DEVELOPMENT OF A NOVEL DIABETIC FOOT RISK ASSESSMENT FOR LOW-RESOURCE HEALTHCARE SETTINGS: A CASE STUDY OF LEAN DESIGN

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ABSTRACT

Interest in applying a "lean" philosophy to design has been slowly growing in recent years, but there are still few broadly applicable methodologies and illustrative cases published in the literature to guide lean design processes. Lean approaches promise cost reduction and increased product value, which could be particularly beneficial in product development for low- and middle-income country markets, where value demands are high. We use the clinical need of efficient diabetic foot risk assessment in low-resource healthcare settings to present an example of lean early-stage design of a medical device. The background of existing medical literature and commercial products is intentionally leveraged throughout the design process to streamline development and minimize the need for independent validation of product strategies and design features. Our approach resulted in an efficient design process that generated a novel, purely mechanical plantar pressure evaluation device that can indicate high risk of diabetic foot ulcer in resource-constrained settings. This case provides a practical example of how design processes can be adapted to be leaner where there are large gains from minimizing design cycle time and cost.

Keywords: Lean design, New product development, Biomedical design, Diabetic foot, Medical device

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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 (International Diabetes Federation, 2021).

The costliest complications of diabetes are those affecting the lower extremities, accounting for one third of all spending on diabetes treatment (Armstrong et al., 2020). 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 (Volmer-Thole and Lobmann, 2016), are among the top 10 conditions causing disability worldwide (Lazzarini et al., 2018), and have a mortality rate near that of cancer (Armstrong et al., 2020). Up to a third of diabetics will develop a DFU in their lifetime (Armstrong, Boulton, and Bus, 2017), and at least 1 million have a lower extremity amputated every year (International Diabetes Federation and International Working Group on the Diabetic Foot, 2005). Even for patients who eventually recover, low rates of access to quality prosthetics and other rehabilitative therapies in LMICs leaves many permanently disabled and immobile (Sexton, 2016).

Encouragingly, the etiology of and risk factors for DFU are fairly well understood, and most DFUs are therefore theoretically preventable. Barriers to realization of prevention potential remain, though, as consensus guidelines on DFU prevention call for extremely resource-intensive interventions based on a coarse risk stratification system (Schaper et al., 2019). These guidelines recommend a series of careful procedures for risk level determination intended to be performed by a specialist. Few diabetic patients in LMICs have risk assessments performed on their feet due to the demanding nature of these methods, in terms of both time and specialized knowledge and training, paired with the severe resource constraints affecting many healthcare settings (Saurabh et al., 2014; Sibbald, Woo, and Ostrow, 2008; Taksande, Thote, and Jajoo, 2017). However, some risk evaluation is important to enable efficient allocation of limited resources toward those at greatest risk (Abbas, 2015). Sriyani et al. (2013, p. 3) 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."

This important need embodies a major challenge to designers: designing for LMIC markets (likely foreign to the designer) where both performance and affordability demands are high (Mattson and Wood, 2014; Winter and Govindarajan, 2015). Imported medical technologies in particular have a long history of failure in LMICs due to contextual factors that impose constraints not present in most high-income settings; the clinical need is unlikely to be satisfied by de-featuring some existing product (Malkin, 2007).

In recent years, there has been slowly growing interest in applying a "lean" philosophy, which has been a popular cost-saving approach to manufacturing for decades, to design in order to reduce design cycle time and cost and to maximize product value (Baines et al., 2006). These savings could be especially beneficial in product development for LMIC markets, now home to 85% of the world's consumers, though there are few cases to this effect in the literature. Furthermore, medical devices represent a product category with higher than average development costs. Many of the lean product development methodologies presented in the literature are either quite abstract or are not well-suited to some product categories (e.g. medical devices for which a minimum viable product cannot be rapidly deployed) (Baines et al., 2006; Pease, Dean, and Van Bossuyt, 2014; Mueller and Thoring, 2012).

Hence, in this paper, we present an educational case in lean early-stage design for LMIC markets through the development of a novel DFU risk assessment tool. In the sections that follow, we describe our design methodology, its outcomes, and learnings from this case.

2 METHODOLOGY

Toward an efficient medical device design process, we applied "overt" design, per Pannunzio, Kleinsmann, and Snelders' (2019) health design strategy typology. We opted not to conduct novel health research to inform the design ("convergent health design") to minimize costs to LMIC market

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users while still generating a robustly engineered product (as opposed to an improvised, "silent" design). Rather, we draw on a well-established medical literature throughout a structured design process.

To our knowledge Pease, Dean, and Van Bossuyt (2014) propose the only lean design methodology specifically for "developing world" products. They suggest selecting a product concept based on prior consumer spending; drafting value, growth, and impact hypotheses; identifying customer needs and product specifications; and launching a minimum viable product, followed by iteration. However, we find their starting from a concept based on documented spending and rapid deployment of a minimum viable product inappropriate for some product categories, including medical devices. Instead, we first defined system-level qualitative design requirements using a theory of change model, which does have some similarities to Pease, Dean, and Van Bossuyt's value, growth, and impact hypotheses. Guided by these requirements, we applied an iteratively divergent-convergent version of the prescriptive design process described by Ulrich and Eppinger (1995), whereby solution strategies are ideated and down selected, followed by concept generation and selection, and then system design, detail design, and testing. We find this process' breaking up of solution strategies and concepts as well as system and detail design useful due to the large possible solution space of this open-ended problem and the different requirements that it imposes at the sociotechnical system level and the technical detail level. The repeated divergence-convergence creates space for creative thought in an otherwise linear process (Howard, Culley, and Dekoninck, 2008). In the latter stages of this process, we employ rapid, iterative, experimental prototyping, which is a common feature of lean approaches (Mueller and Thoring, 2012).

2.1 Design requirements

Medical, economic, and anthropological literature regarding healthcare and diabetes care in LMICs (Malkin, 2007; Dupas and Miguel, 2017; Kremer, Rao, and Schilbach, 2019; Abbas, 2015; Sriyani et al., 2013; Sibbald, Woo, and Ostrow, 2008; Taksande, Thote, and Jajoo, 2017) and communications with healthcare providers in LMICs were used to draft system-level design requirements and a theory of change model for the ultimate desired impact (Figure 1) (Taplin et al., 2013). The theory of change embodies the concepts of the value and impact hypotheses proposed by Pease, Dean, and Van Bossuyt (2014) for lean product development. Critical assumptions and bottlenecks in the model, shown in red, were identified and made explicit. The final list of requirements was drawn from the theory of change model, with the critical assumptions and bottlenecks in the theory informing the following order of requirements:

1. Provide an actionable output
2. Be affordable over the product lifetime
3. Be understandable by non-specialist healthcare providers and diabetic patients
4. Be usable and interpretable quickly by operators with minimal training and external equipment, and within existing workflows
5. Be safe and comfortable for diabetic patients
6. Offer some educational or communication value
7. Be portable enough for use by mobile healthcare providers
8. Be cosmetically attractive to healthcare providers and patients
9. Be durable and reliable over a long service life

These qualitative design requirements guided our conceptual thought process while the solution space was still too expansive to define specific, quantitative requirements.

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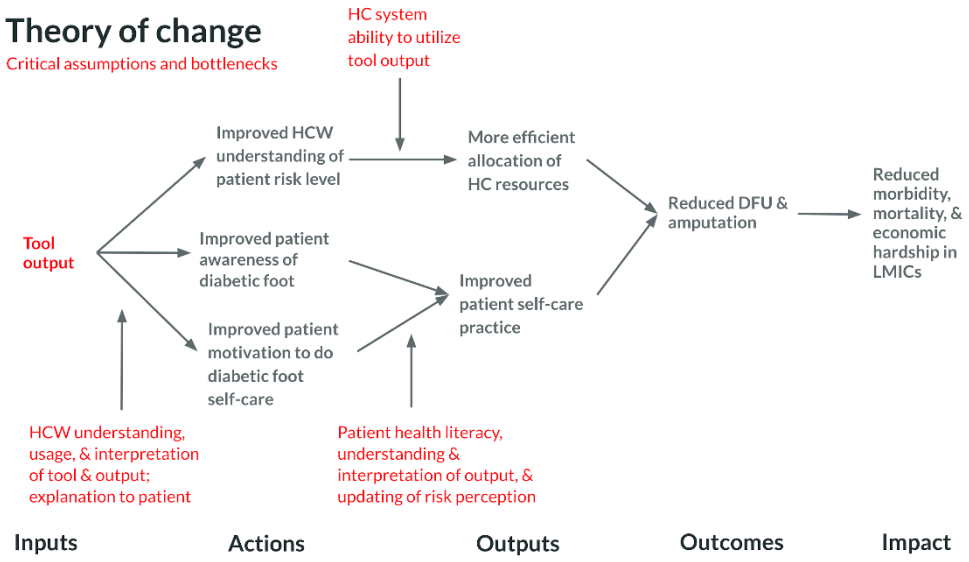

Figure 1. Theory of change, with critical assumptions and bottlenecks in red. "HC" abbreviates "healthcare," and "HCW" abbreviates "healthcare worker"

2.2 Strategy ideation and selection

To identify potential strategies for DFU risk assessment through the "overt" design process, we consulted the medical literature. Several metrics have been theoretically and empirically associated with DFU development. A predictor not yet incorporated into the current risk stratification system was sought to avoid duplication of efforts in settings where some factors are measurable. One of the most sensitive, specific, and empirically supported remaining predictors is plantar pressure, the pressure experienced by the bottoms of the feet. 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. Concurrent weakening of the skin under these high pressures results in vulnerability to ulcers. Plantar pressure has been implicated in the development of DFUs for many years by both retrospective and prospective studies, with reports of sensitivities on the order of 60-80% and specificities ranging from 40-75% (Veves et al., 1992; Frykberg et al., 1998; Pham et al., 2000; Lavery et al., 2003; Lott, Zou, and Mueller, 2008; Ledoux et al., 2013; Fernando et al., 2016; Chatwin et al., 2020).

Despite robust evidence for its predictive value, plantar pressure has scarcely been utilized in routine clinical practice. Two classes of plantar pressure measurement tools exist: electronic sensing equipment, which uses arrays of hundreds to thousands of small electronic pressure sensors (Razak et al., 2012), and imprinting with either ink or carbon, creating visual footprints whose darkness at different locations is interpreted into discrete pressure ranges based on relative pigment concentration compared to a reference. Many 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 significant 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 requirements and inter-observer variation make them a poor fit for health systems in which patients mostly see generalist nurses (Cisneros, Fonseca, and Abreu, 2010). Thus, we were able to leverage existing knowledge to efficiently identify a product strategy, but a novel method of assessing plantar pressure is needed for feasible implementation in LMICs.

2.3 Concept ideation and selection

With a narrower solution space, further design requirements surfaced. For example, we opted for an analog mode to ensure affordability and compatibility with settings without stable electricity or computational capacity (e.g. mobile providers). We also sought to produce a binary output (i.e. indicate whether a person has a peak plantar pressure above or below a relevant threshold) to simplify interpretation of the output for providers. Concepts for analog pressure "sensors" were generated through several brainstorming sessions and include buckling columns, viscous fluid displacement

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through valves, imprinting, deformation of solid films, thermoforming, and bistable compliant mechanisms. After an internally imposed concept generation deadline, concepts were evaluated for compatibility with the design requirements using a Pugh chart. Each of these concepts could potentially produce a readable response to an applied pressure, but a bistable compliant mechanism is a particularly appropriate concept given that it can be used non-destructively, function with minimal hardware and external equipment and without consumables, and provide a binary output.

2.4 System design

Some features of existing plantar pressure measurement products with experimental support for DFU prediction were incorporated into the system design to reduce development risk and maintain a lean process by not innovating where unnecessary. For example, we utilize the form factor of a mat containing a grid of sensors that users step onto, which all other commercially available plantar pressure measurement systems use.

The system design effort focused on the "sensor" mechanisms, which required innovation based on our design requirements and benchmarking. A plastic, bistable compliant mechanism using material elasticity under elastic bending as the source of resistance to movement was designed. Each "sensor" is a simple, two-part structure, made up of a "switch" and a "base." The switches are three-sided semi-rectangular shells that fit over a base part, with each part including obstructive features on the surfaces in contact with the other part. The rectangular shell shape creates a flat, safe 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. The extent of the bending induced by a pre-determined pressure threshold allows the obstructive features on the switch and base to slide past each other and the switch to move to a second stable position.

2.5 Detail design

As in the system design phase, we drew on existing literature to inform detail design decisions and speed up the development process. Pressure sensors studied in the 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 1200kPa. Recent reviews by Lazzarini et al. (2019) and Wang et al. (2019) both suggest that sensor size not exceed 10mm. Contextualizing our requirements within this literature, sensor size was set to the maximum acceptable 10mm ($100mm^2$) to minimize cost. The ideal pressure threshold likely depends on provider preference and use case, but in order to maximize patient safety by minimizing false low-risk results, a threshold of 200kPa was selected for an initial proof-of-concept prototype (Owings et al., 2009).

Switches for the initial prototype were to be 3D printed. Various sizes and shapes of obstructive features were iteratively 3D printed out of several different plastics to experimentally identify appropriate material-geometry combinations to generate a 200kPa pressure requirement to move the switches to their second stable position ("trigger pressure"). Trigger pressures were then measured using a force gauge. This experimental prototyping accelerated the detail design, as material property variance with printing methods and conditions makes analytical modeling of this system challenging. ABS parts with semi-cylindrical features of modest size on both the switches and bases yielded trigger pressures on the order of 200kPa. Base dimensions were then specified to be easily manufacturable and to have a low, stable profile, and the ABS switch dimensions were fine-tuned experimentally, as above, given the base geometry, resulting in the geometry in Figure 2 (right). Both part designs can be inexpensively manufactured.

2.6 Prototyping and testing

Following detail design, a full-scale prototype was constructed. Switches were 3D printed from ABS, and bases were CNC machined from Delrin in strips (Figure 2, left). The strips were aligned and secured on another thin slab of Delrin with machine screws and nuts. To set up the device for use, a 3D printed switch is placed on top of each base profile, producing 392 sensors, shown in Figure 3. A force gauge was used to confirm that the sensors snap into their lower position under roughly 2kg of force, equal to approximately 200kPa over the switches' $1cm^2$ area. The prototype was taken to Kenya

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and shared with 19 healthcare providers in July 2022. Feedback was very positive, motivating the filing of a provisional patent application.

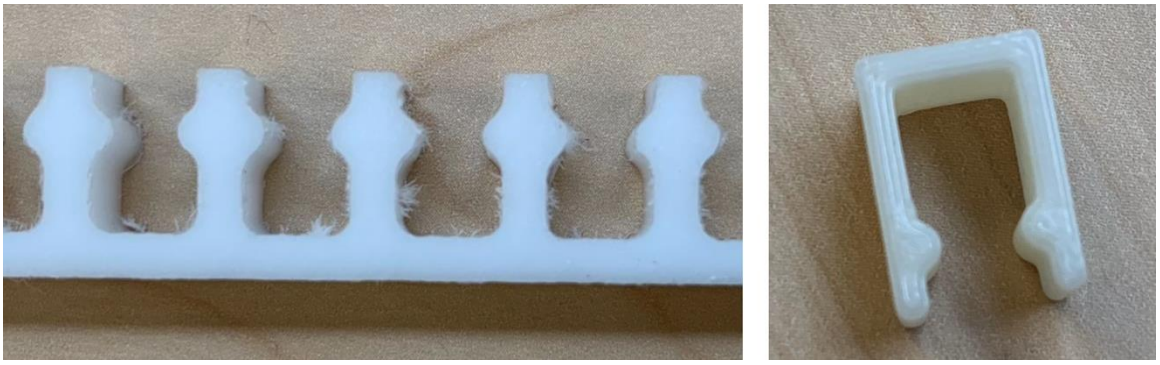

Figure 2. Part of a CNC machined strip of base parts (left) and a 3D printed switch (right)

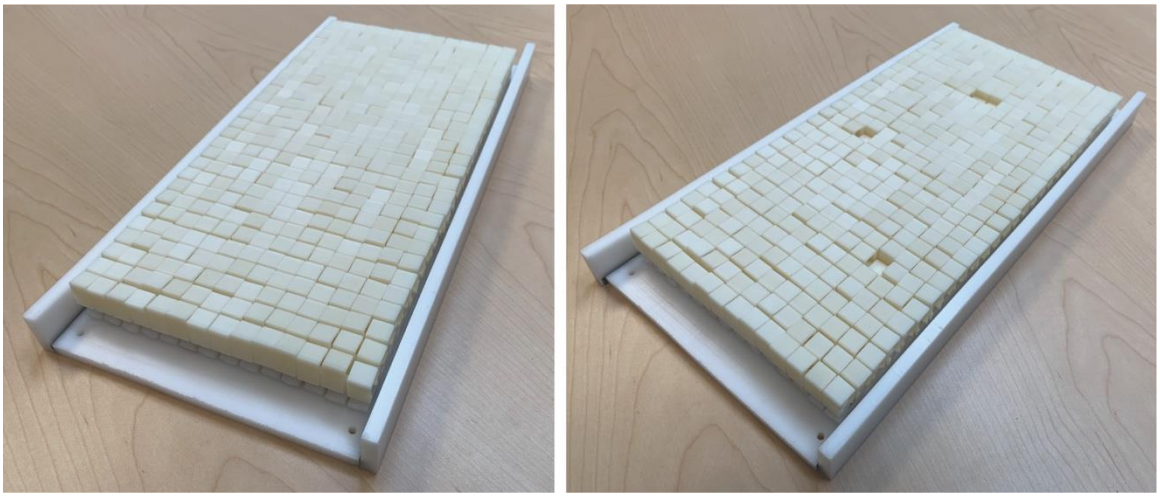

Figure 3. Fully assembled prototype (left) and prototype where four sensors have been triggered by high pressure (right)

3 RESULTS AND 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. Its low cost, durable materials, compact design, ease of use and interpretation, and quick procedure make it especially suited to time-, money-, space-, and personnel-strained healthcare settings. 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, and a patient can step onto and off of it with one foot at a time with a natural gait. The subject and test administrator can then visually observe the device, noting if any of the switches have been triggered by a pressure greater than the set threshold to move, as in Figure 3 (right). The administrator can then use that information in a number of ways, from prescribing pressure reduction therapies to counseling the patient about precautions that they should take with their feet. Reusable or disposable sheets of thin, flexible material may be laid over the top of the device before use for sanitation purposes so long as they do not prevent the transmission of pressure.

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 and advise them to check the high-pressure area for injury regularly. 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 only). Measurement

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error could arise from abnormal patient gait or device wear or dirtiness, and providers will need some amount of instruction in order to administer the test effectively. However, as opposed to only considering a patient's demographic and disease characteristics (which constitute most of the other unused DFU predictors) where standard tests cannot be performed, a physical and visual test could aid in patient-provider communication, the physical artifact perhaps prompting questions from patients or explanations by providers. The tangible experience may make any resultant counseling more memorable and motivate patients to take greater preventative action.

Next steps in the development of the device will include further prototype demonstrations and feedback collection in LMIC healthcare settings, which will inform a new design iteration. An updated prototype will be tested against an electronic sensing system that already has empirically established predictive value. The device's long-term effect on health outcomes and return on investment in real-world conditions should then be studied.

Despite the benefits of a lean design process to product development for LMIC markets, the literature on this subject is sparse. Many of the published lean design methodologies are vague and/or not applicable to some important product categories, such as medical devices (Baines et al., 2006; Mueller and Thoring, 2012). The only methodology proposed for product development specifically for LMICs that we are aware of is that of Pease, Dean, and Van Bossuyt (2014). While interesting, we believe that the strategy of first identifying a product concept from documented consumer spending patterns and only considering needs later has limited applicability. In emerging markets in particular, many successful and quality-of-life-improving products are market-creating technologies or technological leaps, and much consumer spending is undocumented. Hence, we began this work from an expressed but underserviced problem and based our product strategy and concept upon user-centered design requirements. Additionally, deploying minimum viable products and conducting several iterations after launch is not always cost effective, for example, due to medical product regulatory requirements or economies of scale in manufacturing.

While procedurally it resembled a more traditional design process, our early-stage design methodology was made lean through the restriction of the bulk of our creative activities to where we as designers could add the most value, which was not in the medicine behind DFU prediction but in the engineering of a pressure sensing mechanism. We found what Pannunzio, Kleinsmann, and Snelders (2019) characterize as "overt" design to be an efficient strategy for health innovation for LMIC markets. By leveraging existing medical literature, we were able to generate a functional prototype of a novel medical device that appears to satisfy design requirements in a matter of months and with a minimal, four-figure budget. The medical and commercial backgrounds de-risked and sped development, as well as provide our product strategy and system and detail designs some credibility even prior to prototype testing. Overt design of medical devices may not be possible for addressing problems lacking a strong medical understanding, but where one exists, we recommend the overt approach for its resource savings, which are of particular value in projects targeting LMIC markets. An overt design-type philosophy may also be applied outside of the medical domain through deliberate decisions about where to innovate and where to rely on existing knowledge. Analogous springboards or sources of information to the medical literature in this case in other fields may include other literatures, existing technological platforms, off-the-shelf components, or technologies successful in other markets.

Heavy use of background information in design may limit the level of technological innovativeness of products designed "overtly," though most products based on entirely new science are not commercially viable in LMICs. Our relatively low level of engagement with users and customers early in the design process is another limitation of the methodology described here. We regret that richer collaboration with diabetic patients and healthcare professionals in LMICs was obstructed by COVID-19. We believe that any resources required for stakeholder engagement would yield returns via improved design suitability and reduced development risk earlier on and thus would not detract from the overall leanness of the process.

While we do not assert that the methodology used in this study is ideal for all lean design for LMIC markets or in general, this case may serve as an example of how a design process may be made lean by applying the philosophy of overt design, utilizing existing background throughout the design process and only innovating where necessary. As demonstrated by this case, such a process can still result in a novel design that satisfies yet unmet needs.

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4 CONCLUSION

Despite the potential value of the "lean" philosophy to product development for low- and middle-income country products and medical devices, there is little published literature on the subject to guide designers. This study presents the lean early-stage design of a new method of diabetic foot risk assessment for low-resource healthcare settings. An overt health design approach is taken, whereby existing medical literature is utilized in the design process to speed up and de-risk development. The highly efficient process resulted in a novel, purely mechanical plantar pressure evaluation device that can indicate high risk of foot ulcer. This case demonstrates how design processes can be made lean to lower design cycle time and cost.

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