# A Purely Mechanical Plantar Pressure Evaluation Device for Diabetic Foot Assessment in Low-Resource Healthcare Settings

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November 15, 2022

### Abstract

As global diabetes rates skyrocket, diabetic foot complications constitute a massive and rapidly growing global health problem, causing at least one million lower-extremity amputations every year. These amputations are typically preceded by largely preventable diabetic foot ulcers. However, 80% of the world's more than half a billion diabetics now live in low- and middle-income countries (LMICs), where many healthcare settings lack the resources to implement recommended diabetic foot assessment and ulcer prevention practices. Evidence from LMICs suggests the need for a novel method of diabetic foot risk evaluation specifically for low-resource contexts. In this study, we present the design of a device that enables a new mode of measuring plantar pressure, a variable established in the medical literature as an accurate predictor of future diabetic foot ulceration. The purely mechanical pressure evaluation device consists of a grid of plastic bistable compliant mechanisms that a subject can step onto and off of with natural gait. Under a relevant pressure threshold, the compliant mechanisms move to a second stable position, an event that can be observed and interpreted by a healthcare provider as indicative of high risk for future ulceration. In settings where standard diabetic foot risk screening is infeasible or insufficient, healthcare providers may evaluate patient foot ulcer risk using the device in a matter of seconds with no need for electricity, computation, or a specialist. Using this simple screening method, strained health systems may be able to allocate scarce healthcare resources more efficiently to prevent costly diabetic foot ulcers and amputations.

## 1 Introduction

The International Diabetes Federation estimated in 2021 that at least 537 million adults, or 10.5%, are diabetic, more than three times as many as in 2000. Despite the disease's longer history in high-income settings, 80% of the world's diabetics now live in low- and middle-income countries (LMICs). Furthermore, 94% of the new diagnoses between 2021 and 2045 are predicted to be in LMICs [1].

The most costly complications of diabetes are those affecting the lower extremities, accounting for roughly one third of all spending on diabetes treatment [2]. Impaired circulation, motor function, and sensation in the feet make diabetics vulnerable to diabetic foot ulcers (DFUs). DFUs are the most common reason for hospitalization among diabetics [3] and are responsible for 61% of the years lived with disability for diabetics, putting them conservatively among the top 10 conditions causing disability worldwide [4]. 19-34% of diabetics will develop a DFU in their lifetime [5], and at least one million diabetics have a lower extremity amputated every year [6], causing extreme financial, physical, social, and emotional distress [7, 8], and significantly increasing risk of mortality [3, 9, 10]. The mortality rate of DFUs is nearly identical to that of cancer [2]. Even for patients who eventually recover, low rates of access to quality prosthetics and other rehabiliataive therapies in LMICs leaves many disabled and immobile [11, 12].

Encouragingly, the etiology of and risk factors for DFU are fairly well understood, and most DFUs and resultant amputations are therefore theoretically preventable [6, 13, 14]. Barriers to realization of prevention potential remain, though, as consensus guidelines on DFU prevention call for resource-intensive interventions based on a coarse risk stratification system [13]. These guidelines recommend a series of careful procedures for risk level determination, including checking for sensation at various points on the feet using specific tools, palpating pulses in certain locations, and looking for deformities.

Few diabetic patients have risk assessments performed on their feet in LMICs due to the demanding nature of these methods, in terms of both time and specialized tools and training, paired with the severe resource constraints affecting many healthcare settings [15, 16, 17, 18]. However, some risk evaluation is important to enable efficient allocation of limited resources toward those at the greatest risk [19]. Sriyani et al. [20] summarize the unmet clinical need: "detection of these factors should be by a simple, less time consuming tool which is preferebly [sic] suitable to be administered even by a paramedical personnel." Hence, the objective of the present study is to develop a novel DFU risk assessment tool that can be practically applied in low-resource contexts.

First, design requirements for a diagnostic for low-resource settings were defined from the literature and contact with stakeholders in LMICs. Second, a variable with empirical support from the medical literature as a DFU predictor was selected. Next, strategies and concepts for the evaluation of the predictor were ideated and analyzed. Finally, a design was generated and prototyped.

## 2 Design requirements

From medical, economic, and anthropological literature regarding healthcare and diabetes care in LMICs [15, 21, 22, 23, 24, 25, 26], overt and latent needs were identified. The first author was also in contact with several diabetes and diabetic foot specialists in India and across Sub-Saharan Africa, and these personal communications further informed the functional requirements and relevant associated parameters in Table 1. Where precise quantitative requirements are unclear, directionality is noted.

| Functional requirements | Design parameters |
| --- | --- |
| provide an actionable output by identifying diabetics at higher than average risk of DFU via evaluation of an empirically supported predictor | test sensitivity and specificity (optimize sensitivity-specificity trade-off) |
| be affordable over the product lifetime | purchase cost (100USD or less), accessory tools needed (minimize), use of consumables (minimize), use of electricity and computation (minimize), maintenance requirements (minimize) |
| be portable enough for use by mobile providers | weight (5kg or less), volume ($0.01\text{m}^3$ or less), use of electricity and computation (minimize) |
| be understandable by non-specialist providers and patients | intuitiveness of operation (maximize) |
| be usable and interpretable quickly and repeatably by operators with minimal training and within existing workflows and routines | time and space required to operate (minimize), procedural complexity (minimize), volume of information output (minimize) |
| be safe and comfortable for patients | procedure invasiveness (minimize), innocuous device appearance (maximize) |
| offer some educational and/or communication value | visualization of output (maximize) |
| be cosmetically attractive to providers and patients | polished device appearance (maximize) |
| be durable and reliable over a long service life | material stress induced by operation (minimize), durability of materials (maximize) |

Table 1: Functional requirements and corresponding design parameters for a diabetic foot ulcer risk diagnostic for LMICs.

# 3   Selecting a DFU predictor

There are several available metrics that have been found to be associated with DFU development that are not incorporated into the current risk stratification system, including duration of diabetes, blood sugar control, eye complications, education level, sex, use of inappropriate footwear, and plantar pressure. Much of this information should be readily accessible to even under-equipped healthcare providers (if they ask for or observe the information), with the exception of potentially the most useful predictor: plantar pressure, the pressure experienced by the bottoms of the feet. Plantar pressure has been implicated in the development of DFUs for many years [27, 28, 29] by both retrospective [30, 31, 32, 33, 34] and prospective [27, 35, 36, 37, 38] studies, with reports of sensitivities on the order of 60-80% and specificities ranging from 40-75%. Despite robust evidence for its predictive value, it has scarcely been utilized in routine clinical practice because (1) it is simply not necessary in high-income settings, where plantar pressure reduction is initiated for even those at low risk because the resources are accessible, and (2) current measurement tools are too expensive or impractical to use in LMIC settings.

Plantar pressure is a useful ulceration predictor because of its central role in a common ulceration pathway. Loss of motor and sensory function in the feet leads to deformities and associated points of high pressure on the plantar surfaces that the patient may not feel. Many also experience skin dysfunction and skin barrier weakening and cracking due to hyperglycemia. Ulcers can form from acute wounds, or the simple repetitive trauma of walking can give way to ulceration when the pressure, or mechanical stress, on and within the skin exceeds the strength of the skin. An abnormally high plantar pressure measurement can thus be predictive of ulceration. Because of the pathogenesis of high plantar pressure, it is also highly correlated with other predictors, such as neuropathy, presence of foot deformity, and other diabetes complications [36, 37, 39, 40]. The distinct value in plantar pressure then is its more direct role in ulcer etiology compared to, for example, neuropathy, and in the fact that it offers another option for risk assessment in health systems that are poorly equipped to objectively, repeatably measure the more commonly used variables.

Two broad classes of plantar pressure measurement tools exist. The first is electronic sensing equipment, which consists of arrays of hundreds to thousands of small electronic pressure sensors. There are several commercially available electronic systems, and many more have been developed for research purposes. A wide range of different sensing technologies can be found in this class, including optical, piezoelectric, inductive, capacitive, resistive, and MEMS [41]. A majority of plantar pressure studies employ an electronic system. These are also used for some special purposes, such as custom footwear prescription, but not in routine practice for diabetic foot evaluation.

The second class uses imprinting with either ink or carbon, creating visual foot prints that are then interpreted into discrete pressure value ranges based on relative darkness at different locations compared to some reference. These systems are now difficult to find on the market but occasionally make appearances in LMICs. Several commercial products from both classes have been experimentally validated for use in diabetic foot screening, but neither electronic nor imprinting systems meet the needs of a typical LMIC clinical setting. The electronic systems are far too expensive, necessitate computation and electricity that some settings still lack, demand too much set-up time, and produce more information than is necessary or tractable for many providers. The imprinting systems use consumables, which can be burdensome to replace in facilities that are under-funded and under-staffed. Additionally, the training needs and inter-observer variation make them a poor fit for health systems in which patients mostly see generalist nurses or community health workers [42, 43, 44]. Thus, a novel method of assessing plantar pressure is needed for feasible implementation in LMICs.

# 4   Design

We set out to design a novel method for plantar pressure evaluation guided by the design requirements in Table 1 and based in the principles used by experimentally validated existing products. We opted early on for an analog mode to ensure affordability and compatibility with settings without stable electricity or computational capacity (e.g. mobile providers). Strategies considered include:

- column buckling

- viscous fluid displacement

- imprinting

- solid film deformation

- thermoforming

- bistable compliant mechanism

Each of these strategies could potentially produce a readable response to an applied pressure, but a bistable compliant mechanism is a particularly appropriate strategy. A bistable compliant mechanism can be used non-destructively (unlike some film deformation, thermoforming, and column buckling); function with minimal hardware and external equipment and without consumables (unlike fluid displacement, imprinting, and thermoforming); and provide a clearer binary output than fluid displacement, film deformation, and thermoforming. Hence, a bistable compliant mechanism was selected as the strategy toward a simple pressure sensing system.

Various manifestations of a bistable compliant mechanism for pressure evaluation were ideated. Concepts were narrowed to the below list after initial consideration of the potential of each concept to meet design requirements:

- domed bistable buttons, with reversal of the curvature direction at a pressure threshold

- snap fit using a compression spring for resistance

- snap fit using friction for resistance

- snap fit using material elasticity under elastic strain for resistance

Buttons in which the direction of curvature flips under a certain force were determined unsuitable because of the relative lack of stability, low forces accommodated by existing components, and high predicted material costs compared to the snap fit concepts. The three snap fit mechanisms were further explored through preliminary calculations and sketches. Ultimately, a bistable snap fit using material elasticity under elastic strain as the source of resistance was selected as the most promising concept. This concept requires fewer parts than a snap including a spring. Relative to a snap using friction for resistance, it is simpler to control the pressure required for the mechanism to transition to a second stable position. In the elastic strain mechanism, the primary parameters involved are material properties and part geometry, whereas the friction mechanism involves precise surface roughness. Material properties and part geometry are easier to tightly control and are more likely to remain consistent over many cycles than surface roughness in a low-cost product.

To achieve elastic strain under vertical pressure within the range of plantar pressure thresholds supported in the literature (200-1200 kiloPascals) while maintaining properties over many cycles as well as low cost, plastic was selected as the material for the "sensors." Bending is a favorable mode of deformation under vertical pressure in the 200-1200kPa range, as these pressures can generate modest but measurable elastic bending in small plastic components. To create a bistable switch controlled by elastic bending under vertical pressure, a simple, two-part structure was designed. The "sensor" comprises a semi-rectangular shell ("switch") paired with a base, each including obstructive features on the surfaces in contact with the other part (Figures 1 and 2). A rectangular shell shape creates a flat, safe, and comfortable interface between a grid of the sensors and the plantar surface. Interference between the obstructive features applies outward forces to the sides of the partial rectangular shell when the shell is under vertical pressure, generating elastic bending at the inner corners. Enough bending there allows the obstructive features on the switch and base to slide past each other and the switch to move to the second stable position.

## 4.1 Sensor size and threshold specification

Pressure sensors studied in the published literature for diabetic plantar pressure measurement range in size from 1.6mm to 15mm, and pressure thresholds used to indicate high ulcer risk range from 200kPa to about 1200kPa. Sensor size and pressure threshold are critical and related, as highly localized information can be lost in systems with large sensing elements. From a small 1996 sample, Davis et al. recommend a sensor size of 6mm [45]. More recently, Berki and Davis find that 8mm sensors offered

adequate resolution, whereas 9.6mm sensors generated reduced pressure signals [46]. 2019 reviews by Lazzarini et al. and Wang et al. both suggest that sensor size not exceed 10mm [47, 48].

For ease of prototyping and to minimize cost, a sensor on the larger side of the acceptable range was desirable. Sensor size was set at 10mm (100mm$^2$) based on the above literature. To compensate for any potential reduction in pressure perceived by the sensors due to their size [46], a corresponding pressure threshold on the lower side of the empirically supported range was sought. The lowest experimentally supported threshold found in the literature is 200kPa, recommended by Owings et al. for in-shoe measurements [49]. Barefoot pressure values are hypothesized to be similar to in-shoe values for patients wearing popular footwear found in LMICs (hard- and flat-soled shoes), and barefoot walking is common in some areas. Further, a lower threshold reduces the rate of false negatives, which pose greater health risk to patients than false positives. Thus, a threshold of 200kPa was selected for the 10mm sensors.

Switches for the initial prototype were to be 3D printed. Because material properties vary with printing methods, modeling and analysis alone could not be relied upon to specify part dimensions to generate a precise 200kPa pressure requirement to move the switches to their second stable position ("trigger pressure"). Thus, various sizes and shapes of obstructive features were iteratively 3D printed out of several different materials to experimentally identify appropriate geometry-material combination options. Trigger pressures were then measured using a force gauge. Semi-cylindrical features of modest size on both the switches and bases in ABS plastic generated trigger pressures on the order of 200kPa and slid over one another easily. After electing to use semi-cylindrical obstructive features, the base dimensions were specified, and the switch was to have its dimensions fine-tuned experimentally given the base geometry. The bases were specified with the dimensions shown in Figure 1 to have easily manufacturable features, a low profile, and to create a 10x10mm sensor.

Switches with the general shell shape described above were printed out of ABS with various wall thicknesses and semi-cylindrical feature radii and locations until a combination of these specifications generated a trigger pressure of approximately 200kPa when placed atop a machined base part, as measured by a force gauge. A 1.75mm thick shell with 1.25mm radius semi-cylindrical features 8.5mm from the top surface, printed front to back, was found to satisfy this requirement while maintaining structural integrity. To form a 10x10mm sensor, the switches are 10mm wide and deep (Figure 2). Small radius fillets were added to both parts to reduce stress concentrations. Both the base and switch designs can be extruded or injection molded, both inexpensive manufacturing processes, from a small volume of plastic.
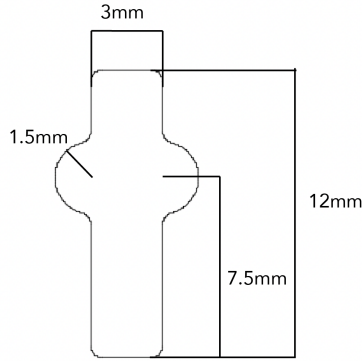
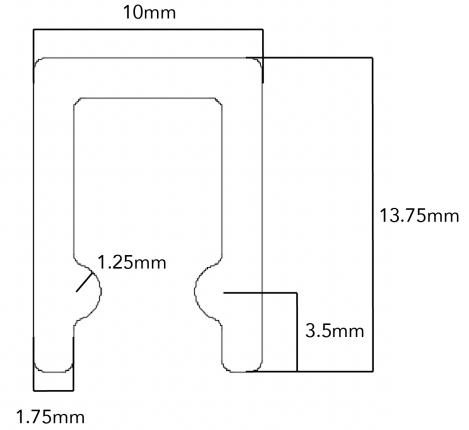Figure 1: Front view of the base design with dimensions.

Figure 2: Front view of the switch design with dimensions.

# 5  Prototype construction

A prototype of the initial design was constructed over the course of a month. The bending switches were FDM 3D printed from ABS plastic (Figure 3), and the base of the device was CNC machined

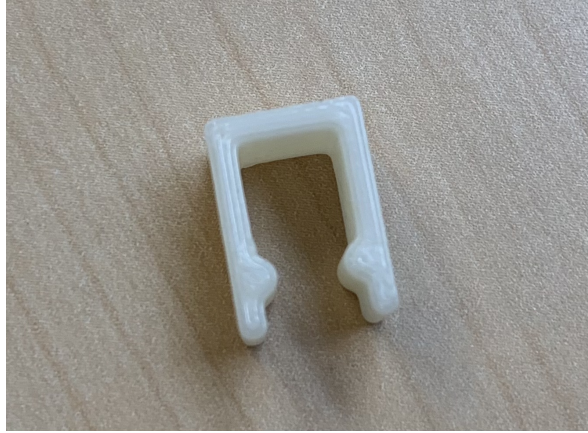from a 10mm thick Delrin slab in 14 300mm long strips (Figure 4).
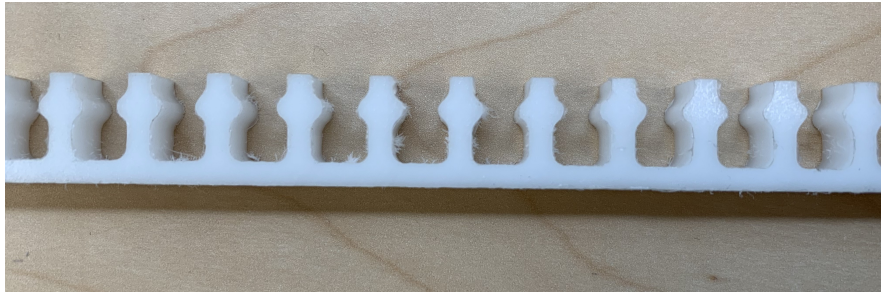


Figure 3: A 3D printed switch part.



Figure 4: A machined strip of base parts.

A 3.175mm hole was drilled using a drill press between the two profiles nearest the ends of each machined base strip. An additional 6mm thick slab of Delrin was used to secure all of the base strips together, and 14 sets of corresponding 3.175mm holes were drilled by CNC into this slab. These holes were bored on the bottom side in order to house 4x40 nuts without any protrusion. The strips were aligned on the Delrin slab and secured with 4x40 machine screws and nuts, as in Figure 5. To set up the device for use, a 3D printed switch was placed on top of each machined profile on the base, producing a total of 392 sensors, shown in Figure 6. Strips of Delrin were adhered to the sides of the base to prevent switches from falling off of the base. A force gauge was used to confirm that the switches snap into their lower position under approximately 2kg of force, equal to roughly 200kPa over their 100mm$^2$ area.

The device can be used similarly to how existing commercial systems are used for plantar pressure measurement: it can simply be placed on the floor near a measurement subject, and they can step onto and off of it with one foot at a time with a natural gait. The subject and the person administering the test can then visually observe the device, noting if any of the switches have been triggered by a pressure greater than 200kPa to move, which appears as in Figure 7. The administrator can then use that information in a number of ways, from prescribing pressure reduction therapies to counseling the subject about precautions that they should take with their feet, depending on their resources and expertise. While not yet formally quoted, we believe that the device can likely be manufactured for less than 10USD at scale based on eligible manufacturing processes and materials. Initial feedback from stakeholders, including healthcare providers in LMICs, has been very positive, motivating the filing of a provisional patent application.
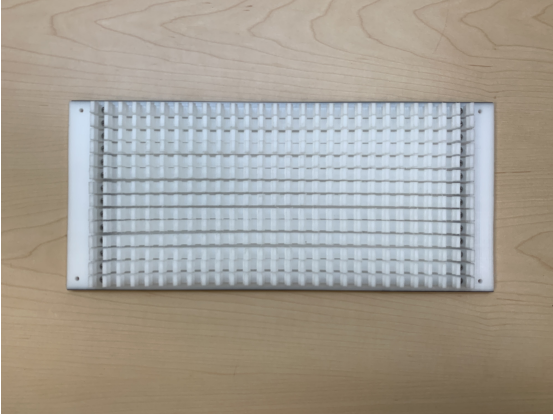
Figure 5: Top view of the assembled base of the prototype.



Figure 6: Angled view of the fully constructed prototype.

# 6    Discussion

The device designed in this study is purely mechanical, consists of only plastic and a few off-the-shelf fasteners arranged in a small grid, and provides a visual series of binary outputs. The force gauge testing, roughly estimated 10USD or less manufacturing cost, roughly 150x350x30mm size, and 1kg weight attest that this initial prototype meets our first three functional requirements (given that we rely on Owings et al. [49] for sensitivity-specificity optimization). We are optimistic that its simple and visualizable mechanical operation and output and quick use procedure promote ease of understanding, use, interpretation, and communication in personnel-strained healthcare settings. The flat top surface and low profile do not raise immediate safety concerns. Whether the design will be perceived as aesthetically attractive in target markets remains to be studied, and durability will depend on forthcoming materials and manufacturing decisions.

While not a replacement for standard risk assessments, the device could serve as a simple risk evaluation tool for low-resource contexts in which no foot assessments are performed at present or as a supplement to more extensive assessments. A small dispensary staffed by a nurse, for example, may use the device as its sole screening tool and spend more time counseling a patient who produces a high-pressure result about foot care measures and advise them to check the high-pressure area for injury regularly. Where diabetic patients do not have their feet examined, many are unaware of diabetic foot complications and do not know to promptly seek care for foot injuries, so lowering the barrier to providing any attention to feet may raise awareness and be beneficial to patients. Alternatively, a better equipped facility may use the device as an additional foot evaluation tool to discern patient risk in greater detail than allowed by the standard assessment in order to allocate scarce resources more efficiently (i.e. provide the single offloading therapy to the patient with loss of sensation and high plantar pressure rather than the patient with loss of sensation but normal plantar pressure).

A third scenario in which the device may be useful is when a facility has some capacity to perform standard risk assessment procedures (e.g. with sufficient time to examine patients and a healthy supply of monofilaments and Dopplers) but lacks the highly-trained staff to perform them accurately and repeatably. The plantar pressure evaluation system presented here allows less room for error than traditional sensation and pulse checks, which require a great deal of precision on the part of the healthcare provider. Still, measurement error may arise from abnormal patient gait or application of weight to the device, and providers will need some amount of instruction in order to be able to administer the test effectively.

As opposed to only considering an individual's demographic and disease characteristics to predict ulcer risk where standard tests cannot be performed (or for supplemental purposes), a physical and visual test may aid in communication between providers and patients, the physical artifact perhaps prompting questions from patients or explanations by providers. The tangible experience may make any resultant counseling or education more memorable for patients. Evidence from around the world shows that patient education and motivation are among the most effective strategies for improving self-care and preventing DFUs [19, 50, 51, 52], making any facilitation of patient education valuable.
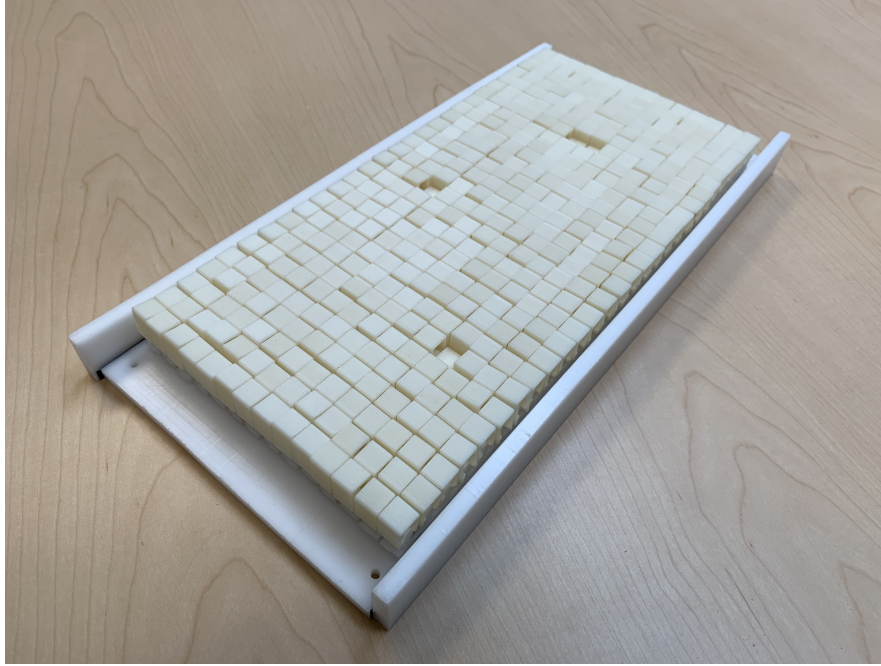
Figure 7: Fully constructed prototype where four sensors have been triggered by high pressure.

The patient seeing their result, especially if high risk, may convince the patient of their risk and motivate them to take preventative action, which is critical in cultures and socioeconomic conditions where de-prioritization of preventative care is common [21].

Based on early feedback from stakeholders and initial in-lab use tests, future work will include the addition of a module to quickly reset any triggered switch parts to their starting positions, modification of the base profiles to prevent the switches from falling off of the base profiles when turned upside down for storage or transport, and the addition of foot outlines to the sensor surfaces or covering and labels to each row and column of sensors to facilitate localization of pressure points and recording of results. An updated prototype will be tested in a study with diabetic patients against an electronic sensing system that already has empirically established predictive value. Subjects will undergo plantar pressure measurements by both devices, and results will be compared to ensure that our device captures high pressures comparably to the validated system.

Prototype demonstrations and tests in LMIC healthcare settings will follow, with particular focus on whether our intuition regarding ease of understanding, use, and interpretation and educational value translate to target settings, and whether the sensitivity-specificity trade-off is appropriately calibrated. We regret that greater collaboration with providers in LMICs throughout the design process on these fronts was obstructed due to COVID and are prepared to pursue further design iterations if requirements are not adequately satisfied. In future design iterations, design for manufacturing and durability will also be considered, and more precise cost estimates will be sought.

Finally, the device's effect and return on investment in real-world conditions should be studied. As is unfortunately the case with some promising interventions, predictive and educational value and ease of use may not ensure significant positive impact on long-term health outcomes, so we hope to conduct longitudinal prospective studies comparing outcomes at facilities that do and do not have the device. Upon quantifying the device's value proposition, manufacturing cost and willingness to pay in target markets will be compared to determine commercial viability.

If there is adequate technical performance and market interest, alternative and more complex versions of the device may be explored. The pressure threshold designed into the device can be easily changed for various applications by changing part materials or geometries. Viable combinations for different thresholds can be found using simple cantilevered beam deflection analyses and finite element simulations. More than one threshold can also be designed into devices by adding additional sets of features to either the base or switch parts. Since electronic plantar pressure measurement systems are considered cumbersome and expensive to use even in most high-income clinical settings, some version

of the device may have potential as a reverse innovation in high-income markets.

# 7   Conclusion

This study presents the development of a novel method of diabetic foot risk assessment based on existing medical literature and with low-resource healthcare settings in focus. In many low- and middle-income country contexts, the international consensus risk assessment is impractical due to resource constraints. Here, we designed a purely mechanical plantar pressure evaluation device that can indicate high risk of diabetic foot ulcer. Plastic bistable mechanisms make up the device and move to a second stable position under a pressure threshold found to be predictive of ulcer development in prior medical research. The device can be used and interpreted quickly without electricity, computation, or a specialist and may help stressed healthcare settings allocate resources more efficiently to prevent diabetic foot ulcers and resultant amputations. Future work will include design improvements for ease of use and ruggedness, a comparison study with a previously validated electronic system, prototype demonstrations and tests in LMICs, design for manufacturing, a longitudinal multicenter prospective study, and exploration of other device embodiments for different applications.

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