

Article

A Resource-Efficient Plantar Pressure Evaluation System for Diabetic Foot Risk Assessment

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Abstract: Diabetic foot complications constitute a large and rapidly growing global health problem, causing one million lower-extremity amputations annually. These amputations are typically preceded by preventable diabetic foot ulcers (DFUs). However, 80% of the world's diabetics now reside in low- and middle-income countries, where many healthcare settings lack the resources required to implement recommended DFU risk assessment and prevention strategies. There is an unmet need for a more resource-efficient DFU risk assessment method. In this study, a low-cost, purely mechanical plantar pressure evaluation device was designed toward this end. The device consists of a grid of plastic bistable compliant mechanisms, which present a visual series of binary outputs in response to applied pressure. By having diabetic patients step on the device, non-specialist healthcare providers can easily assess patients' plantar pressures, which are predictive of future DFUs. A prototype was fabricated and pilot-tested with 41 healthy subjects. It demonstrated a sensitivity of 25.6%, although sensitivity reached 60% for heavier subjects. Sensitivity could likely be significantly improved by lowering the device's profile and increasing the sensing area. Strained health systems may then be able to use this device to allocate scarce healthcare resources more efficiently to prevent costly DFUs and amputations.

Keywords: diabetic foot; plantar pressure; risk assessment; prevention; low-resource



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1. Introduction

In 2021, the International Diabetes Federation estimated that 537 million adults, equal to 10.5% of adults worldwide, are diabetic—more than three times as many as in 2000. Despite the historical association of diabetes with high-income settings, 80% of the world's diabetics now reside in low- and middle-income countries (LMICs). Moreover, 94% of new diabetes diagnoses between 2021 and 2045 are anticipated to be in LMICs [1].

The costliest complications of diabetes are those affecting the lower extremities, accounting for a third of all spending on diabetes treatment [2]. Impaired sensation, circulation, and motor function in the feet make diabetics vulnerable to diabetic foot ulcers (DFUs). The most common reason for hospitalization among diabetics [3], DFUs are among the top 10 causes of disability worldwide [4], and their mortality rate is near that of cancer [2]. Up to a third of people with diabetes will develop a DFU in their lifetime [5], and at least one million have a lower extremity amputated due to these wounds every year [6]. Low rates of access to quality prostheses and other rehabilitative therapies in LMICs leave many amputees permanently disabled, immobile, and excluded from social and economic life [7].

Encouragingly, the etiology of and risk factors for DFUs are fairly well understood, making most DFUs theoretically preventable. Consensus guidelines on DFU prevention exist; however, they call for extremely resource-intensive interventions and risk assessment methods. The recommended risk assessment consists of a series of careful procedures, including at least six different clinical measurements intended to be performed by a specialist [8]. The demanding nature of these methods is incompatible with the resource

constraints of many settings [9,10], an issue that has received little attention from the international community. As one example of the scale that podiatry resource constraints reach in some regions, it is estimated that there are fewer than five podiatrists in the entire country of Kenya, which has a population of over 53 million [11]. Thus, few diabetic patients in LMICs ever have their DFU risk evaluated [12–14].

Just as many health systems cannot provide thorough DFU risk assessments, they likewise cannot offer comprehensive preventative care to all patients and must decide how to allocate their limited resources. The most efficient, impactful allocation would direct resources toward patients with the greatest risk, making some form of risk evaluation critical [15]. Hence, the objective of the present work was to develop a DFU risk assessment tool that can be practically applied in low-resource settings.

Several indicators have been theoretically and empirically associated with DFU development (e.g., neuropathy and foot deformities). In order to avoid duplication of efforts in settings in which some risk factors are measurable, a predictor not incorporated into the current risk stratification system [8] was targeted. The pressure experienced by the plantar surfaces of the feet, i.e., planar pressure, is one of the most sensitive, specific, and empirically supported remaining predictors of DFU. Loss of motor function in the feet due to high blood sugar can cause deformities and associated points of high pressure to develop on the plantar surfaces. Sensory impairment can prevent patients from noticing these high pressures. Concurrent weakening of the skin of the plantar surfaces results in vulnerability to ulcer development [16,17]. Several prospective and retrospective studies have implicated high plantar pressure in DFU development, reporting sensitivities ranging from roughly 60 to 80% and specificities from 40 to 75% [18–25].

Despite robust evidence attesting to its predictive value, plantar pressure is not commonly utilized in clinical practice. There are two main classes of plantar pressure measurement tools, namely electronic sensing systems, which use arrays of hundreds to thousands of small electronic pressure sensors of various types [26], and imprinting tools that use ink or carbon to create visual footprints, the darkness of which can be related to discrete pressure ranges based on relative pigment concentration according to a reference card. A variety of commercial products belonging to both classes have empirical support for their use in diabetic foot screening, but no existing products are compatible with typical clinical settings in LMICs. Electronic systems are excessively costly; require computation and electricity, which many settings still lack; demand significant set-up time; and output more information than is necessary or tractable for many healthcare providers. Imprinting systems necessitate consumables, which can be burdensome to replace in facilities lacking sufficient staffing and funding. Additionally, inter-observer variation and subsequent training requirements make them a poor fit for low-resource health systems in which patients mostly see generalist nurses or community health workers [27–29].

Thus, a novel method of assessing plantar pressure is needed for routine plantar pressure screening to be widely implemented in LMICs. This article proposes a plantar pressure measurement system design and presents results of pilot testing of the proposed design with healthy adults. Results suggest promise for the clinical performance of the device after some design refinement.

2. Materials and Methods

The methods used to conceptualize, design, fabricate, and pilot test the proposed plantar pressure measurement system are described in the subsections that follow.

2.1. Conceptualization and Design

First, several design requirements for a plantar pressure measurement system to be effective for DFU risk screening in LMICs were defined in order to direct the design process. Medical, economic, and anthropological literature regarding healthcare and diabetes care in LMICs [9,10,13–15,30–33] and communications with healthcare providers in India, Kenya, Tanzania, and South Africa informed the following set of requirements:

1. Provide an actionable output;
2. Be affordable throughout the life of the product;
3. Be easily understood by non-specialist healthcare workers and diabetic patients;
4. Be usable and quickly interpretable by operators with minimal training and additional equipment and within existing clinical workflows;
5. Be safe and comfortable for diabetic patients;
6. Offer opportunity for patient education and/or patient–provider communication;
7. Be portable enough to enable use by mobile healthcare providers;
8. Be cosmetically attractive to patients and healthcare providers;
9. Be durable and reliable over a long service life.

The general form factor employed by existing barefoot plantar pressure measurement systems was used, namely a low-profile grid of sensors that patients step onto and off of. An analog sensing mode was sought to ensure affordability and compatibility with settings without reliable electricity or computational capacity (e.g., rural clinics and traveling community health workers). It was also hypothesized that a binary output (i.e., indication of whether a patient has a peak plantar pressure above or below a relevant threshold) would be simpler for providers to interpret compared to outputs in the forms of discrete pressure ranges or continuous pressure data. Such a binary indication is made meaningful by several studies establishing the sensitivities and specificities of different peak plantar pressure thresholds for the prediction of future DFU development [18–21,34–39].

To generate a binary pressure response in an analog manner, a bistable compliant mechanism was designed. Such a mechanism involves a mechanical structure that can move between two stable positions in reaction to some force (like a typical light switch). A bistable compliant mechanism is an advantageous mode for pressure measurement since its use is non-destructive and requires minimal hardware and consumables, and it can provide a clear visual output.

Our plastic, bistable compliant mechanism uses material elasticity (stiffness) under elastic bending as the source of resistance to movement from the first to the second stable position. Each “sensor” is a simple, two-dimensional, two-part structure made up of a “switch” part and a “base” part. The switches are three-sided semi-rectangular shells that straddle a base part. The switch and base parts each include semi-cylindrical obstructive features on the surfaces in contact with the other part, as shown in Figure 1. Downward pressure on the switch causes interference between the obstructive features on the two parts, generating lateral forces outward on the sides of the switch. These forces cause elastic bending at the inner corners of the partial rectangular shell, as shown in Figure 2. This bending overcomes the interference between the cylindrical features, allowing the switch to move to a second, lower, stable position on the base when the applied pressure reaches a certain threshold. The mechanisms can be dimensioned such that this pressure threshold is a clinically relevant pressure. The sensor size was set to 10 mm (100 mm²), which two recent reviews report can provide adequate resolution for clinical use [40,41].

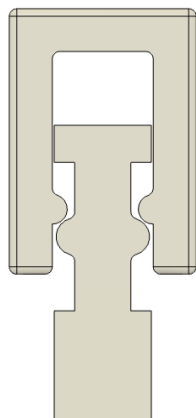


Figure 1. Computer-aided design (CAD) model of the sensor mechanism design (1 cm wide × 2.2 cm tall).

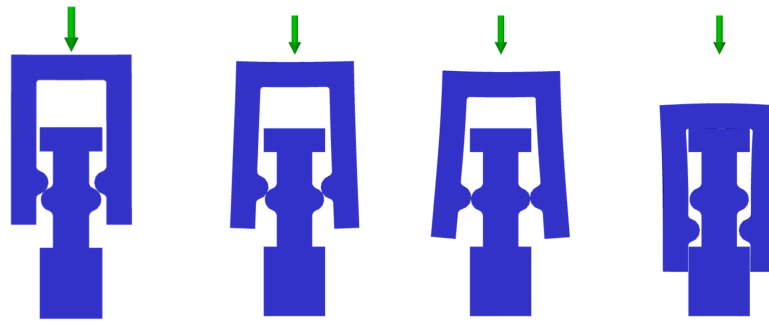


Figure 2. Simulation of a switch bending under vertical pressure (green arrow) and snapping into a second, lower, stable position on the base.

For ease of manufacturing, the entire base of the device, comprising many individual base elements, was designed as a single part consisting of 30 rails, each 15 cm long, connected together at their ends (Figure 3). A rectangular feature at the top of the base profile (which can be seen in Figure 1) prevents the switches from falling off of the bases when turned upside down (e.g., for storage, transport, cleaning, etc.) and minimizes lateral wobbling of the switches. Cutouts between the base rails enable the user to visually identify any switches that have moved to their lower stable position, which we term “triggered switches”, from the bottom of the device, as shown in Figure 4. They can then push on the ends of the sides of these switches through the cutouts with their fingers until the semi-cylindrical features on the switch and base slide over one another and the switch returns to its higher stable position, or “starting position”. This reset method is intuitive and does not require any external tools or additional parts.

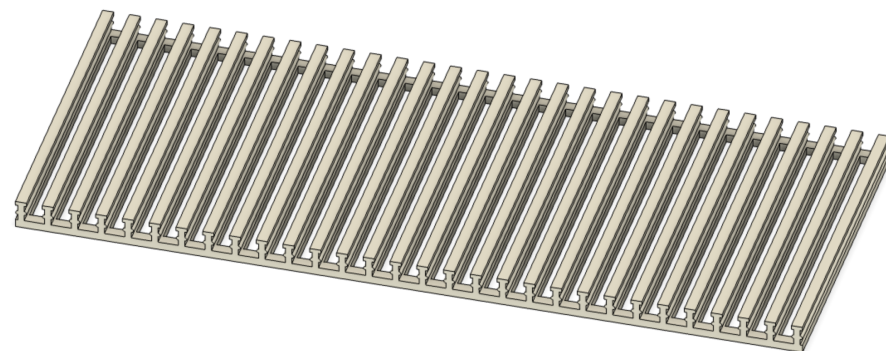


Figure 3. CAD model of the base part of the device (36.8 cm × 15 cm × 1.4 cm).



Figure 4. Bottom of part of a prototype of the base where three switches can be seen in their triggered positions.

A detailed mechanical engineering analysis of the design was performed, and the precise geometries of the parts were specified based on this analysis, which is reported in [11]. The switches can be engineered to move to the triggered position under a range of different applied pressures, i.e., to have a range of different “trigger pressures”. Only the switch design for the prototype used in this pilot study, with a trigger pressure of 380 kiloPascals (kPa), will be presented here. The dimensions of the switches were tuned to achieve this trigger pressure by iteratively 3D printing and testing prototypes with a digital force gauge. Relevant dimensions were iteratively revised according to trigger pressure results to increase or decrease trigger pressure until it converged to 380 kPa.

A quote was sought from a U.S.-based manufacturer to estimate the cost to injection mold the parts. A prototype of an earlier but very similar design was taken to Kenya and demonstrated to 20 healthcare providers, ranging from nurses to podiatrists, in July 2022. Further detail on the methods and findings of this qualitative study can also be found in [11].

2.2. Prototype Fabrication

The base of the prototype to be used in the pilot sensitivity study described below was 3D-printed on a Stratasys J55 polyjet printer from VeroUltraWhite plastic material in three parts (due to print bed capacity), which connect at linking hooks on their ends. Switches were 3D-printed from polylactic acid (PLA+) on fused deposition modeling (FDM) machines. The trigger pressures were verified by measuring them twice each, placing every switch at two different locations on the base and pushing them to their triggered positions using a digital force gauge. The experimental prototype as initially assembled, with seven sensors in the lower left in triggered positions, is shown in Figure 5.



Figure 5. Prototype to be used in the pilot sensitivity study (15 cm × 36.8 cm × 2.2 cm). Seven sensors in the lower left are shown in triggered positions.

2.3. Pilot Sensitivity Study

A pilot study comparing dynamic (walking) plantar pressure measurements of healthy adults collected by a commercial pressure measurement device and a prototype of the device designed here was conducted as a preliminary evaluation of our design’s sensitivity to high pressures, with measurements collected by the commercial device considered to be the true values. This pilot study was performed with healthy adults to avoid unnecessary risk to diabetic patients at the early stages of the device’s development. The study was approved by the MIT Committee on the Use of Humans as Experimental Subjects (COUHES).

2.3.1. Statistical Power and Sample

Since existing data for healthy adult peak plantar pressure were available but highly variable, a tentative a priori power analysis was performed using the formula for sample

size for diagnostic tests for a minimum sensitivity from [42] (Equation (1)). A 90% confidence interval was set ($z = 1.65$, $W = 0.1$). Sensitivity of the device in this study was defined relative to measurements performed by the commercial device above the prototype's trigger pressure. No particular minimum was desired for sensitivity, so the sample size calculation was maximized with respect to this variable ($SN = 0.5$). A trigger pressure was selected such that, based on prior work [34,37,43–46], approximately 50% ($P = 0.5$) of a healthy sample could be expected to have a peak plantar pressure greater than this pressure (380 kPa). These values yielded a sample size of 136.1, rounded up to 69 participants with measurements collected from both feet ($N = 138$).

$$N = \frac{z^2(SN(1 - SN))}{PW^2} = \frac{1.65^2(0.5(1 - 0.5))}{0.5 * 0.1^2} = 136.1 \quad (1)$$

This calculation was iteratively updated as data were collected, as can be appropriate when the available data used for the calculation are not reliable [42], and the sample size was adjusted accordingly.

Subjects were convenience- and snowball-sampled on MIT's campus. People between the ages of 18 and 80 without medical diagnoses affecting the feet, inability to walk normally at the time of the study, or any wound or infection affecting either lower limb were eligible to participate.

2.3.2. Devices

Each eligible and consenting subject had plantar pressure measurements taken by both the experimental prototype and a commercial plantar pressure measurement system. For the purposes of the pilot sensitivity study, a laser-cut acrylic frame was fit around the experimental prototype to hold the base parts in place and to fix alphanumeric labels to the rows and columns of switches to facilitate standardized recording of results. Foot outlines and a heel target were also added to the top surface of the switches to aid in the localization of high pressures.

A TekScan (Boston, MA, USA) MobileMat(R) (Figure 6) was used as the comparator device. The MobileMat is a pressure measurement mat comprising 2112 “sensels” with a spatial resolution of 1.0 sensels/cm², similar to that of the experimental prototype. Sensels are 7.6 mm × 7.6 mm and spaced 2.6 mm apart [47]. Sensor recordings were taken at 50 Hz. Recordings were triggered by any 10 N force applied to the mat, and frames in between a last contact force of 5 N and the next first contact force of 10 N were automatically deleted by the system's accompanying software. A noise threshold of 3 N was set to filter out irrelevant signals.



Figure 6. The TekScan MobileMat on the low-pile office carpet where the pilot study was conducted.

2.3.3. Procedure

Participants gave verbal consent after reading a consent form, then self reported their age, sex, race/ethnicity, weight, and shoe size. The MobileMat was re-calibrated for each subject. Every other participant (chronologically) stepped on the MobileMat first and the experimental prototype second and vice versa. The devices were set up on low-pile office carpet, as shown in Figure 6. Subjects removed their shoes and wore their own socks during the study. A clean, new pair of diabetic ankle socks was provided to one participant whose socks had holes in them. Socks can affect plantar pressure distribution [48], but subjects kept their socks on for study procedures for their comfort and for sanitary purposes. They wore socks for measurements by both the MobileMat and the experimental prototype, so any distortion of plantar pressure by their socks was expected to be repeatable between the two devices.

For both devices, participants took one step on the floor, took their second step onto the device, and then stepped off (two-step protocol [49]), all at a self-selected pace. They were instructed to apply all of their weight to the devices and to use their natural gait. They self selected their starting points after optional, unrecorded test steps and were offered tape to mark starting locations on the floor. Five trials were performed for each foot on each device based on prior work using a similar TekScan device and another pressure platform, which reported high reliability of measurements within three to five trials [50].

Participants chose which foot they began with. On the MobileMat, participants walked back and forth across the mat from both directions continuously. For measurements by the experimental prototype, participants stepped on from the same side in every trial due to the directional foot outline and heel target. In both cases, they alternated stepping onto the device with their left and right legs.

Participants were told that parts on the experimental prototype were supposed to move in some cases. When sensors in the experimental prototype were triggered, the letter–number identifiers of the triggered switches were recorded, the device was quickly reset, and participants continued their trials. Participants who were visibly using an abnormal gait or not applying their full weight to either device were encouraged to try to walk as naturally as possible.

2.3.4. Data Analysis

An example of the output of the MobileMat from one step is shown in Figure 7. The maximum pressure in the forefoot, defined as the region of the foot from the midpoint of the medial longitudinal arch to the ends of the toes, and rearfoot, defined as the region from the end of the heel up to the midpoint of the medial arch, were recorded for each footstep captured by the MobileMat. The median of these peak pressures for the forefoot and rearfoot were taken as the “true” subject conditions and compared to the experimental prototype’s output. The medians of the MobileMat measurements were used in this analysis as opposed to the means, since they are less easily skewed by a single unusual footstep. A prior study using a similar TekScan device supported this notion, reporting that the median of multiple measurements was more reliable than the mean [51].

Sensitivity (true positives/total positives) of the experimental prototype was first calculated for whole feet (i.e., region of the foot was not considered, and a positive result anywhere on the foot was a positive for the whole foot). Whole-foot sensitivity was determined for three different experimental prototype trial configurations, namely (1) designating any sensor triggering in any of the five trials as a positive result, (2) considering only the first experimental prototype trial, and (3) designating a positive result only if sensors were triggered in a majority of the five trials. Separate sensitivity calculations were performed for each of these while considering the experimental prototype’s trigger pressure to be the mean trigger pressure of the sensors tested prior to the pilot study (380 kPa) and considering the prototype’s trigger pressure to be the maximum trigger pressure of the sensors used in the prototype (420 kPa). For subsequent analyses, the trigger pressure was

the clinic with fewer resources. For the purposes of this pilot study, sensors were designed to have a trigger pressure of 380 kPa, which we estimated to be the average healthy adult peak plantar pressure based on existing literature.

3.2. Prototype Fabrication

The mean trigger pressure of the 3D-printed switches was 380 kPa. The standard deviation was 37 kPa. The variance, which is expected in low-fidelity 3D printing, is hypothesized to be due to slight differences in printing conditions and random material variation. Switches with trigger pressures within about one standard deviation of the mean, ranging from 340 to 420 kPa, were included in the prototype (placed atop the base). Others were discarded. Switches with trigger pressures further from the mean but within one standard deviation were placed around the perimeter of the device. The prototype as configured for the pilot study is pictured in Figure 8.

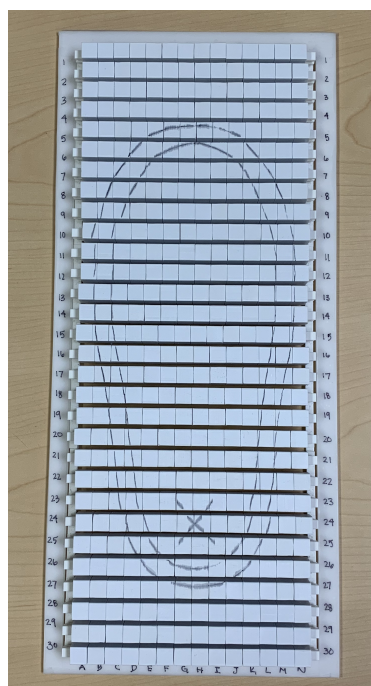


Figure 8. Prototype as used in the pilot sensitivity study.

3.3. Pilot Sensitivity Study

A greater proportion of subjects than anticipated based on previous literature were positive for median peak plantar pressure exceeding the experimental prototype's trigger pressure and thus considered to be positive for the "condition" used to calculate test sensitivity. The power calculation was iteratively updated throughout data collection to reflect the actual rate of positives (P in Equation (1)). A level of 90% confidence was achieved at $N = 68$ (34 subjects with measurements taken from both feet).

A total of 41 subjects ($N = 82$ feet) participated in the pilot study. Subject demographics are displayed in Table 1. Subjects ranged in age from 18 to 43 and weighed between 52 and 114 kg, with most subjects weighing between 52 and 71 kg. One subject only completed four trials for each foot on the experimental prototype before having to leave. All 40 other participants completed five trials for each foot on both devices. For one participant, one stance did not appear to have been accurately captured by the MobileMat (showed no pressure data from the forefoot) and was thus excluded from that participant's median peak pressure calculation.

Table 1. Subject demographics.

Demographic		N (%)
Self-reported gender	Male	23 (56.1%)
	Female	18 (43.9%)
Self-reported age	18–24	21 (51.2%)
	25–30	15 (36.6%)
	31–35	3 (7.3%)
	35–40	0 (0.0%)
	41–43	2 (4.9%)
Self-reported race/ethnicity	White/Caucasian	24 (58.5%)
	Asian	11 (26.8%)
	Black	3 (7.3%)
	Hispanic	1 (2.4%)
	Mixed	1 (2.4%)
	Decline to report	1 (2.4%)
Self-reported weight	52–61 kg	13 (31.7%)
	62–71 kg	14 (34.1%)
	72–81 kg	4 (9.8%)
	82–91 kg	7 (17.0%)
	92–101 kg	1 (2.4%)
	102–111 kg	1 (2.4%)
	111–114 kg	1 (2.4%)

Twenty-one of the 82 tested feet (25.6%) produced a positive result on the experimental prototype in any of their five trials. According to the MobileMat, all 82 feet had median peak plantar pressures over 380 kPa, and 81 had median peak plantar pressures over 420 kPa. Thus, the whole-foot sensitivity of the experimental prototype, considering any sensor triggering in any of the five trials as a positive result (configuration 1), was calculated to be 25.6% when the trigger pressure was assumed to be 380 kPa and 25.9% when the trigger pressure was assumed to be 420 kPa. (All results presented from this point onward use 380 kPa as the experimental prototype's trigger pressure.) The sensitivity was poorer in the other two configurations; the prototype's sensitivity was 13.4% both when using only the first prototype trial and when designating a positive result only if sensors were triggered in a majority of the trials. Results presented beyond this point all assume configuration 1.

Whole-foot, left-foot, right-foot, forefoot, and rearfoot sensitivities (calculated taking 380 kPa as the device's pressure threshold and designating a positive result if relevant sensors were triggered in any of a subject's five trials) are presented in Table 2. Sensitivity was slightly higher for right feet than for left feet (29.3% versus 22.0%, respectively). Sensitivity was also much higher for the forefoot (23.2%) than for the rearfoot (8.2%). The order in which the two devices were used did not impact experimental prototype sensitivity. Whole-foot specificity was 100%, although this result is not meaningful, since there were no negatives (median peak pressures less than 380 kPa) recorded by the MobileMat.

Table 2. Prototype sensitivity for all whole feet, left feet, right feet, all forefeet, and all rearfeet.

Region	Sensitivity
Whole feet (all)	25.6%
Whole left feet	22.0%
Whole right feet	29.3%
Forefeet	23.2%
Rearfeet	8.2%

Feet with positive results on the experimental prototype had approximately 20% higher median peak plantar pressures than those with negative results (mean of 833.6 kPa versus 692.9 kPa). This difference, depicted in Figure 9, is statistically significant ($p = 0.006$). Feet with positive results triggered sensors in an average of 2.67 of their five trials. Positive trials were roughly equally distributed among the five trials (i.e., the first, last, and middle trials produced positive results a similar number of times). Seven subjects with positive results had positive results for both feet, and seven had positive results for only one foot.

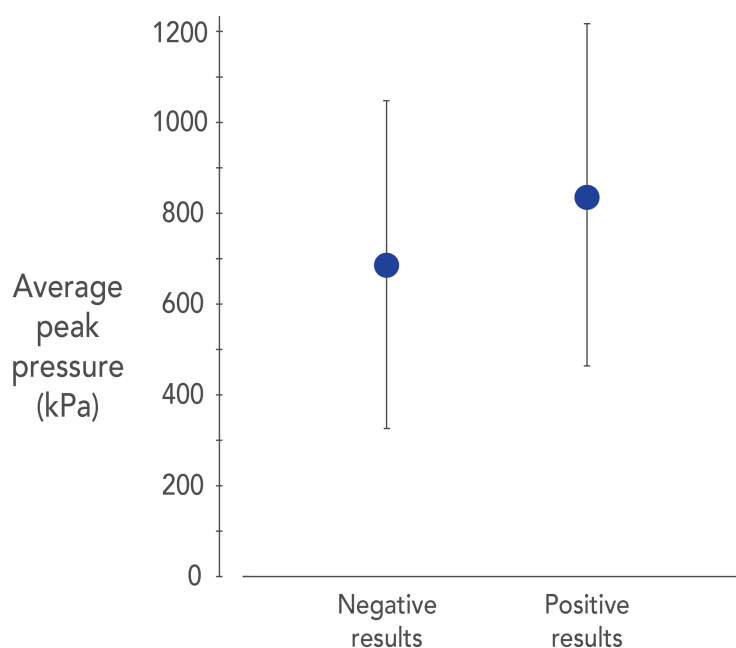


Figure 9. Average median peak plantar pressures of subjects with negative and positive results from the prototype \pm 2 standard deviations. The difference is statistically significant ($p = 0.006$).

Many subjects visibly avoided applying their full weight or using a normal gait to step onto the experimental prototype. Some placed and removed their whole foot flatly onto and off of the prototype as opposed to stepping in a normal heel-to-toe motion, which decreases plantar pressure. It is hypothesized that this intentional offloading directly caused the high rate of false negatives and poor sensitivity. Stepping flatly onto the prototype can also explain the discrepancy in sensitivity between the forefoot and rearfoot. Subjects had a greater ability to offload at heel-strike, when pressure is greatest under the rearfoot, compared to toe-off, when pressure is greatest under the forefoot. This is because their opposite foot was on the ground and could bear weight at heel-strike but swinging forward in the air and unable to bear weight during toe-off. This could translate into the much higher sensitivity at the forefoot compared to the rearfoot. Several subjects commented that they engaged in intentional offloading because the experimental prototype was small in area, high in profile, and delicate looking relative to the MobileMat.

Weight was related to sensitivity, as shown in Figure 10, possibly because heavier subjects applied more weight and pressure to the prototype compared to lighter subjects, even if purposefully offloading. For subjects weighing more than 80 kg ($N = 10$ subjects, 20 feet), sensitivity was 60%, whereas sensitivity was only 15% for subjects weighing less than 80 kg ($N = 31$ subjects, 62 feet). The pilot study sample skewed young and lightweight, so the sensitivity may have been significantly higher with a sample more representative of the global diabetic population.

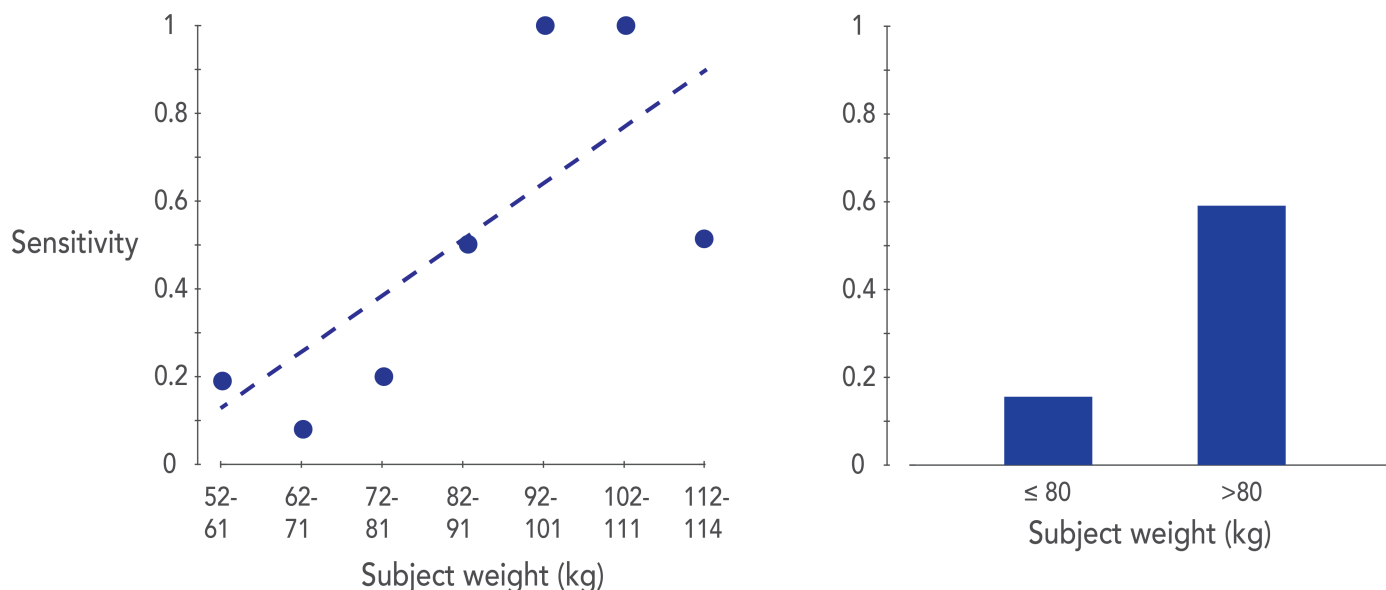


Figure 10. Sensitivity versus weight and best fit dashed line (left) and sensitivity for subjects under/over 80 kg (right).

4. Discussion

The diabetic foot risk assessment device designed in this study evaluates plantar pressure using mechanical means, allowing it to be made from plastic for only about USD 100 at scale. Furthermore, it provides a visual series of binary outputs that are simple to understand. Its low cost, compact design, usability, ease of interpretation, and quick procedure make it well-suited to healthcare settings severely limited in time, money, space, and personnel (although its performance against all design requirements remains to be rigorously studied).

While not a replacement for standard risk assessments, the device could function as a basic risk evaluation tool for low-resource contexts in which no foot assessments are currently performed or as a supplement to more extensive tests. For example, a small, nurse-run dispensary may use the device as its sole screening tool and warn a patient who produces a high-pressure result about foot complications and advise them to check the high-pressure area for injury regularly or refer them to a higher level of the healthcare system. Better-equipped facilities may use the device as an additional tool to discern patient risk in greater detail than allowed by their usual assessment in order to allocate scarce resources more efficiently (i.e., reserve the small number of offloading therapies for patients with neuropathy and high plantar pressure rather than patients with only neuropathy).

The device could also have value for facilities that have some capacity to perform standard risk assessment procedures, for example, sufficient time to examine patients and a healthy supply of monofilaments and Dopplers, but that, at least some of the time, lack the highly trained staff required to perform these procedures accurately and repeatably. The risk assessment method presented here permits less room for error than traditional sensation and pulse checks, which require considerable skill and precision on the part of the healthcare provider. Such facilities may use this plantar pressure evaluation device in place of standard assessments where necessary to improve their DFU risk prediction reliability.

Measurement error in this system could arise from the use of abnormal gaits by patients, device wear, or environmental contaminants (e.g., dust), and providers will need some amount of training in order to use the device effectively. However, unlike most of the other DFU predictors excluded from recommended risk assessments (e.g., patient demographic and disease characteristics), plantar pressure evaluation presents the opportunity to perform a tangible test. The physical and visual experience could potentially aid in patient-provider communication by prompting questions from patients or explanations by providers. The patient's active participation may make any subsequent counseling more

memorable and motivate patients to take preventative action more seriously. Evidence from around the world shows that patient education and motivation are among the most powerful strategies for improving diabetic foot self-care and preventing DFUs [15,53–55], making any facilitation of patient education valuable.

Lab testing of the sensing mechanisms designed here using a force gauge demonstrated that the design can predictably respond to applied pressures in principle; however, the prototype constructed in this work displayed clinically unacceptable performance in terms of detecting plantar pressures from walking human feet, as judged by comparison to the plantar pressures that were captured by the TekScan MobileMat. The overall whole-foot sensitivity was 25.6%. It is hypothesized that the low sensitivity was due to intentional offloading of pressure by subjects in response to the prototype's higher profile, smaller area, and lower-fidelity appearance relative to the MobileMat.

Many participants were observed stepping onto and off of the prototype flatly, which reduces plantar pressures compared to natural heel-to-toe gait. This hypothesis is further supported by the relationships between peak plantar pressure and sensitivity and subject weight and sensitivity. Sensitivity increases with both, which may be because, even while attempting to offload, subjects with higher weights and peak plantar pressures still applied more pressure to the prototype than subjects that were lighter and had lower peak plantar pressures. Additionally, the much higher sensitivity in the forefoot than the rearfoot can be explained by intentional offloading, as subjects had a greater ability to offload their rearfoot than their forefoot. Sensitivity could reasonably be expected to be higher for the global diabetic population and may be significantly improved by lowering the device's profile or embedding it in a longer platform so that there is minimal level change when stepping onto the device. Increasing the area of the sensing surface may also help encourage normal gait for measurement subjects by making them less concerned with aiming their step. Higher-fidelity devices could further assure measurement subjects that they can safely apply their full weight.

In future work, device constructions with improved strength and durability will be pursued through alternative materials and manufacturing processes. Other contactless sensor architectures will also be explored to make the device more resistant to environmental contaminants and wear. A limitation of this study is that subjects were healthy adults with no diabetes diagnosis. The device may perform differently for diabetic patients. A similar sensitivity study will be repeated with a prototype modified as described above and with subjects from target populations (diabetic patients in LMICs). Ideally, sensitivity and specificity should be high with a single trial. A prospective study using several devices with different trigger pressures may be warranted to determine the optimal trigger pressure for predicting DFU using this particular technology. Following successful demonstration of acceptable sensitivity and specificity to relevant pressures, the device's long-term effects on health outcomes and return on investment should be studied in real-world conditions.

Quick surface cleaning of the device remains a challenge due to the many surfaces and crevices created by the array of switches. However, healthcare providers in LMICs have explained that most clinics use autoclaves to sanitize this type of equipment, which, assuming heat- and moisture-tolerant materials are used, the device could be compatible with. Additionally, as previously noted, disposable or easily sanitizable sheets of material may be placed over the top of the device for use, although if and how this affects pressure transmission has yet to be formally studied. With these potential solutions available, device sanitation is not anticipated to be a significant barrier to adoption.

5. Conclusions

This work presents the design of a novel method of diabetic foot risk assessment for low-resource healthcare settings. In many low- and middle-income country contexts, international risk assessment guidelines are impractical due to resource constraints. In this study, a purely mechanical plantar pressure evaluation device that can potentially indicate high risk of diabetic foot ulcer development was designed. Plastic bistable mechanisms act as pressure sensors and move to a second stable position under a pre-determined pressure of medical significance. The device can be used and interpreted quickly without the need for electricity, computation, or a specialist and may assist stressed healthcare settings in allocating resources more efficiently to prevent diabetic foot ulcers and resultant amputations. Fabrication of a prototype demonstrated the technical feasibility of the device, but a pilot study with healthy adults suggested that sensitivity to dynamic plantar pressures is not yet clinically acceptable. In future work, the device will be made larger in area, lower in profile, and more robust, which is hypothesized to substantially improve its clinical sensitivity.

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Abbreviations

The following abbreviations are used in this manuscript:

DFU	Diabetic foot ulcer
LMICs	Low- and middle-income countries
CAD	Computer-aided design
kPa	kiloPascals

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