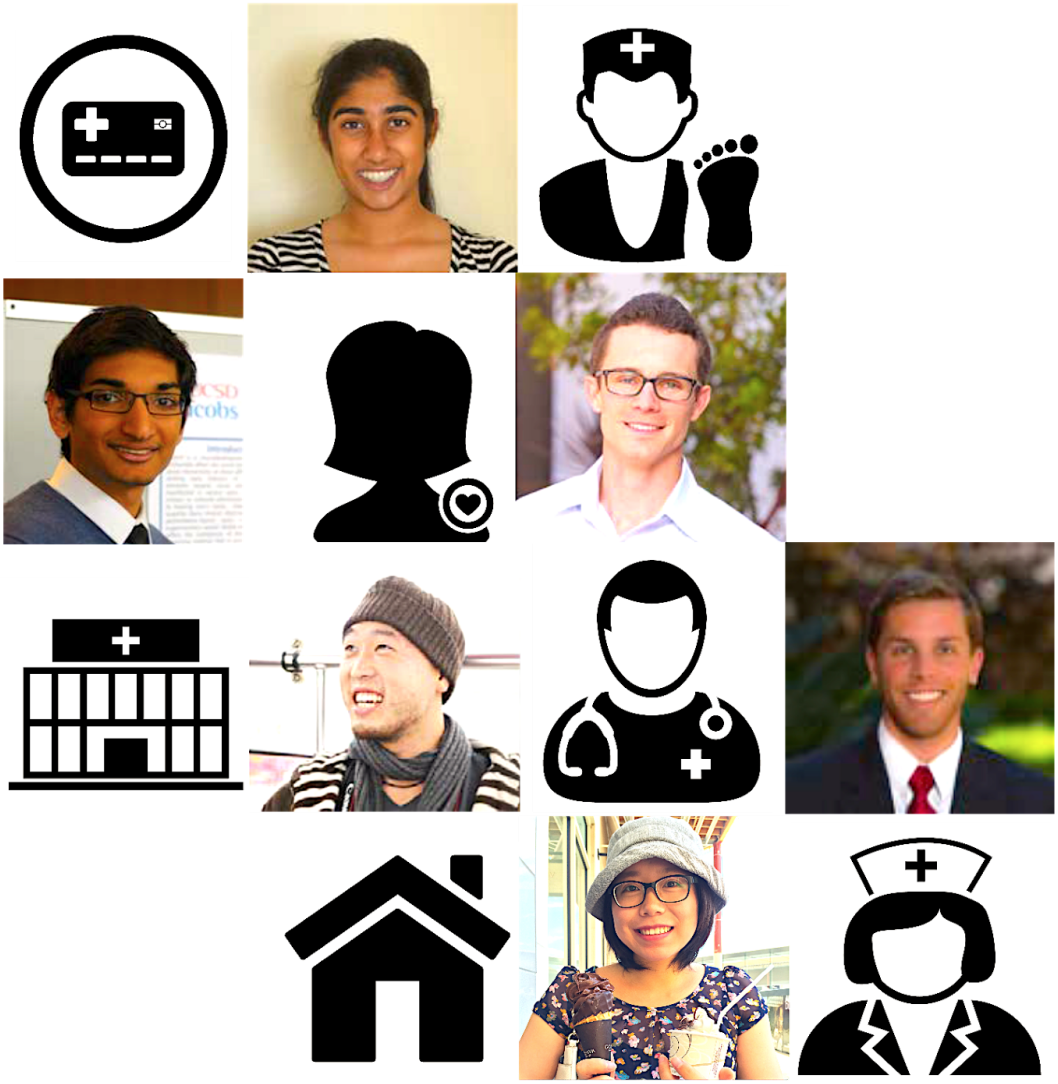
Recurrent Diabetic Foot Ulcers (Footie)



Spring Final (Team 4)

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1.0 The need: Diabetic foot ulcer prevention

1.1 Problems for patients

There were about 30 million Americans with diabetes in 2014. And about 15 to 25% of people with diabetes develop at least one foot ulcer during their lifetime. The most frequent underlying etiologies are neuropathy, trauma, deformity, high plantar pressures, and peripheral arterial disease. Combine this with high comorbidity of vascular disease, healing of ulcers once they develop is extremely difficult. The healing time may take the order of months to years, if they ever heal. Relatedly, the recurrence of ulcers can be very high, with some studies quoting rates as high as 78% in the first 12 months. This is costly and time consuming, placing a huge burden on the patients. They have to frequently follow up in wound care clinics, up to several times a week. In addition, they may be asked to offload their weight by limiting their normal activities or wearing special cumbersome shoes for months to years. These strict recommendations are difficult to comply with and the wounds may never heal. When wounds are persistent, they may become complicated with infections and gangrene, potentially requiring amputations. Unfortunately, this horrible complication of diabetes is under recognized and under emphasized.

1.2 Problem for healthcare providers

Cost to the healthcare system due to diabetic foot ulcers approaches $10 billion per year in the United States alone. There has been little incentive for prevention in the current healthcare landscape and this is evident in lack of knowledge about the risk in the current diabetics. Literature also supports this, with many patients either not knowing to check their feet daily or failing to do so, despite the knowledge. In addition, the population associated with this condition is complicated by multiple comorbidities like poor eyesight, obesity with large abdomen, joint stiffness, and low socioeconomic status - all of which likely contribute to poor compliance towards prevention.

Even when patients have experienced diabetic foot ulcers, they usually receive treatments for the active issue without much focus on future prevention. Recurrence has been noted to be very high, up to 30-70% in the first 12 months following their first ulcer. The first line providers for these issues, including primary care physicians often lack the time, resources, or incentives to prevent future diabetic foot ulcers. Overall, the burden on the healthcare providers are also extremely high without a good current solution.

1.3 Need statement

Problem: Recurrent foot ulcers arising in diabetic patients and their subsequent complications lead to a significant loss in quality of life for the patient and a marked increase in medical costs.

Population: Patients who have had previous diabetic foot ulcers because they are at particularly high risk for developing another severe, slow-healing ulcer on the foot.

Outcome: To reduce downstream medical costs associated with the treatment of foot ulcers.

> ***Need Statement:*** *A way to prevent recurrent foot ulcers in high-risk diabetic patients to reduce the costs associated with amputations and ulcer treatment and increase QALYs for patients.*

1.4 Need criteria

Must-have need criteria	Nice-to-have need criteria
• Reduces ulcer development by >25%	• Can be recommended by any healthcare provider
• COGS not exceeding $400-1,500 to allow pricing that enables ROI for payer	• Minimal interruption to patient lifestyle
• As easy to use as stepping on a weight scale	• Allows patient to maintain mobility

See appendix for rationale for need criteria.

2.0 Solution: An end-to-end service to prompt early intervention for diabetic foot ulcers

2.1 High-level description

Due to poor blood supply and loss of sensation, small issues like a minor foot prick can progress quickly into ulcers and big problems in diabetics. Early identification has shown to reduce incidence of recurrent ulcers, even in high risk populations[1]. However, from our interviews, compliance is always an issue in real life, even for patients who have had previous diabetic foot ulcers. Thus, we ask the following questions: how might we make the daily foot inspection simple to operate for patients and how might we support physicians to make timely diagnosis of their patients? We converged on an end-to-end service that automatically collects images of a patient's feet on a daily base using a camera-embedded footrest, transmits those photos to an in-house health care professional

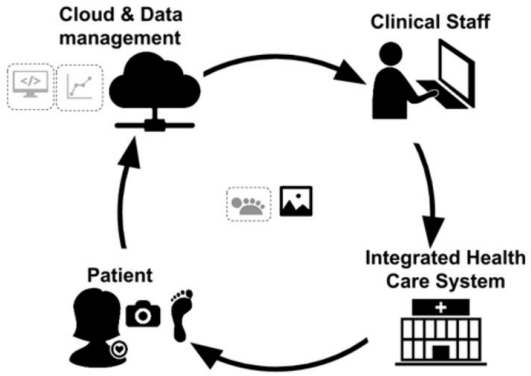


Figure 1: A flowchart of the end-to-end service

[1] Lavery, Lawrence A., et al. "Preventing Diabetic Foot Ulcer Recurrence in High-Risk Patients Use of temperature monitoring as a self-assessment tool." *Diabetes care* 30.1 (2007): 14-20.

who assesses the images for early-stage ulcers. And our integrated healthcare system alerts the patient and the health care provider if an early-stage ulcer is detected.

2.2 Product design

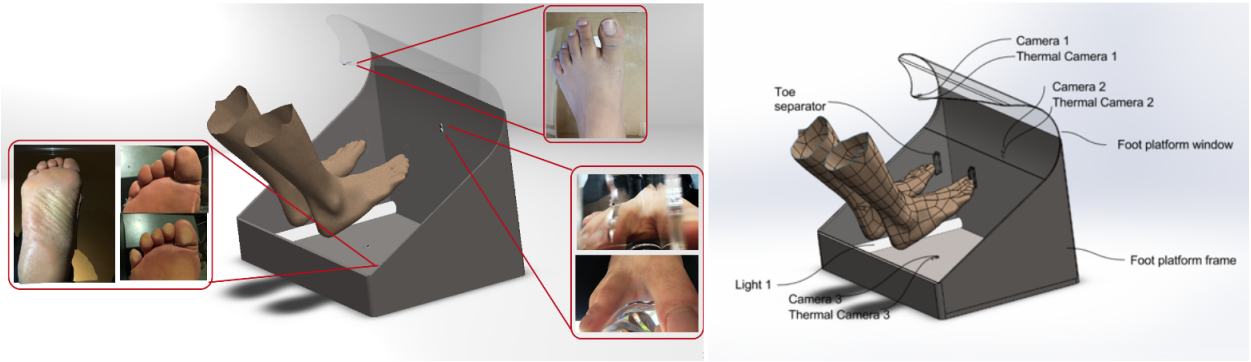


Figure 2: The footrest design and imaging function

As shown in Figure 2, The footrest platform is composed of a clear window made of one-way light material to create a controlled imaging environment inside, several regular cameras positioned at the top, side and bottom to capture multi-angle images of the patient's entire feet, distributed lighting installed at the bottom of the platform, toe separators to open up toes as well as to position the feet on the window, and the foot platform frame. High quality images for the plantar and dorsal sides of the foot are technically feasible to retrieve through acrylic plastics (0.093'') based on our initial prototyping and testing. Areas between toes require the toe separator's design to fit with different foot conditions and to be easy to use, without sacrificing image quality. Figure 3 shows our initial designs of the toe separators, further high-fidelity prototypes with clinic studies are needed to evaluate its effectiveness. Key dimensional specifications are devised based on prototyping and testing: Footrest Window Size: 14'' (L) × 20''(W); Camera's Minimum Distance to Foot Plantar: 9.5''; Camera's Minimum Distance to Foot Top: 5''and Camera's Minimum Distance to Toe: 1.5''. The design of a footrest also allows us to collect foot images with the foot pressed against the window, which gives the clinician additional insights to evaluate ulceration risks based on whether blanching happens, because extravasated blood will not blanch.

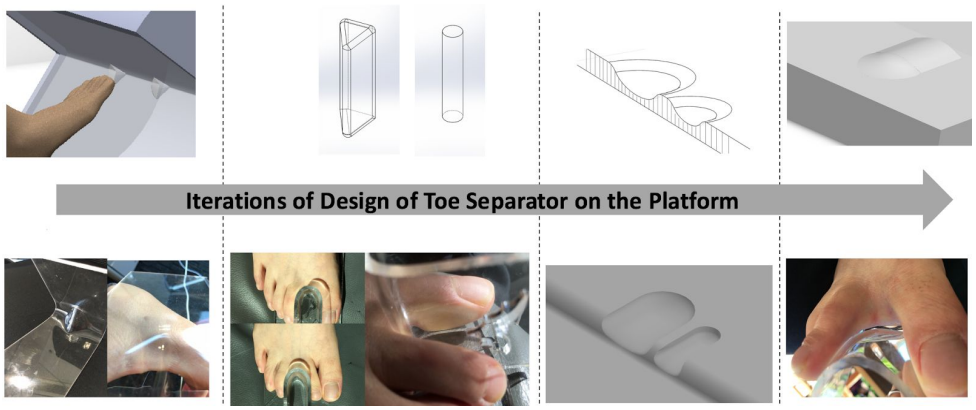


Figure 3 Our initial designs of toe separator on the foot platform

Regular cameras are good enough and meet with existing clinical practices. In the near future, we plan to include both a normal spectral imaging function and an infrared thermal imaging function to better support the decision-making about patients foot status.

2.3 Value proposition

For patients, the system provides avoidance of the complications of ulcers. The longer ulcers are allowed to develop, the longer the recovery time is and the higher the costs. For health care providers, the system provides significant reduction in the costs related to treating ulcers.

2.4 Differentiation from existing solutions

Current clinically adopted measures for preventing diabetic foot ulcers have largely been ineffective from a usability and/or technical standpoint. Patient education to take care of their own feet is limited to an initial, brief education by the nurse with little follow-up. Therefore, patients have low adherence to frequently checking their own feet. Telescoping mirrors have aimed at making this self-examination better. However, this patient population typically have other afflictions such as obesity and diabetic retinopathy which increase the difficulty of self-checking and decrease adherence.

For high-risk diabetic patients, a podiatrist or nurse will evaluate the feet every 3 months. However, this frequency is too low to detect early stage infection or ulceration. Diabetic shoes are another method to prevent ulceration in diabetic patients. However, the shoes are only applicable to a certain population[2]. We also gained from our interviews that adherence is low because of the aesthetic factors are subpar and many subjects find the shoes "ugly".

There are emerging technologies aimed at preventing diabetic foot ulcers. One of the more prominent companies is Podimetrics, invested in by Rock Health. Thermometry only detects the plantar side of the foot[3]. Because a majority of ulcers (52%) develop also on the dorsal side of

[2] Singh et. al., Preventing Foot Ulcers in Diabetic Patients. Clinical Review.

[3] Podimetrics. MIT Summer Accelerator Demo Day.

the foot and between the toes, we would have an advantage in the range of photos we could capture[4]. In addition, photographs are widely clinically adopted to track podiatric assessments unlike thermometry, which while it has scientific validity, there is little clinical adoption.



	SenseGO pressure sensor sock	Podimetrics temperature mat	Footie imaging platform
In home technology	✓	✓	✓
Transmission to clinician		✓	✓
Durable		✓	✓
Comprehensive etiologies		✓	✓
Detect entire feet	✓		✓
Clinician friendly			✓

SenseGo is useful in detecting ulcers that have a pressure-related etiology[5]. However, our device would detect an ulcer from all etiologies because of the camera based method.

3.0 Business model

3.1 High-level description

We plan to sell this service to health plans, large self-insured employers, and other population managers. These populations managers would subscribe to our service on behalf of their individual patient members through the per patient per month revenue model that is becoming standard across preventative and digital health solutions. In turn, their patient members gain access to our device and associated risk monitoring service. Population managers then realize a reduction in costs related to expensive diabetic foot ulcer interventions. This reduction in cost is significantly more than the annual subscription fee they pay us, resulting in a high ROI (100%+) realized within a year.

Key to our sales plan is conducting pilots and free trials to prove our value proposition. Another option to drive adoption is to use a pay-for-performance marketing model in which we go "at risk" by offering to refund the service if our healthcare provider partner doesn't benefit. Potential early adopters include integrated health systems such as Kaiser Permanente, the VA, and Intermountain Healthcare as well as large self-insured employers that have embraced preventative digital health models (e.g., Safeway).

Our company costs should be low. The device itself is estimated to cost less than $50 in materials and manufacturing at scale. As such, we plan to offer the personal imaging device to patients free of charge to limit barriers to adoption. Additional costs are related to software development and labor, mainly image review by healthcare providers. These providers do not

[4] Pompers L., et al.High prevalence of ischaemia, infection and serious comorbidity in patients with diabetic foot disease in Europe. Baseline results from the Eurodiale study.Diabetologia. 2007 Jan;50(1):18-25. Epub 2006 Nov 9.
[5] Pressure-Sensing Socks Feel the Pain of Diabetic Patients. Biodesign Israel.

have to be US based doctors; they could be PAs or RNs in either the US or in a low-wage economy (e.g., India). We can offer two options for population managers: (1) send images to their facility for review or (2) have images reviewed by our own staff. The first would be at a lower price point. The second is hands off for the systems and allows us to have quality control.

In the end-state, our business model will resemble that of a software company or wireless network. To acquire customers, we would incur sales costs (which should be relatively small when amortized over the large patient populations) and free trials that we estimate would cost ~$80 per acquired patient. The $80 comes from giving the device ($50) away for free and proving six months of free image assessment which amounts to approximately $30 in direct labor expenses. After acquiring patients, we would capture revenue indefinitely in the form of annual subscriptions worth ~$900 per year. As such, the unit economics are attractive, especially at scale.

3.2 Total market opportunity

It is estimated there are over 29M diabetics in the US with 1.4M new diagnoses every year. Additionally, another 86M Americans are pre-diabetic and at risk of developing diabetes. Overall, diabetes is the 7th leading cause of death in the US and accounts for an estimated $176B in direct medical costs and $69B in economic costs from reduced productivity.[6]

Of those with diabetes, ~2.1M have diabetic foot ulcers and thus could benefit from our service. Our business model calls for focusing our efforts the subset of those patients who are covered by a larger payer or integrated provider since their cost reduction incentives align tightly with our value proposition. Approximately 1.3M patients with diabetic foot ulcers are covered by such payers/providers.

Our estimated core addressable market is thus these 1.3M patients multiplied by the estimated $900 per patient per year we expect to charge for our service. This yields an annual sales market of ~$1.2B.[7] Given that the number of diagnosed diabetics has increased by ~4% per year over the past decade, we expect that our market size would increase at a similar rate in the future.[8]

Beyond the core US market, additional lucrative opportunities are available. Diabetes is a global disease, with an estimated ~425M diabetics in the world. Thus if we expand to treat even a fraction of this global population our market size could potentially increase by an order of magnitude. Additionally, our model of remote monitoring, analytics, and integration with healthcare providers could be used to address additional diseases. For example, it could be possible to monitor heart failure patients for signs of edema to predict a decompensation episode.

[6] American Diabetes Association http://www.diabetes.org/diabetes-basics/statistics/?referrer=https://www.google.com/
[7] Sources: AHRQ 2011. Cavanagh 2005. Yock 2015. Internal estimates.
[8] CDC 2014 http://www.cdc.gov/diabetes/statistics/prev/national/figpersons.htm

4.0 Risk mitigation

4.1 Technical feasibility

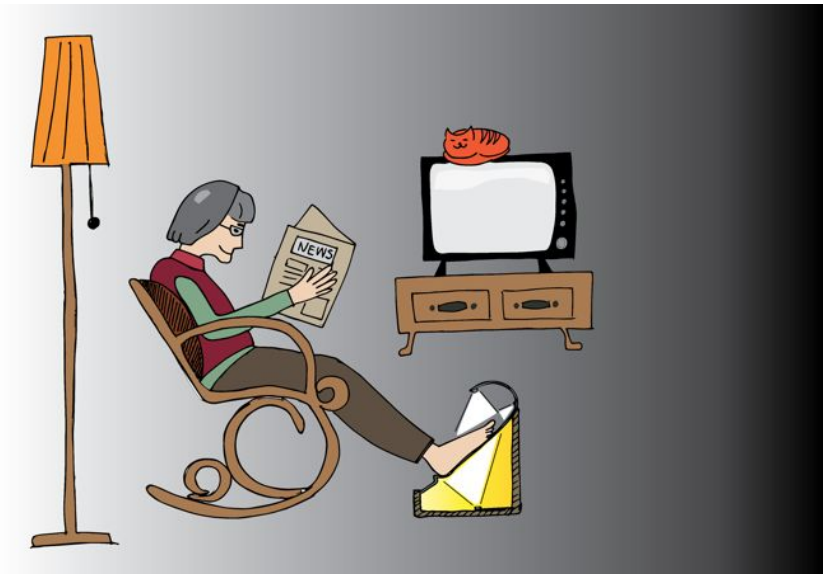
This concept is technically feasible. The basic techniques behind the camera include a regular camera, potentially equipped with an infrared thermal sensor[9]. The cameras are attached to a foot rest platform which enables a patient, who might have limited mobility or have poor vision, to easily check their feet. LEDs that help control lighting levels are triggered when the camera is being used. The foot rest has an overhang with a camera attached, which allows for the dorsal surface of the foot to be captured. The region upon which the patient rests their feet is a window made of a transparent material, such as Plexiglass. The region below the window contains the LED lighting system and an additional camera to capture the plantar surface of the foot. Future iterations of the device may additionally include toe separators made of a transparent material with integrated cameras and lighting in order to capture the area between the toes. Built-in software transmits the images to a physician or other provider who is dedicated to read photos in order to make diagnostic decisions. In future iterations of this concept, preliminary analysis can be done with image analysis algorithms that would utilize data collected from images that were confirmed to have ulcers. This preliminary analysis could help physicians to make more accurate diagnostic decisions without needing to see the patient in-person. For the development of the image analytics, we would be able to leverage the vast amount of data collected from the field with our initial design, in which images are analyzed and confirmed by a trained professional. Thus, we believe our final design is technologically feasible because all hardware could be off the shelf or simple to manufacture, and the software is purely data aggregation and transmission.

4.2 Clinical feasibility

To ensure clinical feasibility, we decided to design the camera carrier in a form of foot platform. The clinical feasibility has two key areas: patient compliance and photograph usability. As we learned from patient interviews, some non-obvious but alarming signs (e.g., purple dots) may be ignored by patients, so a trained eye is often necessary. We utilize the foot platform because we believe it requires very minimal knowledge, time, and effort from the patient's perspective. The simplicity of a foot platform would enable patients to use it regularly. As the images are sent to a trained healthcare provider, a nascent ulcer can be identified. The patient would be subsequently contacted for necessary follow-up. However, the question remains whether the images retrieved from foot platform outside a clinical environment are consistent in quality and effectiveness. Thus, we will also explore other mechanisms to ensure reliability of the photos including image recognition software to ensure the entirety of the foot was capture, dynamic lighting systems, and autofocusing cameras.. In the long term, we can conduct data analysis based on a large database

[9]van Netten, Jaap J., et al. "Infrared thermal imaging for automated detection of diabetic foot complications." Journal of diabetes science and technology 7.5 (2013): 1122-1129.

of early stage foot ulcer photos, to better inform doctors about patient status. In sum, the clinical feasibility is biased to the positive side for this concept.



4.3 IP assessment

In terms of imaging technology, infrared thermal imaging for detection of diabetic foot complications is not new. However, we have not found any patent about the described method and apparatus to inspect the foot with combined normal and thermal images for multiple regions of the foot. For the software part of the invention, there are some relevant patents for methods of retrieval, storage and transmission of medical image data (e.g., US20080005059, US20110238449 A1, US 20070118540 A1). However, according to our IP consultant, we probably will not have issues with freedom to operate (FTO), although our patentability specifically on the software may be limited. However, the device component of our solution and method of taking pictures with blanching could likely be protected. We have filed a provisional patent for protection of these aspects of our solution. Thus, we believe our IP pathway should be relatively straightforward.

4.4 Regulatory assessment

Our initial concept should have a very simple regulatory pathway because we plan to simply transfer images from the patient to appropriately trained clinical staff, without doing additional analysis on the images. Under Sec. 892.2020 of the 21 Code for Federal Regulations (CFR), medical image communications devices are classified as class 1 and are exempt from premarket notification procedures. Future iterations of this concept may leverage big data to perform initial analyses or diagnoses on feet, which would require clinical testing and validation and FDA approval.

4.5 Payment pathway

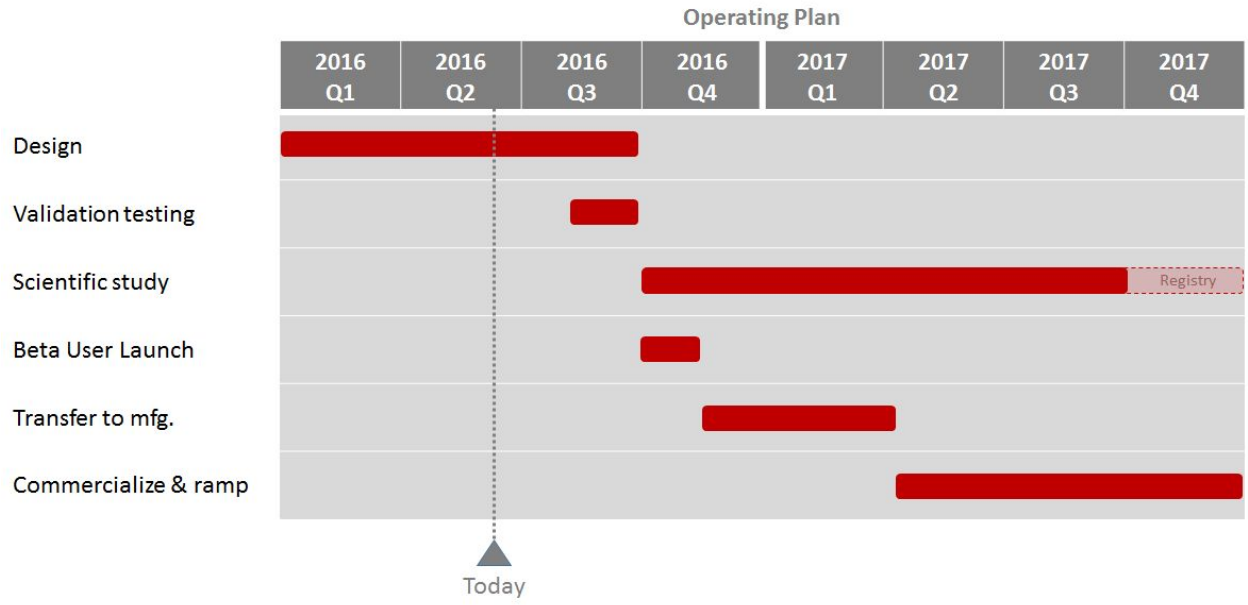
Reimbursement and business model are tightly linked for the foot platform based end-to-end service concept. This innovation isn't a procedure nor is it a an intervention device. Therefore, in a fee-for-service world, this concept would be hard to obtain reimbursement. In general, reimbursement for preventative solutions are still developing. However, physicians could get reimbursed and thus incentivized for reviewing the image. For instance, in ophthalmology there is a CPT code for the remote view of ocular photos. A similar one could be created for the review of diabetic foot ulcer images.

As noted in the Business Model section, our payment pathway primarily is through working with capitated systems (e.g., Kaiser, the VA, Medicare Advantage, ACOs) and potentially self-insured employers. Cost reduction incentives are aligned with these organizations, and we plan to share in the value from such cost reductions.

5.0 Operating plan

5.1 High-level plan

The operating plan is shown below. We plan to run a clinical study in parallel to commercialization after we finalize our product. The clinical trial would study 100 patients with diabetic foot ulcers, randomly splitting the patients into two groups: one receiving the standard of care (quarterly foot exams) and one receiving our service. The endpoints at the end of one year will include reulceration rate, total ulcer treatment costs, ulcer infections, and ulcer related amputations. (see Next Steps for additional study details)



5.2 Funding requirements

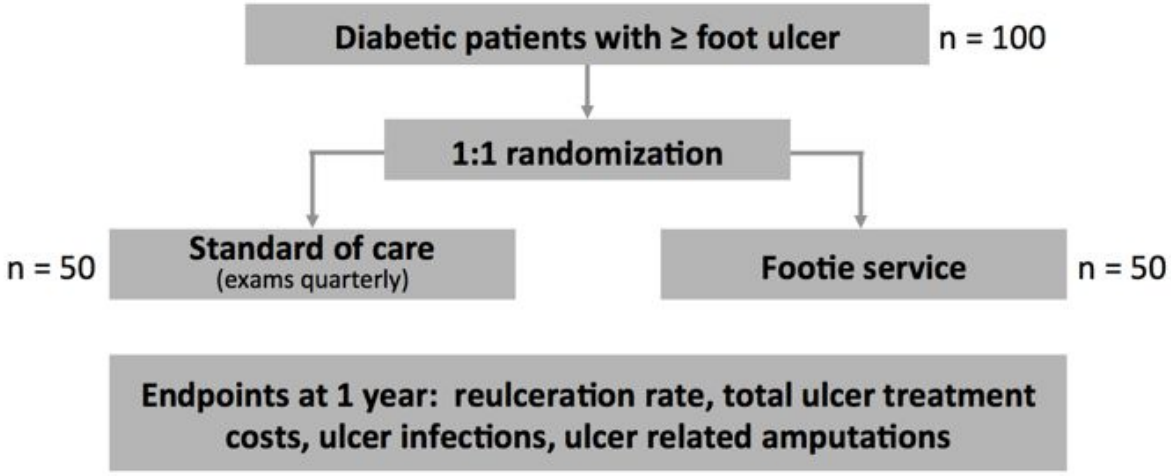
Our funding requirements should be low compared to a traditional medical device because our regulatory pathway does not require FDA approval. As such, we anticipate our funding through 2017 will include several FTEs (hardware and software engineers, a clinical coordinator to help monitor the trial, etc.) and the COGS of devices that are provided free of charge for the scientific study and pilots with early adopters. We estimate this amounts to ~$750K in FTE costs and $50K in COGS costs through 2017. As such, our funding requirement is estimated to be approximately $1M to provide some buffer.

6.0 Next steps

A major risk is achieving patient adherence with our device. For good efficacy, a patient needs to be utilizing the device on a weekly basis at minimum. Therefore, the goal would be to launch a clinical pilot study which follows patient's adherence pattern over the course of 2 months. Subjects of the clinical study would be able to rate the device on multiple factors including aesthetics, ease-of-use, motivation for continuing the program, and many others. This will give us a platform for understanding the patient's needs in terms of the product design and move us toward a higher compliance. During this clinical study we would save the photographs of the feet to a local data storage apparatus coupled to the foot platform device.

Another key risk area would be the quality of the images taken. During the 2 month pilot clinical study mentioned above, we would collect pictures of the feet that were saved on a local data storage on the devices. These images were then be displayed to a podiatrist or qualified nurse to examine. The key insights would be to understand what the healthcare providers would need in terms of the quality of the image as defined by resolution, color, lighting, angles of the photos, different foot views, etc. The participants of this study (i.e. providers) would take a survey to rank the images on each of these metrics. This will help us define what a minimal viable product would be in terms of image capture.

In order to prove our device works in longer-term care and supports the cost-effectiveness value proposition, we would conduct a 1-year clinical study with 100 patients that focuses on endpoints that include re-ulceration rates, total ulcer treatment costs, ulcer infections, and ulcer-related amputations. We emphasize that this study is not for FDA approval, but to show strong value-propositions to integrated healthcare entities and ACO's such as Kaiser Permanente.



Description of scientific study

7.0 Appendix

7.1 Rationale for need criteria

Reduces ulcer development by >25%: A meaningful reduction in ulcer rate needed to justify investment by inventors, patients and physicians. Ulcer reduction is a key to delivering the target outcome of reducing total medical costs. Our interviews and project coach have highlighted 25% as a reasonable estimate of what would "move the needle" for providers and patients.

COGS not exceeding $400-$1,500 to allow pricing that enables ROI for payer: The downside to our preventative model is that insurers have traditionally been reluctant to pay for prevention since the benefits typically accrue after the patient has moved to a new insurer. The insurance industry's rule of thumb is that patients tend to switch insurers every two years or so. To overcome this challenge, our solution needs to deliver an ROI to insurers within the first year of use. This ROI is a function of three parameters: 1) the percentage of ulcers we can prevent (see previous need criterion) 2) the estimated cost saving from preventing an ulcer and 3) the price we charge to insurers. Parameter 2 is fixed at an estimated $14.3K.[10] Thus, we can generate a table with the price we can charge to insurers as a function of our efficacy in reducing ulcers and the ROI we deliver to insurers. From this, it seems a price of ~$800-3,000 could provide a significant one-year ROI (~50%) to insurers depending on our products efficacy. To create a profitable, sustainable business, our gross margins would likely need to be at least 50%, meaning our COGS could be no more than $400-$1500.

		ROI for payer				
		20%	40%	60%	80%	100%
% reduction in ulcers	10%	$353	$303	$265	$236	$212
	20%	$707	$606	$530	$471	$424
	30%	$1,060	$909	$795	$707	$636
	40%	$1,413	$1,211	$1,060	$942	$848
	50%	$1,767	$1,514	$1,325	$1,178	$1,060
	60%	$2,120	$1,817	$1,590	$1,413	$1,272
	70%	$2,473	$2,120	$1,855	$1,649	$1,484
	80%	$2,827	$2,423	$2,120	$1,884	$1,696
	90%	$3,180	$2,726	$2,385	$2,120	$1,908
	100%	$3,533	$3,029	$2,650	$2,356	$2,120

Figure 1: Price of our solution to insurers as a function of reduction in ulcers and ROI to insurers

As easy to use as stepping on a weight scale: Widespread adoption and high patient compliance is only likely if the solution is relatively straightforward to learn and use regularly. Ease of use can be measured through patient surveys. The benchmark of stepping on a weight scale is instructive because Omada Health, a digital health company, has shown high compliance levels

[10]Diabetes Care: The Health Care Costs of Diabetic Peripheral Neuropathy in the US, 2003

in a pre-diabetic population using daily transmission of weight data from stepping on a weight scale that automatically translates the recording back to Omada.

Can be recommended by any healthcare provider: Diabetic patients see a variety of healthcare providers (PCP, podiatrist, endocrinologist, occupational therapist, physical therapist, etc.). It would be preferable to have all of these providers be able to recommend our product to broaden the funnel and capture more patients.

Minimal interruption to patient lifestyle: Patient compliance with existing solutions (e.g., diabetic shoes) can be low in part because the solutions are bulky and look overly medical. To ensure high compliance with our solution, it is important to make the product integrate into the patient's lifestyle.

Allows a patient to maintain mobility: Preventative measures will only be used if the patient is able to maintain a semblance of a "normal" life, which in the case of foot ulcers means maintaining mobility.