootCare when they had their DFU for a long time and could not see any progress. Our findings align with related work with chronic disease patients [6], which suggests that their willingness to self-monitor is associated with the sense of control that they perceive over the disease. If patients feel that they cannot control health outcomes and do not expect to see any improvements, then they are less willing to self-monitor because the cost (in terms of time and effort required) is perceived to be higher than the anticipated benefits [6]. Participants also stopped using MyFootCare permanently when they did not feel confident using smartphones or when they experienced frustration from ongoing usability problems. These barriers could potentially be addressed by caregivers who are comfortable using smartphones and who can conduct the manual analysis (as well as take photos). We seek to address usability barriers in future work (see Section 4.3), but we do not expect that this would change the low engagement levels of long-time DFU patients with MyFootCare. These patients require a different approach [5].

4.2. Practical Implications

For healthcare professionals interested in engaging DFU patients more actively in their self-care through digital systems or foot photos, we suggest three recommendations. First, it seems important to identify suitable patients who are more likely to engage. For example, patients are more likely to engage if they have suitable smartphones and feel confident using them. DFU patients are often older adults [45], and diabetes can also negatively affect their vision [46] and their hand function and dexterity [47], which can all affect their use of smartphones. Patients require the support of a caregiver to take high-quality foot photos in their own home. Familiarity with having foot photos taken is also beneficial.

Second, digital self-care worked best for patients and carers who were already dedicated to self-care and who were looking for additional ways to promote DFU healing. MyFootCare did not motivate participants who had difficulties with adhering to other forms of self-care, such as dressing changes and offloading. Such patients need other forms of (behavioural) support [8].

Finally, healthcare professionals need to provide ongoing support to patients. Initially, they need to help them set up MyFootCare with the first foot check. Follow-ups are required to assist patients with usability issues, to actively inquire during their consultation into data collected, and to promote the integration of digital foot checks with existing dressing-change routines. Like others [48], we suggest that healthcare professionals can benefit from training, so that they can educate their patients on digital technologies and elicit patient data during consultations more effectively.

4.3. Limitations and Future Work

This study was based on 12 participants, which limited the validity of the quantitative results presented. Whilst quantitative information is provided in figures and tables, this information is descriptive only, and the main findings about the perceived value of MyFootCare, as well as the barriers and enablers for engagement, are based on qualitative data. Due to the small cohort and the 3-month period, we did not find an association between app engagement and ulcer healing; however, our methods were also not designed to detect such an association. If we would have found one, it could also have been by chance. A larger and primarily quantitative study is needed to investigate such an association. Instead, the strength of the current study was its high ecological validity through qualitative results about app engagement in real-world contexts over a 3-month period. This 3-month period was also sufficient to achieve our aims to evaluate engagement and app usage, as app engagement did not change after week 6.

This study identified several barriers that need to be addressed in future work. First, more work is required to simplify the foot check. Related work [16] suggests that patients benefit from having a selfie stick to take their own photos. We had tried selfie sticks in our usability tests but found them too difficult to use as they required long arms and flexibility. However, we see potential in a dedicated apparatus such as the "Foot Selfie" system [14], which consists of a phone holder and an apparatus to rest their foot on and allows patients to take photos on their own with minimal training.

Second, patients would benefit from simplifying the analysis to segment ulcer and foot in an image and to improve the accuracy and reliability. The current analysis requires a manual process to identify the wound patient, which can help to engage the patient but which also introduces subjectivity to the segmentation of the DFU. Even with clinicians, studies document that manual wound measurements involve a trade-off between accuracy and feasibility (time required and risk of contamination) [49]. To address these limitations, we see large potential in machine learning techniques, where recent studies provide reasonable results in segmenting DFUs in foot images [50,51]. We envision that analysis of foot images could be automated through a system that securely exchanges foot images taken on a patient's phone with an internet-based analysis service. Furthermore, machine learning techniques also show potential to identify complications like infection and ischemia [52] in foot images, which could be used to alert patients to seek treatment.

Third, the current MyFootCare design is limited to tracking a single wound on the plantar surface of the foot. We focused on plantar wounds because these are the most common and are not visible to the patient [53]. However, participants with DFUs at the edge of the plantar surface reported difficulty with their analysis, as did participants with very small wounds. A different app design is needed to better support these patients.

Finally, MyFootCare did not allow remote monitoring by healthcare professionals. Patients can benefit from two-way communication with healthcare professionals to reduce the number of visits to the clinic [13]. When designing MyFootCare, we decided not to include electronic data sharing for a number of practical reasons: potential privacy risks, difficulty with diagnosing ulcers from images alone [54], and potential interference with the care provided by podiatrists. On a more fundamental level, we felt that remote monitoring by healthcare professionals would disempower the patients because it could increase their reliance on clinical care instead of empowering patients in their own care. Hence, in the spirit of participatory healthcare [55], we focused on how MyFootCare can provide patients with new insights for their own care, which they can share during consultations to give them a voice in their conversations with healthcare professionals.

5. Conclusions

For people whose DFUs are healing and who can access MyFootCare on their own phone, using an app for self-monitoring their DFU provides value through new health insights and through reflection on the events that promote or hinder progress. Successful engagement depends on various facilitators and barriers and can be achieved for some but not for all people. More work is needed to improve MyFootCare to address usability issues and to enhance its accuracy through standardised photos.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/s23052547/s1, Document S1: Interview guide.

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Appendix A Tailored Feedback Messages

MyFootCare provides the following feedback messages to users to motivate them to continue monitoring their ulcer. Each message is designed in a playful and informative way to show the percentage of the wound size, feedback text, and a badge. Below are the requirements for each message. The first condition that is met is shown to the user.

If it is their **first** entry:

- Great Work!
  You have completed your first foot check!
  Your wound tracking started today, we will measure your wound size against its original size. So your wound starts at 100%.
  If it is their **second** entry:
- Great to see you back!
  Keep in mind that the results are not always perfect and can vary depending on the quality of photos and analysis.
  If they have been using the app **for a month:**
- It's been 4 weeks!
  Remember to check in regularly with a health professional.
  Your wound is X% of its original size.
  If they have reached their **goal**:
- You've Reached Your Goal!
  Your wound has now shrunk by 50% or more.
  Your wound is X% of its original size.
  If this is the **first entry for the week**:
- It is the start of a new week.
  Remember to try and do three foot checks per week.
  If their wound is **greater than their starting size**:
- Keep it up!
  Remember to change your dressing regularly!
  Your wound is X% of its original size.
  If this **is not their first entry for the week**:
- You're on a roll!
  You have completed 2 checks this week... One to go!
  If this is their **third or greater entry for the week**:
- Week Complete!
  You have done the three recommended checks for this week... Great work!

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Adherence and Wearing Time of Prescribed Footwear among People at Risk of Diabetes-Related Foot Ulcers: Which Measure to Use?

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Abstract: Adherence to prescribed footwear is essential to prevent diabetes-related foot ulcers. The aim was to compare different measures of adherence and wearing time of prescribed footwear with a reference adherence measure, among people with diabetes at high risk of foot ulceration. We followed 53 participants for 7 consecutive days. A temperature sensor measured wearing time of prescribed footwear and a triaxial accelerometer assessed weight-bearing activities. Subjective wearing time was self-reported. Reference adherence measure was proportion of weight-bearing time prescribed footwear was worn. We calculated Spearman's correlation coefficients, kappa coefficients, and areas under the curve (AUC) for the association between the reference measure and other measures of adherence and wearing time. Proportion of daily steps with prescribed footwear worn had a very strong association (r = 0.96, K = 0.93; AUC: 0.96–1.00), objective wearing time had a strong association (r = 0.91, K = 0.85, AUC: 0.89–0.99), and subjective wearing time had a weak association (r = 0.42, K = 0.38, AUC: 0.67–0.81) with the reference measure. Objectively measured proportion of daily steps with prescribed footwear is a valid measure of footwear adherence. Objective wearing time is reasonably valid, and may be used in clinical practice and for long-term measurements. Subjective wearing time is not recommended to be used.

Keywords: diabetic foot; foot ulcer; treatment adherence and compliance; patient compliance; footwear; shoes; validation study

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1. Introduction

Adherence to wearing prescribed footwear by people with diabetes mellitus at risk of foot ulceration is important in the prevention of foot ulcers. Of people with diabetes, 19–34% develop a diabetes-related foot ulcer during their life time [1]. International [2] and national evidence-based guidelines [3–5] recommend the use of therapeutic footwear to reduce this risk. However, several studies have reported that patients' adherence to wearing therapeutic footwear is often low, with patients wearing the footwear for approximately 50% of waking day time [6,7] or 70% of daily number of steps [8], which may contribute to the high recurrence rate of foot ulcers [1,9,10]. Researchers have tried to address this by investigating predictors of adherence [6,11,12] and evaluating interventions to improve adherence [13]. However, studies on different aspects of adherence are difficult to compare and synthesize as the studies have used different methods, both objective and subjective, to assess adherence and wearing time of prescribed footwear [14,15].

The preferred definition of adherence is wearing time of prescribed footwear during and as percentage of weight-bearing activities, as weight-bearing activities typically expose

the feet to risk of developing foot ulcers [14,16]. This definition of adherence implies that the reference standard for adherence measurement should include simultaneous and objective measurement of wearing time of prescribed footwear and weight-bearing activities. This can be achieved by securing a sensor in the footwear and an activity monitor on the body, which measures type and duration of weight-bearing activities such as walking and standing [8,10,13,17–23]. Some studies have used pedometers that record number of steps; however, this measure does not record other weight-bearing activities, such as standing duration, which also puts stress on the feet [24]. Other studies have only measured wearing time of the footwear, without assessing weight-bearing activities of the person; in these studies it is unknown how much the footwear was worn during weight-bearing activities that exposed the feet to risk of foot ulcers [25,26]. In addition to these objective methods, a number of studies have used subjective methods, such as structured interviews and questionnaires, to estimate wearing time [14]. Typically, patients answer a multiple-choice question regarding the daily number of hours (or the proportion of daytime) they use their prescribed footwear. In some studies, this self-reported hours of daily use is weighted by the self-reported number of days the footwear is worn each week [7,14,27,28]. However, each study usually uses only one method to measure adherence or wearing time, which is why we cannot know if the different measures are comparable. We are aware of only one study comparing different measures, reporting a strong correlation ($r = 0.87$) between objectively measured wearing time and objectively measured proportion of steps the prescribed footwear was worn [8]. No study has investigated the validity of different measures of adherence and wearing time in comparison with the proportion of weight-bearing activity time that prescribed footwear is worn, the reference standard for adherence measurement. Thus, the aim of the study was to compare different objective and subjective measures of adherence and wearing time of prescribed footwear to the reference adherence measure, among people at risk of diabetes-related foot ulcers.

2. Materials and Methods

2.1. Participants

Participants were recruited at the two locations of Amsterdam UMC and at podiatry practice Voeten op Texel, in the Netherlands, as part of the study DIALOAD (https://www.trialregister.nl/trial/8839, accessed on 15 December 2022). The DIALOAD is a prospective observational cohort study in which people at high risk of diabetic foot ulceration are followed for 12 months with the aim to unravel biomechanical and behavioral mechanisms of foot ulceration. During August 2020–May 2022, high-risk people visiting the outpatient clinic consultation hours were consecutively screened for eligibility to participate in the study. One hundred three potential participants were informed about the study and asked for interest to participate. Sixty-three people provided written informed consent to participate in the study, whereof three were excluded due to not meeting the criteria to be included, giving sixty people participating in the data collection. Inclusion criteria were age $\geq$ 18 years; diabetes mellitus type 1 or 2; recent history of a diabetes-related foot ulcer (<1 year); or forefoot/midfoot barefoot peak plantar pressure > 600 kPa, being ambulatory and loss of protective sensation (inability to feel a 10 g monofilament and tuning fork following criteria of the IWGDF guidelines [29]). Exclusion criteria were diabetes-related foot ulcer; open amputation site; active Charcot neuro-osteo arthropathy; or use of walking aid for full support and severe peripheral artery disease (WIfI grade 3 [30]).

2.2. Procedures and Data Collection

At study baseline, the participants underwent a physical examination and the participant with semi- or fully custom-made footwear answered the Monitor Orthopaedic Shoes questionnaire [28]. Weight-bearing activities were measured with a triaxial accelerometer for seven consecutive days after the baseline visit (DynaPort MoveMonitor, McRoberts, The Hague, The Netherlands) [31]. The accelerometer had to be worn in the middle of their back, at level L5, and could only be removed during water activities. It has a 100 Hz sampling

frequency, ±6 g range, and 12-bit resolution. The accelerometer had to be worn ≥ 75% of 24 h [32], or ≥12 h if not worn at night [33]. To assess wearing time of prescribed footwear, a temperature sensor (Orthotimer, Rollerwerk, Balingen, Germany), validated in a previous study [26], was secured in the medial arch support of the prescribed footwear's insole (and in a maximum of four pairs) of each participant [25]. One sensor was used per pair of footwear. The sensor was placed in the most appropriate shoe based on foot health, that is, presence of deformities, amputations, pre-signs of ulceration, and/or previous ulcer location. The sensor measured and stored time-stamped temperatures every 15 min. Wearing time was assessed for the same seven days during which the accelerometer was worn. At least four valid days of both activity and temperature data were required for the participant to be included in the analysis [32].

2.3. Measures of Adherence

Objectively measured proportion of weight-bearing time the prescribed footwear was worn was the reference standard, that is, the measure to which the other measures of adherence and wearing time were compared. Two objective and two subjective measures were compared to this reference standard. The reference standard and both objective measures were based on the data from the accelerometer and temperature sensor. The raw data from the accelerometer were categorized using the validated algorithms of the manufacturer into periods of walking, standing, shuffling, stair walking, lying, sitting, cycling, and nonwearing [34,35]. We defined walking, standing, shuffling, and stair walking as weight-bearing activities. The raw data from the temperature sensor were used to determine when the footwear was worn and not worn, using the adapted validated Groningen algorithm [25]. The first objective measure ("Proportion of steps") was defined as the proportion of steps that the prescribed footwear was worn. The second objective measure ("Objective wearing time") was defined as the average daily time that the prescribed footwear was worn. All objective adherence measures were obtained by using custom-written scripts in Matlab (R2021b, The MathWorks, Inc., Natick, MA, USA) and averaged over all valid days.

The two subjective measures were based on two questionnaire items asking for the number of hours (h) each day and number of days each week the prescribed footwear was worn [28]. Rating scales were >12, 8–12, 4–8, 1–4, and <1 h/day, and 6–7, 4–5, 2–3, 1, and 0 days/week, respectively. The first subjective measure ("Subjective wearing time") consisted of the participant's answer regarding the number of h/day the prescribed footwear was worn. The second subjective adherence measure ("Weighted subjective wearing time") consisted of the median self-reported h/day multiplied with the median self-reported days/week divided by 7 (days) [7]. For example, if a participant answered ">12 h/day" and "6–7 days/week", the average wearing time would be $14 \times 6.5/7 = 13$ h/day (assuming 16 h/day out of bed, ">12 h/day" was given the median value of 14).

2.4. Statistical Analysis

Data distributions were first tested for normality using the Shapiro–Wilk test. As neither the reference measure ($p = 0.001$) nor any of the other four measures of adherence and wearing time (p-values < 0.001–0.019) were normally distributed, Spearman's correlation coefficient was calculated for all correlations. First, we calculated the correlation between the reference adherence measure and each of the other measures. We also calculated the correlation between the remaining pairs of measures. Correlation coefficients between 0.00–0.09 were considered negligible, 0.10–0.39 weak, 0.40–0.69 moderate, 0.70–0.89 strong, and 0.90–1.00 were considered very strong [36]. We then calculated the kappa coefficient (K) with quadratic weights between the reference measure and the other measures of adherence and wearing time. In this analysis, the reference measure and proportion of daily steps footwear was worn were categorized into 0–20%, >20–40%, >40–60%, >60–80%, and >80–100% adherence and proportion of steps footwear was worn, respectively. Objective wearing time was categorized according to the increments used as the rating scale for subjective wearing time, i.e., >12, 8–12, 4–8, 1–4, and <1 h/day. Kappa values in the range 0–0.20

were considered to reflect no agreement, 0.21–0.39 minimal agreement, 0.40–0.59 weak agreement, 0.60–0.79 moderate agreement, 0.80–0.90 strong agreement, and >0.90 almost perfect agreement [37]. Finally, we calculated the area under the curve (AUC) in the receiver operating characteristic (ROC) curve, and sensitivity, specificity, positive predictive value, and negative predictive value for each measure. In these analyses, we dichotomized participants into highly and lowly adherent according to the reference measure, using 60%, 70%, 80%, and 90% as cut-offs. An AUC of 1.0 indicates that the measure perfectly classifies participants as highly or lowly adherent. An AUC range 0.7–0.8 is considered acceptable, 0.8–0.9 is considered excellent, and >0.9 is considered outstanding [38]; *p*-values < 0.05 and 95% confidence intervals not overlapping zero were considered to indicate statistical significance in all tests. We used the Vasserstat website (http://vassarstats.net/, accessed on 15 December 2022) to calculate the kappa coefficient and IBM SPSS Statistics for Windows, version 26.0 (Armonk, NY, USA: IBM Corp.) for all other analyses.

3. Results

Seven of the sixty participants were excluded after data collection due to missing temperature sensor data for one or more sensors (n = 3), less than four valid days of activity (n = 3) and no activity data due to lost accelerometer (n = 1). The 53 participants who were included in the analyses consisted of 43 men and 10 women with a mean age of 65.3 years; 81.1% of the participants had diabetes type 2, all but 2 participants had a history of foot ulcers and the average body mass index was close to 30. More characteristics of the participants can be found in Table 1.

Participants spent on average 3.5 h/day in weight-bearing activities (Table 1), and wore their prescribed footwear on average 62.2% of the weight-bearing activity time. Participants took on average 5835 daily steps and wore their prescribed footwear for 63.9% of these steps. Objective wearing time of prescribed footwear was on average 10.3 h/day. Median subjective wearing time was 8–12 h/day and average weighted subjective wearing time was 9.3 h/day (Figure 1).

Table 1. Characteristics of study participants and daily activities with and without prescribed footwear.

Participants' Characteristics			**Mean (SD) or n (%)**
Sex, men/women			43 (81.1)/10 (18.9)
Age, years			65.3 (9.4)
BMI			29.6 (5.6)
Diabetes type, type 1/2			10 (18.9)/43 (81.1)
Diabetes duration, years			18.9 (12.0)
HbA1c (n = 6 missing)	NGSP, %		7.7 (3.8)
	IFCC, mmol/mol		60.6 (17.9)
Foot deformities a	Absent		0
	Mild		2 (3.8)
	Moderate		45 (84.9)
	Severe		6 (11.3)
History of foot ulcer			51 (96.2)
Amputations b	No		33 (62.3)
	Smaller toes		8 (15.1)
	Hallux or more proximal partial foot		10 (18.9)
	Through or above ankle		2 (3.8)
Type of prescribed footwear	Prefabricated		6 (11.3)
	Semi-custom-made		14 (26.4)
	Fully custom-made		33 (62.3)
Steps and weight-bearing activities with and without prescribed footwear			
	With prescribed footwear	Total, with and without prescribed footwear	Proportion with prescribed footwear, %

Table 1. *Cont.*

Participants' Characteristics			Mean (SD) or n (%)
Number of daily steps, mean (SD)	3678 (2784)	5835 (3731)	63.9 (24.5)
Number of hours of daily weight-bearing activity time, mean (SD)	2.2 (1.3)	3.5 (1.6)	62.2 (23.4)

BMI, body mass index; SD, standard deviation. [a] Foot deformities were classified according to the foot with the worst deformity. Mild deformities were pes planus, pes cavus, hallux valgus, hallux limitus, hammer toes, and lesser toe amputation; moderate deformities were hallux rigidus, hallux or ray amputation, prominent metatarsal heads, and claw toes; severe deformities were Charcot deformity, (fore)foot amputation, and pes equines. [b] Amputations were classified according to the side with the most proximal amputation. Continuous variables are reported as mean (SD) and categorical variables as *n* (%).

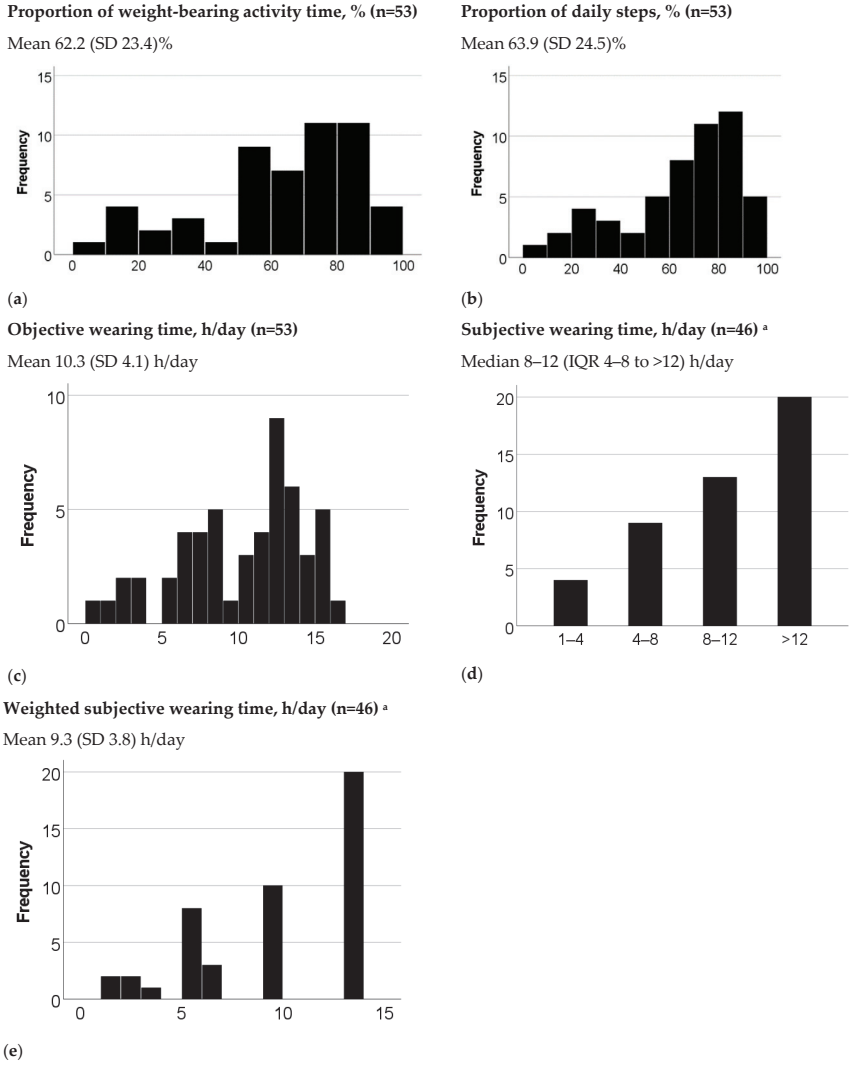


Figure 1. Summary of results on measures of adherence and wearing time. SD, standard deviation; IQR, interquartile range: [a] The six participants with prefabricated footwear did not answer the questions on subjective wearing time and one participant with fully custom-made footwear had missing answers.

The two subjective measures of wearing time had a very strong correlation, r = 0.99 ($p < 0.001$). Therefore, we decided to only include the (unweighted) subjective wearing time in the further analyses. Proportion of steps that the prescribed footwear was worn correlated very strongly (r = 0.96, $p < 0.001$) and objective wearing time correlated very strongly (r = 0.91, $p < 0.001$) with the reference measure (Figure 2). Subjective wearing time had a moderate correlation with the reference measure (r = 0.42, $p = 0.004$). Proportion of daily steps footwear was worn correlated strongly with objective wearing time (r = 0.87, $p < 0.001$) and moderately with subjective wearing time (r = 0.43, $p = 0.003$). Objective wearing time of footwear correlated moderately with subjective wearing time (r = 0.46, $p = 0.001$).

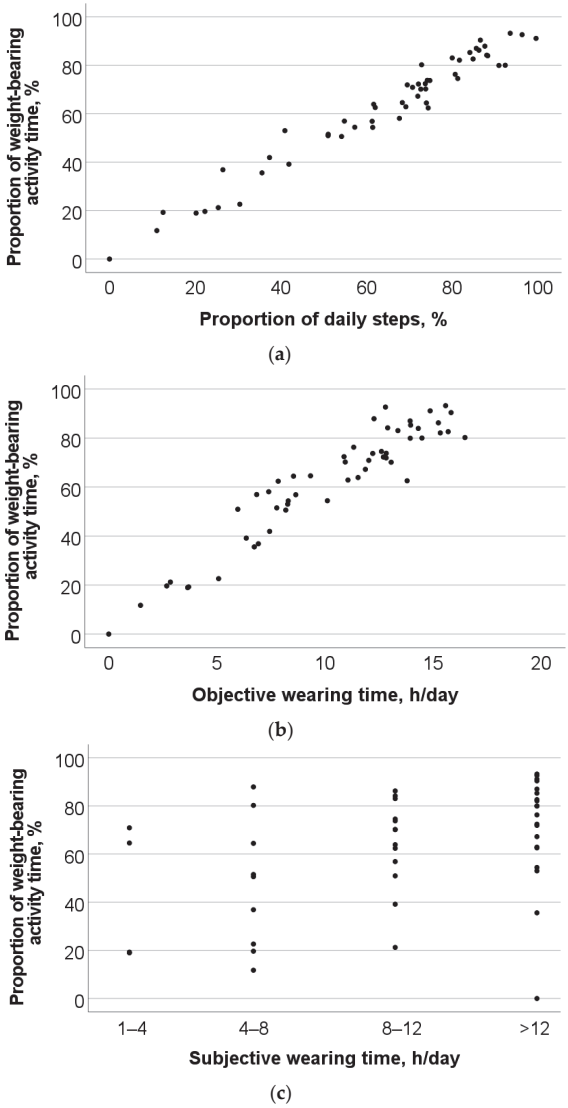
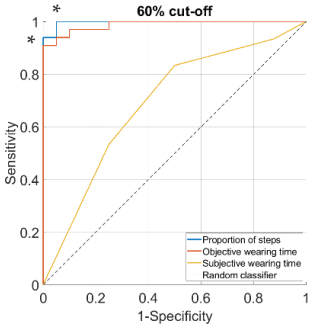
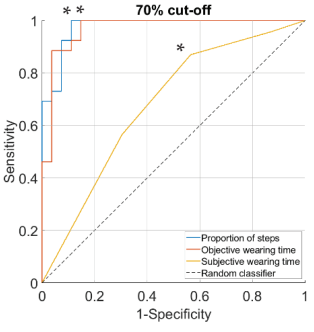
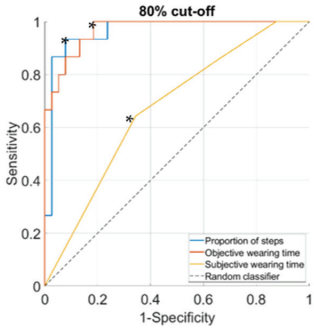
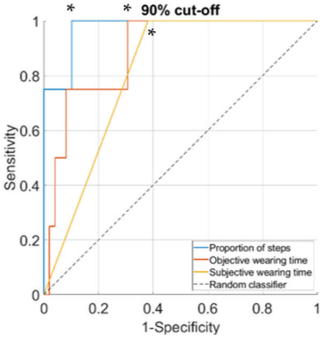


Figure 2. Scatter plots and Spearman's correlation coefficients (r) for the associations with the reference measure: (**a**) r = 0.96 ($p < 0.001$), (**b**) r = 0.91 ($p < 0.001$), (**c**) r = 0.42 ($p = 0.004$).

Proportion of daily steps prescribed footwear was worn had almost perfect agreement (K = 0.93, 95% CI not possible to calculate), objective wearing time had strong agreement (K = 0.85, 95% CI not possible to calculate), and subjective wearing time had minimal agreement (K = 0.38, 95% CI: 0.15–0.61) with the reference adherence measure. The AUC was outstanding for proportion of steps (0.96–1.00), ranged from excellent to outstanding for objective wearing time (0.89–0.99) and ranged from not acceptable to excellent for subjective wearing time (0.67–0.81), for the different cut-offs used to classify participants as highly or lowly adherent (Table 2).

Table 2. Area under the curve (95% confidence interval) and receiver operating characteristic (ROC) curves for the associations with the reference measure.

	Cut-Off for "High Adherence" According to the Reference Measure	
	60%	**70%**
Proportion of steps	1.00 (0.99–1.00)	0.98 (0.94–1.00)
Objective wearing time	0.99 (0.97–1.00)	0.97 (0.92–1.00)
Subjective wearing time	0.69 (0.52–0.85)	0.68 (0.52–0.84)
ROC curves		
	80%	**90%**
Proportion of steps	0.96 (0.91–1.00)	0.97 (0.92–1.00)
Objective wearing time	0.97 (0.93–1.00)	0.89 (0.76–1.00)
Subjective wearing time	0.67 (0.51–0.84)	0.81 (0.66–0.95)
ROC curves		

Note: diagonal lines in the ROC curves are the result of ties in the data on subjective wearing time; * suggested cut-offs, see details in Table 3.

Sensitivity was 93–100% for proportion of steps, 91–100% for objective wearing time, and 64–100% for subjective wearing time (Table 3). Specificity was 89–95% for proportion of steps, 69–100% for objective wearing time, and 43–66% for subjective wearing time.

The positive predictive value was 44–97% for proportion of steps, 21–100% for objective wearing time, and 20–76% for subjective wearing time. The negative predictive value was 97–100% for proportion of steps, 87–100% for objective wearing time, and 62–100% for subjective wearing time.

Table 3. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for different cut-offs for "high adherence" according to the reference measure.

60% cut-off for "high adherence"					
Measure	**Cut-off [a]**	**Sensitivity**	**Specificity**	**PPV**	**NPV**
Proportion of steps	≥61.6%	100%	95%	97%	100%
Objective wearing time	≥10.5 h/day	91%	100%	100%	87%
Subjective wearing time	≥category "8–12 h/day"	83%	50%	76%	62%
70% cut-off for "high adherence"					
Measure	**Cut-off [a]**	**Sensitivity**	**Specificity**	**PPV**	**NPV**
Proportion of steps	≥69.4.0%	100%	89%	90%	100%
Objective wearing time	≥10.5 h/day	100%	85%	87%	100%
Subjective wearing time	≥category "8–12 h/day"	87%	43%	61%	77%
80% cut-off for "high adherence"					
Measure	**Cut-off [a]**	**Sensitivity**	**Specificity**	**PPV**	**NPV**
Proportion of steps	≥77.4%	93%	92%	82%	97%
Objective wearing time	≥12.2 h/day	100%	82%	68%	100%
Subjective wearing time	≥category " > 12 h/day"	64%	66%	45%	81%
90% cut-off for "high adherence"					
Measure	**Cut-off [a]**	**Sensitivity**	**Specificity**	**PPV**	**NPV**
Proportion of steps	≥86.4%	100%	90%	44%	100%
Objective wearing time	≥12.7 h/day	100%	69%	21%	100%
Subjective wearing time	≥category " > 12 h/day"	100%	62%	20%	100%

CI, confidence interval. [a] The cut-off that maximized the sum of sensitivity and specificity.

For all cut-offs used to classify participants as highly and lowly adherent, the sensitivity and specificity values were equal or higher for proportion of steps than for the corresponding values for subjective wearing time (Table 3). In most cases, the sensitivity and specificity values for objective wearing time fell between the corresponding values for proportion of steps and subjective wearing time. For example, using ≥70% of weight-bearing activity time prescribed footwear is worn as cut-off for high adherence, wearing prescribed footwear for ≥69.4% of daily steps had a sensitivity of 100% and a specificity of 89%, an objective wearing time of ≥10.5 h/day had a sensitivity of 100% and a specificity of 85%, and a subjective wearing time of ≥8–12 h/day had a sensitivity of 87% and a specificity of 43%.

4. Discussion

This is the first study that focused on the comparison of different methods to measure adherence and wearing time of prescribed footwear among people at high risk of developing diabetes-related foot ulcers. As adherence to wearing prescribed footwear is essential to reduce the risk of foot ulcers [10], it is important to assess adherence in a valid way. We found that the reference measure of adherence, proportion of weight-bearing activity time that the prescribed footwear was worn, was very strongly associated with proportion of daily steps footwear was worn, strongly associated with objective wearing time, but only weakly associated with subjective wearing time. We used different cut-offs to dichotomize the participants into those with high and low adherence, as different cut-offs have been suggested in the literature [15]. However, the main results were not dependent on the particular cut-off chosen: proportion of daily steps was the most valid measure in all comparisons and subjective wearing time was the least valid measure.

These findings suggest that proportion of steps that prescribed footwear is worn is a valid estimate of proportion of weight-bearing activity time that the footwear is worn, in both research and clinical contexts. This implies that findings of studies using these two measures as outcomes are comparable, and that simple and less expensive activity monitors, e.g., validated pedometers, can be used to determine adherence [35]. The strong correlation of objective wearing time with the reference measure implies that wearing time may be valid to estimate proportion of weight-bearing activity time that the footwear is worn. Measuring wearing time only requires a sensor in the footwear and is therefore less burdensome to patients and less expensive than the other objective measures that require an additional activity monitor to be worn on the body [14]. In addition, wearing time sensors typically can record and store data for longer times than accelerometers, enabling long-term measurements. However, although objective wearing time may be useful to measure in clinical practice, the association with the reference measure of adherence may not be strong enough in all research contexts. Therefore, as the outcome measure, research studies on footwear adherence should preferably use proportion of steps or proportion of weight-bearing activity time prescribed footwear is worn.

The two subjective measures of wearing time of prescribed footwear correlated very strongly with each other. Therefore, we chose to only include one of them in further analyses, where we found that the correlations with the reference measure and the other two objective measures were weak. This suggests that these two subjective measures of wearing time are not valid to be used. This is an important finding as similar subjective measures of wearing time have frequently been used in research studies [11,14] and are often used in clinical practice. Because subjective methods are easy to use in any setting, further development and testing of other subjective measures than the ones tested in this study may provide a more valid subjective alternative. Potential subjective measures could include footwear wearing diaries or more elaborate questionnaires to estimate wearing of prescribed footwear from a number of different questions.

There is no gold standard measure of adherence [39]. The adherence measure used as reference in this study is based on the assumption that adherence is defined in terms of using prescribed footwear during all weight-bearing activities. The purpose of using prescribed footwear in people with diabetes is to protect the feet against all acute and chronic trauma that could trigger the development of a foot ulcer in the presence of predisposing risk factors, such as, loss of protective sensation, foot deformities, and peripheral artery disease [40]. Under the assumption that ulcer-inducing trauma can only occur during weight-bearing activities, such as standing and walking, it is reasonable to define adherence as the proportion of weight-bearing activity time prescribed footwear is used, and use the reference measure of this study as the method in which to compare other measures. However, for some patients, ulcer-inducing trauma may present outside weight-bearing activities. For example, for a patient sitting in a wheel-chair all day, adherence could be defined as the proportion of overall out-of-bed time the prescribed footwear is worn and, thus, objective wearing time is a more appropriate adherence measure to be used as reference. This has implications for the definition of adherence to prescribed footwear. The International Working Group on the Diabetic Foot defines adherence to offloading intervention as "the extent to which a person's behavior corresponds with agreed recommendations for treatment from a health care provider, expressed as quantitatively as possible; usually defined as the proportion of time using the prescribed offloading intervention of the total time in which the intervention is prescribed to be used (e.g., % of the total weight bearing time that the patient was wearing the prescribed offloading device)" [41]. In the context of adherence to prescribed footwear to prevent diabetes-related foot ulcers, this definition may need to reflect all situations that include risk of ulcer-inducing trauma.

Strengths of the study were that different measures of footwear adherence and wearing time were compared in the same people, and validated algorithms were used to classify activities and determine when footwear was worn. Furthermore, we measured wearing time with temperature sensors in up to four pairs of footwear per participants. Although

six participants had more than four pairs of prescribed footwear, we believe these are too few to have had any substantial impact on the results. A limitation of the study was the missing data on the subjective wearing time of prescribed footwear, which resulted in wide confidence intervals on the estimations of the AUC for subjective wearing time.

5. Conclusions

Objectively measured proportion of daily steps prescribed footwear is worn is a valid measure of footwear adherence. Objectively measured wearing time is reasonably valid, and may be used in clinical practice and for long-term measurements. The two subjective measures of wearing time are not recommended to be used.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki. The requirement for ethical review and formal approval of the study by a certified ethical committee were waived under the Medical Research Involving Human Subjects Act in the Netherlands by the certified medical ethics committee of Amsterdam UMC (registration number: W19_429#19.495).

Informed Consent Statement: Informed consent was obtained from all participants in the study.

Data Availability Statement: The datasets generated and analyzed during the current study are not publicly available due to current Dutch ethical legislation and the European Union GDPR Act.

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Conflicts of Interest: G.J. is a consultant for Novo Nordisk. C.M.H., T.E.B.-W., J.J.v.N. and S.A.B. declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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Could an Internet-Based Foot–Ankle Therapeutic Exercise Program Modify Clinical Outcomes and Gait Biomechanics in People with Diabetic Neuropathy? A Clinical Proof-of-Concept Study

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Abstract: Previous studies have shown the efficacy of foot–ankle exercises in people with diabetic peripheral neuropathy (DPN), but the quality of evidence is still low. This proof-of-concept study pursues preliminary evidence for potential clinical and gait biomechanical benefits from an internet-based foot–ankle therapeutic exercise program for people with DPN. We randomized 30 individuals with DPN (IWGDF risk category 1 or 2) into either the control group (CG) receiving the usual care or the intervention group (IG) receiving the usual care plus an internet-based foot–ankle exercise program, fully guided by the Sistema de Orientação ao Pé Diabético (SOPeD; translation: Diabetic Foot Guidance System) three times per week for 12 weeks. We assessed face-to-face clinical and biomechanical outcomes at baseline, 12 weeks, and 24 weeks (follow up). Participants had good adherence to the proposed intervention and it led to only mild adverse events. The IG showed improvements in the ankle and first metatarsophalangeal joint motion after 12 and 24 weeks, changed forefoot load absorption during foot rollover during gait after 24 weeks, reduced foot pain after 12 weeks, and improved foot function after 24 weeks. A 12-week internet-based foot–ankle exercise program using the SOPeD software (version 1.0) has the potential to reduce foot pain, improve foot function, and modify some important foot–ankle kinematic outcomes in people with DPN.

Keywords: diabetic neuropathies; exercise therapy; foot-related exercises; eHealth; rehabilitation technology; proof of concept

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1. Introduction

It is estimated that between 12 and 50% of people with diabetes have some degree of diabetic peripheral neuropathy (DPN), which is the most prevalent chronic complication 10 to 15 years after a diabetes diagnosis [1,2]. DPN compromises the structure and functioning of the peripheral nerves, which, in turn, causes sensorimotor disorders [3]. As a result of these disorders, musculoskeletal and biomechanical alterations arise in daily living activities, affecting the quality of motion and functional performance. The most common musculoskeletal alterations are changes in the mechanical properties of joint tissues due to the accumulation of advanced glycation products [4], increased stiffness and reduced range of motion (ROM) in distal joints [5,6], loss of lower-limb muscles strength [7,8], and atrophy of the foot–ankle intrinsic and extrinsic muscles [9–12]. Biomechanical alterations arise from progressive musculoskeletal changes that compromise proper foot rollover during gait, increasing the loads on the plantar surface [13–15], which, in turn, increases the risk for foot ulcers [13–18].

From the 2000s to the present day, there have been significant advances in the investigation of the effects of therapeutic exercises targeting the main musculoskeletal and biomechanical deficits of the foot–ankle in people with DPN. These studies have proven the efficacy of these exercises for reducing DPN symptoms and increasing foot–ankle ROM, although the quality of evidence is still low [19]. Therefore, there is still room for investigation of the efficacy of different exercise approaches on biomechanical and clinical outcomes as well as the evaluation of new outcomes, such as foot kinematics and foot–ankle kinetics, which have not yet been addressed [20–22]. Although the most recent guidelines from the International Working Group on the Diabetic Foot (IWGDF) [23] incorporated foot–ankle exercises as a new intervention to treat modifiable risk factors for ulceration, this kind of exercise is still poorly recognized among clinicians and not yet widely adopted among rehabilitation professionals. Thus, only a few patients have had the opportunity to benefit from this recommended intervention.

Recently incorporated in healthcare contexts due to the COVID-19 pandemic, telerehabilitation and web-based therapeutic interventions have emerged as promising strategies for including foot–ankle exercises in people's daily routine because of their convenience, reduced costs, and accessibility [24–27]. This e-health intervention could help address the adherence and compliance problems usually reported among these patients, such as low self-motivation, treatment costs, and longer treatment duration [28]. Inspired by this scenario, our research group developed and validated the Sistema de Orientação ao Pé Diabético (SOPeD; translation: Diabetic Foot Guidance System; www.soped.com.br, accessed on 19 May 2022), which customizes foot–ankle exercises and stimulates self-care and self-management actions in people with diabetes and DPN. This free software has emerged as an alternative to face-to-face physiotherapy to treat musculoskeletal disorders arising from diabetes and DPN [29]. The proposed clinical proof-of-concept study pursues preliminary evidence for the potential efficacy of a 12-week internet-based foot–ankle therapeutic exercise program for people with diabetes and DPN to promote clinical and gait biomechanical changes.

2. Method

2.1. Study Design

This clinical proof-of-concept study is part of a full randomized controlled clinical trial, the Foot Care I (FOCA-I). Reporting is based on the Consolidated Standards of Reporting Trials extension for web-based and mobile-health interventions (CONSORT-EHEALTH) [30]. The main trial was approved by the ethics committee of the School of Medicine of the University of Sao Paulo (CAAE: 90331718.4.0000.0065) and was prospectively registered at ClinicalTrials.gov on 8 July 2019 (NCT04011267). The full protocol is detailed elsewhere [31]. This clinical proof-of-concept study and the main trial were designed as a parallel-group, two-arm, superiority trial with a 1:1 allocation ratio.

Allocation to the control group (CG; n = 15) and intervention group (IG; n = 15) was performed after acquiring baseline data using a randomization sequence [32] that was kept in opaque and sealed envelopes after having been organized into blocks by an independent researcher. Only the physiotherapist responsible for the intervention's prescription was aware of group allocation. The Brazilian General Law for the Protection of Personal Data (No. 13.709/2018) was respected by encoding the names of the participants and keeping the personal data confidential before, during, and after the study. The study statistician and the two other researchers responsible for all clinical and biomechanical assessments were blinded to the allocation. The participants were assessed at baseline, after 12 weeks of intervention, and after 24 weeks from baseline (follow-up measure) at the Physical Therapy Department of the School of Medicine of the University of São Paulo.

Data for this clinical proof-of-concept study were collected between September 2019 and September 2021 (Figure 1). Participants were recruited from the patient database of the Endocrinology Outpatient Clinic of the Hospital das Clínicas, School of Medicine, University of São Paulo.

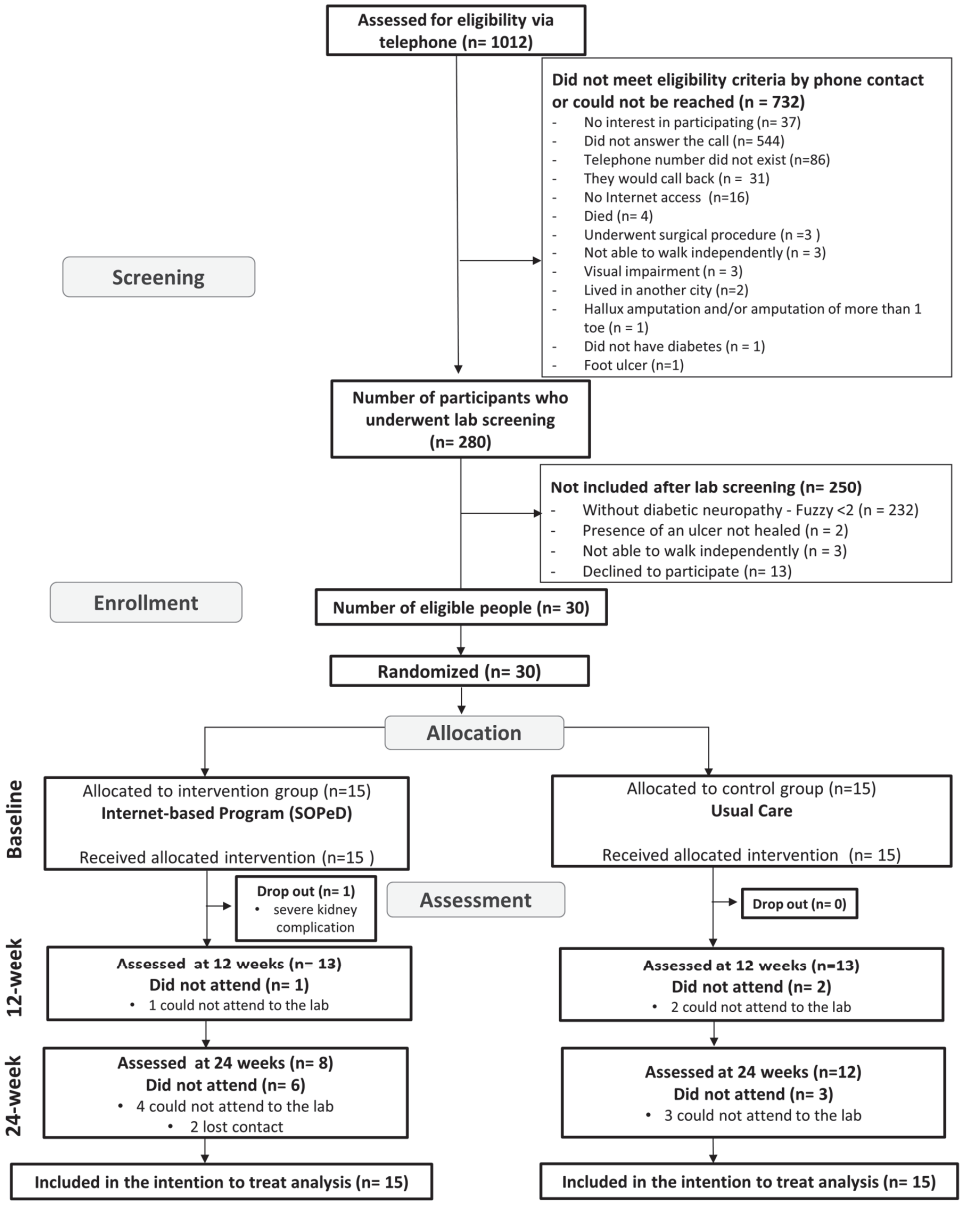

Figure 1. Flowchart of recruitment, assessment, and follow-up process of the proof-of-concept study.

2.2. Participants

The first 30 adults from the FOCA-I trial were included in this study. Adults of both sexes, between 18 and 65 years old, and with a clinical diagnosis of type 1 or 2 diabetes and DPN (IWGDF risk category 1 or 2) were considered. The first contact with the patient was made by telephone, and the potential participants were assessed at the biomechanics laboratory to confirm the eligibility criteria: independent walking ability, access to the internet and ability to use electronic devices (e.g., computer, mobile phone, or tablet), and DPN severity score above 2 confirmed by the Decision Support System for Classification

of Diabetic Polyneuropathy [33] (www.usp.br/labimph/fuzzy, accessed on 19 May 2022). This system is based on fuzzy logic and three input variables: signs and symptoms extracted from the Brazilian version of the Michigan Neuropathy Screening Instrument (MNSI-BR), vibration sensitivity evaluated by a tuning fork (128 Hz), and tactile sensitivity measured by a 10 g monofilament.

Participants with any of the following criteria were not included: amputation of any foot parts; an ulcer that had not healed for at least 6 months and/or an active ulcer; history of surgical procedures in the foot, ankle, knee, or hip or indication of surgery or arthroplasty; arthroplasty and/or orthosis of lower limbs or indication of lower-limb arthroplasty throughout the intervention period; diagnosis of other neurological disease outside diabetes etiology; dementia or inability to provide consistent information; receiving any physiotherapy or offloading devices throughout the intervention; use of assistive devices for walking; and major vascular complications and/or severe retinopathy as determined from medical files. The principal investigator explained to each eligible participant all stages of the study, possible risks, and expected benefits. Upon agreeing to participate, they were asked to sign an informed consent form.

2.3. Treatment Arms

CG participants received the usual care, including treatment recommended by the medical team, standard pharmacological treatment, and self-care guidelines based on the IWGDF [34]. According to IWGDF recommendations, the use of therapeutic footwear or a custom-made insole is mandatory for patients with high ulcer risk (IWGDF category 3). As there is no mandatory prescription for low and moderate ulcer risk patients (IWGDF categories 1 or 2), the use of therapeutic footwear or a custom-made insole was not prescribed for the participants included in this study. These self-care guidelines, adjusted for our study, were printed on a flyer given to all participants and included educational orientations (Supplementary Material—flyer of self-care based on IWGDF).

IG participants followed the usual care plus an internet-based foot–ankle exercise program guided by the SOPeD. The exercise program had a total of 36 sessions (three sessions per week for 12 consecutive weeks) and each session, including eight exercises, lasted 20 to 30 min and was performed at a time convenient for the participant. The comprehensive therapeutic exercise protocol is detailed elsewhere [29,31], but in summary, the SOPeD includes a total of 104 functional, stretching, and strengthening exercises of the extrinsic and intrinsic foot muscles (Figure 2A). The progression for each exercise in intensity and complexity was customized based on the individual's perceived effort as determined by an algorithm (Figure 2B). If the effort category selected by the participant was "not tiring" or "a little tiring" the software increased the exercise intensity at the next session. If the user selected "tiring" the software advanced to the next intensity level after two sessions at the current exercise intensity. If "very tiring" was selected, the software decreased the difficulty/intensity and returned to the previous level. No changes were made to the software content, and the intervention protocol algorithm remained the same throughout the clinical trial. The SOPeD includes gamification components [35] to increase adherence and encourage users to continue exercising (Figure 2C).

The first session was delivered face to face by the physiotherapist to explain the use of the software, ensure the correct execution of the exercises, and deliver a kit with materials for performing the exercises (cotton balls, a towel, a pencil, mini elastic bands, balloons, light- and moderate-resistance elastic bands, a massage ball, and finger separators) to the IG participants. The main physiotherapist supervised all of the other 35 sessions remotely via the SOPeD interface. Participants in the intervention group received access to use SOPeD that aims to provide self-care and allows the user to choose the best and most convenient time to carry out the exercise sessions. The exercise sessions were not monitored synchronously, but the main researcher could have access to SOPeD administrator, at any time, to monitor how often they accessed the software and how many exercise sessions were performed by each participant. Participants were instructed to stop exercising and

communicate with the main researcher if they experienced cramps, moderate to severe pain, excessive fatigue, or any other condition that caused discomfort.

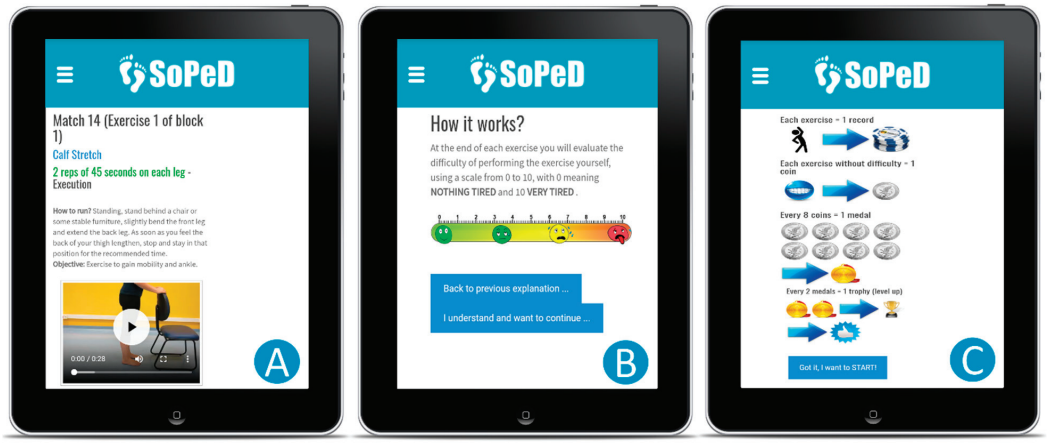

Figure 2. Sistema de Orientação ao Pé Diabético (SOPeD; translation: Diabetic Foot Guidance System). (**A**) Layout of the exercises page with video, audio, and written instructions. (**B**) Perceived effort scale to be completed after each exercise performed. (**C**) Exercise protocol rules with gamification components.

Every two weeks, a physiotherapist called the participants to check on their performance, difficulties, and the occurrence of any adverse events. If the IG participant did not access the software for more than three sessions in a row, an email was automatically sent, and the main researcher made a phone call to those participants who did not respond to email reminders. During the follow-up period, IG participants were encouraged to follow the same exercise schedule set by the SOPeD program until the end of the study (24 weeks), but they were not remotely monitored.

The average number of sessions completed (36 sessions total) by IG participants was used to calculate the adherence to the program [36]. The number of all completed sessions was obtained from the SOPeD user databank and computed, even if the participant did not complete the full set of exercises in a given session.

2.4. Outcome Measures

The primary outcomes were DPN symptoms and severity, as both were subject to improvements after therapeutic foot–ankle exercises [21,37], are important modifiable factors, and DPN severity is an outcome assessed using a more comprehensive score than just using symptoms as outcomes, which includes DPN symptoms and signs (vibration and tactile sensitivities). Symptoms were measured using the MNSI-BR, which comprises 15 questions with a total score ranging from 0 to 13 (with 13 representing the worst DPN) [38]. DPN severity was determined by the Decision Support System for Classification of Diabetic Polyneuropathy [33], the scores of which range from 0 to 10, with a higher fuzzy score indicating more severe DPN. The secondary outcomes included foot health and functionality, toe and hallux strength, plantar pressure distribution, and joint kinetics and kinematics during gait.

Foot health and functionality were assessed using the Brazilian version of the Foot Health Status Questionnaire, for which the scores range from 0 to 100 points, where 100 represents the best condition and 0 the worst [39]. Hallux and toe isometric strength was assessed standing using a pressure platform (emed-q100; novel GmbH, Munich, Germany) according to the protocol by Mickle et al. [40]. Maximum force (N) was normalized by body weight and analyzed for the hallux and toe areas separately using a standard mask from

novel Multimask software v.9.35 (novel GmbH). The average of the four trials (right and left side) was used for statistical purposes following the rationale described by Menz [41].

Peak pressure, pressure–time integral, and contact area during gait were acquired by the emed-q pressure platform at 100 Hz. The participants walked six times barefoot over the platform at a self-selected comfortable speed. Seven plantar regions of interest (heel, midfoot, medial forefoot, central forefoot, lateral forefoot, hallux, and toes) were assessed by a geometric mask using the novel software. The average of the six trials (right and left side) was used for statistical purposes [40].

The foot–ankle kinematic parameters were recorded using eight infrared cameras at 100 Hz (Vicon VERO; Oxford Metrics, Oxford, UK). Forty-two passive reflective markers (9.5 mm in diameter) were positioned on both lower limbs following the Plug-In Gait and Oxford Foot Model [42] setup protocols. Ground reaction forces for the joint moment calculations were acquired by a force plate (AMTI OR-6-1000; AMTI, Watertown, MA, USA) with a sampling frequency of 1 kHz. A 16-bit analog-to-digital converter was used to synchronize and sample the kinematic and ground reaction force data.

Participants were instructed to walk at a comfortable self-selected speed along a 10 m track with a maximum variation of 5% between measurements. The speed was monitored by two photoelectric cells (Model Speed Test Fit; CEFISE, Nova Odessa, Brazil) to ensure that the same speed was maintained in all assessments (baseline, 12 weeks, and 24 weeks). Five valid steps were acquired during gait and the average (right and left side) was used for statistical purposes [40].

The Motion Capture Nexus 2.6 software (Oxford Metrics) was used for automatic digitizing, three-dimensional reconstruction of marker positions, kinematic and kinetic data filtering, and joint moment calculations. Kinematic data were processed using a zero-lag second-order low-pass filter with cutoff frequency of 6 Hz. Ground reaction force data during walking were processed using a zero-lag low-pass Butterworth fourth-order filter with cutoff frequency of 50 Hz. The bottom-up inverse dynamics method was used to calculate the ankle joint moment in the sagittal plane. For the calculation of the ankle power, the calculated joint moment and angular velocity of the ankle in the sagittal plane were considered. All discrete variables from the angles and moments time series were calculated with the open-source Python package pyCGM2 (http://www.pycgm2.github.io, accessed on 19 May 2022), which replicates the Vicon Plug-In Gait protocol and the Oxford Foot Model Plug-In.

2.5. Statistical Analysis

The main trial sample size was calculated using two important outcomes for patients with DPN. Considering the primary outcome (DPN symptoms), a medium effect size (0.52) was adopted and, for the secondary outcome (peak pressure at forefoot), a small effect size (0.20) was adopted. In order to obtain the largest sample size, the smallest effect size (0.20) was used. A statistical design of F-test repeated measures and interaction between and within factors with two repeated measures and two study groups, a statistical power of 0.80, an alpha of 0.05, and an effect size of 0.20 were used for the sample size calculation. The resulting sample size was 52 individuals. A final sample size of 62 patients was then chosen after estimating a drop-out rate of 20%. The current study presents the findings for the first 30 participants.

According to normal data distribution (Shapiro–Wilk test, $p > 0.05$), the baseline participants' characteristics were reported as means and standard deviations, numbers and percentages, or medians and interquartile ranges (IQRs). An intention-to-treat approach and the Generalized Estimating Equation (GEE) method were used with an exchangeable correlation structure and the following fixed factors: groups (CG and IG), assessment timepoint (baseline, 12 weeks, and 24 weeks), and the interaction effect (group–time). The Gamma distribution was used to select the GEE model based on the quasi-likelihood under the independence model criterion, resulting in a better model fit. Between-group differences at 12 and 24 weeks and their 95% confidence intervals were reported [43]. All

statistical analyses were carried out using SPSS v.22.0 (IBM, Armonk, New York, NY, USA) with a significance level of 5%.

3. Results

Participant flow, attendance at follow-up assessment visits, and reasons for dropout are presented in Figure 1. At baseline, the groups were similar for all characteristics and outcomes assessed (Table 1). In the IG, 14 participants (93.3%) completed the 12-week internet-based foot–ankle therapeutic exercise program and the adherence was 62.0%. The dropout rate in the IG, that is, the number of participants who did not attend both assessments at 12 and 24 weeks, was 6.6% (one participant). Unfortunately, some participants in both groups did not attend the 12- and 24-week follow-up visits due to the COVID-19 pandemic (lost to follow up). The lost-to-follow-up rate at 12 weeks was 10% for the whole sample, 13.3% in the CG (two participants), and 6.6% in the IG (one participant). The lost-to-follow-up rate at 24 weeks was 20% in the CG (three participants) and 40% in the IG (six participants). In addition, two patients from the IG reported mild adverse effects of the intervention, which were delayed onset muscle soreness and cramping in the foot muscles. None of the participants withdrew from the trial due to adverse effects.

Table 1. Clinical, demographic, and anthropometric outcomes at baseline for the control and intervention groups.

	Control Group (n = 15) Mean (SD)	Intervention Group (n = 15) Mean (SD)
Age (years)	56.5 (9.9)	51.1 (10.2)
Body mass (kg)	81.5 (18.6)	80.0 (16.5)
Height (cm)	161.0 (0.1)	169.0 (0.1)
Body mass index (kg/m^2)	31.8 (8.1)	28.0 (5.1)
Sex (Female) (n, %)	(F = 10/66.6%)	(F = 8/53.3%)
Type 2 Diabetes (number of participants, %)	14 (93%)	13 (86.6%)
Time of onset of diabetes (years)	10.8 (7.4)	18.8 (11.8)
Education (number of participants, %)		
Elementary education incomplete	0 (0%)	1 (6.6%)
Elementary education complete	2 (13.3%)	0 (0%)
High school incomplete	3 (20.1%)	0 (0%)
High school complete	7 (46.7%)	5 (33.4%)
Higher education incomplete	1 (6.6%)	0 (0%)
Higher education complete	2 (13.3%)	9 (60.0%)
Socioeconomic status (number of participants, %)		
1 to 3 Brazilian minimum salary/month	13 (86.7%)	7 (46.7%)
3 to 5 Brazilian minimum salary/month	2 (13.3%)	1 (6.6%)
Up to 5 Brazilian minimum salary/month	0 (0%)	7 (46.7%)
DPN symptoms (MNSI score)	6.9 (1.5)	7.3 (1.8)
DPN severity (Fuzzy score)	3.5 (1.8)	4.3 (2.3)
Tactile sensitivity (number of areas, Median [IQR])	0 [0–0]	0 [0–1]
Vibration Perception (number of participants, %)		
absent-L	1 (6.6%)	5 (33.3%)
reduced-L	0 (0%)	3 (20%)
absent-R	3 (20%)	3 (20%)
reduced-R	2 (13.3%)	4 (26.6%)
FHSQ (score)		
Foot pain	39.8 (21.3)	50.9 (22.5)
Foot function	56.2 (27.2)	68.7 (24.1)
Shoes	41.7 (37.8)	59.4 (37.8)
Foot health	22.5 (19.8)	15.8 (12.0)
Foot Strength (%BW)		
Hallux	17.0 (6.8)	10.9 (4.1)
Toe	10.3 (5.2)	8.2 (3.8)

Data are presented as mean (SD) or as n or %; and median (interquartile range IQR). Abbreviation: MNSI-Michigan Neuropathy Screening Instrument; L—Left; R—Right; FHSQ—Foot Health Status Questionnaire; DPN diabetic peripheral neuropathy; BW—body weight.

After 12 and 24 weeks, the IG displayed no significant interaction effects for any clinical or plantar pressure outcomes but did show group and time effects (Tables 2 and 3). The between-group analysis showed a significant reduction in foot pain in the IG compared

to the CG at 12 weeks (group effect: $p = 0.023$, post hoc: $p = 0.004$) and within the IG after 12 weeks (post hoc: $p = 0.001$) and 24 weeks (post hoc: $p = 0.010$) compared to baseline (time effect: $p = 0.002$). An improvement in the foot function was also observed in the IG compared to the CG (group effect: $p = 0.083$, post hoc: $p = 0.040$) and within the IG after 12 weeks (post hoc: $p = 0.006$) and 24 weeks (post hoc: $p = 0.012$) compared to baseline (time effect: $p = 0.001$) (Table 2). The pressure-time integral in the medial forefoot was significantly increased in the IG compared to the CG at 24 weeks (group effect: $p = 0.004$, post hoc: $p = 0.048$) (Table 3).

Interaction effects were identified after 12 and 24 weeks for gait kinetics and kinematics (Table 4). The ankle plantar flexion angle at push-off was significantly increased in the IG compared to the CG (interaction effect: $p = 0.049$) at 12 weeks (post hoc: $p = 0.013$) and 24 weeks (post-hoc: $p = 0.014$). The within-group analysis showed a significant increase in the IG participants after 12 weeks (post hoc: $p = 0.001$) and 24 weeks (post hoc: $p = 0.001$) compared to baseline (time effect: $p = 0.001$). The within-group analysis showed changes in the hindfoot to tibia peak angle in the IG after 24 weeks compared to baseline (time effect: $p = 0.017$, post hoc: $p = 0.033$) and this improvement was greater in the IG compared to the CG after 24 weeks (interaction effect: $p = 0.038$, post hoc: $p = 0.009$). The hallux to forefoot ROM increased in the IG compared to the CG at 24 weeks (group effect: p =0.028, post hoc: p=0.003), and the hallux to forefoot peak angle increased in the IG compared to the CG (group effect: $p = 0.049$) at 12 weeks (post hoc: $p = 0.016$) and 24 weeks (post hoc: $p = 0.021$). Finally, at 12 weeks, the maximum arch height (group effect: $p = 0.049$, post hoc: $p = 0.015$) and minimum arch height (group effect: $p = 0.044$, post hoc: $p = 0.020$) were smaller in the IG compared to the CG.

Table 2. Estimated mean (standard error; SE), *p*-values from Generalized Estimating Equation (GEE), and between-group mean differences at 12 and 24 weeks (95% confidence interval) of the clinical outcomes for the control and intervention groups.

	Intervention Group (n = 15)			Control Group (n = 15)			Between-Group Difference (CI 95%)		GEE Analysis (*p*-Values)		
Variables	**Baseline Estimated Mean (SE)**	**12-Week Estimated Mean (SE)**	**24-Week Estimated Mean (SE)**	**Baseline Estimated Mean (SE)**	**12-Week Estimated Mean (SE)**	**24-Week Estimated Mean (SE)**	**12-Week (Intervention X Control Group)**	**24-Week (Intervention X Control Group)**	**Group**	**Time**	**Group X Time (Interaction Effect)**
DPN symptoms (MNSI score)	7.3 (0.4)	5.1 (0.6)	5.0 (0.6)	6.9 (0.4)	6.1 (0.6)	5.4 (0.4)	−0.9 (−2.6 to 0.7)	−0.4 (−1.9 to 1.1)	0.545	<0.001	0.152
DPN severity (Fuzzy score)	4.3 (0.6)	3.5 (0.7)	3.7 (0.8)	3.5 (0.5)	3.2 (0.5)	3.3 (0.5)	0.2 (−1.4 to 1.9)	0.3 (−1.5 to 2.2)	0.534	0.096	0.534
FHSQ Foot pain (score)	50.9 (5.6)	72.6 (6.4) *	72.0 (8.7)	39.8 (5.3)	47.7 (5.8) *	51.3 (7.8)	24.9 (8.0 to 41.8) *	20.7 (−43.5 to 2.1)	0.023*	0.002	0.514
FHSQ Foot function (score)	68.7 (6.0)	80.8 (6.6)	84.1 (6.3) #	56.2 (6.8)	69.6 (7.0)	63.3 (7.9) #	11.2 (−7.8 to 30.1)	20.7 (0.9 to 40.5) #	0.083	0.001	0.619
FHSQ Shoes (score)	68.6 (8.4)	61.5 (9.1)	68.3 (10.2)	52.1 (9.7)	60.9 (8.2)	55.1 (7.7)	0.6 (−23.4 to 24.7)	13.2 (−11.8 to 38.2)	0.271	0.976	0.414
FHSQ Foot health (score)	23.7 (1.2)	41.9 (6.3)	43.50 (7.7)	30.7 (4.7)	37.7 (4.5)	42.0 (6.3)	4.2 (−11.1 to 19.5)	1.4 (−18.0 to 21.0)	0.781	0.001	0.234
Hallux strength—(%BW)	10.9 (1.0)	14.4 (1.3)	10.0 (1.1)	14.9 (1.7)	14.7 (1.7)	12.1 (1.1)	−0.3 (−4.4 to 3.8)	−2.0 (−5.0 to 0.9)	0.640	0.002	0.064
Toes strength—(%BW)	8.2 (0.9)	7.9 (1.0)	8.5 (1.1)	10.3 (1.3)	8.7 (1.1)	8.1 (1.4)	−0.8 (−3.7 to 2.1)	0.4 (−3.1 to 4.0)	0.594	0.343	0.207

Abbreviation: MNSI—Michigan Neuropathy Screening Instrument; FHSQ—Foot Health Status Questionnaire; BW—Body Weight. * group effect $p = 0.023$, between-group difference at 12 weeks (post hoc $p = 0.004$). # group effect $p = 0.083$, between-group difference at 24 weeks (post hoc $p = 0.040$).

Table 3. Estimated mean (standard error; SE), p-values from Generalized Estimating Equation (GEE), and between-group mean differences at 12 and 24 weeks (95% confidence interval) of the plantar pressure variables during gait for the control and intervention groups.

		Intervention Group (n = 15)			Control Group (n = 15)			Between-Group Difference (CI 95%)		GEE Analysis (*p*-Values)		
Region of Interest	**Variables**	**Baseline Estimated Mean (SE)**	**12-Week Estimated Mean (SE)**	**24-Week Estimated Mean (SE)**	**Baseline Estimated Mean (SE)**	**12-Week Estimated Mean (SE)**	**24-Week Estimated Mean (SE)**	**12-Week (Intervention X Control Group)**	**24-Week (Intervention X Control Group)**	**Group**	**Time**	**Group X Time (Interaction Effect)**
Toes	Contact Area [cm^2]	9.96 (0.67)	9.90 (0.65)	8.15 (1.48)	10.86 (0.86)	10.93 (0.90)	10.89 (1.31)	−1.02 (−3.22 to 1.16)	−2.73 (−6.63 to 1.16)	0.173	0.579	0.607
	Peak [kPa]	282.94 (38.86)	350.65 (54.87)	362.50 (75.14)	307.61 (45.61)	302.11 (47.54)	343.86 (49.21)	48.53 (−93.75 to 190.83)	18.63 (−157.42 to 194.70)	0.838	0.194	0.209
	Pressure-time integral [(kPa) * s]	88.80 (14.17)	90.89 (14.19)	97.32 (22.45)	95.52 (15.72)	90.13 (15.12)	117.53 (21.07)	0.76 (−39.88 to 41.41)	−20.21 (−80.57 to 40.14)	0.683	0.385	0.593
Hallux	Contact Area [cm^2]	7.63 (0.66)	7.94 (0.71)	6.37 (0.40)	8.41 (0.59)	8.34 (0.57)	6.71 (0.49)	−0.39 (−2.19 to 1.39)	−0.33 (−1.59 to 0.56)	0.441	<0.001	0.911
	Peak [kPa]	337.00 (35.28)	378.33 (54.69)	186.89 (26.25)	304.11 (31.19)	361.34 (36.73)	193.88 (20.39)	16.98 (−112.15 to 146.13)	−6.99 (−72.15 to 58.16)	0.765	<0.001	0.731
	Pressure-time integral [(kPa) * s]	100.35 (11.03)	102.16 (20.56)	52.86 (6.89)	89.67 (13.45)	95.86 (11.27)	62.64 (6.75)	6.29 (−39.67 to 52.26)	−9.78 (−28.29 to 9.12)	0.990	<0.001	0.363

Table 3. *Cont.*

		Intervention Group (n = 15)			Control Group (n = 15)			Between-Group Difference (CI 95%)		GEE Analysis (*p*-Values)		
Region of Interest	**Variables**	**Baseline Estimated Mean (SE)**	**12-Week Estimated Mean (SE)**	**24-Week Estimated Mean (SE)**	**Baseline Estimated Mean (SE)**	**12-Week Estimated Mean (SE)**	**24-Week Estimated Mean (SE)**	**12-Week (Intervention X Control Group)**	**24-Week (Intervention X Control Group)**	**Group**	**Time**	**Group X Time (Interaction Effect)**
Medial forefoot	Contact Area [cm^2]	18.18 (0.83)	18.39 (0.98)	22.49 (0.84)	19.29 (0.61)	19.53 (0.81)	23.81 (0.92)	−1.14 (−3.65 to 1.36)	−1.32 (−3.78 to 1.14)	0.244	<0.001	0.997
	Peak [kPa]	488.72 (46.36)	502.26 (52.29)	542.34 (43.35)	378.16 (26.13)	421.85 (32.08)	462.98 (28.43)	80.40 (−39.85 to 200.65)	79.36 (−22.25 to 180.97)	0.060	<0.001	0.181
	Pressure-time integral [(kPa) * s]	175.21 (15.40)	169.81 (20.84)	193.26 (13.94) *	134.42 (11.49)	145.85 (12.04)	161.42 (8.09) *	23.96 (−23.22 to 71.14)	31.84 (0.25 to 63.44) *	0.004 *	0.066	0.124
Central forefoot	Contact Area [cm^2]	21.67 (0.42)	21.05 (0.73)	16.13 (1.20)	22.21 (0.45)	22.35 (0.51)	17.73 (1.31)	−1.30 (−3.05 to 0.44)	−1.59 (−5.09 to 1.89)	0.228	<0.001	0.228
	Peak [kPa]	496.72 (42.08)	473.09 (37.50)	474.92 (41.43)	425.27 (33.56)	496.47 (50.99)	382.98 (28.44)	−23.37 (−147.44 to 100.69)	91.93 (−6.56 to 190.44)	0.278	0.159	0.073
	Pressure-time integral [(kPa) * s]	180.73 (12.57)	159.71 (12.08)	165.24 (12.76)	157.37 (11.41)	169.43 (16.21)	139.13 (9.45)	−9.71 (−49.34 to 29.91)	26.11 (−5.02 to 57.25)	0.341	0.097	0.086
Lateral forefoot	Contact Area [cm^2]	14.48 (0.73)	12.93 (1.08)	7.82 (0.96)	13.23 (0.96)	14.14 (0.93)	9.39 (0.91)	−1.21 (−4.02 to 1.59)	−1.57 (−4.18 to 1.03)	0.558	0.000	0.128
	Peak [kPa]	286.22 (55.89)	303.63 (64.53)	146.13 (38.34)	216.22 (18.87)	224.48 (26.17)	102.29 (12.62)	79.14 (−57.34 to 215.63)	43.84 (−35.26 to 122.95)	0.155	0.000	0.942
	Pressure-time integral [(kPa) * s]	99.08 (15.76)	97.46 (17.97)	44.78 (13.51)	80.90 (7.27)	81.92 (9.50)	39.52 (5.58)	15.53 (−24.31 to 55.39)	5.25 (−23.40 to 33.92)	0.444	0.000	0.941
Midfoot	Contact Area [cm^2]	24.54 (0.80)	23.26 (1.25)	29.79 (1.49)	24.58 (1.10)	24.66 (1.08)	32.08 (1.45)	−1.40 (−4.67 to 1.84)	−2.29 (−6.37 to 1.79)	0.428	0.000	0.422
	Peak [kPa]	284.33 (38.70)	284.64 (37.30)	380.68 (43.88)	241.88 (13.83)	242.24 (15.79)	299.93 (23.23)	42.39 (−37.00 to 121.80)	80.75 (−16.57 to 178.07)	0.156	0.000	0.793
	Pressure-time integral [(kPa) * s]	97.75 (16.31)	80.99 (12.51)	124.26 (16.44)	77.57 (6.36)	77.97 (7.71)	106.94 (9.32)	3.01 (−25.79 to 31.82)	17.31 (−19.74 to 54.38)	0.388	0.000	0.083
Heel	Contact Area [cm^2]	38.19 (1.05)	32.53 (1.17)	28.38 (1.50)	36.72 (1.65)	29.14 (1.95)	27.17 (1.40)	3.38 (−1.09 to 7.86)	1.20 (−2.82 to 5.23)	0.266	0.000	0.506
	Peak [kPa]	238.76 (17.85)	420.95 (33.05)	477.34 (42.44)	217.59 (19.37)	384.48 (29.89)	373.75 (32.45)	36.46 (−50.88 to 123.81)	103.59 (−1.12 to 208.32)	0.097	0.000	0.338
	Pressure-time integral [(kPa) * s]	338.91 (36.91)	130.80 (12.97)	145.55 (14.57)	354.94 (35.86)	126.30 (10.72)	122.06 (10.39)	4.50 (−28.49 to 37.49)	23.49 (−11.59 to 58.57)	0.596	0.000	0.413

* group effect $p = 0.004$, between-group difference at 24 weeks (post hoc $p = 0.048$).

Table 4. Estimated mean (standard error; SE), p-values from Generalized Estimating Equation (GEE), and between-group mean difference at 12 and 24 weeks (95% confidence interval) of the foot–ankle kinematics and ankle joint kinetics during gait for the control and intervention groups.

	Intervention Group (n = 15)			Control Group (n = 15)			Between-Group Difference (CI 95%)		GEE Analysis (*p*-Values)		
Variables	**Baseline Estimated Mean (SE)**	**12-Week Estimated Mean (SE)**	**24-Week Estimated Mean (SE)**	**Baseline Estimated Mean (SE)**	**12-Week Estimated Mean (SE)**	**24-Week Estimated Mean (SE)**	**12-Week (Intervention X Control Group)**	**24-Week (Intervention X Control Group)**	**Group**	**Time**	**Group x Time (Interaction Effect)**
ANKLE											
Ankle ROM (degree)	23.14 (1.14)	32.53 (1.17)	28.38 (1.50)	22.82 (0.65)	29.14 (1.95)	27.17 (1.40)	3.38 (−1.09 to 7.86)	1.20 (−2.82 to 5.23)	0.630	0.001	0.839
Ankle dorsiflexion at heel strike (degree)	3.14 (0.64)	2.18 (0.40)	3.36 (0.85)	3.13 (0.57)	3.47 (1.09)	4.54 (0.84)	−1.28 (−3.56 to 0.99)	−1.17 (−3.53 to 1.18)	0.249	0.194	0.525
Ankle plantarflexion at push off (degree)	1.73 (0.01)	4.44 (0.78) [&]	4.14 (0.68) [&]	2.14 (0.68)	2.20 (0.66) [&]	2.15 (1.05) [&]	2.74 (1.19 to 4.28) [&]	2.40 (1.05 to 3.75) [&]	0.001	0.001	0.049[&]
Ankle flexor moment at heel strike (Nm/(BM * Height)	−0.04 (0.01)	−0.05 (0.01)	−0.04 (0.02)	−0.03 (0.01)	−0.04 (0.01)	−0.03 (0.00)	−0.01 (−0.05 to 0.02)	−0.01 (−0.04 to 0.01)	0.224	0.419	0.898
Ankle extensor moment at push off (Nm/(BM * Height)	1.36 (0.04)	1.41 (0.03)	1.43 (0.04)	1.30 (0.03)	1.35 (0.04)	1.37 (0.03)	0.06 (−0.03 to 0.16)	0.05 (−0.05 to 0.16)	0.171	0.160	0.948
Ankle peak eccentric power at the push off (W/BM * Height)	2.49 (0.14)	2.58 (0.9)	2.36 (0.15)	2.45 (0.16)	2.48 (0.11)	2.34 (0.15)	−0.1 (−0.56 to 0.31)	−0.2 (−0.46 to 0.25)	0.397	0.198	0.591
OXFORD FOOT MODEL											
Hindfoot to tibia ROM (degree)	23.12 (1.55)	21.68 (1.09)	23.01 (2.76)	23.48 (1.21)	23.15 (1.32)	24.92 (1.25)	−1.46 (−4.83 to 1.90)	−1.90 (−7.86 to 4.04)	0.495	0.410	0.801
Hindfoot to tibia peak angle (degree)	16.62 (2.34)	17.31 (3.09)	15.01 (1.31) *	22.79 (7.91)	14.92 (1.31)	9.32 (1.72) *	2.38 (−4.21 to 8.98)	5.68 (1.43 to 9.94) *	0.011	0.017	0.038[*]
Forefoot to hindfoot ROM (degree)	17.82 (2.75)	16.08 (1.86)	14.62 (0.79)	14.23 (0.99)	14.40 (1.79)	13.43 (0.69)	1.68 (−3.38 to 6.75)	1.18 (−0.88 to 3.25)	0.191	0.283	0.658
Forefoot to hindfoot peak angle (degree)	8.62 (1.35)	8.15 (0.80)	8.75 (1.20)	14.24 (6.17)	7.84 (1.27)	7.48 (1.13)	0.30 (−2.64 to 3.26)	1.26 (−1.97 to 4.51)	0.595	0.411	0.338
Hallux to forefoot ROM (degree)	23.34 (2.23)	26.03 (2.49)	28.76 (1.70) [#]	21.06 (1.93)	21.07 (1.10)	21.65 (1.62) [#]	4.96 (−0.37 to 10.30)	7.10 (2.48 to 11.73) [#]	0.028 [#]	0.186	0.346
Hallux to forefoot peak angle (degree)	22.06 (1.67)	26.78 (1.49) [a]	27.12 (2.19) [a]	21.94 (2.11)	21.15 (1.79) [a]	20.50 (1.85) [a]	5.63 (1.05 to 10.21) [a]	6.61 (0.98 to 12.24) [a]	0.049 [a]	0.402	0.073
Maximum arch height (cm)	11.05 (0.35)	10.58 (0.26) [b]	11.49 (0.89)	11.70 (0.38)	12.19 (0.60) [b]	11.24 (0.44)	−1.61 (−2.91 to −0.31) [b]	0.25 (−1.70 to 2.21)	0.049 [b]	0.198	0.139
Minimum arch height (cm)	8.78 (0.34)	8.38 (0.37) [c]	8.60 (0.79)	9.75 (0.34)	9.87 (0.51) [c]	8.95 (0.41)	−1.48 (−2.73 to −0.23) [c]	−0.34 (−2.10 to 1.41)	0.044 [c]	0.476	0.327

[&] interaction effect $p = 0.049$, between-group difference at 12 weeks (post hoc $p = 0.013$) and 24 weeks (post hoc $p = 0.014$). * interaction effect $p = 0.038$, between-group difference at 24 weeks (post hoc $p = 0.009$). [#] group effect $p = 0.028$, between-group difference at 24 weeks (post hoc $p = 0.003$). [a] group effect $p = 0.049$, between-group difference at 12 weeks (post hoc $p = 0.016$) and 24 weeks (post hoc $p = 0.021$). [b] group effect $p = 0.049$, between-group difference at 12 weeks (post hoc $p = 0.015$). [c] group effect $p = 0.044$, between-group difference at 12 weeks (post hoc $p = 0.020$).

4. Discussion

This clinical proof-of-concept study aimed at gathering preliminary evidence for the potential clinical and gait biomechanical benefits of the SOPeD, an internet-based foot–ankle therapeutic exercise program for people with diabetes and DPN. Some beneficial effects in terms of foot function, pain, and foot–ankle kinematics were revealed. After 12 weeks of intervention, participants had less foot pain intensity and frequency, improved foot function, increased ankle and first metatarsophalangeal (MTP) joint motions, favorably altered foot arch motion, and increased forefoot loads during gait.

The pain reduction and function improvement could be explained by the improved foot–ankle ROM, as better joint mobility positively affects the overall foot functionality and, thus, pain. Because there was a reduction in foot pain after 12 weeks and an improvement in foot function only after a longer period of 24 weeks, we believe that the improvement in foot function is not necessarily related to pain reduction but is the result of changes in other functional components due to the exercises, such as improved foot–ankle joint mobility. A feasibility study from this trial showed a significant improvement in foot pain in the IG [27], and this proof-of-concept study confirmed these findings by demonstrating that an internet-based foot–ankle intervention achieved this secondary outcome.

Some studies have shown that individuals with diabetes and DPN have a reduction in the ankle and first MTP joint mobility, and these movement restrictions may contribute to ulcerations at all forefoot locations [6,44–47]. Due to their reduced ankle mobility, people with DPN appear to pull their legs forward during the push-off phase, mainly using the hip flexor muscles, which is known as the hip strategy. In contrast, the ankle strategy, which is characterized by propelling the body forward while relying on the plantar flexor muscles, is seen in the gait of people without diabetes and DPN [48,49]. We found that this 12-week internet-based foot–ankle exercise program was effective in improving some of the foot–ankle joint motion (hindfoot to tibia angle, plantarflexion at push-off, and hallux to forefoot ROM and angle), which may help the subjects to prioritize the use of the physiological ankle strategy instead of the hip strategy and, thus, promote a more physiological foot rollover.

Recent studies have shown positive results for the improvement in ankle ROM and first MTP joint mobility using foot-related exercise programs with group-based [37,50] and home-based [20,21,51] approaches. Even though those interventions were either conducted face to face with the physiotherapist or at home with only the guidance of videos or booklets, this still corroborates our results. None of these previous interventions used a rehabilitation technology to promote foot–ankle exercises targeting the main musculoskeletal deficits in the lower limbs. Thus, performing foot–ankle exercises with the support of a web-based software—the SOPeD—has the potential to be as effective as performing face-to-face (group-based) or home-based therapeutic programs.

The intervention promoted an increase in the pressure-time integral at the medial forefoot in the IG after 24 weeks, which can be attributed to the gains obtained in the foot–ankle and first MTP mobilities. Greater mobility of the medial forefoot region, including the first MTP joint, is desirable during the mid-stance phase of gait to better adjust the foot to the ground in the pronation movement expected in this phase, thus, favoring the propulsion through the first ray of the foot. As a consequence, changes in the plantar pressure distribution in this foot area would reveal greater anterior support during the mid-push-off phase of gait. Furthermore, factors affecting foot biomechanics, such as reduced joint range of motion and foot deformity, have been linked to changes in plantar pressure distribution [52], which is consistent with our findings of an improvement in hallux to forefoot ROM and peak angle. Additionally, the increase in the pressure-time integral at the medial forefoot could have potentially contributed to a more physiological foot rollover. Our findings agree with the results of Sartor et al. [53], who also found an increase in the pressure-time integral at the medial and lateral forefoot and hallux and attributed this change to an improved foot rollover into a more physiological process and a better functional condition of the foot–ankle complex. While attention is usually given

to peak pressure and pressure-time integral reductions as targets to reduce the risk of ulceration, these variables only represent vertical loading during a very short time in the stance phase and are not optimal variables for describing changes in the whole foot rollover process, which should be the main aim of rehabilitation strategies, such as foot-related exercise programs. Although the increased pressure-time integral at the medial forefoot in the IG participants might represent a functional improvement in gait, attention must be given to keeping plantar loadings under a safe pressure range in foot areas at higher risk for ulceration [54].

The proposed 12-week exercise program has the potential to change the maximum and minimum arch height during gait, with the IG showing lower values after the intervention. The plantar arch should be flexible in response to gait loads, allowing foot-joint adjustments to dampen impacts via multiple mechanisms, such as stiffness and power absorption, but it should also be rigid enough to allow for propulsion during the push-off phase [55]. Our exercise program may have improved the plantar intrinsic muscles' ability to provide force-dependent changes in the MLA and facilitate efficient foot-to-ground contact during walking [56,57].

An analysis of 101 papers conducted as part of a systematic review with the goal of analyzing adherence to web-based interventions revealed an average adherence rate of 50%, confirming that non-adherence is a problem with web-based interventions. The level of adherence varied greatly, with six programs scoring less than 10% and only five interventions achieving 90% or more [58]. The gamification principles, a wide variety of exercises to avoid monotony, and the short duration of the exercise sessions were the strengths of the foot–ankle therapeutic exercise program used in this study, which may have contributed to maximizing the adherence (62%) and minimizing the compliance problems commonly reported in this population [28]. In this study, the reported reasons for not following the online program were internet problems and a broken cell phone.

One of the clinical goals of this proof-of-concept study was to improve participants' self-management, which can be affected by the individual's education level [59]. Therefore, having only 6.6% of the participants with a lower level of education may have contributed to our positive results. The study was carried out with participants with ulcer risk (IWGDF categories 1 or 2) and presented positive results that we believe may even contribute to the prevention of the development of foot ulcers and amputations. However, it should be noted that further studies are needed with patients with ulcer risk (IWGDF category 3), since we did not test the intervention in this population. This study also revealed the potential therapeutic effectiveness of our program, which was similar to other previously studied foot-related interventions using face-to-face strategies and emphasizes the importance of an internet-based exercise program as a low-cost, convenient, and easily accessible tele-rehabilitation strategy for people with DPN. These results suggest that this intervention has benefits for people with DPN (low and moderate ulcer risk) and, therefore, its use in clinical practice is promising.

Although the proposed intervention was superior to the usual care and demonstrated the potential to modify some biomechanical and clinical outcomes, such as foot pain, it did not improve the primary outcomes (DPN severity and symptoms, such as burning pain, muscle cramps, and prickling feelings). Our study did not monitor participants' blood glucose and glycated hemoglobin levels, which may have influenced the primary outcome results. An increase in blood glucose levels may contribute to a greater manifestation of DPN symptoms, which, in turn, would have also influenced the DPN severity, as the fuzzy classification took into account MNSI-BR scores. In addition to the above-mentioned limitation, because no formal calculation of statistical power is performed in proof-of-concept studies, this preliminary analysis should be interpreted with caution.

5. Conclusions

This study found that a 12-week internet-based foot–ankle exercise program using the SOPeD software had moderate adherence among participants and has the potential to

reduce foot pain, improve foot function, increase foot–ankle and first MTP joint motion, and change forefoot load absorption during foot rollover during gait in people with DPN.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/s22249582/s1, Flyer of self-care based on IWGDF was given to all participants and included educational orientations.

Author Contributions: All authors have made substantial contributions to the manuscript. R.H.C.-J., J.S.S.P.F., É.Q.S., R.L.M., E.Y.S. and I.C.N.S. were responsible for the conception and design of the study; R.H.C.-J., J.S.S.P.F., É.Q.S., J.L.V. and. R.L.M. were responsible for data acquisition and data processing; É.Q.S., J.S.S.P.F., J.L.V., R.L.M. and I.C.N.S. were responsible for data analysis and interpretation; R.H.C.-J. and I.C.N.S. were responsible for drafting the paper; I.C.N.S. and R.H.C.-J. revised the manuscript critically. All authors read, provided feedback, and approved the submitted version. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: This study was registered at ClinicalTrials.gov as NCT04011267 (8 June 2019) under the name "Effect of Customized Software for Foot-related Exercises (SOPeD) for Prevention and Treatment in People With Diabetic Neuropathy". The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee in Research of the School of Medicine of the University of Sao Paulo (Protocol 3.319.047-10 May 2019).

Informed Consent Statement: The principal investigator explained to each eligible participant all stages of the study, possible risks, and expected benefits. Upon agreeing to participate, they were asked to sign an informed consent form. Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data are owned by the Laboratório de Biomecânica do Movimento e Postura Humana-LaBiMPH, Departamento de Fisioterapia, Fonoaudiologia e Terapia Ocupacional, Faculdade de Medicina da Universidade de São Paulo. The data presented in this study are available on request from the corresponding author (icnsacco@usp.br). It is worth mentioning that this proof of concept analyzed preliminary data from a main RCT, and after its conclusion, the data will be available for access in the data repository of the University of São Paulo, which can be accessed at the following link: https://repositorio.uspdigital.usp.br/?codmnu=9980, accessed on 5 December 2022.

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Conflicts of Interest: The authors and the software developers (J.S.S.P.F. and I.C.N.S.) declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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sensors

MDPI

Review

Adherence and the Diabetic Foot: High Tech Meets High Touch?

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Abstract: Diabetic foot ulcers, which are a common complication of diabetes, can have a negative impact on a person's physical and mental health, including an increased risk of depression. Patients suffering from depression are less likely to keep up with diabetic foot care, thus increasing the risk of developing ulcers. However, with the use of artificial intelligence (AI), at-home patient care has become easier, which increases adherence. To better understand how new technologies, including machine learning algorithms and wearable sensors, might improve patient adherence and outcomes, we conducted a literature review of several sensor technologies, including SmartMat© and Siren Care© socks for temperature, SurroSense Rx/Orpyx© for pressure, and Orthotimer© for adherence. An initial search identified 143 peer-reviewed manuscripts, from which we selected a total of 10 manuscripts for further analysis. We examined the potential benefits of personalized content and clinician support for those receiving mobile health interventions. These findings may help to demonstrate the current and future utility of advanced technologies in improving patient adherence and outcomes, particularly in the context of diabetes management and the link between behavior and complications in diabetes, such as diabetic foot ulcers.

Keywords: diabetes; technology; artificial intelligence; depression; diabetic foot ulcers; adherence

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1. Introduction

Diabetic foot ulcers (DFU) can have a significant impact on a person's physical and mental health, and numerous investigators have shown that there is a link between diabetic foot ulcers and depression [1,2]. People with diabetic foot ulcers may experience feelings of frustration, hopelessness, and low self-esteem due to their limited mobility and the challenges of managing their condition [3]. These negative emotions can contribute to a cycle of poor adherence to treatment and self-care, which can lead to the worsening of a foot ulcer and an increased risk in complications such as amputation [3].

Newer monitoring and wearable technologies, such as smart socks and insoles, can help improve patient adherence and outcomes by providing real-time data on foot pressure and temperature, alerting patients and healthcare providers to potential problems before they become serious, as highlighted in this manuscript. These technologies can also help people with diabetic foot ulcers to better understand and manage their condition, which can improve their overall quality of life and reduce the risk of depression. By providing ongoing support and monitoring, wearable technologies can help people with diabetic foot ulcers to feel more in control of their health and more confident in their ability to manage their condition.

Research focused on investigating the influence of comorbid depression on the development and advancement of foot ulcers has shown that depression can lead to healing delays and a triple rise in mortality risk within 18 months after the onset of a foot ulcer [3]. Depression has been linked to the reduced likelihood of healing and increased mortality in this high-risk population [4]. Self-inflicted behavioral habits that precipitate a diabetic foot complication often make real-time/long-term monitoring adherence a challenge. Patients

with depression demonstrate a threefold decrease in adherence to treatment plans for chronic illnesses when compared to those without depression [5]. Professionals trained in the diagnosis and treatment of depression and diabetic foot ulcers should screen and evaluate patients. To be effective, patient home caregivers and significant others should be integrated into their respective treatment plans. With the global prevalence of diabetes increasing, it is imperative to identify previously undetected depression (mild, moderate, or severe) in individuals with diabetes [4]. This identification should occur either before complications arise or when complications are already present, as it is essential for enabling timely intervention [4]. Technology-based self-help treatment approaches for depression, such as the Internet and mobile platforms, enhance accessibility for individuals. These tools can be utilized conveniently in the comfort of one's home, at a self-determined schedule and pace, without compromising privacy. Moreover, these solutions can provide valuable guidance and support to help patients improve their adherence to treatment. There are emerging technologies to help combat and/or help prevent the formation of diabetic foot ulcerations, which include monitoring systems that measure pedal temperature, mechanical plantar foot stress, and orthoses time adherence. Increasing adherence to diabetic foot care across different disease spectra involves essential components such as educating patients about their condition, emphasizing the significance of following prescribed treatments, and providing psychosocial support. These elements are considered fundamental pillars in promoting diabetic foot care adherence. The purpose of this review is to describe micro-climate regulating, stress monitoring on plantar tissue, and wear time of boots monitoring technologies that might help bridge the gap between patient adherence, patient and patient family actualization, and improved outcomes in those with diabetic lower extremity complications.

2. Diabetic Peripheral Neuropathy

Symptoms of diabetic peripheral neuropathy (DPN) include pain, tingling, and numbness [6]. The incidence of DPN ranges from 30 to 50% [7]. It often coexists with various other health conditions, such as cognitive impairment, depression, autonomic neuropathy, peripheral artery disease (PAD), nephropathy, retinopathy, cardiovascular disease, and medial arterial calcification [7,8]. Diagnosis of DPN is typically established through suggestive clinical symptoms and neurologic tests [9]. However, some patients with DPN may not exhibit overt signs of nerve damage, despite demonstrating evidence of neurologic deficits in nerve conduction studies (NCSs) or electromyography [9]. A significant characteristic of diabetic peripheral neuropathy involves diminished sensitivity to cold (threshold), heat, and touch [6]. There is a multitude of various causative factors that could be responsible for tissue damage and changes in sensation, including free radical damage, a metabolic byproduct of cell glycolysis, edema, and a chronic inflammatory process [6]. The meticulous regulation of reactive oxygen species (ROS), including Nitric Oxide, Hydrogen Peroxide, etc., is essential for cellular homeostasis due to their critical involvement in normal cellular functioning. Additionally, these species are highly sensitive to glycemic control, further emphasizing their significance [10]. If glycemic control is not managed, it causes an imbalance and overproduction of harmful levels of reactive oxygen species (ROS) [10]. Excess ROS can lead to cellular proteins and membrane lipid damage, resulting in the accumulation of toxic peroxidation products that bind to the cellular nuclear material [10]. This process can trigger apoptosis, cause DNA damage, reduce axonal transport, and decrease the levels of neurotrophic factors responsible for maintaining normal nerve function [11].

Various macro-level factors that may heighten the risk of developing diabetic neuropathy are as follows [12]:

- Coronary artery disease;
- Increased triglyceride levels;
- Obesity;
- Smoking;
- High blood pressure.

Clinical recommendations advocate for enhancing the quality of diabetic foot care through the use of evidence-based risk assessments. Substantial evidence supports the early identification of ulceration risk through these evaluations of the diabetic foot, leading to a reduction in ulcer development [12]. It has been shown that patients who follow professional foot care recommendations (monitoring their foot temperatures, monitoring their foot pressures, or continuously wearing therapeutic footwear) have significantly better outcomes than those who do not follow or are unable to easily follow diabetic foot care protocols [13,14]. Patients suffering from depression are less likely to follow through with ulcer care; however, artificial intelligence (AI) monitoring has made it relatively easy for patients to keep up with adherence to care.

3. Methods

3.1. Search Strategy

Patients suffering from depression are less likely to keep up with diabetic foot care, thus increasing the risk of developing ulcers. However, with the use of artificial intelligence, at-home patient care has become easier, which increases adherence. We conducted a literature search on the database PubMed in order to find studies that relate to diabetic foot ulcers (DFUs) and artificial intelligence (AI). We set the time from 2005 to 2022. In order to narrow down the search for study, we looked into some of the leading causes of DFUs. We found them to be: plantar temperature, plantar pressure, and adherence to footwear. From there, we researched keywords that relate to AI, DFUs, and those causes. Here are the final search queries we did on PubMed: (Diabetic Foot ulcers) (Causes), (Diabetic Foot) (Wear Time) (Sensors), (Orthopedic footwear) (Temperature Sensor), (Diabetic Foot ulcers) (Plantar Temperature), (Diabetic Foot Ulcers) (SurroSense Rx©/Orpyx (Calgary, AB, Canada)), (Diabetic Foot Ulcer) AND (Sensor Socks), (Diabetic Foot Ulcers) AND (Remote Temperature Monitoring System; Podimetrics, Inc., Somerville, MA, USA). These findings can potentially demonstrate the utility of using robust technologies to improve patient adherence and demonstrate the potential benefits of integrating treatment pathways for the bidirectional relationship between depression and complications related to diabetes.

3.2. Analysis

The search yielded 134 peer-reviewed manuscripts. We filtered them down to works that mentioned plantar temperature, plantar pressure, and adherence. We also eliminated any papers that did not report quantitative data or include the use of a portable and wearable at-home monitoring device. After reading through the research, we narrowed down the type of artificial intelligence (AI) we wanted to focus on based on the risk factors that lead to ulcer formation (Figure 1). Table 1 summarizes the risk factors focused on in this paper. We analyzed SmartMat© and Siren Care© sensor socks for temperature, SurroSense Rx/Orpyx© for pressure, and Orthotimer© and SmartBoot for adherence.

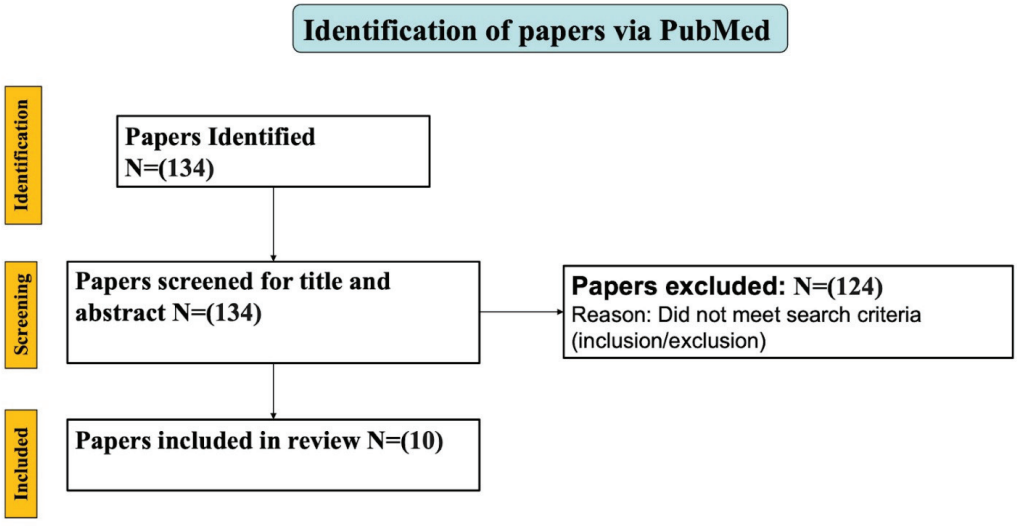

Figure 1. Flowchart of how the papers were filtered.

Table 1. Risk factors for DFUs with current management and AI management.

Risk Factors	Current Management	Issues with Current Management	Sensors/Devices	Potential Impact on Prevention	References
Lesions occurring prior to ulceration, arising from irregularities in temperature	Hand-held thermometer device	Might be difficult and time consuming for patients	Continuous at-home plantar temperature monitoring system	Minimizing the risk of potential sites susceptible to ulcer development	[15–17]
Elevated plantar pressure	Offloading footwear	Irregular adherence	Continuous at-home plantar pressure monitoring system with patient feedback on a mobile device	Improvement of timely offloading and potentially reducing ulcer occurrence	[18–20]
Irregular adherence	Total Contact Cast (TCC)	Prevent daily wound inspection and dressing changes	Monitoring adherence with temperature sensors and patient feedback on a mobile device	Prolongs patient adherence with diabetic orthopedic wear, which can potentially reduce ulcer recurrence	[21,22]

4. Results

4.1. Diabetic Foot Micro-Climate Regulating Technology

The foot micro-climate refers to intrinsic and extrinsic factors that regulate pedal health, including temperature, pressure, humidity, shear, and stress. Studies conducted by Armstrong et al. revealed that patients who had previously experienced ulceration demonstrated elevated local skin temperatures during their follow-up visits before experiencing re-ulceration [15], thus highlighting the potential benefit of assessing skin temperature measurements to predict ulcer formation. Despite the growing evidence of skin temperature monitoring, there are no current diagnostic algorithms in any current clinical practice guidelines. One significant challenge is patient adherence to daily temperature measurements, including any potential learning curve in using these technologies. Some patients

may find it difficult to learn how to use certain temperature monitoring technologies. This learning curve might deter a lot of patients from wanting to keep up with regular temperature monitoring. Additionally, some patients might also find incorporating regular temperature monitoring into their daily routine difficult. This issue can also increase in patients suffering from depression. Depression can have a significant impact on a patient's ability to keep up with care plans put in place by their physicians, including adherence to daily temperature measurements. The lack of motivation, low energy levels, and a sense of hopelessness caused by depression can make it difficult for patients to want to continue to engage in monitoring their health [23]. Patients suffering from depression might also have difficulty with memory and concentration, which might also be a reason for not keeping up with their regular temperature readings, as they might forget to monitor their temperature. To address these challenges, healthcare providers have started to incorporate easy-to-use AI technology to make temperature monitoring easy and accessible for all types of patients.

Frykberg and their coworkers [16] designed SmartMat, an AI-centric device that has three key performance indicators: assessing the mat's efficacy in identifying plantar DFU at an early stage, examining participant adherence to its usage over time, and gaining insights into participant perceptions regarding potential benefits and user-friendliness. SmartMat uses specialized sensors that integrate an image processing system to compare temperatures between normal and abnormal feet [16]. This mat was designed to be used at home and only requires the participant to step on the mat with both feet for 20 s [16]. The collected data are subsequently uploaded to a cloud storage system through a built-in cellular component integrated within the mat. The research showed that by setting the temperature to an asymmetry of 2.22 °C, the mat was able to accurately predict 97% of DFUs with only a false positive rate of 57% [16]. The mat also had a high adherence rate of 86% with the use of the mat averaging 3 days per week [16]. Patients throughout the study documented the ease of using the mat. Making the mat extremely accessible and easy to use helped increase the adherence to monitoring plantar temperature. Patients suffering from depression might appreciate the simplicity and continue incorporating it into their daily care treatment. The high success rate and adherence to SmartMat seem promising for effectively incorporating this in patient care to reduce the risk of re-ulceration [16].

There are other wearable technologies that help improve adherence to the daily monitoring of plantar temperature. Siren Care utilizes a specialized sock with embedded sensors that continuously monitor daily plantar foot temperatures [17]. This sock is embedded with six sensors—at the metatarsal points, midpoint, and heel—that read the patient's plantar temperature in 10 s intervals [17]. These specialized sensors monitor daily activity levels while continuously aggregating plantar foot data points (temperatures). The microsensors in the socks are paired with a cellphone via Bluetooth and show any increase in plantar temperature on the mobile device [17]. The pilot study conducted showed that the temperature measured was within 0.2 °C of the clinically observed temperatures [17]. Based on the comfort and simplicity of the socks, adherence was noted to be higher [17]. This technology may assist in the improvement of ulceration in patients that are at high risk of DFU.

Incorporating sensors into socks can be a solution to the challenge of patient adherence, especially for those suffering from depression. By removing the need for patients to remember to take their own temperature and instead having a sensor attached to their socks, the cognitive load on patients is greatly reduced. This is especially important for patients with depression who may struggle with attention and memory [24]. Simplifying healthcare plans can help these patients manage and follow through with their treatment plans. With the sensor already in place, depressed patients are more likely to stick with their healthcare plans without the added stress of having to remember to take their own plantar temperature. Overall, incorporating sensors into socks can provide a convenient and effective method to improve patient adherence and health outcomes for those with depression. The Siren Care socks have the potential to mitigate the risk of ulcer development, thus reducing the likelihood of severe complications, like foot amputations.

In order for the treatment of diabetic foot ulcers to be effective, patients must monitor their plantar temperature daily. Different types of AI incorporated in sensors are making it easier for patients to stick to their care regimen, thus increasing adherence. A study conducted on PodoTemp, another temperature monitoring technology, compared both the platform's accuracy and consistency in repeated testing, as well as the usability and adherence in patients' home environments [25]. PodoTemp is equipped with 120 temperature sensors embedded in each foot [25]. Each sensor is used to individually measure the temperature of the foot while the patient stands on the platform for 40 s [25]. The platform was originally designed to be easy to use and incorporate into any at-home patient DFU care. The built-in algorithm on the platform helps patients gather their plantar temperature and analyze the measurements without needing any help [25]. This would be especially helpful to incorporate in patients who are at risk of developing ulcers and suffering from depression.

The first part of the study by Veneman et al. was conducted on patients who lost all protective sensation due to peripheral neuropathy. Each participant stood on the platform for 40 s to get a reading of the plantar temperature [25]. In order to accurately compare the results, TempTouch (Diabetica Solutions, San Antonio, TX, USA), an infrared handheld skin thermometer was used. The TempTouch was used as a reference because it is the most commonly used equipment in studies revolving around foot temperature monitoring [15,26–28]. The first part of the study showed the accuracy of the PodoTemp measurements, as the results were very similar to the handheld infrared skin thermometer. The second part of the study aimed to test the usability and the increase in adherence to the platform. Over the course of two weeks, participants were asked to use the PodoTemp platform in their home environment [25]. Participants were then asked to complete a survey about their experience with the platform. A total of 87% of the participants expressed that the platform was easy to use, and 67% of the participants were motivated to continue to monitor their plantar temperature on a daily basis [25]. It was reported that participants felt that the platform was quicker to use and required little to no action on their end, thus increasing their desire to continue monitoring their temperature on a daily basis. The platform was designed in order to be easy to use and mass-produced at a relatively low cost. The platform's accurate ability to execute and analyze temperature measurements without being difficult on patients is a major advantage, especially for those suffering from depression, compared to many other available foot temperature monitoring devices—like the handheld thermometer—and can potentially be incorporated for use at patients' homes to treat diabetic foot ulcers.

As demonstrated, SmartMat, Siren Care, and PodoTemp all play a vital role in the care and prevention of diabetic foot ulcers. Each technology brings a unique approach to monitoring plantar temperature, as demonstrated in Table 2. These distinct features contribute to enhanced patient care and a reduced risk of ulcer formation. While the functionalities and data analysis methods may vary among these technologies, their shared objective is to facilitate early detection of foot ulcers and enable timely intervention, ultimately improving patient care and mitigating the likelihood of additional complications.

Table 2. Comparison of functionality, data collection and analysis, user interface, and intervention/alerting for SmartMat, Siren Care, PodoTemp, and TempTouch.

Technology	Functionality	Data Collection and Analysis	User Interface	Intervention and Alerting	References
SmartMat	Sensors embedded in a mat that integrates an image processing system to compare temperatures between normal and abnormal feet	After 20 s, the data are collected and then uploaded onto a cloud using a cellular component that is already in the mat	Temperature is not displayed on the mat; results are uploaded to a server	No alerts given; however, the temperature measurements will help physicians make informed decisions regarding intervention	[16]
Siren Care	Temperature sensors embedded in socks to detect change in temperature throughout the day	Collects the temperature data and sends them to a smartphone for monitoring and analysis	Uses a smartphone to show temperature data and alerts	Smartphone application provides alerts if there is a temperature change and will allow for timely intervention	[17]
PodoTemp	Total of 120 temperature sensors embedded for each foot on a platform that measures temperature differences between each foot	Provides instant readings for analysis after 40 s	Displays the temperature on the device	No alerts given; however, the temperature measurements will help physicians make informed decisions regarding intervention	[25]

4.2. Monitoring Stress on Plantar Tissue

The nefarious effects of diabetic peripheral neuropathy can sometimes leave repetitive foot stress vectors unaddressed in patients with diabetes [18]. Repetitive microtrauma along prominent osseous foot structures inherently causes tissue breakdown [18]. Ulcer formation can be attributed to sequelae related to sensory, motor, and autonomic neuropathy [18]. Patients with diabetes also tend to have poor tissue quality, making their feet more susceptible to tissue breakdown [18]. This susceptibility highlights a critical component in the management of plantar foot stress vectors in the neuropathic diabetic foot. One of the main tenets of diabetic foot care is the utilization of proper offloading devices [18]. Existing offloading devices lack a feedback mechanism to address tissue breakdown. SurroSense Rx© (Orpyx Medical Technologies, Calgary, AB, Canada) is an AI device that has the ability to monitor plantar foot stress. The core of this technology is within a customized insole (with integrated sensors) that connects wirelessly to a smartwatch. The SurroSense Rx© can provide real-time alerts to patients about plantar pressure distribution [19]. Table 3 provides detailed parameters of SurroSense Rx©.

Table 3. Comparison of functionality, data collection and analysis, user interface, and intervention/alerting for SurroSense Rx©.

Technology	Functionality	Data Collection and Analysis	User Interface	Intervention and Alerting	References
SurroSense Rx©	Insoles embedded with eight pressure sensors per foot; measures pressure on plantar side of feet	Collects pressure readings and sends it to smartwatch if an alert is needed	Displays alerts and readings on smartwatch	Wirelessly connects to a smartwatch to send real-time alerts to patients about plantar pressure distribution	[19]

A recent study demonstrated that participants in remission wore the New Balance 929 Diabetic Walking shoe with two pressure-sensing insoles and a smartwatch [19]. Each

insole was embedded with eight pressure sensors—three on the metatarsal heads, two on the lateral plantar surface, one on the heel, one on the great toe, and one in the distribution of the lateral toes [19]—as shown in Figure 2. The smartwatch sent alerts to the participant if greater than 95% of the measured pressure was above the determined threshold of 35–50 mmHg for more than 15 minutes [19]. The watch also measured the success rate of the patient's response. A successful response meant the pressure was offloaded in less than 20 min after the alert was sent. Patients on average wore the insoles for about 5.38 $\pm$ 3.43 h per day and got about 3.38 $\pm$ 3.81 alerts per day throughout the study [19]. The study revealed that an alert is required every two hours for patients to respond to any potential issues [19]. The smart insole's alert feedback is effective for high-risk diabetic patients and could help reduce the pressure on high-risk areas of the foot, which will help reduce repeated stress on the plantar tissue.

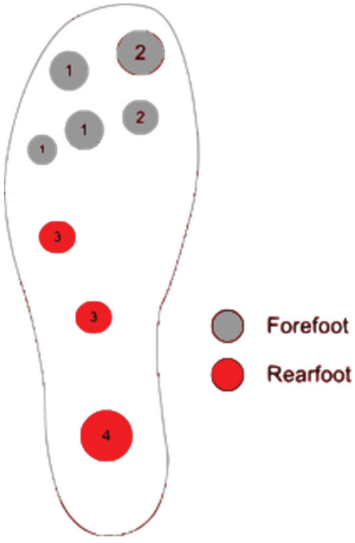

Figure 2. Location of the eight pressure sensors on the insole. Numbers indicating the different sensors and different colors are for the forefoot and rearfoot [19,29].

The smart insoles' alert feedback system provides a major benefit to patients with depression. Individuals with depression often struggle with memory and cognitive functioning, and the repeated reminders sent by the insoles can be especially helpful. By sending regular alerts to offload pressure on the plantar region, patients no longer have to constantly remember to take care of their health and offload pressure. This reduction in stress and cognitive load can significantly improve patients' abilities to adhere to their treatment plans, ultimately decreasing the risk of ulcer development.

A recent, randomized proof-of-concept from two multidisciplinary outpatient diabetic foot clinics in the UK was randomly assigned to either an intervention (SurroSense Rx© insole system) or control. The intervention group received audiovisual and vibrational alerts from the smartwatch, encouraging the patient to offload by walking or removing the weight from the affected foot [20]. Once the pressure was offloaded, the alert on the device cleared, and patients were able to resume normal activity. The control group received no alerts, regardless of plantar pressure being detected. The pressure detected was considered high if 95–100% of the readings were above 35 mmHg and low if 0–34% of the readings were above 35 mmHg [20]. Based on the findings from the study, ulcer incidence was reduced by 86% in the intervention group versus the control group [20]. The results from this study infer that continuous plantar pressure monitoring and dynamic offloading guidance can potentially lead to a reduction in diabetic foot ulcer site recurrence.

4.3. Monitoring Wear Time of Boots

Another key factor leading to diabetic foot ulcer recurrence is patient adherence to prescribed diabetic foot care [21]. Adherence is oftentimes defined as a patient's behavior that corresponds directly to the agreed-upon recommendations from their respective healthcare provider [21]. There is a direct correlation between poor adherence to diabetic foot care and ulceration recurrence [21]. However, new technologies can now help with monitoring footwear adherence, thus potentially improving patient outcomes. Orthotimer© (Balingen, Germany) is a temperature-sensing modality used to monitor how long patients are using their prescribed footwear [21].

Lutjoboer et al. conducted a recent study using a temperature monitoring system for patient adherence. Ten healthy participants were monitored over a duration of 48 h using the sensor in their footwear. The technology utilizes a microsensor to record temperature every 15 min [21]. If the leg was visible in the photograph, the patient was noted to be adherent (wearing the device). The average footwear measured using the camera was 8.10 h per day, and the average footwear measured using the sensor was 8.16, 8.86, and 4.91 per day [21]. The similarities in the results proved how effective the sensor was in determining whether the footwear was in use or not. The accuracy of the results demonstrates how using the Orthotimer© could be an effective way of determining how long a patient was wearing the required footwear. This can help doctors adjust their course of patient care and help increase patient adherence to the footwear [21].

Another effective way to help increase patient adherence when it comes to the required footwear is SmartBoot [30]. This boot uses a smart offloading system in order to remotely monitor a patient's real-time adherence to the required footwear. The smart offloading boot is used with a smartwatch and stores the data on a cloud dashboard in order to collect a patient's adherence and activity [30]. In order to improve the effectiveness of healing through boots and preventing DFUs, adherence to offloading devices needs to be monitored. Currently, there are four different ways to promote offloading [31]. These methods include wearing different footwear, like shoes and insoles; surgery, like silicone injections; offloading devices, like removable and non-removable devices; and offloading techniques, like wheelchairs and bed rest [31]. Although these techniques might be beneficial in protecting patients from developing diabetic foot ulcers, they are not as effective in increasing adherence [31]. One way that clinicians found around this issue was by introducing a non-removable offloading device [30]. Even though this offloading device is very good at treating foot ulcers, it comes with severe limitations [30]. Having a non-removable offloading device hinders a lot of patients' daily activities. Although this helped increase adherence to footwear devices, patients were not very satisfied and comfortable with the treatment. Having a smart offloading device was one way to address this issue. This device uses the smartwatch to send alerts to increase adherence, thus reminding the patients to continue wearing their boots [30]. The SmartBoot is able to remotely monitor a patient's weight bearing activity. A study conducted by Park et al. reported that patients were extremely satisfied and comfortable with the Smartboot [30]. They felt that they were able to do their daily activities and still continue wearing the device, thus increasing adherence.

Orthotimer© and SmartBoot are invaluable technologies that play a crucial role in promoting adherence and aiding in the prevention of diabetic foot ulcers. Table 4 illustrates their distinct approaches to monitoring and enhancing adherence. Despite their differing functionalities and data analysis methods, both technologies serve as essential tools for mitigating the risk of ulcer formation.

Table 4. Comparison of functionality, data collection and analysis, user interface, and intervention/alerting for Orthotimer© and SmartBoot.

Technology	Functionality	Data Collection and Analysis	User Interface	Intervention and Alerting	References
Orthotimer©	Microsensor embedded in footwear to monitor how long patients are using the prescribed footwear	Collects temperature every 15 min	Patients cannot see collected temperature	No alerts given; however, the temperature measurements will help physicians make informed decisions regarding intervention and	[21]
		computer		whether patients are adhering to the prescribed footwear	
SmartBoot	Uses a smart offloading system in order to monitor real-time adherence to prescribed footwear and monitor patients' weight bearing activities	Paired with a smartwatch to collect data on patient's adherence and stores them on a cloud dashboard	Alerts shown on the smartwatch	The smartwatch sends alerts to remind patients to continuously wear the prescribed footwear	[30]

5. Summary/Conclusions

Thinking creatively about targeting both diabetic foot complications and behavior change as it relates to treatment adherence is vital for overall patient outcomes. In order for these digital health technologies to optimize their effectiveness, they must address diabetic-related conditions in a more holistic way that promotes patient engagement while also monitoring adherence. Encouraging patient engagement is particularly important in a diabetic patient who suffers from clinical depression. Technologies that are able to address the intersecting connection between pathology and psychosocial variables in patient care could potentially set the stage for future treatment algorithms. Adhering to clinical practice guidelines, routine assessment, screening, and treatment of depression in patients with diabetes is recommended. Implementing advanced technologies that integrate artificial intelligence can prevent diabetic-related complications, thus improving quality of life and potentially reaching a decrease in both patient and health service costs by engaging in a less expensive and more accessible treatment.

This literature review highlights the significant impact of diabetic foot ulcers on physical and mental health, particularly in relation to the link between DFUs and depression. The emotional toll of limited mobility and the challenges of managing the condition can lead to frustration, hopelessness, and low self-esteem among individuals with DFUs. These negative emotions contribute to a poor adherence to treatment and self-care, resulting in worsening foot ulcers and increased preventative complications, such as amputations.

This review emphasizes the potential of smart wearable technologies, including smart socks and insoles, in reducing the risk of ulcer formation and improving patient adherence. These technologies provide real-time data on plantar pressure and temperature, enabling early detection of potential ulcer formation and facilitating timely intervention. Moreover, they empower patients with DFUs to better understand and manage their condition, leading to an improved quality of life and reduced risk of depression.

Comorbid depression has been found to significantly impact the incidence and progression of foot ulcers, leading to delayed healing and increased mortality rates. Individuals with depression are less likely to adhere to medical regimens and require integrated treatment approaches that involve professionals trained in both depression and diabetic foot

ulcers. Engaging patient home caregivers and significant others in the treatment plan is also crucial for effective management.

This review further highlights the value of technology-delivered self-help treatment approaches for depression, which can be easily accessed and utilized in the privacy of a patient's home. These approaches overcome transportation-related obstacles and provide cost-effective solutions. The incorporation of AI technologies, such as continuous plantar temperature monitoring systems and sensor-equipped socks, addresses the challenges of patient adherence, particularly for individuals with depression. These technologies simplify monitoring routines, reduce cognitive load, and improve patient engagement with their healthcare plans.

Overall, the literature supports the use of robust technologies to enhance patient adherence and improve outcomes in individuals with diabetic foot complications. The integration of AI monitoring holds promises for reducing the incidence of DFUs, promoting timely intervention, and improving overall diabetic foot care adherence. By embracing these advancements, healthcare providers can optimize patient care, prevent complications, and ultimately improve the lives of individuals who are at risk of or currently suffering from diabetic foot ulcers. Further studies into micro-climate regulation, stress monitoring on plantar tissue, and the monitoring of the wear time of boots with integrated sensors will highlight the significance of integrating AI tools into patient care regimens.

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sensors

MDPI

Case Report

A Multi-Faceted Digital Health Solution for Monitoring and Managing Diabetic Foot Ulcer Risk: A Case Series

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Abstract: Introduction: Diabetic foot ulcers (DFU) are a devastating complication of diabetes. There are numerous challenges with preventing diabetic foot complications and barriers to achieving the care processes suggested in established foot care guidelines. Multi-faceted digital health solutions, which combine multimodal sensing, patient-facing biofeedback, and remote patient monitoring (RPM), show promise in improving our ability to understand, prevent, and manage DFUs. Methods: Patients with a history of diabetic plantar foot ulcers were enrolled in a prospective cohort study and equipped with custom sensory insoles to track plantar pressure, plantar temperature, step count, and adherence data. Sensory insole data enabled patient-facing biofeedback to cue active plantar offloading in response to sustained high plantar pressures, and RPM assessments in response to data trends of concern in plantar pressure, plantar temperature, or sensory insole adherence. Three non-consecutive case participants that ultimately presented with pre-ulcerative lesions (a callus and/or erythematous area on the plantar surface of the foot) during the study were selected for this case series. Results: Across three illustrative patients, continuous plantar pressure monitoring demonstrated promise for empowering both the patient and provider with information for data-driven management of pressure offloading treatments. Conclusion: Multi-faceted digital health solutions can naturally enable and reinforce the integrative foot care guidelines. Multi-modal sensing across multiple physiologic domains supports the monitoring of foot health at various stages along the DFU pathogenesis pathway. Furthermore, digital health solutions equipped with remote patient monitoring unlock new opportunities for personalizing treatments, providing periodic self-care reinforcement, and encouraging patient engagement—key tools for improving patient adherence to their diabetic foot care plan.

Keywords: diabetic foot ulcers (DFU); remote patient monitoring (RPM); sensor-based monitoring; diabetes complications; neuropathy; plantar pressure; wearables; health technology; temperature monitoring

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1. Introduction

Diabetic foot ulcers (DFU), or wounds on the foot, are a devastating and complex complication of diabetes [1]. DFU development can stem from mechanical or ischemic factors [2]. With the mechanical pathway of DFU development, peripheral neuropathy and loss of protective sensation (LOPS) interfere with an individual's ability to sense and offload harmful sustained plantar pressures [2,3]. Additional risk factors that may contribute to abnormal plantar pressures include loss of intrinsic foot muscles, changes in foot shape, foot deformities, and altered gait and posture biomechanics [2–4]. Abnormal plantar pressures can result in callus formation, inflammation, and tissue damage or ulcers extending to the subcutaneous tissue or deeper [2].

Of people living with diabetes, 34% are likely to develop a DFU during their lifetime [5]. DFU recurrence rates are high, with an estimated 40% of ulcers recurring within the first year of healing [5]. Over one-third of DFUs result in lower extremity amputation (LEA) of the toes, the entire foot, or the lower leg [6]. The consequences of DFUs extend beyond amputation and place patients at risk for numerous other adverse events such as falls, fractures, reduced mobility, frailty, and mortality [7].

Fortunately, it is estimated that 75% of DFUs are preventable using established foot care methods and are treatable when detected early [6,8]. The International Working Group on the Diabetic Foot (IWDGF) offers evidence-based guidelines on the prevention and management of DFUs as part of integrative foot care best practices [9]. However, there are numerous challenges with achieving these recommendations and adhering to the guidelines (Table 1).

Table 1. The International Working Group on the Diabetic Foot (IWDGF) guidelines on the prevention and management of DFUs, challenges with adhering to these guidelines, and how multi-faceted digital health solutions overcome existing challenges to enable and reinforce these guidelines.

IWGDF Guideline [9]	Challenges	How Multi-Faceted Digital Health Solutions Enable and Reinforce Diabetic Foot Care Guidelines
Identifying the at-risk foot: examination and screening for signs and symptoms that place a patient at risk	Discontinuities in foot care due to other comorbidities or life circumstances (e.g., difficulty accessing office visits, or other social determinants) [10]. Difficulty for clinicians to personalize care and education to a patient's lifestyle and risk profile.	Remote patient monitoring (RPM) enables continuity of care when access is a barrier. Digital health technologies provide specific data trends of concern for review by the clinical treatment team, enabling personalized, proactive management.
Regular self-exams	Difficulty performing foot self-exams due to mobility or vision limitations [7]. Limited at-home support [11].	RPM interventions in response to data trends of concern involve self-exam, if possible. Structured education with regards to self-exam importance and technique are delivered and reinforced at regular intervals.
Structured education around appropriate foot self-care	Limited retention or recall of provided medical information when not reinforced [12]. Limited opportunities to re-emphasize the self-care regimen [5].	RPM engagement enables periodic reinforcement of foot self-care best practices to maximize effect.
Self-monitoring of foot skin temperatures once daily	Difficulty performing foot self-exams due to mobility or vision limitations [7]. Difficulty recognizing the subtle early signs of a wound [13,14].	Continuous, objective temperature monitoring enabled by handheld thermometers or plantar temperature monitoring technologies; adherence is quantifiable.
Adherence to appropriate footwear, including custom-made insoles, orthotic interventions, or pressure-relieving interventions.	Insufficient adherence [15,16]. Difficulty successfully offloading plantar areas of risk.	Digital health technologies can quantify adherence to aspects of the care plan (e.g., prescription footwear or activity adherence). RPM interventions in response to decreased adherence aim to encourage patient participation in the care plan. Continuous, real-time pressure monitoring and active offloading cues enabled by plantar pressure monitoring technologies.
Treating ulcer risk factors Treatment of any pre-ulcerative signs or callus on the foot	Difficulty recognizing the subtle early signs of a wound [13,14].	Multimodal sensing and RPM intervention may help with earlier detection of pre-ulcerative signs and risk factors, escalating those patients for clinical assessment and treatment.
Foot and mobility related exercises aimed to reduce DFU risk factors, including communication around safe activity levels	Insufficient information on patient activity and its impact on patient risk.	Activity quantification through activity monitoring technologies aids in the management of activity prescription and counselling regarding appropriate activity modifications.

Several strategies have been proposed to address the challenges of established foot care guidelines (Table 1). First, real-time plantar pressure offloading through biofeedback (e.g., via an intelligent insole system [17]) has been suggested as a strategy to compensate for the loss of plantar sensation due to diabetic peripheral neuropathy. Active plantar pressure offloading is believed to support DFU prevention by reducing the periods of elevated, repetitive, and undetected plantar pressures that can cause cumulative tissue mechanical stress [4,18] or exceed capillary perfusion pressure across a time window capable of causing tissue injury [19,20].

Second, temperature monitoring has been proposed as a strategy to identify an inflammatory response as a preliminary sign of tissue damage [21]. Reduced ambulatory activity in response to "hotspot" detection (e.g., contralateral temperature asymmetries > 2.2 °C) is believed to provide the offloading necessary to reduce inflammation and DFU risk. Protocols typically involve contacting a care provider when the hotspots are detected. While skin temperature monitoring was initially enabled by handheld daily temperature measurements with infrared dermal thermometers [21], sensor-based digital health technologies (e.g., sensory socks [22], smart mats [23], etc.) have been developed to facilitate improved consistency and ease of measurement.

Third, strategies have been suggested to encourage adherence to the diabetic foot health management care plan. Several technologies have been proposed to monitor prescribed footwear use or adherence to other aspects of the care plan [15]. Integrating these data into remote patient monitoring (RPM) systems offers objective insights to encourage patient engagement, including personalized structured education and reinforcement of self-care practices [24].

While these individual strategies have shown the potential for reducing DFU risk, a multi-faceted digital health solution (i.e., fusion of multimodal sensing, direct patient biofeedback, and RPM) may better align with the multifactorial causal pathway of DFU formation. However, such holistic strategies for reducing DFU risk are underexplored, and the compounding benefits are unknown [24,25].

In this case series, we present patient narratives, physiologic data, and RPM engagement from a multi-faceted digital health solution that highlights both a multimodal approach to diabetic foot monitoring (plantar pressure, plantar temperature, activity, and device adherence monitoring via a sensory insole), as well as multiple data-driven action pathways (direct patient biofeedback and remote patient monitoring). The purpose of this case series is to explore how a multi-faceted digital health solution may enable and reinforce established diabetic foot care guidelines and evaluate how such holistic solutions can improve our ability to understand, prevent, and manage patients at risk for DFUs.

2. Materials and Methods

A prospective cohort study was conducted at a single office-based podiatry clinic in Ohio, USA. Three non-consecutive case participants who presented with pre-ulcerative lesions (a callus and/or erythematous area on the plantar surface of the foot) during the study were selected for presentation in this case series. Presented cases were selected as they were illustrative of situations that may arise in the clinical management of the diabetic foot. The study received Institutional Review Board (IRB) approval through WCG IRB (20220828). Informed consent was obtained from all patients in the study. Patients who had type 1 or 2 diabetes, peripheral neuropathy, and a history of a previous plantar foot ulcer were candidates for recruitment. Patients with active ulcer(s) or other open chronic wounds, presence of severe vascular disease, history of a non-neuropathic foot ulcer, or a serious underlying balance issue were excluded.

All three case participants were provided with custom sensory insoles (Orpyx® Sensory Insoles, Orpyx Medical Technologies Inc., Figure 1) to track, analyze, and trend plantar pressure, plantar temperature, step count, and usage data as they went about their daily activities. Participants wore the sensory insole system for at least 8 months (chosen arbitrarily based on the amount of sensory insole usage at the time of writing) and were instructed to

wear the insoles in standardized diabetic footwear for a minimum of 4.5 h per day [17]. The digital health solution included adjunct RPM, provided through the in-house RPM service at Orpyx Medical Technologies. While the Orpyx Sensory Insoles were used for patient monitoring in this study, there is great flexibility in selecting a sensor-based technology for integration with RPM, with the goal of balancing effectiveness and practicality of the digital health solution for a specific use case [25].

Figure 1. The Sensory Insole System (Orpyx® Sensory Insole System, Orpyx Medical Technologies Inc., Calgary, AB, Canada) includes custom-milled insoles that are placed into the patient's shoes; a patient-facing app that provides real-time pressure feedback, step count, and wear time information; and a web-based dashboard accessed by a remote patient monitoring nurse and provider to review the data collected from the sensory insoles.

2.1. Plantar Pressure

Each insole (depending on the insole size) comprises an array of 22–37 discrete force sensitive resistors (FSR) to record plantar pressure. Each FSR element operates as a switch at pressures greater than 35–50 mmHg, a threshold chosen based on estimates of capillary perfusion pressure at the foot [17]. When 95% or greater of the insole pressure measurements exceed the calibrated pressure threshold over a 15 min sliding time window, the sensor would be marked as being in a "high-pressure state" and the app-based display would provide real-time patient-facing biofeedback for pressure offloading [17]. The sensory insole technology has been shown to reliably detect pressures above a calibrated pressure threshold for most sensor locations [26]. For RPM review, high-pressure states were distilled to six anatomical foot regions per insole (Figure 2A). When any combination of foot regions was in a high-pressure state for greater than 40% of usage time for a day, a warning indicator was generated for the RPM review.

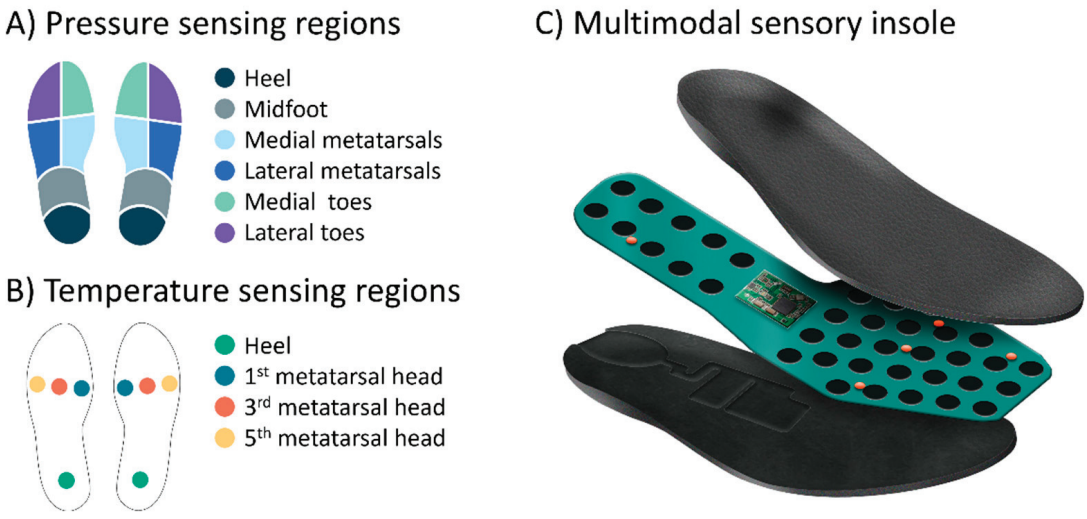

Figure 2. Insole sensory regions. (**A**) Pressure-sensing regions. (**B**) Temperature-sensing regions. (**C**) Multimodal sensory insole system containing pressure, temperature, and motion sensors embedded in a custom orthotic. Large black circles illustrate the array of discrete force sensitive resistors (FSR) to record plantar pressure. Small orange circles illustrate the five temperature sensors located beneath the high-risk bony prominences in the foot (metatarsal heads 1, 3, and 5, the heel, and the big toe). At the time of the study, temperature asymmetry monitoring was inactive at the big toe. The inertial measurement unit (IMU) is embedded in the electronics chip in the center of the insole.

2.2. Temperature

Each insole consisted of 5 temperature sensors located beneath high-risk bony prominences in the foot (metatarsal heads 1, 3, and 5, the heel, and the big toe, Figure 2B). At the time of the study, temperature asymmetry monitoring was inactive at the big toe. The temperature measured by the sensors are accurate within 0.6 °C of a reference standard (unpublished data), similar accuracy to other wearable plantar temperature monitoring solutions [22]. Temperature was summarized as the daily contralateral temperature difference between left and right corresponding foot locations (temperature asymmetry). Temperature was also summarized as the daily ipsilateral temperature difference between a foot location and the average of all foot locations on the same foot. At the time of this study, for consistency with escalation processes in previous randomized clinical trials that examined temperature asymmetries [21], measurements were evaluated at a single time point. When two consecutive daily temperature difference measurements exceeded a 2.2 °C threshold, a warning indicator was generated for RPM review. The product did not include any real-time patient-facing biofeedback triggered by temperature asymmetries.

2.3. Step-Count, Daily Insole Usage, and Adherence Monitoring

An inertial measurement unit (IMU) was embedded in the sensory insole to record foot motion. Daily insole usage was estimated as the duration of daily data collection triggered by foot motion. A custom step-count algorithm was used to report daily step count. Daily usage and step count were used to contextualize patient behavior and monitor adherence. Given that the sensory insole was placed in the patient's diabetic footwear, sensory insole usage also served as a surrogate measure of adherence to wearing the diabetic footwear. If no usage was detected for a period of three consecutive days, an adherence warning indicator was generated for RPM review.

2.4. Remote Monitoring and Case Escalation

Participants were remotely monitored by a U.S.-based qualified healthcare professional who routinely reviewed the data collected by the sensory insoles published to a dashboard (Figure 1). Data trends of concern generated warning indicators for the RPM nurse to review. Participants were contacted by the RPM nurse based on a mutually agreed upon escalation protocol or in accordance with their clinical judgement. Contact with patients typically entailed a discussion of the data trend of concern, remote assessment of the patient's feet, if possible, and coaching and education on reducing risk factors through foot care best practices. When a significant or persistent data trend of concern emerged, or when RPM engagement with the patient revealed a potential concern, the patient was escalated to the referring clinician and an in-person clinic visit was scheduled at their discretion. The type of RPM engagement (successful phone call, as defined by having a patient interaction, vs. data review only) and duration was automatically tracked in the dashboard.

3. Results

3.1. Case 1

Case 1 is a 49-year-old female with a 20-year history of poorly controlled type 2 diabetes, and a history inclusive of psoriatic arthritis. They demonstrated complete loss of protective sensation bilaterally on the basis of 5.07 monofilament testing and had a history of recurrent DFUs on the left second toe and right heel (Figure 3F). The patient had forefoot varus in their right foot as well as a triple arthrodesis, which resulted in a fused and locked subtalar joint, and angular alignment of the right heel.

During the 8-month usage period, the patient wore the sensory insoles for an average of 4.3 ($\pm$1.9) h per day with an average step count of 1583 ($\pm$917) steps (Figure 3D).

Between months 3 and 5, the patient experienced consistent high-pressures in the left foot lateral metatarsal region (Figure 3A). The lateral left foot high-pressures in this time range are consistent with a compensatory loading strategy due to the right foot deformity [27]. In view of these sustained high-pressure patterns, the RPM nurse maintained frequent engagement with the patient and periodically monitored the sensory insole data to ensure that there were no other data trends of concern (Figure 3E). Prior to the patient's scheduled clinic visit, the RPM nurse engaged with the patient and their data 32 times (7 unique phone calls and 25 unique data review sessions) (Figure 3E, months ~0–5). During the phone calls, the patient did not report any visible abnormalities or concerns on self-exam despite the persistent high-pressures measured by the sensory insoles.

In communication with the provider about the pressure data trend of concern, in-person patient assessment was deferred to their scheduled follow-up. During that in-clinic visit (vertical black dashed line in Figure 3A–E), the patient presented with a callus and cracking on the left lateral foot underneath the fifth metatarsal head. The clinician addressed the callus by adding a lateral post to the left insole (a strip of tapered material on the lateral side of the insole running from the heel past the fifth metatarsal head).

After the clinic visit and insole modification (Figure 3, months ~5–6), the observed plantar pressures on the left and right feet did not change significantly. Subsequently, sensory insole data revealed continued high-pressure on the left lateral foot, and a trending increase in high-pressure on the right foot (Figure 3A,B, months ~6–8).

This patient did not generate many temperature asymmetries in the 8-month usage window. Only two non-consecutive data days with a contralateral temperature difference exceeding a 2.2 °C threshold were detected (Figure 3C).

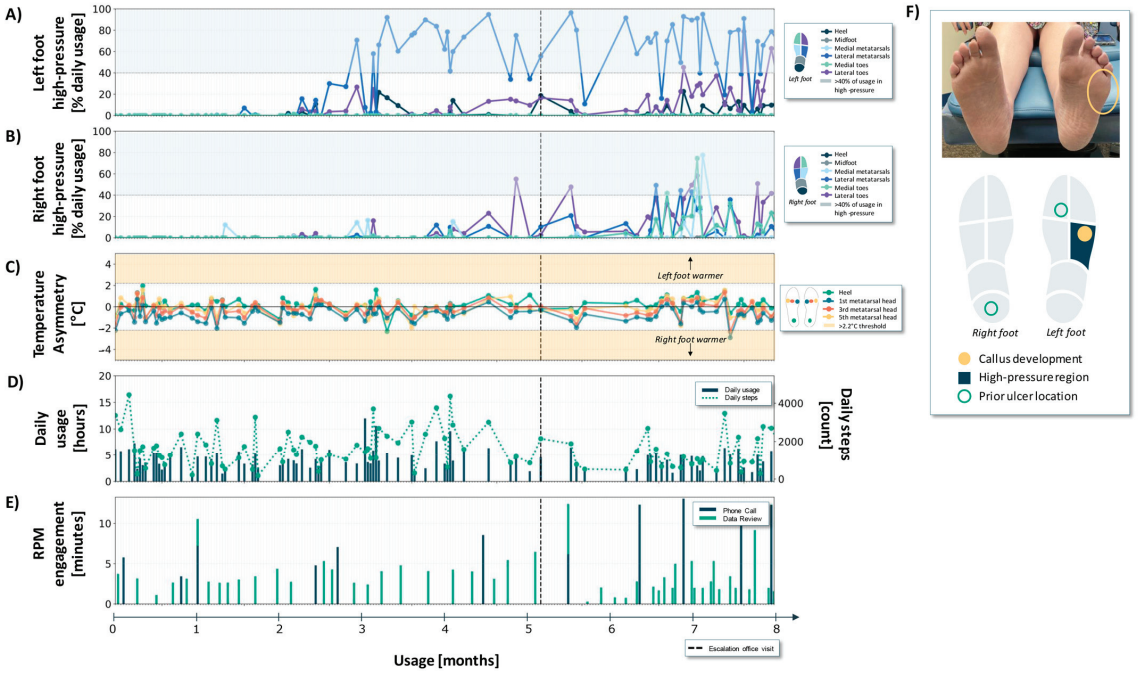

Figure 3. Pressure, temperature, daily usage, and RPM engagement metrics over an 8-month period for Case 1. (**A**,**B**) High-pressure states, expressed as a percentage of daily usage, for the different regions of the left and right foot, respectively. Any regions falling in blue-shaded area were in a high-pressure state for more than 40% of the usage time. (**C**) Temperature asymmetries. Data points in the upper and lower yellow regions indicate one foot is at least 2.2 °C warmer than the other. (**D**) Daily usage and step count. (**E**) RPM engagement phone calls and data review. It is possible that more than one RPM engagement occurred in a single day. (**F**) Photographs of the plantar surface of the patient's feet highlighting areas of callus development seen in-clinic, alongside a foot map summarizing high-pressure regions and prior ulcer locations.

3.2. Case 2

Case 2 is a 60-year-old male with a history of type 2 diabetes, severe peripheral neuropathy, and renal transplant for end stage renal disease (ESRD) from diabetic nephropathy. The patient also had a history of a cerebrovascular accident (CVA) with a resulting left lower extremity motor deficit, but they were ambulating independently at enrollment. They had a history of previous DFUs on the right fifth metatarsal head, right lateral foot, and left first toe. They also had a history of a DFU to the right first toe, and subsequent right first toe amputation (Figure 3F).

During the 8-month usage period, the patient wore the sensory insoles for an average of 11.4 (±2.4) h per day with an average step count of 1993 (±639) steps (Figure 4D).

During a clinic visit that occurred early in the study window (black dashed vertical line in Figure 4A–E), the patient noted receiving biofeedback from the digital display warning of sustained high plantar pressures. The patient presented with a pre-ulcerative, erythematous, callused area on the plantar surface of the right fifth metatarsal head and lateral foot, as well as callus under the left first metatarsal head (Figure 4F).

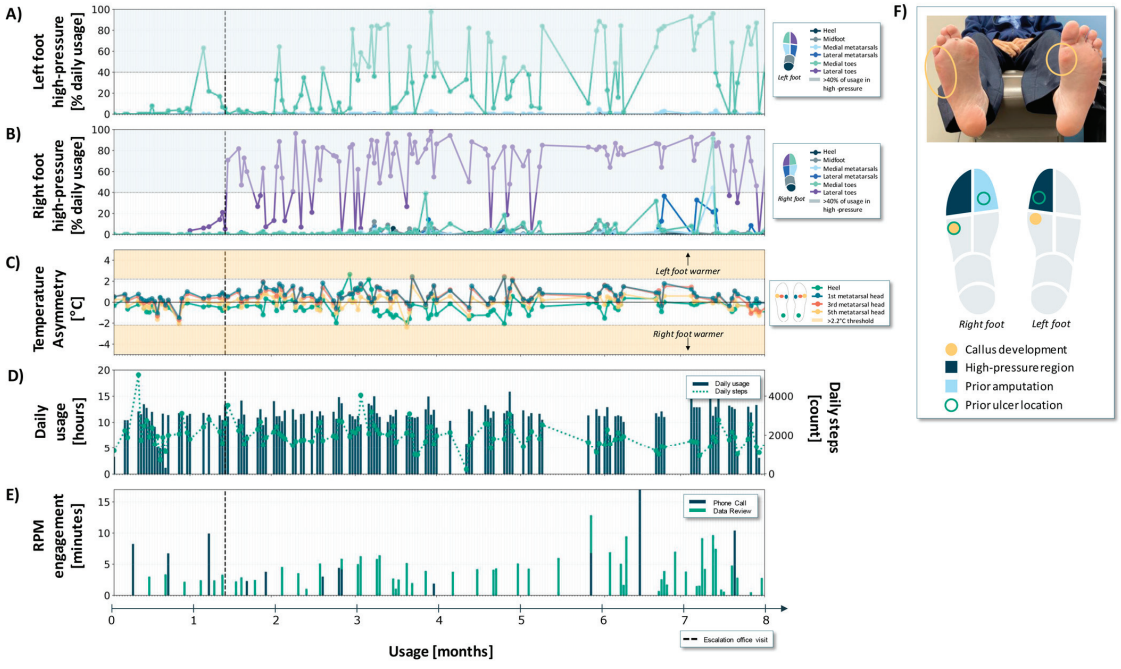

Figure 4. Pressure, temperature, daily usage, and RPM engagement metrics over an 8-month period for Case 2. (**A**,**B**) High-pressure states, expressed as a percentage of daily usage, for the different regions of the left and right foot, respectively. Any regions falling in the blue-shaded area were in a high-pressure state for more than 40% of the usage time. (**C**) Temperature asymmetries. Data points in the upper and lower yellow region indicate one foot is at least 2.2 °C warmer than the other. (**D**) Daily usage and step count. (**E**) RPM engagement phone calls and data review. (**F**) Photographs of the plantar surface of the patient's feet alongside a foot map summarizing high-pressure regions, areas of callus development seen in the clinic, and prior amputations and ulcer locations.

While a limited amount of sensory insole data was available prior to this clinical presentation, it is posited that the observed plantar tissue damage is consistent with compensatory loading in response to the right first toe amputation [27]. Consequently, the patient shifts pressure away from the right medial foot towards the lateral side of the right foot and medial side of the left foot.

During the clinic visit, a dancer pad insole modification was placed underneath the left first metatarsal head to offload and redistribute pressure directly under that area. Additionally, a lateral post was added to the right insole to help redistribute elevated pressures from the right lateral foot to the right medial foot, away from the callused right fifth metatarsal head.

Following the clinic visit, the patient had high-pressure at the left medial toes and right lateral toes (Figure 4A,B). A total of 44 high-pressure flags throughout the 8-month window prompted 71 engagements (14 unique phone calls, 57 unique data review sessions) from the RPM nurse.

The patient did not generate many temperature asymmetries, despite the erythematous nature of the lesion on the right fifth metatarsal head. Contralateral temperature differences only exceeded the 2.2 °C threshold on five non-consecutive days during the usage window (Figure 3C) and none that preceded their in-office assessment.

3.3. Case 3

Case 3 is a 75-year-old female with a history of type 2 diabetes, peripheral neuropathy, and prior DFU on the right fourth metatarsal head as well as the left second metatarsal head (Figure 5F). The patient had a history of chronic, recurrent DFUs (presenting approximately one to two times per year for the last 4 years) and non-reducible hammertoes on both the left and right foot. The patient's right and left foot are similar in shape and biomechanical deformity. The combination of these foot flexion deformities and neuropathy results in poor balance.

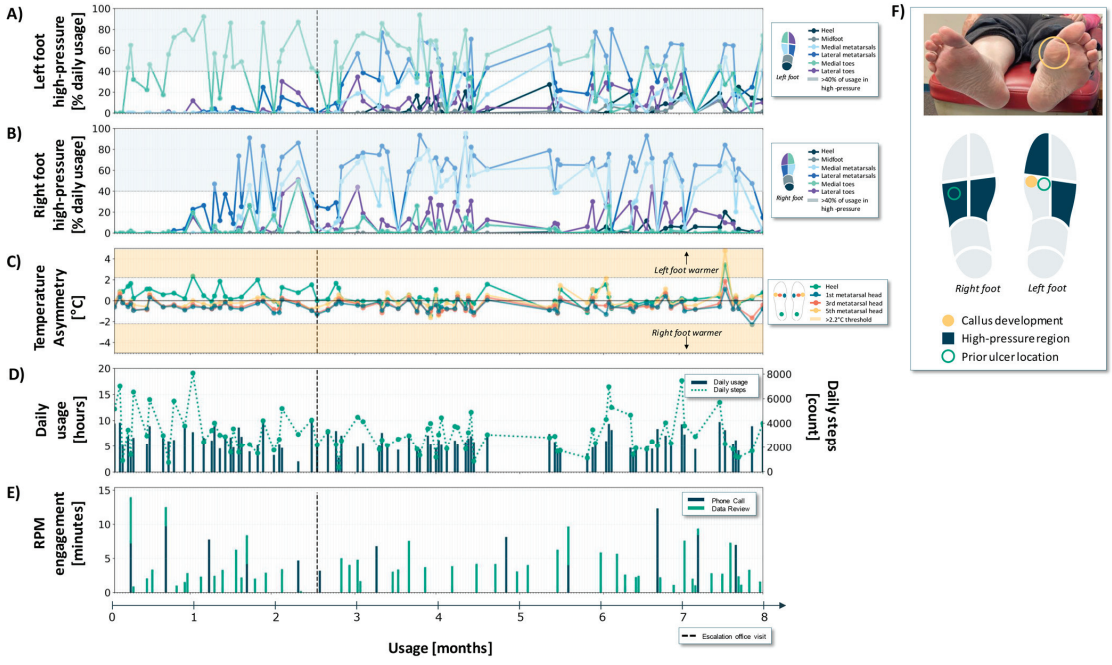

Figure 5. Pressure, temperature, daily usage, and RPM engagement metrics over an 8-month period for Case 3. (**A**,**B**) High-pressure states, expressed as a percentage of daily usage, for the different regions of the left and right foot, respectively. Any regions falling in the blue-shaded area were in a high-pressure state for more than 40% of the usage time. (**C**) Temperature asymmetries. Data points in the upper and lower yellow region indicate that one foot is at least 2.2 °C warmer than the other. (**D**) Daily usage and step count. (**E**) RPM engagement phone calls and data review. (**F**) Photographs of the plantar surface of the patient's feet alongside a foot map summarizing high-pressure regions, areas of callus development seen in the clinic, and prior ulcer locations.

During the 8-month usage period, the patient wore the sensory insoles for an average of 6.2 (± 1.8) h per day. The patient showed consistent usage and a relatively high average step count of 3104 (± 1628) steps (Figure 5D). A gap in usage around month 5 is a consequence of the patient undergoing surgery unrelated to their feet.

The patient generated 46 elevated pressure flags in the 8-month window, primarily on the left medial toes. Elevated pressures were also generated on the right medial foot and bilateral lateral foot regions (Figure 5A,B). Based on the pressure flags generated, the RPM nurse escalated the patient to their treating clinician for a clinic visit (black dashed vertical line in Figure 5A–E). During that visit, the patient presented with a callus at the plantar surface of the left first metatarsal head (Figure 5F). This callus was debrided by the clinician during the visit. No structural interventions were provided, as the patient's

foot deformities could not be easily addressed through insole modifications or non-surgical offloading mechanisms, nor was there a clear indication for surgery.

Following the clinic visit, the patient continued to generate elevated pressures in the left and right metatarsals (Figure 5A,B, months ~2.5–8). During this period, repeated high-pressure events prompted 33 RPM engagements with dashboard data and seven patient phone calls.

No significant temperature asymmetries were generated in the 8-month usage window. Contralateral temperature differences only exceeded the 2.2 °C threshold on four non-consecutive days (Figure 5C).

4. Discussion

Approximately 40% of DFUs recur within one year of ulcer healing [5] and average recurrence rates at 6 months are estimated to be 30% [28–30]. Three illustrative patients with a history of recurrent plantar foot ulcers developed no ulcers while utilizing a multi-faceted digital health solution for an 8-month monitoring window. Through the combination of multimodal sensing, dynamic patient-facing biofeedback, RPM review of data trends of concern, and the human touch provided by RPM engagement, a holistic prevention system is established. As of the time of writing, all three patients are ongoing users of the system, and none have re-ulcerated. For these patients, this multi-faceted system of care appears to have successfully disrupted their chronic ulcer recurrence cycle.

4.1. Measuring and Managing Plantar Pressure Offloading

To the authors' knowledge, this case series is the first study to demonstrate that remote plantar pressure monitoring is a valuable tool for the ongoing measurement and management of plantar pressure offloading adherence (see IWDGF guideline *"Adherence to appropriate footwear, including custom-made insoles, orthotic interventions, pressure-relieving interventions"*, Table 1). While the results from a randomized controlled trial demonstrated patient-directed pressure offloading feedback to be effective in reducing DFU recurrence [17], the present study extends on this work by incorporating plantar pressure monitoring into an RPM system of care. Leveraging continuous plantar pressure monitoring for multiple data-drive action pathways offers numerous benefits.

First, the identification of plantar pressure data trends of concern directly informed offloading treatment strategies. For example, in Case 1, a consistent trend of lateral left foot pressure measured by the sensory insole, along with clinical presentation of callus and cracking on the plantar surface, motivated an additive insole modification (left lateral post). The intention of this data-driven modification was to redistribute pressure away from the lateral left foot to mitigate sustained high-pressure and DFU risk at the callus site.

Second, continuous monitoring of sustained high plantar pressures offered insight into pressure offloading following additive insole interventions. For example, in Case 1, ongoing pressure monitoring revealed a trend towards a gradual change in sustained high-pressures following the addition of a lateral post, consistent with an expected, if delayed, impact in gait retraining. Alternatively, in Case 2, continuous monitoring revealed persistent regions of sustained high-pressures following the insole modifications, suggesting the additive insole modification did not impact the sustained high plantar pressure as expected. Motor learning of gait modifications is a complex process that can take significant time [31] and it is plausible that further gait modifications and changes in elevated and sustained pressures could have manifested beyond the monitoring window of this study. Given that approximately 50% of wounds recur on the contralateral foot, and most remaining recurrences are at a different location on the same foot [32], continuous plantar pressure monitoring further serves to ensure that offloading treatments do not unintentionally introduce pressure overload risk at anatomical sites distant from the previous wound.

Third, in all three cases, the pressure-offloading education delivered during the frequent RPM engagements was informed by data trends of concern (Figures 3, 4 and 5E) and supplemented patient-facing biofeedback (pressure offloading cues). It is well-established

that offloading adherence is especially important for ulcer healing and recurrence prevention [17,33]. The cadence and volume of the RPM interactions (Figures 3, 4 and 5E) are tuned to concerning physiologic data trends that are leading indicators of tissue injury, or gaps in adherence that may be indicative of reduced participation in self-management practices. While we did not quantify the impact of RPM engagement on offloading behavior, we speculate that the frequent reinforcement empowered patients with a high level of self-management (see IWDGF guidelines, *"Adherence . . . pressure-relieving interventions"*, Table 1).

4.2. Multi-Faceted Digital Health Solutions Enable and Reinforce Integrative Foot Care Guidelines

Multi-faceted digital health solutions offer potential for supporting the spectrum of care required for complex conditions such as diabetic foot disease [24]. No single strategy in isolation supports all guidelines for the prevention and management of DFUs (Table 1). Multi-faceted digital health solutions offer key advantages for enabling and reinforcing integrative foot care guidelines.

First, expanding to multimodal sensing (rather than monitoring/actioning on a single physiologic signal) supports the monitoring of warning indicators at several stages throughout the DFU pathogenesis pathway [25]. Despite pressure overload and callus formation playing a central role in DFU pathogenesis [2], many digital health solutions designed for DFU risk reduction focus only on plantar temperature monitoring [19,22,23]. Notably, in the three cases presented, contralateral temperature asymmetries remained in the acceptable range (i.e., no consecutive days with greater than 2.2 °C asymmetry) throughout the monitoring period (Figures 3–5). Conversely, at the stages of DFU development for these cases, plantar pressure monitoring provided warning indicators that supported the management of pressure offloading. It is likely that with continued monitoring of these cases (>8 months), as well as other future patient cases, DFU pathogenesis may progress differently, and as such, temperature monitoring, or a combination of pressure and temperature monitoring is likely vital. Multimodal sensing aligns with the dynamic and time-varying nature of DFU pathogenesis.

Second, multimodal sensing provides redundancy in monitoring when one or more physiological signals are confounded by underlying conditions or external factors. For example, monitoring in the pressure domain may serve as an important adjunct to temperature monitoring regimes, which may be confounded by comorbidities common in individuals with diabetes. Patient immunocompromise may impact the sensitivity of established plantar temperature asymmetry thresholds, while vascular disease may impact the specificity of these measurements [21,34]. Case 2 highlights a patient who is post renal transplant because of ESRD from diabetic nephropathy. Despite their pre-ulcerative lesion having some erythematous (redness) attributes, it did not appear to manifest as an insole-based plantar temperature asymmetry. The capacity of such patients to generate temperature differentials in the foot related to pre-ulcerative inflammation remains understudied. Multimodal sensing offers flexibility and enables care to be personalized to a patient's health profile.

Finally, multi-faceted digital health technologies can offer accessible opportunities to promote patient engagement and adherence to their foot health management plan. Case 3 illustrates a patient at a high risk of recurrence with limited clinical interventions available to guard against recurrent DFUs. In this case, plantar pressure data trends measured by the sensory insoles, alongside a clinical presentation of a callus, informed clinician intervention (debridement). However, additional offloading mechanisms, such as insole modifications, were not indicated in view of the patient's existing foot deformities. Ongoing plantar pressure monitoring, patient-directed active pressure offloading biofeedback, and periodic and convenient interactions with a remote healthcare professional trained in diabetic foot management provided multi-layer care to a patient with few non-surgical treatment options. Multi-faceted digital health technologies offer patients and clinicians alternative and comprehensive treatment plans to fit the patient's medical and lifestyle needs.

5. Limitations

5.1. Study Design Limitations

This case series is limited by its sample size and non-consecutive nature. It is exploratory, and conclusive causal inferences should not be drawn. Larger cohort studies and randomized clinical trials are warranted to explore the benefits of multi-faceted digital health solutions in proactively detecting pre-ulcerative indications and preventing escalations to more serious foot complications.

5.2. Technology Limitations

The sensory insoles used in these case examples only capture plantar physiological data while the patient is wearing the device, and thus do not detect any foot risks that may arise while not being worn. Additionally, the sensory insoles have pressure arrays that are configured and optimized for the detection of sustained high-pressure over time to limit adverse pressure-related events. As such, it would not necessarily be expected to see all impacts of pressure redistribution manifest in the data. Extended pressure monitoring configurations may support valuable evaluations such as the specific pressure redistributions achieved with a given insole modification. Finally, despite the product design choices informed by durability testing, the performance of some sensor components (e.g., mechanical components of pressure sensors) might change over time due to wear and tear to the product. Variability in calibration procedures performed at the time of production may also influence the performance of some sensors (e.g., pressure threshold calibration process).

6. Future Opportunities

Given the emerging nature of multi-faceted digital health programs, there are numerous exciting future research opportunities to evaluate and optimize such care strategies. Based on the learning from the patient journeys in these cases, the authors offer a (non-exhaustive) list of existing uncertainties and underexplored topics surrounding the digital health management of DFU that warrant future research.

First, the individual and combined benefits of each aspect of a multi-faceted digital health solution are unknown (e.g., sensory insole monitoring, real-time biofeedback for pressure offloading, RPM engagement, clinician involvement, and/or insole modifications). Quantifying the impact of each of these individual components may also continue to inform which feedback/action pathway(s) are best paired with each physiological signal. Similarly, the cost effectiveness of multimodal sensor-based RPM programs versus their individual components remains understudied. Although cost savings relating to DFU treatment have been shown with real-time biofeedback and remote temperature monitoring alone [20,35], the cost effectiveness of sensor-based RPM programs warrants further research.

Second, both quantitative and qualitative characterization of user adherence and the barriers to use (e.g., how aspects such as comfort, ease of use, etc., drive adherence) are essential for driving future technological innovations with the aim of further optimizing patient engagement [15]. While no formal user experience analyses were performed in this study, the patients anecdotally reported the system to be comfortable, easy to use, and appreciated the opportunity to actively engage in their foot health through the biofeedback alerts and RPM engagement.

Third, there is always an opportunity for ongoing refinement of the warning thresholds for both plantar pressure and plantar temperature monitoring to balance sensitivity and specificity. These thresholds may need to be tuned to a patient's dynamically changing risk profile, and there may be opportunities in multimodal systems to develop warning thresholds for certain combinations of elevated physiologic parameters.

Fourth, there are infinite combinations of sensor suites and sensor configurations that can be deployed in a given digital health technology. Ongoing product research and development efforts may reveal new combinations of existing sensor suites and

physiological signals, or entirely new wearable sensors that are effective for continuous DFU management.

Lastly, the emerging nature of these technologies limits the ability to systematically correlate the sensor-based data trends with certain clinical conditions and treatments. The system currently relies on the RPM nurse to communicate with the patient to gather medical, behavioral, and lifestyle context, bridge the gap between them, and decide on an action plan. Future wearable technologies might benefit from developing integrated databases that fuse sensor-based data with patient medical history. Furthermore, there are exciting opportunities to integrate monitoring technologies across multiple clinical domains, creating holistic ecosystems for managing chronic conditions.

7. Conclusions

This case series demonstrates the value of a multi-faceted digital health solution combining multimodal data collection, patient-facing biofeedback, and remote patient monitoring to enable and reinforce diabetic foot health management guidelines. Across three illustrative patients, continuous plantar pressure monitoring demonstrated promise for empowering both the patient and provider with information for the data-driven management of pressure offloading treatments. While most remote monitoring digital health solutions for foot ulcer prevention focus on plantar temperature monitoring, some clinical comorbidities may limit or confound the utility of plantar temperature monitoring for DFU risk, highlighting the value of capturing multiple continuous sensor-based physiological data streams.

Multi-faceted digital health solutions can naturally address many of the challenges with established diabetic foot care guidelines, motivating ongoing research to optimize and explore the benefits of such solutions. Rather than relying on a single signal, multimodal sensing across multiple physiological domains supports the monitoring of foot health at multiple stages along the DFU pathogenesis pathway. Furthermore, digital health solutions equipped with remote patient monitoring provide new opportunities for personalizing treatments, providing periodic self-care reinforcement, and encouraging patient engagement—tools for improving patient adherence to their diabetic foot care plan. By serving as a tool to disrupt a patient's chronic ulcer recurrence cycle, holistic digital health solutions support the broader goals of health span extension for patients living with diabetes.

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Data Availability Statement: Data are contained within the article.

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Conflicts of Interest: Brock Liden sits on the Clinical Advisory Board of Orpyx Medical Technologies, Inc. Evan Minty is under a consulting agreement with Orpyx Medical Technologies Inc. (in capacity as Medical Director of their RPM service). Minty discloses equity ownership in Orpyx Medical Technologies and has family members in the employ of Orpyx Medical Technologies Inc. Emily

Matijevich, Emily Bray, Courtney Bachus, and Maryam Hajizadeh are employees of Orpyx Medical Technologies Inc.

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sensors

MDPI

Perspective

Preventative Sensor-Based Remote Monitoring of the Diabetic Foot in Clinical Practice

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Abstract: Diabetes and its complications, particularly diabetic foot ulcers (DFUs), pose significant challenges to healthcare systems worldwide. DFUs result in severe consequences such as amputation, increased mortality rates, reduced mobility, and substantial healthcare costs. The majority of DFUs are preventable and treatable through early detection. Sensor-based remote patient monitoring (RPM) has been proposed as a possible solution to overcome limitations, and enhance the effectiveness, of existing foot care best practices. However, there are limited frameworks available on how to approach and act on data collected through sensor-based RPM in DFU prevention. This perspective article offers insights from deploying sensor-based RPM through digital DFU prevention regimens. We summarize the data domains and technical architecture that characterize existing commercially available solutions. We then highlight key elements for effective RPM integration based on these new data domains, including appropriate patient selection and the need for detailed clinical assessments to contextualize sensor data. Guidance on establishing escalation pathways for remotely monitored at-risk patients and the importance of predictive system management is provided. DFU prevention RPM should be integrated into a comprehensive disease management strategy to mitigate foot health concerns, reduce activity-associated risks, and thereby seek to be synergistic with other components of diabetes disease management. This integrated approach has the potential to enhance disease management in diabetes, positively impacting foot health and the healthspan of patients living with diabetes.

Keywords: diabetic foot ulcers (DFU); remote patient monitoring (RPM); sensor-based monitoring; integrative foot care; chronic disease management; diabetes complications; healthcare costs; sensor-enhanced DFU prevention; activity monitoring; diabetes healthspan

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1. Introduction

Diabetes affects approximately 550 million people (9.3% of the population) worldwide, and the prevalence is projected to increase to 643 million by the year 2030 [1,2]. Of people with diabetes, 34% develop a diabetic foot ulcer (DFU) during their lifetime, half of their DFUs become infected, 20% require hospitalization, 5% lead to lower extremity amputation (LEA), and half of those LEAs lead to LEA of the opposite limb within 5 years [3–7]. Both major and minor amputations have repercussions, such as changes in biomechanics and plantar stiffness, that heighten a patient's risk of subsequent foot complications [2,8].

The consequences of DFUs are not limited to amputation, and include an increased risk of falls, fractures, reduced mobility, frailty, and mortality [9]. The 5-year mortality rate

for those with DFUs is 30.5%, almost identical to the pooled mortality rate of all cancers (31%) [10]. Inevitably, DFUs carry a significant cost to the health system. Annual costs of diabetic foot complications in the U.S. are USD 2.1 billion for emergency department expenses and USD 9.6 billion in hospital admission charges (both amounts adjusted to 2020 USD) [11]. On average, a patient with a DFU has 14 outpatient visits and 1.5 hospitalizations every year, not only driving up healthcare costs but also resulting in lost time from work [11]. More than one-third of patients with DFUs experience symptoms of anxiety or depression, adding to the mental wellness burden on the healthcare system [12].

However, at least 75% of DFUs are preventable using established integrative foot care methods, and DFUs are treatable when detected early [13,14]. Current standard diabetic foot care includes appropriate fitting and/or diabetic footwear, custom insoles (without embedded sensors), education around professional nail care and daily self-checks for redness, callus, and wounds. This care pathway has historically been the same regardless of the patient's baseline risk profile. Performing a foot self-check can be difficult for patients due to impairments in mobility or vision or lack of recognition of early wound lesions. Adherence to footwear prescription or self-monitoring regimens may also be a challenge for some patients. This can limit the effectiveness of current standard-of-care preventative practice for DFU [15].

Sensor-based remote patient monitoring (RPM) has been proposed as a possible solution to overcome the limitations of the established existing care methods and to establish an integrated healthcare pathway that improves prevention and treatment efficacy for patients with DFUs [16–18]. RPM allows healthcare professionals to utilize biometric data from sensor-based devices to detect chronic disease deterioration or exacerbation and enable early intervention to prevent escalation to acute care, providing pathways to care that may be more efficient, more equitable, and tailored to patients' risk profiles [19–24]. The upper bound prevention rate of DFUs may be redefined when sensor-based prevention is paired with effective RPM and foot care best practices.

In diabetes care, RPM has primarily been deployed to support remote review of continuous glucose monitoring data to evaluate insulin dosing, timing, and therapy adherence [24]. RPM has been applied to other chronic disease states, showing early promise in improving outcomes in patients with obstructive pulmonary disease, Parkinson's disease, hypertension, and other cardiovascular diseases (CVD) [25,26]. The American Heart Association published a position statement providing guidance on RPM implementation to encourage its use to improve CVD outcomes, and systematic reviews examining cardiovascular applications of RPM suggest longer-term cost effectiveness of such approaches [27,28].

There have been limited economic evaluations of sensor-based care and adjunct RPM in DFU prevention. Based on the results of an early pilot study with sensor-based insoles providing direct patient feedback in response to sustained pressure, Markov-based economic modeling suggested that the use of that device to reduce DFU recidivism was cost-effective at device prices of less than USD14,275.50 [29]. Over an 18-month period, expected costs decreased from USD 20,028.69 to USD 5753.19 per patient on average and from USD 54,134.94 to USD 6702.54 per ulcer avoided. The pilot results used to parameterize that model are on the order of those that were subsequently found in a randomized control trial (RCT) evaluating the same device [30] and did not involve notifications directed to the care team as an adjunct to patient-facing alerts. Cost effectiveness has also been suggested in DFU prevention using device-based remote temperature monitoring [31]. In the absence of effect estimates specific to the device used in that study, the model was parameterized using estimates from the literature that involved patient-reported thermometry results to a study nurse [32] and suggested cost savings of USD 8027 per patient. There is a need for studies that evaluate the combined impact of patient-facing and care team notification-based RPM, that include impacts of false positive notifications in cost models.

This perspective article offers insights from deploying sensor-based RPM through digital DFU prevention regimens. First, we summarize the data domains and technical architecture that characterize existing commercially available solutions. We then highlight

key elements for effective RPM integration based on data from these domains, including appropriate patient selection and robust background data collection to contextualize biometric data from patients outfitted with sensory technology. The importance of data collection across multiple physical domains of monitoring is emphasized, and guidance on how RPM systems can be effectively integrated into a system of care is offered. This includes considerations with respect to predictive system management and guidance on establishing escalation pathways for remotely monitored patients for both the RPM service provider and the prescribing clinician. Finally, it is suggested that the impact of using sensory technology in monitoring the diabetic foot should be synergistic with other disease management principles in diabetes and to the care of the patient as an individual. By seeking to reduce foot health concerns associated with activity, sensor-based monitoring of the diabetic foot should look to enable the cardiovascular and metabolic risk reduction that can result from gradual activity increases, thereby aiming to improve both foot health and the healthspan of patients living with diabetes.

This perspective is foundationally based on established standards of care, such as those developed by the International Working Group on the Diabetic Foot (IWDGF) and Prevention of Amputation in Veterans Everywhere (PAVE) [33,34]. It has been expanded based on existing sensor-based DFU prevention research and the experiences gained by the authorship through the deployment of RPM through sensor-based digital therapeutic devices. There are limited frameworks and no guidelines available on how to incorporate or respond to data collected through sensor-based RPM in DFU prevention. This perspective addresses this knowledge gap and offers a suggested framework on how to incorporate sensor-based remote patient monitoring, in the context of the diabetic foot, into clinical and preventative care regimens. Collectively, these sources offer insights to other researchers and clinicians looking to sensor-based RPM care as a pathway to save limbs and lives.

2. Technology Architecture and Implementation

The following section provides an overview of the sensor technology architecture and implementation of three sensor-based remote RPM products aimed at preventing DFUs. To our knowledge, there are three commercially available products in this space, and these include the Podimetrics SmartMat™ (Podimetrics, Inc., Somerville, MA, USA), Siren Socks (Siren Care, San Francisco, CA, USA), and the Orpyx SI® Sensory Insole System (Orpyx Medical Technologies Inc., Calgary, AB, Canada). Temperature monitoring is a common functionality among all devices. The product form factor dictates capacities for once a day or more frequent measurements in the temperature domain, and the products vary in their thermistor array implementation and sampling frequency. Pressure and activity monitoring are implemented in one product, and we explore the technical architecture and data feedback mechanisms available for data in those domains. We summarize a comparison between these products in Table 1.

Table 1. Comparison of technology form factor and data measurement domains in existing sensor-based RPM solutions aimed at DFU prevention.

Solution	Podimetrics SmartMat™	Siren Socks	Orpyx SI® Sensory Insole System
Form factor	Mat	Socks	Insole: custom or prefabricated
Data sampling	Once per day	All day	All day
Temperature monitoring	Yes	Yes	Yes
Pressure monitoring	No	No	Yes
Activity monitoring	No	No	Yes

2.1. Temperature Monitoring

All commercially available devices fundamentally monitor temperature differentials on the plantar surface of the foot and note when the temperature at corresponding locations

persistently exceeds an "asymmetry threshold", indicating potential inflammation of the warmer region. These comparisons are most typically evaluated at corresponding high-risk contralateral locations [35–38] but more recently have explored ipsilateral temperatures as comparators [39]. The form factor, use case, and data processing logic varies from product to product.

Orpyx SI® Sensory Insole system: The Orpyx SI® Sensory Insole system contains temperature sensors embedded into an insole that are then placed into the user's footwear for use during their daily activities. After an acclimation period, the sensors track temperature on the plantar surface of the foot at a frequency of one measurement per minute. The assembled device has been tested over a range of 15–40 °C via immersion in a thermostatic water bath and demonstrated an accuracy of ±0.6 °C when compared to a reference standard (510(k) submission ID K231880, pending public release). The sensor data are stored on board and wirelessly transmitted via Bluetooth to a HIPAA-compliant server to be processed and stored. The daily average difference is calculated from all measurements during that day, and comparisons are made both contralaterally (against the sensor location on the contralateral side) and ipsilaterally. Analogous to previous RCTs examining temperature monitoring in DFU detection, when two consecutive daily average measurements exceed a 2.2 °C difference threshold [32,40,41], RPM staff are notified via a flag in a HIPPA-compliant dashboard. At the time of this manuscript, temperature differentials are reported for the 1st, 3rd, and 5th metatarsals and the heel. A hallux temperature sensor is embedded in the insole and is the subject of current research and development prior to its public release.

Siren Socks: The Siren Socks are comprised of six temperature sensors woven directly into the sock fabric to continuously measure temperature across the plantar surface of the foot. The sensors track temperature at 10 s intervals across six areas of the foot: the hallux, metatarsal points 1, 3, and 5, the midfoot, and the heel. The stand-alone sensors have been tested over a range of 20–40 °C via immersion in a thermostatic water bath and demonstrated an accuracy of ±0.2 °C when compared to a reference standard [37]. The sensors embedded in socks were similarly evaluated in a thermostatic water bath and were reported to show high agreement with the reference standard [37]. The sensors connect to a small tag on the sock that houses a microcontroller, battery, and Bluetooth chip, which stores temperature data [37]. Data are transmitted to the cloud through a wireless cellular data hub that connects to the Bluetooth chip on the sock. Data are transmitted both to the physician-facing web portal and patient-facing mobile device. Temperature asymmetry is evaluated at six contralaterally matched locations, and the daily average differential is computed. Temperature asymmetries that exceed a threshold trigger a warning to the clinical staff [31,37,38,42].

Podimetrics SmartMat™: The SmartMat™ is an at-home once-daily use wireless floor mat that contains a high-density array of approximately 1000 thermistor sensors [43]. The patient is instructed to stand on the mat and remain stationary for 20 s while the device records a thermogram of both feet. The thermogram is reported to have an accuracy of ±0.6 °C and a precision of 0.1 °C, and the device is accurate over a range of 15–40 °C [35]. Once the scan is complete, data are de-identified and securely and wirelessly transmitted to a HIPAA-compliant server to be processed and stored. The daily left versus right temperature asymmetry is automatically calculated based on the thermogram and compared to an asymmetry threshold. Temperature asymmetry is evaluated at six contralaterally matched locations: the hallux, first, third, and fifth metatarsal heads, midfoot, and heel. When patients are missing part of the foot due to amputation, temperature measurements from a nearby location on the foot are used. Temperature asymmetries that exceed a threshold trigger a warning to the clinical staff [35,36,44].

2.2. Pressure Monitoring

Pressure overload plays a central role in models of DFU pathogenesis, with different accounts as to the role of peak pressures, shear pressure, or the impact of exceeding capillary perfusion pressure across a pressure time integral [40,45,46]. It is common practice to

prescribe custom footwear or insoles to offload areas of presumed high plantar pressure [47]. A complementary approach, which has shown promise in randomized controlled trial evaluation, has been the provision of patient-directed feedback with regard to the areas of the foot experiencing sustained pressure [30]. This approach can complement the provision of a custom insole prescription. Of the three commercially available sensor-based DFU RPM systems, only one has architecture to support measurement in the pressure domain.

The Orpyx SI®Sensory Insole system contains 22–37 force-sensitive resistors (FSRs, exact number depends on the insole size) embedded in each insole. The design reflects a pressure monitoring regimen designed to detect pressures that, when sustained over time, can cause tissue ischemia. FSRs are calibrated at manufacturing time to a tolerance between 35 and 50 mmHg and operate as a switch at that threshold. This value was chosen based on estimates of capillary perfusion pressure at the foot [48]. Over a 15 min sliding window, if 95% of sensor pressure readings exceed the threshold, the sensor is marked as being in a "high-pressure state" [30]. Each insole is divided into six anatomical regions to simplify pressure data interpretation, namely a heel, midfoot, medial metatarsal, lateral metatarsal, medial toe, and lateral toe region. If any sensors in a region are in a high-pressure state, that region is considered to be in a high-pressure state.

In the Orpyx SI®system, pressure data have two paths for feedback: patient-facing and clinician-facing. For the clinician-facing feedback, when any combination of regions is in a high-pressure state for greater than 40% of usage time for a day, a warning highlighting a pressure data trend of concern is generated for RPM review. For the patient-facing feedback, when a sensor region is in a high-pressure state, the patient is provided with real-time cues for pressure offloading through an app-based display. Patient-facing biofeedback is continuous, but patients are cued no more than once per hour to balance user engagement and alert fatigue [49].

2.3. Activity Monitoring

There are no claims evident in the literature that describe the activity monitoring capabilities of two of the three commercially available systems. The Orpyx SI sensory insole system contains an inertial measurement unit (IMU) embedded in the sensory insole to record foot motion. A step count algorithm is used to report daily step counts based on signals from a triaxial accelerometer. Step count data are wirelessly and securely uploaded for display in the HIPAA-compliant dashboard.

3. Patient Selection

Patient selection is a very important component of any remote monitoring program to ensure that it is effective for both the patient and the treating clinician.

Based on factors that deem a patient to be at risk of developing a DFU, and the importance of engagement in the success of RPM programs, it is recommended that patients have the following characteristics [33]:

- Patients with Type 1 or Type 2 Diabetes with established peripheral neuropathy (PN) and loss of protective sensation (LOPS) as established by the Semmes–Weinstein monofilament test;
- Patients with a previously healed DFU (no active wound present). This is referred to as a person in remission from a diabetic foot ulcer [3,50,51];
- Patients who are willing and open to engaging in their diabetic foot health through digital prevention and an RPM service;
- Patients with the cognitive capacity and technological fluency to understand the digital device and its operation;
- A supportive care environment is also an asset but does not preclude the possibility of benefit from RPM.

These patient selection criteria generally align with risk levels established by international clinical practice guidelines such as PAVE and those written by the IWGDF [33,34].

The alignment of sensor-based care and RPM with the risk levels established by these organizations is outlined in Table 2.

Table 2. Remote patient monitoring recommendations based on international guideline risk levels.

Group	Definition	Risk Level	RPM Recommendation
IWGDF Patient Risk Levels			
0	No LOPS *, no PAD *, no FD *	Very low	Not required
1	LOPS + PAD	Low	In the presence of LOPS
2	LOPS + PAD, or LOPS + FD, or PAD + FD	Moderate	With history of previous (re-epithelialized) foot ulcer
3	LOPS or PAD with one or more of: (1) History of foot ulcer; (2) major or minor LEA *; and (3) ESRD *	High	With history of previous (re-epithelialized) foot ulcer
PAVE Patient Risk Levels			
0	No sensory loss, diminished circulation, ulceration, or amputation	Normal	Not required
1	No sensory loss, diminished circulation, ulceration, or amputation, but any of the following: (1) FD; (2) Minor foot infection; (3) Minor diminution of circulation	Low	Not required
2	Sensory loss and may have: (1) Diminished circulation (absent or loss of protective sensation); (2) FD or minor foot infection and diagnosis of diabetes	Medium	With findings suggestive of LOPS, especially if concurrent foot deformity or poor circulation
3	PN + sensory loss and may have diminished circulation, FD, minor foot infection and any of: (1) ulcer or history of prior ulcer; (2) Severe PAD; (3) Charcot + FD; and (4) chronic kidney disease	High	With history of previous (re-epithelialized) foot ulcer

* loss of protective sensation (LOPS), peripheral arterial disease (PAD), foot deformity (FD), lower extremity amputation (LEA), end-stage renal disease (ESRD).

The performance of some monitoring domains may be adversely affected by a patient's comorbidity profile. When selecting the specific physiologic data collected by an RPM solution, it is important to consider any chronic condition(s) that the patient may have, which may influence data trends. Patients may exhibit chronic limb temperature differences as a variant of normal physiology or mediated by asymmetries in peripheral arterial disease (PAD) or other structural or neurological compromise. All of these may predispose to false negatives or false positives in the temperature domain [35,52–54]. Temperature monitoring may also be impacted by patient immunocompromise, which could serve to partially suppress an inflammatory response to tissue injury. This, as well as immunosuppressive impacts of other commonly occurring comorbidities in people with diabetes (such as end-stage renal disease (ESRD) in the generation of temperature differentials in the diabetic foot, remain understudied [55].

RPM programs should be designed to include comorbid patients, not exclude them, as these patients are often at high-risk for DFU development. By collecting data across multiple modalities at different points of DFU risk and pathogenesis pathways and the provision of a service that emphasizes best practices in self-care, we feel that such patients can benefit from digitally enhanced risk reduction through RPM.

4. Clinical Assessment and Data Collection

Prior to enrollment in a remote monitoring program, a diabetic foot and wound history should be gathered and complemented by a complete medical and surgical history, social history, nutritional history, and physical exam as it pertains to wound healing potential in the lower extremities. This helps to contextualize the biometric data derived from sensor-

based devices and facilitates informed care decisions. Recommended patient history and physical examinations are detailed in Table 3.

Table 3. Clinical history and physical assessment in patients at risk for foot ulceration. Adapted with permission from Ref. [56].

Patient History/Clinical Presentation	Physical Examination

• Medical history
  ○ Arterial macro/micro vessel disease or vascular disease, or both
  ○ Level of diabetic control
• Complete surgical history, including any amputations
• Social history, including substance and tobacco use
• Nutritional status
• Wound history
  ○ Cause and duration
  ○ Infection history
  ○ Medical and surgical treatment history
• Mobility history/Functional status
  ○ Assistive devices
	• Vital signs
	• Lower leg assessment
	  ○ Sensory loss (SW 5.07 Monofilament)
	  ○ Vascular assessment
	  ○ Presence or absence of foot deformity or callus, color, or temperature differences
	• Gait assessment
	• Wound assessment
	  ○ Location
	  ○ Measurement
	  ○ Description
	  ○ Presence or absence of infection
	• Environmental factors under foot (dressings, insole modifications with padding, etc.)

A physical examination should be completed that includes vital signs, lower leg assessment (including sensory loss), vascular assessment, gait assessment, documentation of any foot deformities or differences, a detailed wound assessment, and information detailing any environmental factors that affect the biometric measurements.

A patient's functional status can reveal insights on the localized risk for DFU, as well as broader risks to the patient's wellbeing. A gait assessment is recommended to focus on the presence of any specific gait abnormalities such as calcaneal gait (high risk to heel region) and compensatory gait patterns such as early knee flexion, foot or hip abduction, or foot drop. These gait patterns can contribute to abnormal forces and lead to potential tissue damage [57]. A functional assessment should also consider the use of any assistive devices (i.e., walker, cane, etc.) or any upstream biomechanical issues that may cause compensation at the foot or ankle (i.e., hip tightness, knee contractures, unilateral weakness, etc.). More broadly, neuropathy places patients at increased fall risk, and a functional assessment should optimally be paired with access to services designed to reduce this risk at home.

In patients with diabetes, there are no clinical signs or symptoms that can accurately exclude PAD [58]. As such, a peripheral vascular disease (PVD) assessment, preferably through an ankle brachial index (ABI) with segmental pressures and waveform analysis (if local expertise exists), should be completed at intervals appropriate to local guidelines [58]. These tests can be helpful in contextualizing temperature data from available digital devices. Some devices and monitoring regimens have excluded patients with PVD in the trials contributing to their evidence base [35,40], while others have included patients with non-limb threatening disease [30,59].

Additional investigations that are recommended to capture a clinician's records include those relevant to the assessment of diabetic control and end organ damage, as summarized in relevant disease guidelines [60].

5. Remote Patient Monitoring for Diabetic Foot Ulcer Prevention: Overview

An RPM team is typically comprised of licensed, qualified healthcare practitioners. This team may be part of the clinical practice or be contracted by a third-party group, often the company that supplies the RPM technology. RPM marries the need for improved continuity of care with that of easing patient accessibility to care, ultimately encouraging a collaborative approach and strengthening the overall healthcare offering. With respect to caring for the diabetic foot, there is a continuum of physiologic parameters that evolves

alongside the risk pathway and progression of DFU. Digital prevention, when paired with an RPM service, can be considered preventative of tissue injury or reactive to tissue injury. This important distinction is illustrated in Figure 1.

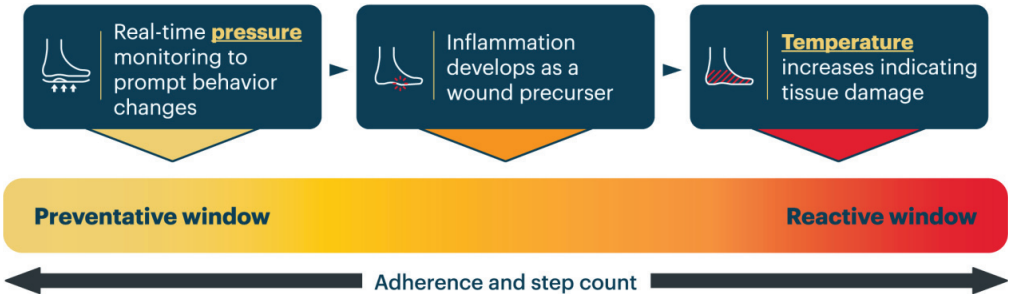

Figure 1. Physiologic parameters contributing to tissue damage on a preventative spectrum. Pressure is the first physiologic parameter that provides insights into formation of a DFU or pre-ulcerative lesion and, thus, is deemed preventative when addressed. Following increased levels of sustained pressure, tissues become inflamed and wound precursors develop. Actions surrounding temperature rooted in DFU or pre-ulcerative lesion formation are considered reactive in nature due to the underlying tissue damage that has taken place and led to the temperature increase being detected.

Figure 2 expands on elements involved in the DFU causal pathway, opportunities for RPM intervention, and, ultimately, maintenance on a path conducive to tissue healing, injury prevention, and diabetes healthspan extension.

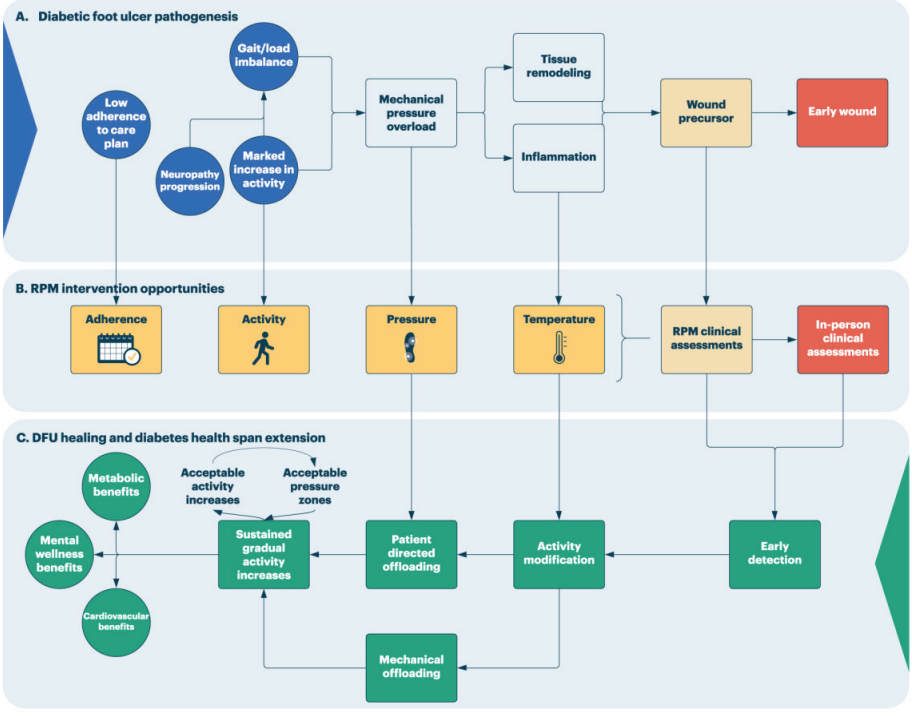

Figure 2. Simplified DFU causal pathway and RPM intervention opportunities.

The left side of Figure 2A outlines a high-level set of causal factors that contribute to DFU risk. These may relate to disease or comorbidity factors (e.g., neuropathy progression/severity) or have complex social determinants. The latter should contextualize how an RPM service and a clinical team intervene in a case. For example, patients may have to be on their feet due to job or transportation constraints and advising these patients to simply stay off their feet without a highly compelling reason is not a reasonable option. These patients likely benefit from preventative care as far upstream as possible in the DFU pathogenesis pathway. As the pathway progresses, gait/load imbalance, marked increases in activity, or contributions of both lead to a state of pressure overload. There are varying accounts as to the contribution of peak pressures, shear pressure, or the effect of exceeding capillary perfusion pressure across a pressure-time integral to pressure injury [30,47,61]. These states of pressure overload can lead to tissue remodeling and in cases of tissue injury, an inflammatory state [45,62]. These ultimately lead to wound precursor lesions and an early wound.

Panel B of Figure 2 illustrates intervention opportunities for a digital prevention-enabled RPM service. Adherence analysis offers opportunities to promote engagement, not only in digital prevention but also in the broader preventative and therapeutic care plan, in keeping with integrative foot care best practices [46,63]. Pressure analysis can offer opportunities to intervene prior to the development of tissue injury, which can be patient-facing to promote immediate patient-directed offloading and/or RPM-facing to be integrated into RPM assessment decisions [30]. Temperature-based analyses can serve as a sentinel to the development of inflammation and tissue injury, although it suffers from high false positive rates [35,54]. Meanwhile, activity monitoring can add important context to data trends of concern in other domains [64].

The net effect of analytics that highlight concerning data trends is to generate an RPM assessment at a data-driven threshold. If RPM services are provided by an external third party, these assessments represent net new clinical assets to the circle of care instead of depleting existing resources. They can also be accessed directly by the patient, thereby improving their awareness and access to care. RPM assessments play an important role in clinical triage, reducing false positive resource drains on existing clinical care teams by seeking to escalate only the concerning cases for an in-person assessment.

The desired ultimate impact of RPM intervention is to interdict DFU pathogenesis and promote tissue and patient wellbeing, as shown in Figure 2C. Proceeding from right to left, improved access to care and clinical triage via the RPM service aims to provide early detection of pre-ulcerative events. Ideally, interventions occur as far upstream in DFU pathogenesis as possible. Intervening at the inflammatory stage, prior to tissue breakdown, may provide opportunities for activity modification. These may include activity reduction, alternatives to weight-bearing exercise or mechanical offloading as arranged by the clinical team. These offloading strategies may benefit from ongoing monitoring in the pressure domain to ensure the desired offloading or gait retraining effect is achieved. Similarly, offloading interventions can apply when data trends of concern develop in the pressure domain in an attempt to prevent tissue injury altogether. In this domain, patient-facing notifications can serve to empower patients to direct an offloading strategy during their daily activities.

The goal of a DFU prevention RPM system should not only be to prevent DFU, but also to promote sustained, acceptable, and gradual increases in activity and overall wellbeing. Exercise is not contraindicated for those at risk of DFU; however, exercise and physical activity interventions should incorporate gradual, sustained increases in activity to limit foot health adverse events [63,65]. By incorporating techniques in health coaching and motivational interviewing, the RPM team can help direct a case to a desired end state where sustained modest increases in mobility can be monitored for adverse impacts on foot health. When sustained over time, this can lead to the anticipated metabolic, cardiovascular, and mental health benefits of increased exercise [66]. In doing so, digital-based DFU prevention

RPM services provide more than just DFU prevention but could potentially provide benefits that impact the diabetes disease trajectory.

6. Prediction System Quality Management in Remote Patient Monitoring Systems

> *"False positives are one of the worst things you can do to an early warning system" (Chesley Sullenberger, Captain of US Airways Flight 1549, "Miracle on the Hudson")* [67]

Sensor-based technologies provide the data inputs for a predictive system that seeks to escalate more concerning cases to clinical attention at a data-driven threshold. Every prediction system needs to balance the risk of false negative and false positive signals. While all seek to minimize the former, the pernicious effects of false positive alerts in clinical environments are well documented in the literature surrounding alert fatigue [68,69]. This is an important consideration when deploying sensor-based technology into a system of care. It is imperative that any RPM system overseeing sensor-based care institutes measures to reduce the introduction of false positive alerts into a busy clinical environment or into the care experience of the patient. To do otherwise risks the necessary engagement with the patient and the treating team, both of which are prerequisites to the success of the care system.

To ensure escalation processes are not adversely impacted by false positives, RPM systems can employ an additional clinical layer into the prediction and assessment process to serve as the first line in alert triage. RPM services that include these additional measures are typically staffed with clinically trained registered nurses (RNs) or other licensed health professionals. This complements existing care teams with additional input to ensure that digital therapeutics do not burden the referring clinical team.

Measures should be instituted to continually evaluate and improve the quality of the prediction system and RPM service being provided. Prediction algorithms benefit from continual efforts in data engineering and ongoing development and evaluation, a field broadly known as machine learning operations [70]. This requires the support of an internal data science team that operates in conjunction with the software and hardware development teams. Additionally, a robust quality system and oversight by trained medical professionals, typically a Doctor of Medicine (MD), Doctor of Osteopathic Medicine (DO), or Doctor of Podiatric Medicine (DPM), further support RPM systems.

7. Implementation, Opportunities, and Limitations of Sensor-Based RPM in Clinical Practice

The addition of a sensor-based RPM program to standard clinical practice should be synergistic with patients' existing care regimens. Successful integration of a sensor-based RPM program should consider the following:

- Patient selection
    - Patient selection plays a key role in the success of any RPM program. Patients should be identified and reviewed against patient selection characteristics, such as those outlined in this perspective, prior to patient enrollment in the RPM program. The goals of the program should be discussed with the patient, along with the responsibilities of the patient, clinician, and RPM service provider.
- Escalation and communication
    - RPM escalation protocols should be reviewed and agreed upon by the treating clinician and should clearly establish and outline communication methods and response timelines.
    - Training of relevant personnel on the sensor-based technology and associated RPM protocols is an important step in the implementation of an RPM program. Training should be provided not only to the patient but also to those involved in the patient's care, including the treating clinician, clinic staff, and the patient's support system.
- Technology selection

- The specific hardware and software deployed to collect the remotely monitored data may differ based on patient-specific requirements and needs. In the context of DFU prevention, this may take the form of sensor-embedded wearables such as insoles or socks that can be used throughout daily activities or non-wearable sensor-embedded technology such as a mat or recording device that can be used at home [30,31,35,71].
- The RPM technology should ultimately be selected based on factors that consider the patient's underlying disease state, lifestyle goals and constraints, technological fluency, and engagement with their overall health. The technology selection will also be influenced by the care providers' familiarity with the technology and whether the technology is covered by insurance [24].

There is great flexibility in how sensor-based RPM may be deployed to maximize both effectiveness and practicality. Given that sensor-based RPM programs are a relatively new offering, it is important to acknowledge the potential barriers and limitations that exist. These barriers and limitations may include:

- Technological learning curve
  - Due to the nature of sensor-based RPM, there is a technological learning curve that patients and clinicians face. Patients that have some experience with technology-based solutions may find it easier to participate in such programs. Patients that are not comfortable with technology or that do not have the appropriate support system to help learn a new technology may face additional barriers to success in a digital-based RPM program and require additional support.
  - Other patient factors, such as dexterity and visual impairment, should be acknowledged, depending on the form factor of the technology.
- Patient acceptance and engagement
  - Success in a digital, sensor-based RPM program relies heavily on patient engagement with the technology and remote monitoring nurse. It is also helpful for the treating clinician to provide support and encouragement to both the patient and RPM nurse, facilitating a team approach to patient care.
- Data privacy
  - It is of the utmost importance that digital, sensor-based RPM providers adhere to standards of digital health information storage. This includes, but is not limited to, the Health Insurance Portability and Accountability Act (HIPAA) in the United States and equivalent provisions in other jurisdictions.

8. Patient Assessment through RPM Services

The desired outcome of a well-calibrated prediction of risk in an RPM system is to prompt the involvement of virtual clinical assessment in an RPM process, as depicted in Figure 2. It is suggested that the following general principles apply with respect to remote assessment in an RPM service.

- When data trends of concern are noted, patients are contacted in accordance with clinical guidelines internal to the RPM service provider. This clinical guidance should be re-evaluated at regular intervals and serves to create predictable care processes and reduce unnecessary care variation within the RPM service.
- When patient contact is initiated, it should include an assessment of the physiologic data generating the concerning trend and the clinical context by a licensed healthcare professional.
- Patient contact includes a remote assessment of the patients' feet (self-guided exam) when possible and reinforces best practices in integrative foot care [13].
- In cases where that assessment reveals visible abnormalities or other signs of clinical concern, the clinician's office is notified directly.

- In cases where there are no such concerns identified, communication of the data triggering the concern, clinical context, and interaction with the patient proceeds via documentation in the legal record of care shared between the RPM provider and the treating team or through some other reporting mechanism. These cases, as well as true positives, should inform further refinement of the prediction system.

An additional benefit to an RPM service is that patients can be provided with ongoing education and coaching surrounding diet, exercise, medication and integrative foot care [13,72]. Patients immediately forget up to 80% of what their healthcare provider communicated during an office visit, and the value of reinforcement of self-care best practices cannot be overstated [73].

9. Clinical Response to RPM Escalation

If a patient presents with any concerning trends in their physiologic data, the remote monitoring healthcare professional may escalate this patient's information to their treating clinician for review and medical intervention. Clinical escalation parameters are governed by a mutually agreed upon RPM protocol between the clinician and RPM service provider.

Figure 3 illustrates the recommended actions for clinicians once a patient has been triaged from remote care to in-office care.

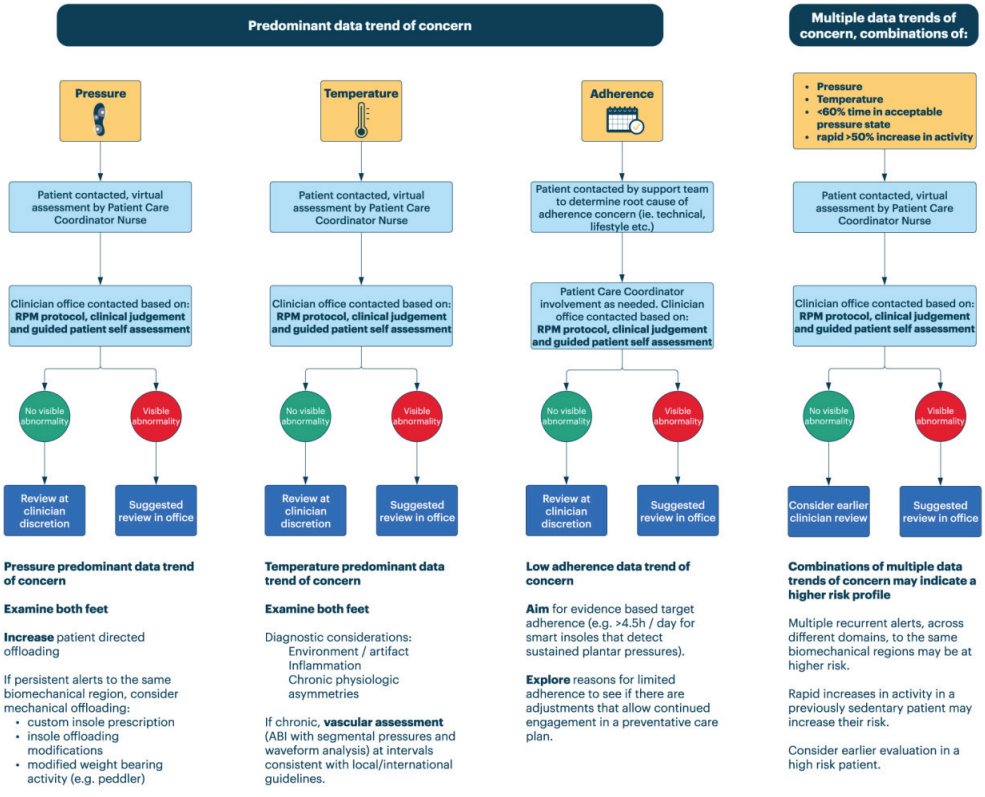

Figure 3. Suggested clinical actions for patients with concerning trends in pressure, temperature, or adherence domains, or across multiple domains.

In cases where an in-person clinical assessment ensues, most elements of that interaction (clinical history, physical exam) proceed in ways that remain rooted in the clinician's existing clinical training and protocols. However, the introduction of digital prevention may introduce additional clinical considerations and opportunities. The possible data

trends of concern revealed through RPM digital technologies are elaborated on below. The clinical guidance recommendations provided in this section are suggestions, and clinicians are encouraged to use their judgement on final care decisions.

9.1. Pressure Predominant Data Trend of Concern

Pressure monitoring generally provides upstream opportunities in prevention, in theory, prior to the development of inflammation from tissue injury. The following recommendations are provided to support clinicians in their assessment of patients escalated to their attention due to a pressure predominant data trend of concern. Note that these are derived primarily from a pressure monitoring regimen that aims to detect sustained elevated pressures.

- Clinicians may be tempted to focus an exam on a particular region that is generating data trends of concern. While that may indeed be an area of pressure overload, anchoring in a particular region should be avoided. **It is important that both feet are assessed**.
    - Early experience suggests pre-ulcerative pathogenesis might see pressure warnings preceding dermal changes in the same region or in different regions.
    - This may proceed through known biomechanical mechanisms (e.g., load switching between metatarsal heads 1 and 5), through patient offloading to a contralateral limb, or simply due to a change in activity that causes a broader alert pattern.
- Higher risk situations may involve recurrent data trends of concern to the same biomechanical regions.
    - Consider mechanical adjustment if this is persistent.
- Changes in activity levels may generate more cumulative load on the foot tissues and more pressure-related data trends of concern [74]. Some research also suggests that high day-to-day variability in activity, regardless of activity volume, may put individuals at higher risk of ulceration [75]. However, risk in such situations must be balanced against established cardiovascular, metabolic, and mental benefits of increasing mobility in high-risk populations. Digital therapeutics and RPM services need to be aligned with broader goals for healthy living.
- In keeping with those goals, the following clinical actions are suggested:
    - In cases of a recent, abrupt increase in activity (absent any evidence as to what is definitively unsafe, a definition of >50% of monthly baseline over a few days is used), consider counselling towards gradual increases instead, if possible [63].
    - If patient-facing alerts are provided by the digital prevention device, counsel towards higher interaction so that risks of increases in the activity to the diabetic foot can be more effectively managed through patient offloading [30].
    - Through health coaching and techniques in motivational interviewing, and in the absence of pressure data trends of concern or in a setting where they are reliably offloaded, aim for monthly increases in activity of 10% [13].

9.2. Temperature Predominant Data Trend of Concern

The following recommendations are provided to support clinicians in their assessment of a temperature-predominant data trend of concern.

- Pre-enrollment vascular assessment (preferably through ABI with segmental pressures and Doppler waveform analysis) at an interval appropriate to local guidelines can be helpful in contextualizing possible perfusion differences [58].
- Clinicians may be tempted to focus an exam on a particular region that is generating temperature data trends of concern. While that may be a focal area of inflammation, anchoring on a particular region should be avoided. **It is important that both feet are assessed**.
- Temperature asymmetry may be driven by areas of relative warmth or coolness.

- Pre-ulcerative inflammation may have a significant lead time, with some studies suggesting >5 days and others suggesting as long as >20 days [32,35]
- Relative temperature differences have low specificity in DFU prediction and may be driven by [54]:
  - Inflammation [37,40,45,54];
  - Environmental factors;
  - Chronic load-bearing differences [76];
  - Perfusion differences (large or small vessel disease asymmetries) [77];
  - Neurological asymmetries (e.g., impaired sympathetic tone) [78];
  - Asymmetries in muscle mass (or other structural asymmetries);
  - Venous insufficiency, edema.
- A meta-analysis of five temperature monitoring RCTs including 772 patients has recently provided low certainty evidence suggesting a risk reduction is associated with home skin temperature monitoring when ambulatory activity is reduced (e.g., by greater than 50% [59]) in response to detected hot spots [16]. Given the prevalence of false positives in the temperature domain [54], the potential impact of such a recommendation on the need for activity promotion in diabetic patients merits some consideration [65]. In view of this, some providers may want to consider other forms of activity modification (e.g., non-weight-bearing exercise). The safety of such approaches should be further studied, and providers should exercise their clinical judgment in balancing foot health concerns against activity promotion goals.

9.3. Adherence Predominant Data Trend of Concern

One of the advantages of engaging in digital-based prevention is the insights that can be generated with respect to patient adherence to preventative therapy. Prospective clinical trials with insoles monitoring sustained pressure have demonstrated that in patients with a previous DFU, a threshold of 4.5 h or more of wear per day led to a risk reduction of re-ulceration of 86% [30].

Reasons for limited adherence may be complex. Chronic disease can be exhausting, and patient circumstances can make prioritization of their health difficult. A significant portion, ranging from 40 to 80%, of information conveyed by providers is immediately forgotten, and approximately half the remembered information is incorrect, which may also undermine adherence to a preventative care plan [79]. An additional benefit to an RPM service can be realized by virtue of consistent, recurrent patient engagement with a licensed healthcare provider to provide coaching and overall support. These healthcare providers can work with patients to promote engagement with preventative technology and other preventative and therapeutic care regimens that are compatible with patient preferences and goals.

In keeping with those goals, the following clinical actions are suggested:

- Aim for an evidence-based adherence target (e.g., >4.5 h per day (for insoles that deliver alerts in response to sustained elevated plantar pressure [30]));
- Explore reasons for limited adherence to see if there are adjustments that can be made to allow for continued engagement in a preventative care plan.

Licensed care professionals excel at creating and maintaining therapeutic relationships and at contextualizing care needs to a patient's preferences. Care remains an intrinsically human endeavor. Those relationships can be a significant asset in chronic disease management, which is something that no digital device alone can completely supplant.

9.4. Multiple Data Trends of Concern

Current evidence exists that correlates the increases in pressure time integrals, temperature, and activity, but their independent contributions within a multifactorial casual pathway have not been established [30,35,40,80]. Although speculative, a reasonable as-

sumption is that greater risk may be conferred by multiple data trends of concern across domains of pressure and temperature to the same biomechanical region when occurring in proximity to a concerning activity context. In cases of multiple data trends of concern, clinical action recommendations may include those suggested for individual data trends of concern, as outlined in the above sections. However, earlier escalation should be considered due to the presumed higher risk level when multiple data trends of concern are detected.

10. Sensor-Based Preventative Care Will Enhance Our Understanding of DFU Pathogenesis and Promote a Systems-Based Approach to Prevention

> *"Everything should be made as simple as possible, but not simpler" (Possibly Albert Einstein, as paraphrased by L. Zukofsky and then R. Sessions).* [81]

It is acknowledged that the representation of the DFU pathogenesis pathway in Figure 2 is both simplified and incomplete. Indeed, we expect that the application of sensor-based technology under the insensate diabetic foot at scale will likely lead us to re-evaluate models for DFU pathogenesis. In our search for a causal model for DFU, there is often an assumption that the risk resides in the culprit foot [82]. Collecting large-scale, real-world sensor data from both limbs will highlight the importance of the interplay between both feet through the gait cycle, activity patterns, and other patient factors [83–86]. Indeed, Petersen and coworkers highlighted that, in remission, recurrence frequently occurs on sites distant from the original lesion, with the leading site for recurrent disease being on the contralateral foot [87]. Current literature recognizes limitations in predicting or detecting ulceration using individual monitoring domains such as temperature thresholds, peak pressure, shear pressure, and total pressure time integrals, or activity [46,47,54,80,86]. This suggests an alternative view, which de-emphasizes the need to define a singular mode of pathogenesis and accepts that when factors interact in a multidetermined system, emergent failures, such as DFUs, are created in ways that are not always directly predictable from the individual components in isolation [88].

This 'systems' view of DFU development is complemented by a systems approach to DFU prevention. One component of that prevention system might entrust RCT data in which dynamic patient directed offloading in response to sustained levels of high, but not peak, plantar pressures over a prolonged period in real-world use demonstrated a 71% reduction in DFU recurrence in the intervention group, which increased to 86% in patients adhering to the threshold of 4.5 h/day of use [30,47]. This could be complemented by dermal thermography [16] and activity measurement, and ideally, other patient data that each contributes some predictive power.

A systems approach to prevention, meanwhile, emphasizes that intervention in human systems is also complex, and in the case of DFU prevention, likely benefits from components that provide direct patient feedback to sensor-based streams, RPM monitoring of data, and through that human interaction, the repeated emphasis of foot care best practices and other disease management principles. Trials evaluating such strategies are needed, and they may well further clarify the relative value of each layer of defense. However, that search for causal contributions should not preclude a systems-based approach that is likely to deliver immediate improvements to DFU care.

11. Conclusions

Diabetes and its associated complications, including DFUs, pose a significant global health burden. DFUs lead to severe consequences such as lower extremity amputations, increased mortality rates, and significant healthcare costs. The current standard of care methods have limitations in early detection and treatment, hindering prevention efforts. Sensor-based RPM programs may help overcome those limitations, encouraging higher adherence to integrative foot care best practices, and complementing them with early warning and patient self-management strategies. Based on our experience in deploying sensor-based preventative RPM programs, we have looked to offer a framework for integrating sensor-based RPM in DFU prevention regimens.

Diabetic foot complications are influenced by various factors, making it important for sensor-based remote patient monitoring (RPM) to collect physiological and behavioral data from multiple domains. Monitoring domains such as pressure, temperature, and activity offer opportunities for RPM services to intervene at different stages of the disease process, drive insights into pathogenesis, and add value to predictive models for DFU. Continuous investment and refinement are necessary for prediction systems to improve accuracy and reduce false positives, which can be burdensome for patients and healthcare teams.

Diabetic foot care delivered through RPM offers an opportunity to become more synergistic with the care plan of patients living with diabetes. Sensor-based monitoring of the diabetic foot should not be viewed in isolation but as a part of a comprehensive disease management approach. The integration of RPM should align with other principles in diabetes care and promote progress toward optimizing glycemic control and reducing cardiovascular risk. Activity monitoring, prescription, and modulation, as well as motivational interviewing, should occupy an important place in a preventative RPM plan informed by sensor-based physiologic data streams. We should seek to reduce the foot health concerns that can serve to create barriers to healthy living so that the metabolic, cardiovascular, and mental health benefits of active lifestyles can be realized by the patients that need them most. In so doing, sensor-based monitoring of the diabetic foot can impact not only foot health but the disease trajectory of diabetes and the healthspan of patients living with this disease.

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