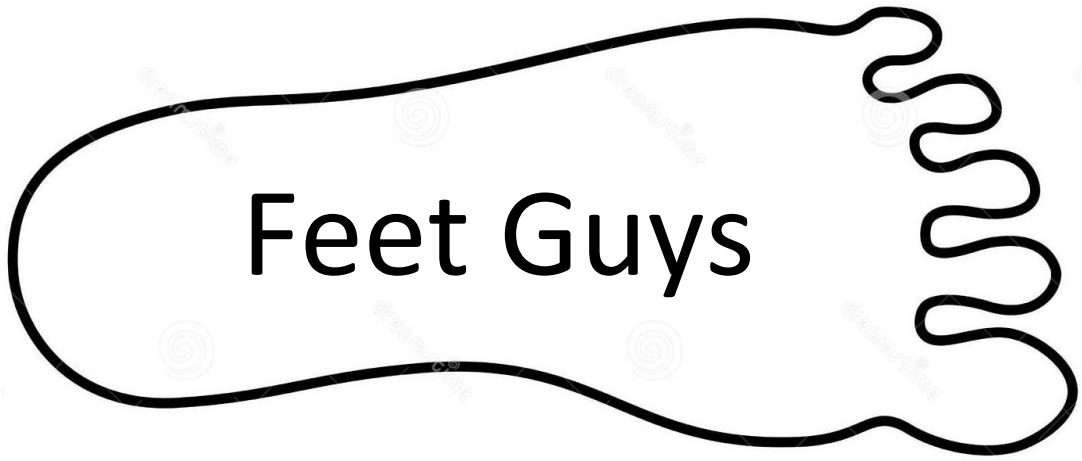
Monitoring Diabetic Foot Ulcers



Design History File

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Problem Definition

Background

In patients with diabetes, it is common for elevated blood glucose and blood fat concentrations to damage small blood vessels, leading to inadequate blood supply to nerves and peripheral neuropathy [1,2,3]. Without proper monitoring, this lack of sensation can cause a patient to overlook the development of an ulcer – often through initial callous formation then subsequent subcutaneous hemorrhage and tissue degradation – without noticing [4,5,6]. This ulcer may even get infected or begin to affect more profound tissues before a patient realizes it is there [4,5].

Consequences

Infection is developed in 50 to 60 percent of diabetic foot ulcers [7]. Amputation is a frequent consequence of diabetic foot ulcers if osteomyelitis is developed. If a moderate to severe ulcer is developed, amputation occurs in 20% of cases, impairing a patient's ability to walk, drive, move out of their bed, and return to their normal working life [8].

Deficit

Many recommended detection options for infection-prone individuals are simplistic or clinical, most notably including self-inspections and foot check-ups [10,11]. A study found that the most effective preventative measure for amputations was screening with a podiatrist, rather than therapeutic footwear and patient education techniques [12]. Remote temperature monitoring mats and insoles are becoming increasingly popular to detect inflammation and ulcers, but mats are somewhat bulky, receive infrequent use, and require a notable degree of patient compliance [13]. Many ulcer detection insoles are in the R&D phase. As a whole, they have not yet been widely integrated into practice [14]. As such, there does not appear to be a widely used technology for the convenient, effective detection and prevention of infection and progressive amputations. Early detection, intervention, and symptom reduction have been shown to improve the likelihood of full healing in the long term [15, 16]. Use of early surgery and antibiotic regimens, which are enabled by early detection, significantly decreases the necessity of future amputation [17]. Other effective techniques that are often implemented upon early detection include contact pressure-offloading casts, topical growth factors, and systemic hyperbaric oxygen [12].

Needs Statement

A method for early detection of neuropathic ulcer development is needed in diabetic patients due to their inability to detect ulcer occurrence and their elevated risk of

infection. A successful solution will decrease ulcer detection time, subsequently decreasing ulcer progression and occurrence rates of compounding outcomes.

II. Design Research

Disease State Fundamentals

Anatomy & Physiology

Over time, diabetes can damage both peripheral arteries and peripheral nerves. This is because high blood sugar levels can damage the blood vessels that supply these tissues with blood.

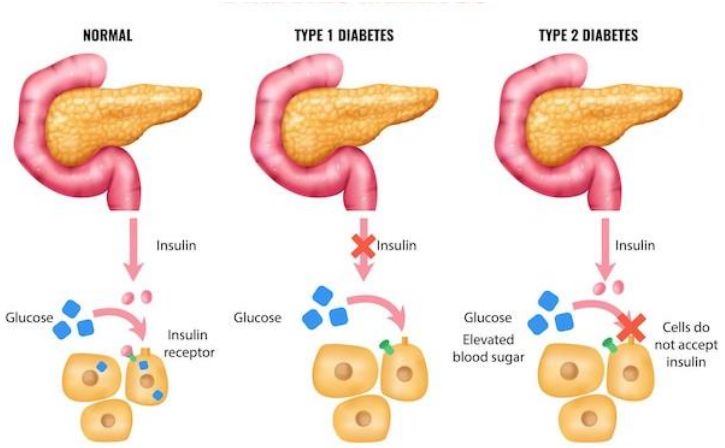


Figure 1. Physiology of Type 1 and Type 2 diabetes [12]

Peripheral arteries are arteries that carry blood to the tissues and organs of the body outside of the heart, brain, and lungs [18]. Peripheral arteries are responsible for delivering oxygen and nutrients to the tissues and organs of the body. The term periphery is often used in a medical context in reference to one's extremities. From distal to proximal, the bones of the lower extremities include the phalanges, meta-tarsals, sesamoid (accessory) bones, cuneiforms, navicular, cuboid, calcaneus, talus, tibia, fibula, and femur. From proximal to distal, the aorta bifurcates into the iliac arteries, which travel toward each femur. The iliac artery bifurcates, and then the external iliac branches into the femoral arteries. Notable arteries of the lower leg and foot include the anterior tibial artery and dorsalis pedis, respectively (Figure 2).

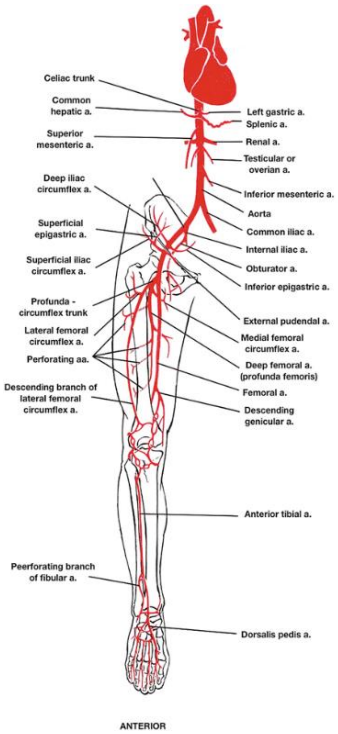


Figure 2. Lower Extremity Vasculature [19]

Peripheral nerves are nerves that are located outside of the brain and spinal cord. They carry signals between the brain and spinal cord and the rest of the body. Peripheral nerves branch off of the 31 pairs of spinal nerves and are responsible for sensation, movement, and reflexes.

Notable nerves in the femoral area include the saphenous (anterior, medial) and sciatic (posterior, contains tibial and peroneal) nerves. Notable nerves in the lower leg include the peroneals (anterior in this region) and sural (posterior) nerves [20]. The foot contains extensions of the sural nerve and tibial nerve, as well as the plantar nerves.

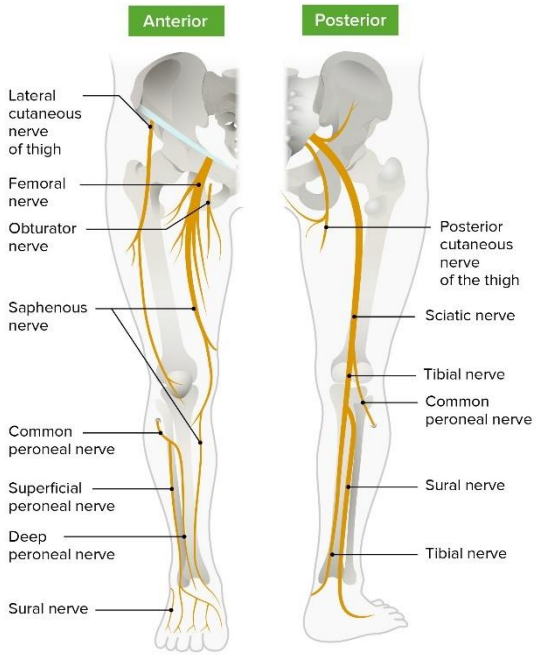


Figure 3. Nerves of the lower extremity [21]

Diabetes can damage peripheral nerves and peripheral arteries in a number of ways. One way is through a process called endothelial dysfunction. The endothelium is the thin layer of cells that lines the inside of blood vessels. Nutrient transport across vascular endothelial cells is essential to normal physiological function. It occurs via paracellular transport (between cells) or transcytosis, in which molecules are endocytosed, transported within the cytoplasm, and exocytosed elsewhere [22]. Nutrients (glucose and other sugars, oxygen, amino acids) and signaling molecules are supplied to adjacent tissues, including nerves, bones, and soft tissue cells. Endothelial dysfunction occurs when the endothelium is damaged and is less able to produce nitric oxide, a molecule that helps to dilate blood vessels and improve blood flow. Endothelial dysfunction can lead to atherosclerosis, a condition in which plaque builds up in the arteries and narrows their passageways.

Another way that diabetes can damage peripheral nerves and peripheral arteries is through inflammation. Inflammation can be triggered by pathogenic antigens, dead cells, toxins, oxidative stress, and even irradiation. It is characterized by readiness, elevated temperature, swelling, and pain. Numerous chemical signaling pathways are involved in inflammatory response, including three major ones shown in Figure 4 called NF-κB, MAPK, and JAK-STAT [23]. Inflammation is initiated upon binding of receptors (including Toll Like Receptors, or TLRs) in both immune cells and non-immune cells. Inflammatory pathways tend to lead to the production of inflammatory cytokines. These attract circulating leukocytes. The cytokines are primarily released from monocytes,

macrophages, and lymphocytes. Mast cells are effector cells that initiate inflammation. Numerous other cells are involved in complex signaling networks. Diabetes can cause inflammation throughout the body, including in the vasculature. Inflammation can damage blood vessels and make them more susceptible to atherosclerosis.

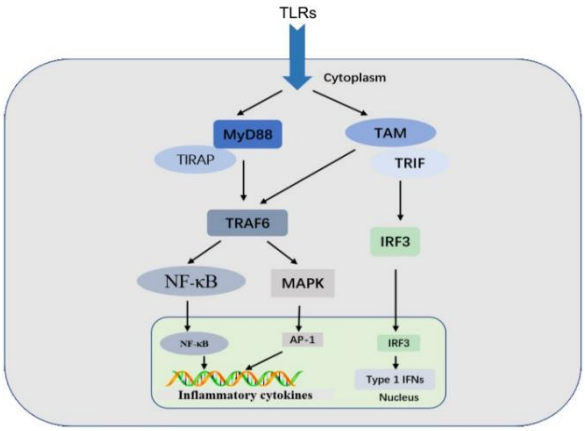


Figure 4. Inflammation Signaling Pathways [23]

Finally, high blood sugar levels can damage peripheral nerves and peripheral arteries by causing them to harden and become less elastic. This can make it difficult for blood to flow through the vessels and can increase the risk of blood clots.

Pathophysiology

When peripheral arteries that supply blood to the legs and feed become narrowed or blocked, it can lead to a condition called peripheral artery disease (PAD). The atherosclerotic occlusion of vessels is a manifestation of PAD (Figure 5). This can reduce blood flow to the feet, making them more susceptible to injury and infection. PAD can cause a variety of symptoms, including pain, numbness, and cramping in the legs. The more proximal the occlusion, the broader and – in many cases – the more significant the effect. Tibial artery occlusion is common, and relevant occlusions may even form in the iliacs and femoral arteries (namely the superficial femoral) [5]. Occlusions alone can result in gangrene amongst patients if significant enough. Insufficient circulation can cause ischemia and tissue death.

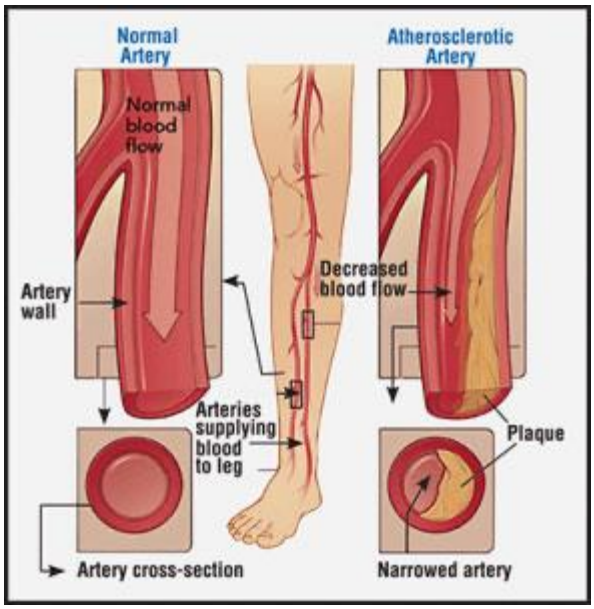


Figure 5. Diabetic Peripheral Artery Disease [24]

PAD and hyperglycemia have also been found to decrease leukocyte activity, causing one's ability to fight infection to be challenged [5]. Arterial deficiencies in the extremities can cause necrosis via malnutrition and oxygen starvation of all adjacent tissues, including motor and sensory neurons.

When peripheral nerves are damaged, it can lead to a condition called diabetic peripheral neuropathy (PN). Peripheral neuropathy causes muscular atrophy in extremities. This creates high pressure regions in the foot on the plantar surface and metatarsal heads, often associated with hammer toe formation [5]. Diabetic peripheral neuropathy can cause a variety of symptoms, including numbness, tingling, pain, and weakness in the feet and legs. PN can lead to people with diabetes not being aware of injuries to their feet, which can delay treatment and increase the risk of complications. High pressure regions and altered foot anatomy are developed in association with peripheral neuropathy (see below for details), causing increased ulcer risk [5]. Plantar pressure has been found to increase from healthy to diabetic patients, in terms of both standing and walking. Furthermore, diabetics with foot-related-issues have an even greater change in pressure distributions (Figure 6). A recent study reported high increases in the peak pressure around the midfoot (25%), medial heel (20%), and lateral heel (15%) across diabetics with corns, compared to the diabetic group. The lowest peak plantar pressure was reported for the healthy control group, followed by the diabetic group, and the highest peak pressure was observed across the diabetics with corns group [6].

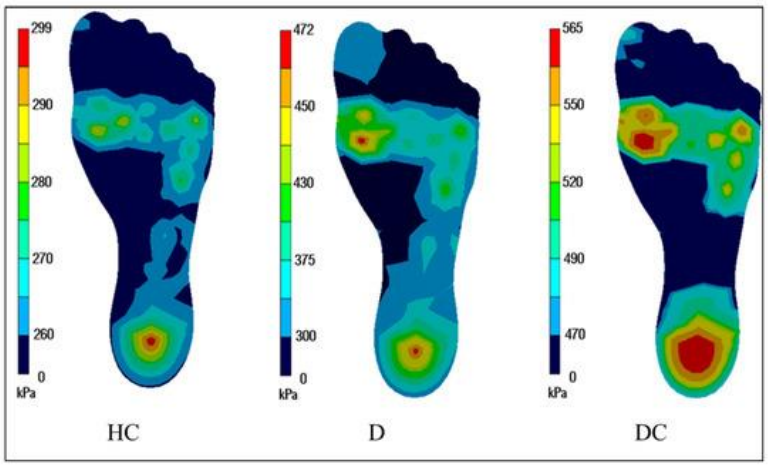


Figure 6. Foot Pressure Distributions [6]

Both PAD and PN can increase the risk of diabetic foot ulcers (DFUs), which are open sores that form on the feet of people with diabetes. They are most common on the soles of the feet and the toes. The development of an ulcer typically can broadly be grouped into three stages [4].

Stage 1: development of a callous as a result of neuropathy

- Motor neuropathy causes physical deformity and sensory neuropathy can cause repeated trauma/pressure to go unnoticed.
- Skin also dries as a result of autonomic neuropathy, which adds to the callous risk.

Stage 2: Trauma of the callous results in subcutaneous hemorrhage

Stage 3: The callous erodes to become an ulcer

- Walking on the callous (possibly as a result of failure to identify the callous) increases the rate of tissue degradation [5].

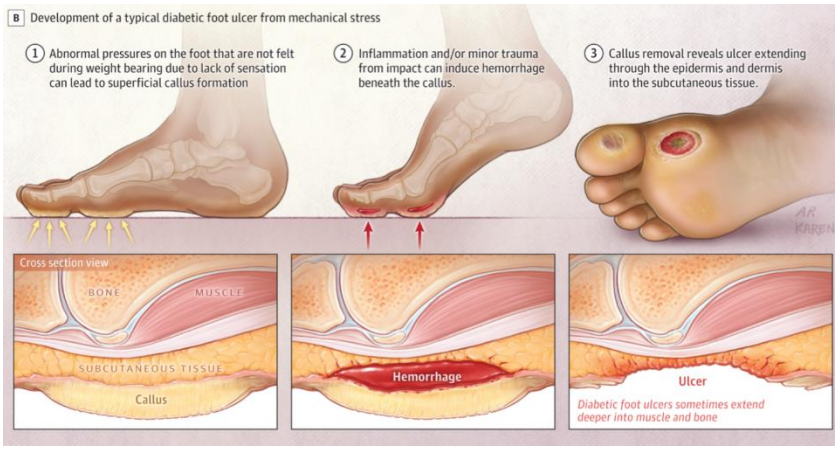


Figure 7. Visual for ulcer development [25]

Figure 8 shows a more refined model classifies ulcer development and ischemia into additional stages [26].

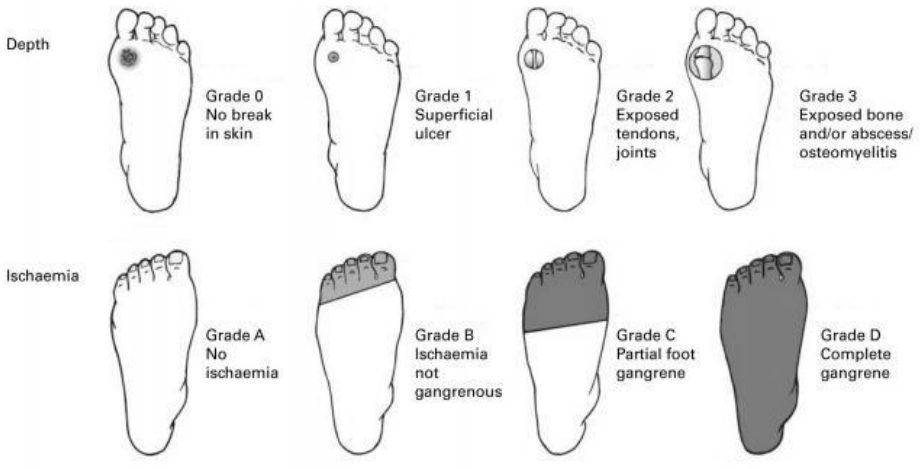


Figure 8. Ulcer Development and Ischemia [26]

DFUs ulcers can be difficult to heal and can lead to serious complications, such as infection, gangrene, and amputation.

Improper footwear and moisturization practices increase the likelihood of ulceration. Risk of ulceration increases by a factor of 32 if neuropathy, foot (muscular) deformity, or previous amputation has occurred [5]. Over time, continued trauma and infection cause tissue damage to become more profound, penetrating deep fascia.

Staphylococcus is the most common infective agent in diabetic ulcers [4]. Antibiotic resistant bacteria are also common, including methicillin resistant Staph aureus [5]. Microbial antibiotic resistance increases the amputation rate in ulcer cases.

Polymicrobial infection with staphylococci, streptococci, enterococci, Escherichia coli, and other Gram-negative bacteria is also common. Infection may take the form of uncomplicated cellulitis (bacterial infection of profound skin layers) initially and develop into necrotizing fasciitis (via continual tissue degradation), which may be life threatening or necessitate amputation [5]. Bacterial penetration is sped up by damaged or poorly perfused skin. This may also lead to sepsis. Some infections may be gas-forming as a result of microbial metabolism.

As can be seen, the relationship between diabetes, peripheral nerves, and peripheral arteries is complex. However, it is evident that high blood sugar levels can damage both peripheral nerves and peripheral arteries, leading to a variety of serious complications.

Clinical Presentation

Given the intricate, multifaceted nature of diabetic foot ulcers and their associated pathologies, examination may involve a complex and diverse set of procedures. Given that our patient population is diabetics, it will be assumed that diabetes has already been diagnosed and explicit description of diagnostic symptoms of diabetes alone will not be discussed.

Firstly, symptoms of physical trauma and damage may be observed [5]. Sorted by order of the degree of development of an ulcer, patients may present with corns, calluses, subcutaneous hemorrhage, and tissue degradation. These are most likely to be observed at pressure points, which should be examined closely [6]. Ulcer occurrence may be bilateral – both lower extremities should be checked. Redness/inflammation, induration, and edema are all risk signs of ulcer development [5]. Tactile response at inflammation sites should be examined to determine if the patient presents tenderness along tendon sheaths and deep structures, indicative of penetration of inflammation/immune response. Patients may present with osteomyelitis, which should also be examined. Foot/toe deformity and lower extremity muscular atrophy (see pathophysiology) should also be examined as precursors for ulcer development. Plantar fat pad dislocation and atrophy may be present. Foreign bodies may be present in ulcers, calluses, or regions of concern for ulceration. Probe-to-bone tests may indicate osteomyelitis, an amputation precursor [4].

Patients may also present with arterial flow deficiencies/occlusion, symptoms of PAD [5]. Doctors should check that a patient has a palpable pulse in the posterior tibial and dorsalis pedis arteries. Insufficient flow as detected by palpation should be further investigated. A quantitative measure of flow can be used to better determine the degree of occlusion that a patient presents. Continuous-wave doppler ultrasound can be used to verify pulsatile flow. Ankle-brachial systolic pressure indices may be below the normal range of 0.9 to 1.3 and toe systolic pressure may be less than 80% of ankle pressure. Such deficiencies are indicators of the localization of peripheral artery disease. It should be noted that calcification can falsely elevate ankle pressure, while toe pressure may be significantly lower (<80%). Artery wall and soft tissue calcifications may be visible in plain radiography studies or MRI/CT angiography.

Patients may present with PN. Patients with PN may display insensitivity to light touch, pin prick, temperature, and vibration. Patients may lose Achilles and patellar reflexes as a result of autonomic nerve necrosis.

Patients may present with microbial infections. Tissue gas (subcutaneous), osteomyelitis, edema, cortical bone erosion and swelling may all be present in radiography and

indicative of infection. Cortical bone erosion is an indicator of chronic infection (>14 days).

There are three main types of DFU: neuropathic (35%), neuroischemic (50%), and ischemic (15%) [27]. These classifications are based on the presence or absence of PN and associated sensory loss (neuropathic), PAD (ischemic), or both (neuroischemic). Classic neuropathic ulcers present as painless, "punched out" round ulceration on the plantar surface of the foot with raised or macerated margins and thick surrounding callous (Figure 9). Ischemic or neuroischemic ulcers are characteristically irregular lesions, often with a necrotic base, sometimes presenting as gangrene or round ulcerations at points of ischemia (Figure 9). Additionally, ischemic and neuroischemic ulcers are more likely than purely neuropathic ulcers to present as larger ulcers, midfoot ulcers, or hindfoot ulcers and to present with abscess or osteomyelitis [27].

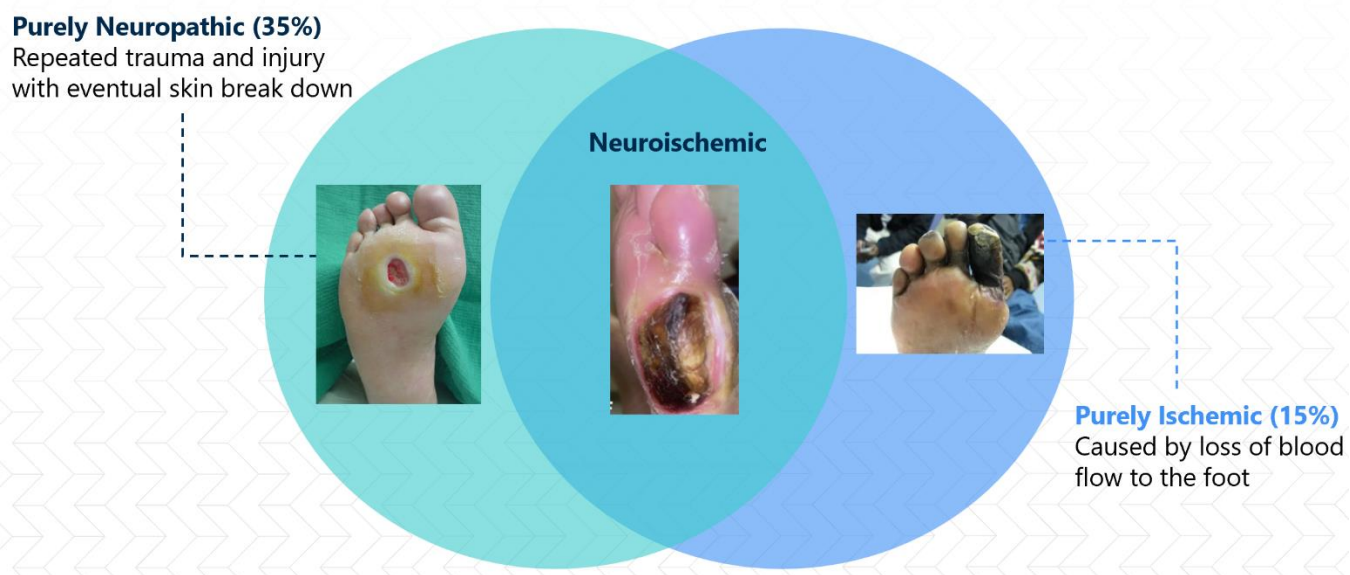


Figure 9. Types of DFUs [28]

Clinical Outcomes

A number of factors and treatment outcomes are possible, the likelihood of which may be influenced by care quality [4]. Success is greatest with interdisciplinary care. Involving a podiatrist, primary care physician (PCP), vascular surgeon, endocrinologist, and infectious disease doctor has been shown to be effective. Patient education, 3 month checkups, self-examination, proper hygiene, and proper footwear are necessary for optimal clinical outcomes [4,5]. The prognosis of ulcers is positive if identified early and treated properly. A major factor in most negative outcomes is delay of care. Negative ulcer outcomes may include gangrene, osteomyelitis, sepsis, permanent deformity of the foot, and amputation. Hospitalization is often necessary if patients are

noncompliant, unable to care for the wound, or unable to offload pressure. Antibiotics are very frequently used to treat infections of ulcers. However, this may cause the development of antibiotic resistance.

About 20% of diabetic patients have unhealed diabetic foot ulcers after 1 year of incidence [7]. Foot ulcers have a recurrence rate of 40% in one year [7]. Diabetics with healed ulcers experience ulcer recurrence within 5 years at a rate of 66% [29]. Infection develops in 50 to 60% of ulcers [8]. The incidence of osteomyelitis in moderate to severe ulcers is 20% [8].

There is an overall 15-20% amputation rate upon the development of an ulcer in a patient with diabetes [30]. Re-amputation is a common outcome after amputation has occurred. Within 5 years of a diabetic patients first amputation, 46% will have an additional amputation [31]. Amputation results in various compounded adverse outcomes. Psychological outcomes may be affected by amputation – depression occurs in 36% of individuals with limb loss [32]. Lifetime care costs are $140,000 above average for amputees than those without amputations [33].

Survival in DFU patients is significantly worse compared to diabetic patients without foot complications. DFU patients have a 5% mortality rate in the first 12 months and a 5 year mortality rate of 49% [7].

Epidemiology

The global diabetes prevalence in 2019 was estimated to be 9.3%, or 463 million people [34]. The aging of the world population and obesity epidemic in the US are likely to increase the prevalence of diabetes. Roughly 10% of the global population, corresponding to 642 million individuals, are projected to be diabetic by 2040 [35]. The development of foot ulcer in a diabetic patient has been estimated to be 19%-34% throughout their lifetime [7]. It is estimated that 20% of diabetic patients will be hospitalized for a foot condition [5]. The overall annual risk of developing foot ulcers for diabetics is 2.5% [5].

Diabetes and diabetic foot ulcers disproportionately affect underserved populations. As seen below in Figure 10, adults from racial and ethnic minorities have increased prevalences for diabetes for both men and women when compared to Caucasian adults [35].

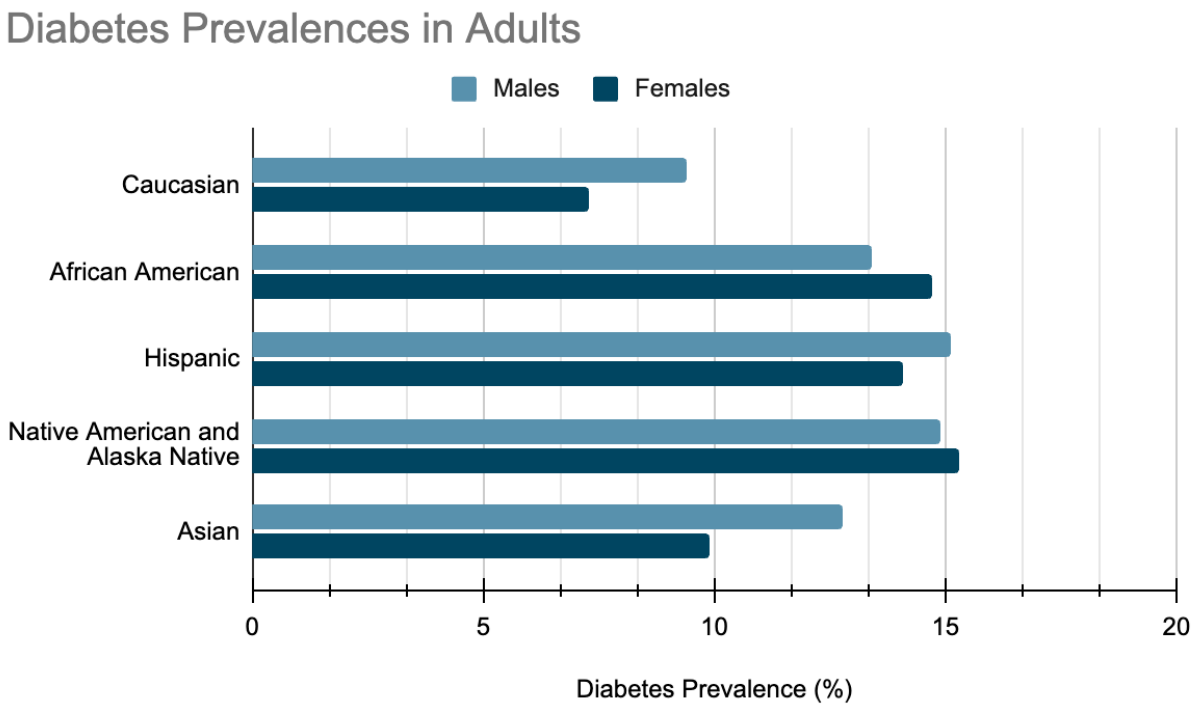


Figure 10. Diabetes Prevalences in Adults.

With increased prevalences of diabetes, Latin American, African American, and Native American populations have the highest relative incidence of diabetic foot ulcers in the US [4]. Many racial and ethnic minorities also experience reduced access to care, leading to later ulcer diagnosis and increased hospitalization risk [35]. For Black and Hispanic individuals, revascularization procedures are less likely and amputations are more likely than for Caucasian adults when accounting for the differences in incidence rates [35]. Several studies measure differences in the negative outcomes of diabetic foot ulcers, often focusing on lower leg amputation rates. About 60% of lower limb amputations result from diabetes or diabetic complications [36]. One study analyzed data from 124,487 people hospitalized because of diabetic foot ulcers [37]. While 17.6% of patients hospitalized with diabetic foot ulcers underwent amputations, this proportion was increased for both rural patients at 18.3% and Black patients at 21.9%. Moreover, patients that identified as both rural and Black had a rate of 28%. The increased rates of negative outcomes highlight the disproportionate burden of diabetic foot ulcers.

Other studies have controlled for time and found similar results [36]. After analyzing the timing of lower limb amputations after the diagnosis of a diabetic foot ulcer in Medicare fee-for-service beneficiaries, researchers found that African Americans had an increased likelihood of having a lower limb amputation within a year of diagnosis. Specifically, African American patients were 1.98 times as likely to receive a lower limb amputation

within a year than Caucasian patients. Black patients additionally were more likely to experience complications after lower limb amputations, decreasing survival rates. Studies that controlled for other factors increasing lower limb amputations found similar racial disparities in lower limb amputations rates [36]. For example, another study found reduced limb salvage attempts before lower limb amputations for African American patients relative to Caucasian patients [38]. Several studies have shown that nonsurgical measures can be effective in treating diabetic foot ulcers, but that there are also racial disparities in access and adherence to these measures that compound the racial gap in outcomes [36].

In addition to racial disparities found, there we gender-based differences in lower limb amputation rates [36]. Hospitalization rates for diabetic men and women for foot ulcers were equal. However, lower limb amputation rates for men were higher while mortality rates because of lower limb amputations were higher for women. Increased severity of comorbidities for women and possible hormonal differences that lead to relative resistance to neuropathy for women were two mechanisms suggested for these differences [36].

Geographic differences also lead to uneven burdens of diabetic foot ulcers. Specifically, rural Americans with diabetic foot ulcers are 1.5 times as likely to undergo major amputations and 1.4 times as likely to die relative to urban Americans [39]. Approximately one in five Americans can be classified as rural Americans so the impacts are widespread. The major reason behind these differences is cited to be the disconnect between urban and rural healthcare systems. As a result, the referral processes across healthcare networks are very demanding of time and effort. The presence of multiple, disjoint health records between the health systems further complicates this process and the lack of nearby specialists can make provider interactions negative for patients. In contrast, urban healthcare networks are typically connected with interdisciplinary teams and vast referral networks with numerous specialists. Thus, there is not a significant disconnect between primary and specialized care in urban healthcare systems as there is in rural healthcare systems. These factors all contribute to a reduced relative access to care for rural populations [39].

Some studies have shown that some of the racial gaps in diabetic foot ulcer outcomes have decreased over time [40]. When analyzing the rates of major lower extremity amputations from 2003 to 2014 for diabetic foot ulcer patients in the largest public inpatient care database, researchers found that the total amputation rate as well as the racial gap in major lower extremity amputations decreased in that time frame. By 2014, there was no longer a significant difference in amputations rates between African American patients and Caucasian patients. However, the length of hospital stays and

total hospital costs associated were still relatively higher for African American patients, although the gap in time of stay and costs had also decreased. The researchers attributed the decrease to several reasons, including the Affordable Care Act (ACA) increasing access to healthcare as well as improved non-invasive intervention and prevention strategies [40].

Another study more directly looked at the ACA to see if it had reduced the gap of diabetic foot ulceration outcomes between Caucasians and racial and ethnic minorities [41]. Specifically, major amputation rates and hospitalization rates were compared in 115,071 hospitalizations across states that adopted the ACA early and states that did not adopt the ACA. Both major amputation rates and hospitalization rates were reduced in early-adopter states relative to non-adopter states. Specifically, hospitalizations increased 3% in ACA-adopted states and 8% in non-adopted states. Meanwhile, amputation rate was stagnant in ACA-adopted states but increased by 9% in non-adopted states. Uninsured adults had a 33% reduced amputation rate in ACA-adopted states and no change in rate in non-adopted states. Thus, policy pathways have shown some improvement in closing the racial gap in diabetic foot ulcers [41]. Similarly, there are likely pathways to close the gaps based on gender and geographical differences. For example, increased connectivity in urban health systems reduced major amputation risk by 40% and can perhaps be extended to encompass and incorporate rural health systems [39].

Economic Impact

The global foot ulcer sensors market size was valued at $158.0 million in 2022 and is estimated to grow at a compound annual growth rate (CAGR) of 3.7% from 2023 to 2030 [42]. Foot ulcers sensors are devices that are used to monitor and track the healing process of foot ulcers, thereby reducing the risk of amputations. There are several types of sensors that can be used to indicate the presence of foot ulcers, including temperature sensors, pressure sensors, and moisture sensors.

Furthermore, foot ulcers sensors technology entails the integration of sensors with other advanced technologies, such as wearables and mobile devices. Wearable devices are being developed that incorporate foot ulcer sensors to monitor foot health in real-time. Mobile apps are also being developed that can receive data from foot ulcers sensors and provide alerts and recommendations to patients and healthcare providers.
North America has dominated the market and accounts for the largest revenue share of 34.2% in 2022. This is owing to the rapidly increasing number of diabetic patients in the region. In 2022, the North American foot ulcer sensors market was valued at $54.0M [42].

Though we do not believe existing technologies provide adequate solutions to the issue of diabetic ulcer monitoring, they are certainly existent [43,44,45,46]. Thus, the market is not entirely untapped, limiting the expected market share of whatever solution we may develop. In 5 years we would like to have 7.5% percent of the US diabetic foot ulcer monitoring market, corresponding to $4.05M. In 10 years, we would like to have a 15% market share, corresponding to $8.1M.

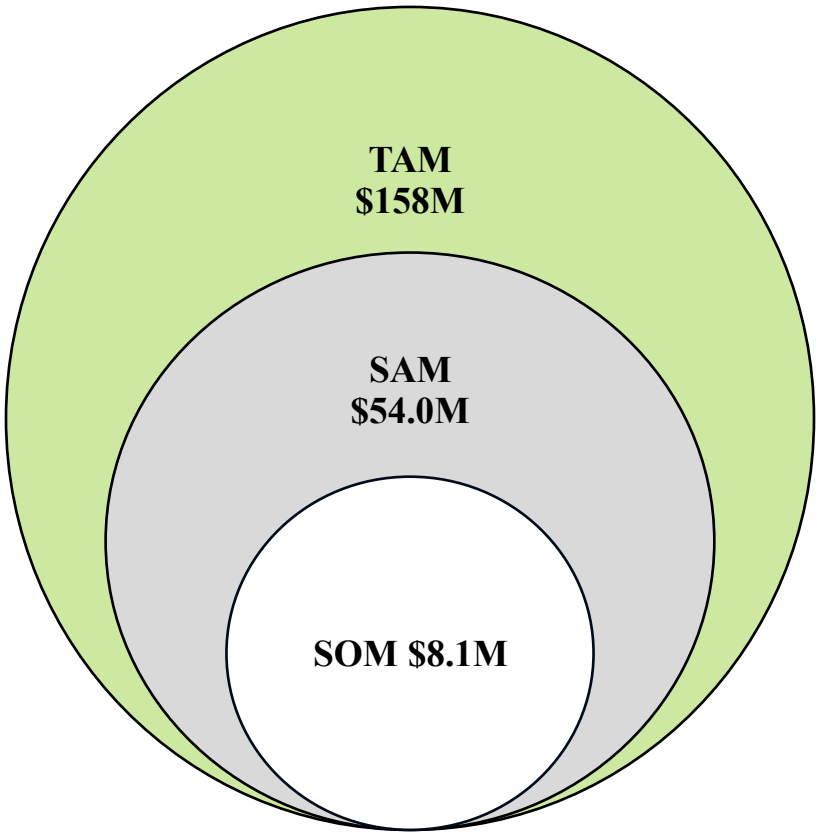


Figure 11. TAM SAM SOM

Treatment Overview

Though the standard of care for ulcer detection in most clinics is simply educating patients on the techniques involved in and value of completing foot checks [15, 16], several additional technologies have been developed.

One existing solution used in certain clinics, such as select Veterans Affairs (VA) care systems [44], is the remote temperature monitoring mat (RTM) [43].

Figure 12. Remote Temperature Monitoring Mat Pathology Detection [44]

Daily foot temperature monitoring with this device is meant to identify inflammation on the foot, which is not easily visible to patients – particularly the large elderly and obese patient populations. Standard use is 20 seconds daily. The most popular RTM system from Podimetrics consists of around 1000 thermistor sensors that creates a thermogram with an accuracy within about 0.6 degrees Celsius [43].

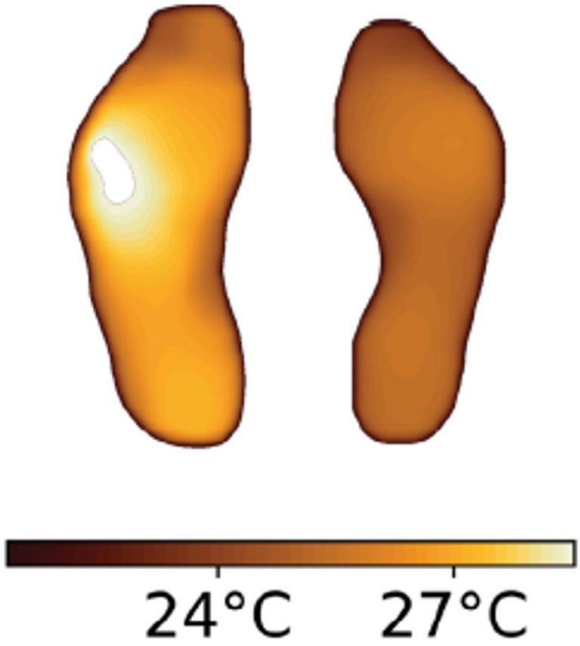


Figure 13. RTM Thermogram Output [47]

Data is de-identified then sent to a server to be processed and stored. This tool allows detection of inflammation in diabetic foot ulcers before a patient enters the clinic. RTM mats are recommended by a large number of clinical/educational organizations as a standard of care, including the International Working Group of the Diabetic Foot and the Wound Healing Society [43]. Early studies suggested that they were effective in decreasing foot ulcers by as much as 85% [43, 44]. RTMs utilize a simple dermal thermometer to identify inflammation. It was determined that a difference in foot temperature greater than 4 degrees F in 6 locations on each foot should be indicative of a need for care. A study found this method to be 97% effective in detecting non acute plantar ulcers with a lead time of 5 weeks. False positive rate was 57%, which is remarkably high. 88% of patients in a study reported that the mat was "very easy to use [43]." The mat was found to be accurate in monitoring patients with partial foot amputations and healed ulcers.

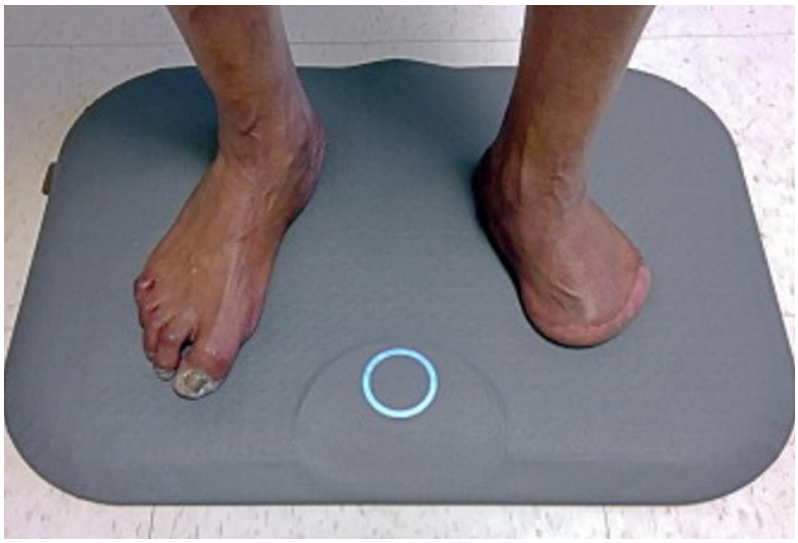


Figure 14. RTM Mat use with Partial Amputation [48]

According to the VA, clinical trial data and audits have shown that RTMs [44]. RTMs had 86% patient engagement over 12 months, caused a 52% reduction in hospitalizations, and caused a 40% reduction in ER visits.

Another existing solution is the smart sock. As done with RTMS, smart socks monitor temperature as a sign of inflammation. The most notable smart sock for monitoring diabetic foot ulcers is produced by the company Siren Care (Figure 15) [45].

Figure 15. Siren Sock Underside Sensor View [45]

Smart socks are designed to be worn daily. They allow for continuous temperature monitoring. The data are sent to nurses for review and to check for signs of inflammation. Care teams are alerted when abnormalities in temperature occur. They function independently of a smartphone, don't need charging, and are machine washable. They are also covered by Medicare. Use as a provider requires training, application, and certification. However, after this, little intervention is required. The company that produces them manages setup, utilization, and technical support.

Figure 16. Typical Siren Sock Package Sent to User Upon Prescription [45]

Smart socks are on the market but not as extensively deployed as RTMs, so data on outcomes, compliance, and other notable factors are not as available. The statistic that they tend to use as a selling point is that temperature monitoring has been shown to reduce the occurrence of diabetic foot ulcers by 87.5% [45].

Another broad category of existing solutions is foot monitoring apps. Numerous mobile apps exist for organizing and encouraging self-monitoring (or clinical monitoring) of diabetic foot ulcers. Two notable examples will be considered.

DFUCare, a deep-learning-based mobile app was trained on an extensive set of 5000 diabetic foot ulcers. It allows for binary classification of infection vs non-infection. It used the pretrained InceptionResNetV2 model for feature extraction. Its diagnosis was on the basis of color and textural feature extraction. It also uses standard image

processing to assess severity of infection over time [46]. This resulted in a binary accuracy of 0.9014.

Another example of a foot monitoring app is MyFootCare [49]. This app is much more well-studied and higher fidelity than DFUCare.

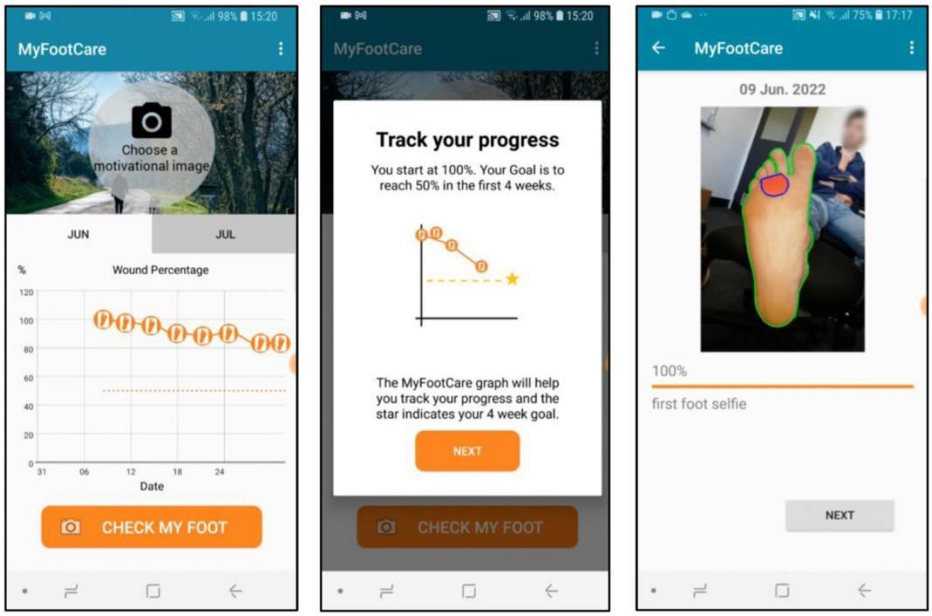


Figure 17. MyFootCare UI [49]

MyFootCare is an app intended to enable "self-monitoring" of foot ulcer healing progression based on pictures from one's smartphone camera. Pictures are generally taken by another person. This app was believed to address a need for automation of foot ulcer monitoring and removal (to some degree) of the physician in this process. Carers are still able to monitor data obtained on this app if desired. Previous apps intended pictures to be remotely assessed by physicians. MyFootCare uses simple visual analytics to monitor ulcer size and track the healing process objectively. It allows users to develop a progress graph, where they can visualize percent reduction in size relative to initial size in ulcers. MyFootCare has simplistic analytical/image processing capabilities. Users must draw lines to help identify the ulcer vs the background. Users must manually add notes about changes and complications.

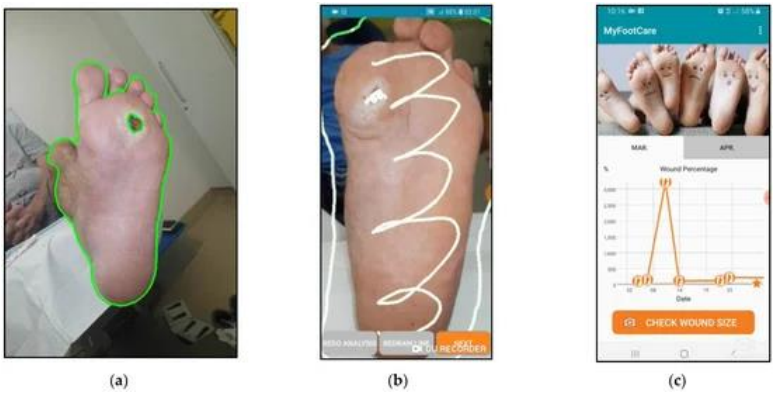


Figure 18. MyFootCare Annotations and Outputs [49]

MyFootCare also stores previous foot checks, sends notifications as reminders (to increase compliance), and displays motivational images. In one study, 10/12 people who used MyFootCare over 3 months found it valuable to monitor progress. However, one third of patients failed to use the app after a few weeks and another third used the app between 10 and 19 times over the 3 month time period [49]. Patients expressed frustration with using their smartphones, lack of accuracy and reliability, as well as frustration with having to re-do foot checks.

As a whole, mobile apps tend to be accessible in some senses – they are accessible anywhere with cell service and do not require a prescription. They are cost-effective after overcoming the cost of purchasing a smartphone. Still, they may not be accessible to the significant portion of the population for whom this is not possible. Like the other devices mentioned, they also enable remote monitoring of foot condition [46]. Many applications intend for a second individual to take pictures. This may decrease the value of a "self monitoring" tool. Still, care teams are not necessarily involved.

One emerging solution is biosensing insoles. Some of these solutions are on the market. However, many biosensing insoles for the purpose of ulcer infection detection and treatment are currently being researched or are in their development phases. These have not been widely clinically integrated. These insoles/orthotics have largely focused on monitoring temperature, providing benefits similar to RTMs. Attempts to measure other biomarkers are not as frequently observed, but pressure monitoring insoles and insoles that monitor both pressure and temperature can be identified [50]. One solution that is currently in development measures both temperature and pressure while also regulating temperature with a cooling system [51].

One low/medium fidelity example of an insole that monitors both temperature and pressure serves as a proof of concept for combinatorial biosignal monitoring in insole form [50]. The device was able to measure pressures and temperatures above a desired

threshold and issue a warning to its user during testing. Testing was not extensively conducted. No relevant clinical data was obtained. This device is purely a proof of concept and results should be interpreted skeptically. The device had Bluetooth control/feedback. Sensors were implanted into a compressive orthotic and other components were set on a PCB (Figure 19).

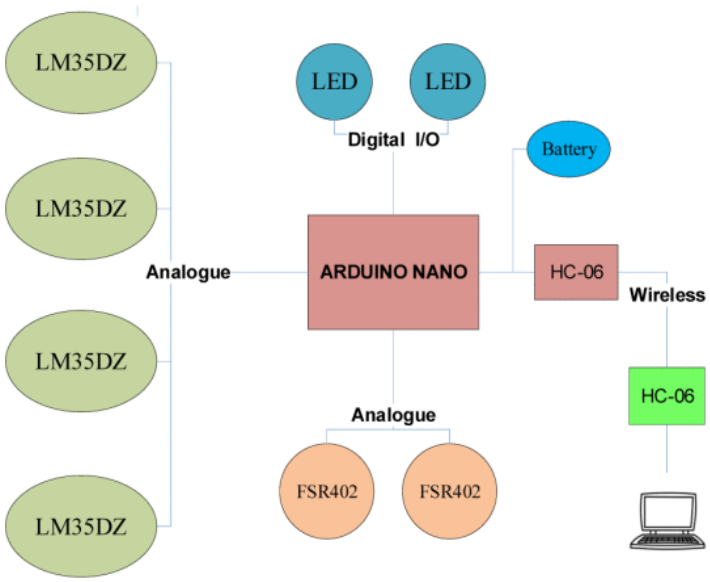
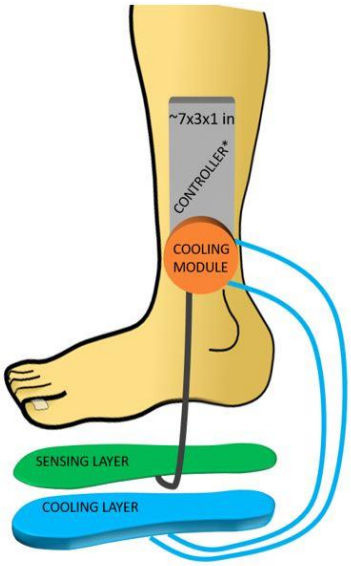


Figure 19. Pressure/Temperature Sensor Block Diagram [50]

Another emerging solution does both temperature and pressure monitoring, as well as temperature regulation. The Temperature and Pressure Monitoring and Regulating Insole (TAPMARI) was designed to monitor key biomarkers for early ulcer detection. It also implemented a "novel cooling/heating technology" with the intention of reducing skin breakdown and ulceration, though this is not relevant to our project, given that it is a therapeutic.



TAPMARI Diagram [51]

TAPMARI was intended to have clinical research applications in studying the efficacy of hypothermia as a treatment model in diabetic ulceration. It may be intended for future use as a prescribed therapeutic. One limited study (n=8; n=3 with diabetic neuropathy) analyzed the effectiveness of TAPMARI at regulating temperature [52]. It also revealed additional information regarding device functionality. The device was shown to be effective at lowering foot temperature, which was believed may decrease metabolic needs of tissues. Temperature was lowered from 28 degrees Celsius at baseline to 26 degrees Celsius after exercise. The mean temperature of the patients' other foot, which was unregulated, was 32 degrees Celsius. Data were also obtained regarding pressure distributions, though this was not the primary goal of the study. The following image depicts the device being worn, peak pressure distributions, baseline foot temperatures, and post-exercise temperatures (Figure 20; R = regulated, C = control). The authors argued that the vasodilative effect of low temperatures would not be damaging to ulcer healing if used during periods of mechanical stress (e.g., walking).

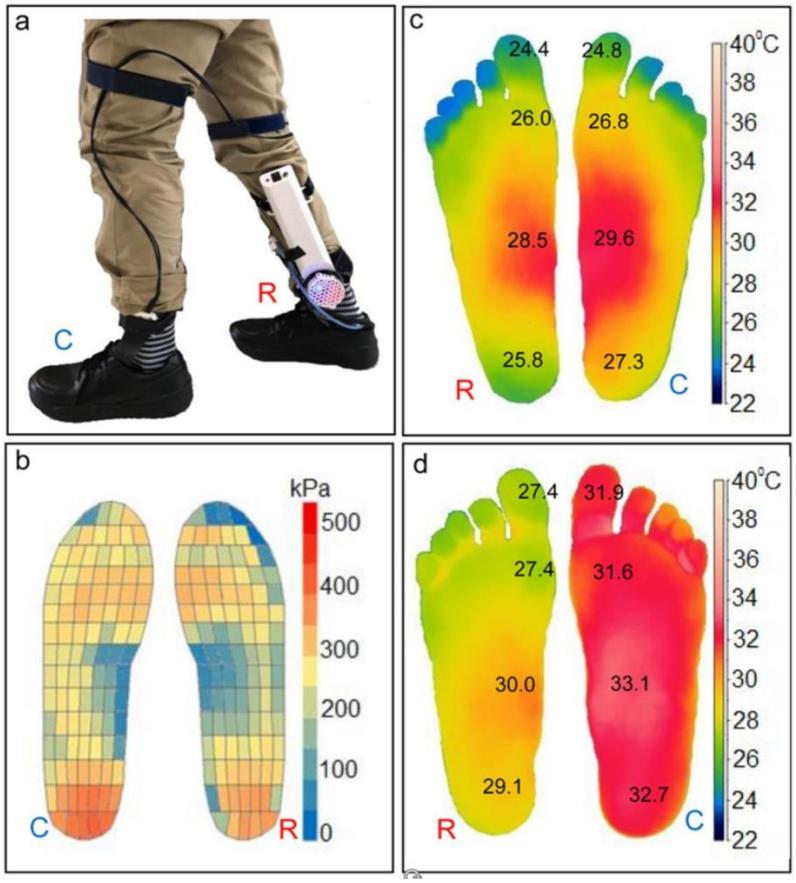


Figure 20. TAPMARI Usage and Outcome [52]

Gap Analysis

The remote temperature monitoring mat (Podimetrics mat) measure local foot temperature signatures as indicator of ulcer presence. However, the measurements are infrequent and episodic [43]. Moreover, this solution is not an entirely comprehensive monitoring tool as it only measures temperature, which leads to high false positive rates and causes it to only detect ulcers once inflammation has progressed significantly [43]. Patients are required to devote time to the act of foot monitoring exclusively, which is inconvenient and may decrease patient compliance.

Smart Socks (Siren Sock) can be a hassle to use because they require greater maintenance (i.e. washing, replacement, troubleshooting), which could decrease patient compliance. Accessibility is also a challenge, as the use of this product requires approval of a provider's application. The technology is not widely integrated into clinical practice.

Existing smart socks also only measure local temperature, causing them to be not an entirely comprehensive monitoring tool for the same reason as the remote temperature monitoring mat. Furthermore, Siren Socks only place temperature sensors at locations they deem to be high risk for ulcer development, allowing for ulcers in other locations to be missed. Finally, the socks are designed for intact feet and may not be a feasible option for patients who undergo an initial amputation.

The foot monitoring apps (MyFootCare, DFUCare) are purely visual/image processing, which may overlook key diagnostic markers and delay detection. The processing techniques are not only noncontinuous, but also are often simple and of limited clinical value. This approach requires involvement of another person, ability to use a smartphone, and for patients to devote time to the act of foot monitoring exclusively (all of which decrease patient compliance and accessibility). In fact, studies have found that patient compliance is very limited [49]. Part of this is attributed to patients expressing issues with usability [49].

Biosensing insoles can be bulky and uncomfortable (especially when integrated with therapeutics, as is the case with TAPMARI) or restrict patients to using particular shoes, potentially decreasing patient compliance. Existing models have not been proven to detect early-stage ulcer or callous formation. Most existing insoles monitor some combination of local temperature and pressure. As with the mats, temperature alone may not be comprehensive enough to yield optimal diagnostic outcomes, given the high false positive rate and the dependency of detection upon progression to notable levels of local inflammation. Local pressure is a valuable biomarker because it indicates locations which may be of high risk for ulcer development but does not indicate the presence of an ulcer itself. Thus, these tools have increased monitoring capabilities and provide valuable insight for ulcer prevention, making them one of the strongest tools for early-stage detection. Still, their inability to detect the presence of callouses and ulcers prior to significant inflammation leaves room for improvement. Furthermore, because of limited insurance coverage, they are very inaccessible. Given that this is an emerging solution, many biosensing insoles are still in early development and not commercially available. Many of these products also have not been designed in a manner that allows them to interface with clinical systems.

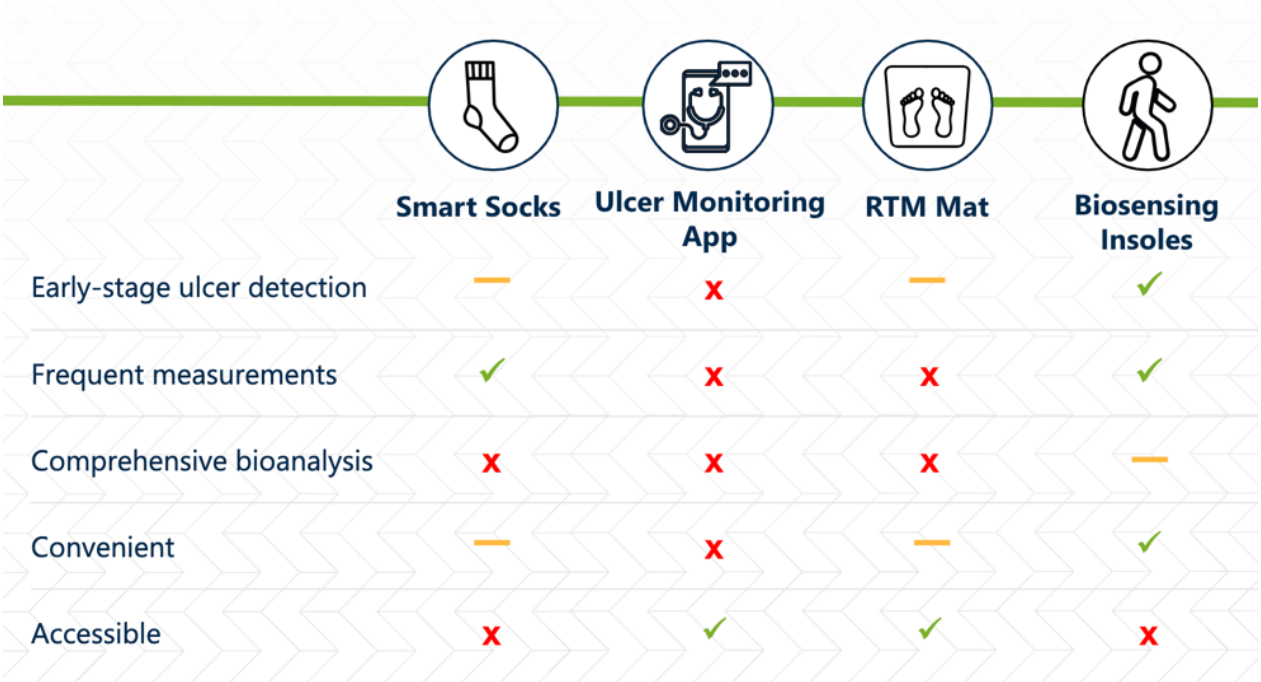


Figure 21. Gap Analysis Visualization

III. Design Inputs

Cycle of Care

A cycle of care diagram outlines the general timeline that DFU patients experience, from the time they develop diabetic symptoms onward. It is important to note that this cycle of care diagram considers only purely neuropathic DFUs, rather than ischemic or neuroischemic.

This diagram emphasizes the negative outcomes that often result from a late diagnosis: osteomyelitis and amputation. The care cycle also shows a more positive clinical outcome as a result of the patient diligently checking his/her limbs. It is important to recognize that existing DFU screening tools are located near the end of the care cycle and are oftentimes only prescribed to patients who experience an ulcer to a certain level of severity. This delayed screening process highlights the need for an earlier screening method to detect DFUs before the patient does.

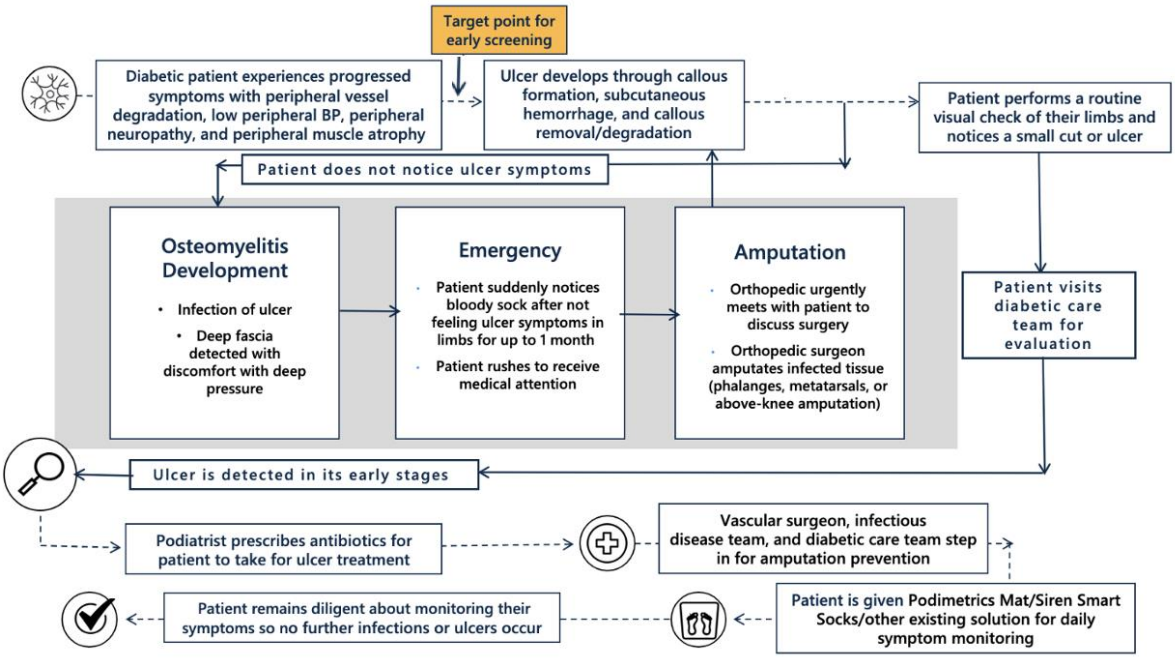


Figure 22. Cycle of Care Diagram

The following diagram shows a simplified version of the cycle of care, in which there are two main cycles a patient can be caught in. The upper (green) care cycle represents the positive outcomes that result from a patient who diligently checks their limbs and notices an ulcer early. The lower (red) care cycle represents the other path, where many patients end up after they wait too long (intentionally or otherwise) to seek care for their foot ulcer. By the time these patients seek care, osteomyelitis, or an infection within the bone, has already set in, and an orthopedic surgeon must amputate the infected tissue.

The dashed arrows in the diagram represent the high likelihood of reinfection, where patients end up back at the start of the care cycle with a new foot ulcer. Unfortunately, many patients end up repeatedly going through the lower care cycle, which has been bluntly coined the “chop shop”, in which patients undergo several amputations that move progressively higher up the leg.

The target for early screening is positioned between the patient unknowingly developing an ulcer and the ulcer worsening by becoming deeper and/or infected. The goal of this screening is to redirect some of the patients towards the upper care cycle, which has much more positive clinical outcomes than the lower.

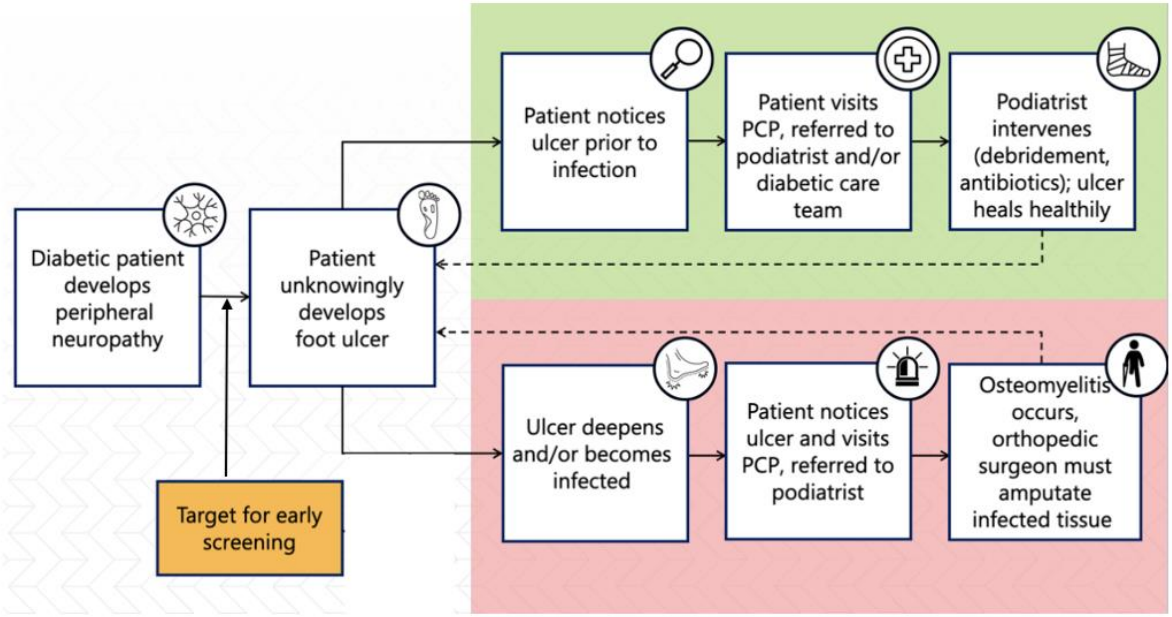


Figure 23. Focused Cycle of Care Diagram

The development of an ulcer is gradual and can be classified on a scale from grade 0 to 3. The goal for early screening is to detect the formation of an ulcer at or before grade 1, since these early-stage ulcers are more easily treatable with noninvasive devices (ie. total contact casts, CAM boots). Intervention at this stage also results in better clinical outcomes, with a high success rate (97% success, according to Dr. Sam Quesada of the Palo Alto VA). Narrowing the target for early screening to grades 0 and 1 is important so that biomarkers for early-stage ulcer development can be more thoroughly researched by the team in preparation for the development of a DFU screening method.

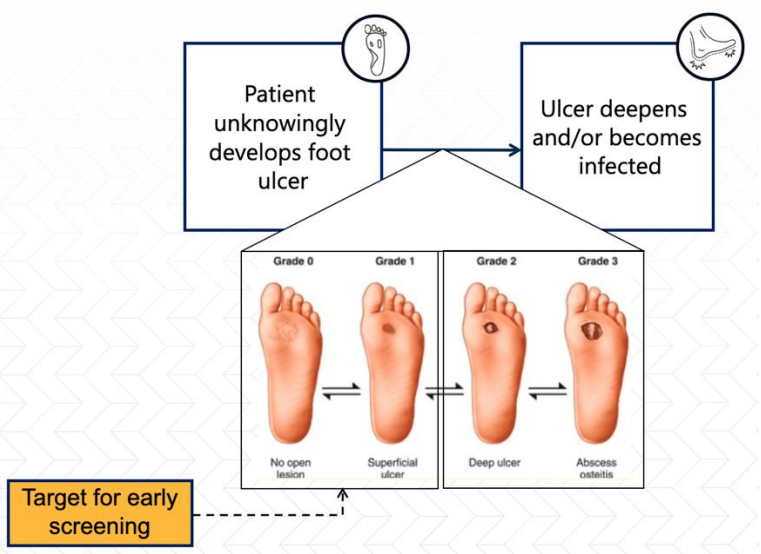


Figure 24. Cycle of Care Target for Device Use

Stakeholders

Below is a table of DFU stakeholders along with their respective roles and needs. The relative priority level of each stakeholder was assigned based on the stakeholder's investment in the problem. Identifying the top stakeholders helps to qualitatively weigh the importance of each of the needs in determining the functional requirements for the solution.

Stakeholder	Role	Needs	Priority
Diabetic patients	Experience diabetes symptoms, have to check limbs for ulcers, risk of amputation	A fast, user-friendly way to detect early foot ulcer development	High
Podiatrists and diabetic care team	Recommend ulcer treatment plan	A way to be notified when their patients have early foot ulcer development	High
Patient family members	Help patients by regularly checking their limbs	A way for diabetic patients to monitor their limbs independently	Moderate
Vascular surgeons and orthopedic surgeons	Perform amputations	A way to lower the number of amputations performed on diabetic patients	Moderate
Hospitals	Pay for ER staffing and resources	A way to lower the number of ER visits from diabetic patients with late-stage ulcer symptoms	Low
Insurance companies	Pay for a portion of medical care	A way to lower the total cost of diabetic ulcer care	Low

Figure 24. Stakeholder Evaluation

Value Proposition

The existing DFU screening solutions provide some patients with an accurate screening method that alerts them about alarming DFU symptoms. Of the devices that are available, there are varying levels of accessibility regarding user interface, especially

considering the older population of diabetic patients. Based on the current market landscape, the area that a solution could add the most value is providing a fast, frequent method of screening for early-stage ulcers in such a way that encourages patient compliance and interfaces with clinical systems.

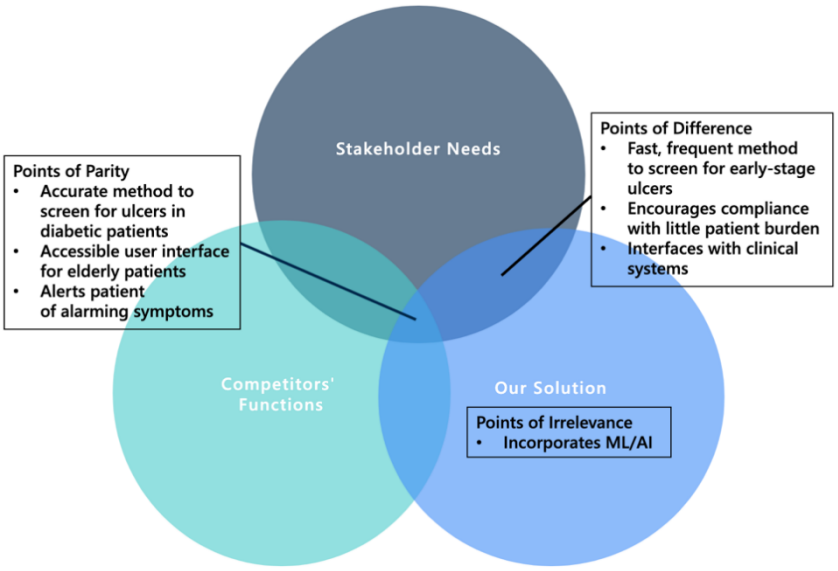


Figure 25. Value Proposition Venn Diagram

Functional Requirements

Based on the needs outlined by the major DFU stakeholders, the functional requirements of the solution are:

1. Detect the presence of an early-stage foot ulcer.
2. Alert the patient about potential pathological abnormalities.
3. Interface with clinical systems to alert the podiatrist and/or diabetic care team about symptoms.

Functional Requirement	Design Specification
Detect early-stage ulcers	Identify ≥ 90% of ulcers at or before Grade 1 on the Wagner scale
Alert patients	≥ 3 different levels of risk severity are considered
Interface with clinical systems	Score > 4 on user-defined scale to assess provider perception of device data integration

Constraints

Constraint	Design Specification
Convenient	Score > 4 on user-defined scale
Safe	User-defined scale and IEC 60601 for medical device electrical safety
Easy to Use	Score > 4 on user-defined scale
Equitable	Score > 4 on user-defined scale

1. Easily integrates into patient's lifestyle (convenient)
2. Safe
3. Ease of use
4. Equitable in diagnosis
5. Durable (resistant to loss of structure or function during repeated, normal use)
6. Universal usage regardless of lower extremity morphology
7. Low cost and/or reimbursable
8. Low profile

Our research highlighted that compliance and usability were the major gaps in existing solutions. These gaps suggest the high importance of constraints one and three. Constraint two, safety, is a given with medical devices and is always important, but compliance was the major gap found and that ties in most with constraint one. Existing solutions like monitoring apps such as MyFootCare, Siren Care smart socks, and remote temperature mats [43] all faced potential issues with compliance and usability. With MyFootCare, compliance issues could be highlighted by a study which found that a third of users stopped using the app after a few weeks while usability issues were highlighted by the users' expressed frustration with using their phones and with having to redo foot checks [49]. With Siren Care smart socks, compliance and ease of use were issues due to the high level of maintenance for the socks with washing them, replacing them, and troubleshooting them [45]. These smart socks also had accessibility issues and clinical integration issues, which further shows the need for constraints one, three, and four [45]. Finally, the remote temperature mat required an inconvenient time commitment from the patient in that they had to actively partake in foot monitoring, posing a compliance threat, and it was also somewhat bulky [43]. Both of these factors with inconvenience and bulkiness harming comfort support the high need for criteria one.

The relative weighting of constraints four are similarly supported by our research which shows how diabetes and diabetic foot ulcers disproportionally affect underserved populations. Racial and ethnic minorities have increased diabetes prevalences, increasing their risk of ulcers, as well as reduced access to care, which could compound

their risk of negative outcomes [35]. Moreover, studies had found that individuals identifying as Black had an increased proportion of amputations, a negative health outcome from ulcers, as did individuals from rural communities [37]. It is important to consider the health inequities related to diabetic foot ulcers when creating a diagnostic device. Accessibility issues can then be addressed so constraint four is important.
In addition to the supporting research, several of our interviews provide insight into our constraint ranking.

In our interview with Dr. Quesada, it was mentioned that many patients do not perform daily visual foot checks or are otherwise non-compliant, primarily due to a lack of ease of use. Dr. Quesada mentioned that "interfacing with medical records, usability, comfort, and frequency" would be crucial design criteria for a diagnostic tool. Medical record interfacing and comfort particularly tie in with easy integration into a patient's life, while usability is closely related to ease of use.

Dr. Sanchez's interview added to the need for ease of use as well as equitability in diagnosis. Many veterans are unable to take care of themselves properly due to educational gaps, so it is important that the device is easy to use and equitable.
Dr. Adams mentioned that many DFU patients are incapacitated such that they cannot see the bottoms of their feet or put on their own shoes. Furthermore, he particularly mentioned that "sometimes they know they have an ulcer, but they don't give a crap because they think it's going to heal." Many DFU patients also live alone. As a result, compliance and ease of use is a major need and easy integration and ease of use would help with this major deficit in compliance. Dr. Adam's also detailed financial inequities that may be responsible for compliance issues in individuals with lower socioeconomic status. He suggested that cost and reimbursability with insurance would be additional considerations to make.

Dr. Forouhi additionally highlighted noncompliance as the major issue. When discussing criteria to emphasize and some possible solution modality spaces, Dr. Forouhi emphasized that solutions should not prevent a person from doing their daily activities and that it "should be part of habit" and "easy to integrate into [their] lifestyle". Comfort was also mentioned. These ideas all suggest the importance of integration into a patient's lifestyle in order to increase compliance. Like Dr. Adams, Dr. Forouhi also mentioned cost as an additional consideration. Ease of use was also mentioned to be very important as many people with DFUs tend to be older.
Finally, Dr. Wamelink again stressed the issue of compliance with existing solutions. Cost was again mentioned in a lesser capacity.

As seen throughout these interview examples, the major issues are compliance and ease of use. Thus, the ability to integrate into a patient's lifestyle and ease of use were among our top constraints. Safety is also a given with medical devices, so it rounded out our top three constraints. Some of our other constraints, like equitability and cost, were reflected in the interviews and the importance that they were given by the interviewee aligned with their ranking relative to the other constraints for the most part. The other constraints were areas that we thought needed to be addressed to contribute to the major constraints mentioned throughout the interviews.

IV. Concept Screening

Idea Generation

1. A sensor idea that could pinpoint local temperature changes by measuring temperature in an array format using thermistors.
2. A sensor idea that measures oxygen concentration (PPG, SpO2) as a way to approximate blood flow to the foot area to predict the severity of neuropathy and severity of the ulcer.
3. A sensor idea that outputs a pressure-dependent voltage to measure pressure on the foot as an indicator of ulcer formation.
4. A method for determining ulcer severity by measuring the relative surface area of the bottom of the foot that is in contact with a sensor.
5. A method for determining the shear modulus of the skin on the bottom of the foot to indicate early-stage risk factors for ulcer development such as callouses
6. A sensor technique that relies solely on visible wavelength light to categorize images of potential foot ulcers
7. A device idea in which a sensor or sensor array can be placed so that continuous monitoring is easy and encourages compliance
8. A device/sensor idea in which displacement sensors are integrated into a mat which the patient stands on to determine high pressure regions of the foot that may have an ulcer
9. An idea to send some sort of foot skin sample to a laboratory to do remote testing to determine if the skin is correlated with certain ulcer indicators
10. A sensor idea in which visible light would be used to categorize images of potential foot ulcers based solely on the color of the skin in/surrounding the ulcer
11. A sensor idea that would (somehow) detect the function of nervous tissue in the extremities to indicate the severity of peripheral neuropathy and the likelihood of ulcer onset
12. A method in which a continuous live stream would be focused on the patient's feet to visually detect changes in foot appearance to indicate ulcer onset
13. A method in which a camera is mounted to the base of a patient's bed so that images of the bottom of their feet can be easily obtained to encourage patient compliance
14. A device idea in which patients would receive feedback about the state of their feet via a mirror that they can interact with, perhaps to interface with a bathroom mat for sensor placement
15. A device idea which acts like the existing temperature mat solution except that it is integrated with an everyday scale to encourage compliance and to allow for interactive features

16. A device idea similar to the existing temperature-based mats, except it looks at a pressure distribution over the area that the patient is stepping on
17. A device idea similar to the existing temperature-based mats, except it looks at a pressure distribution over the area that the patient is stepping on and is specifically designed to work on the shower so that patients automatically stand on it regularly to encourage compliance
18. A device idea in which pressure sensors are integrated into a pair of smart shoes to measure the pressure distribution around the foot to indicate ulcer onset
19. A device/sensor idea in which ultrasound technology is used to determine the stiffness of the skin on the bottom of the foot to indicate potential calluses that could turn into ulcers
20. A device/sensor idea in which IR transmitters/receivers are placed inside of socks and aimed at the foot to measure absorption in different areas of the foot, perhaps to determine relative blood flow to different regions
21. A sensor idea for using light of different frequencies to determine the relative vascularization of different areas of the foot to indicate the severity of peripheral neuropathy
22. A technique in which the bottom of patients' feet can be easily viewed/ sensed through a clear floor (or mat)
23. A method in which the patient would visit a clinic to get a traditional blood test done to scan for certain DFU-related risk factors in the blood
24. A method in which the patient draws a small amount of his/her own blood and places it into a test kit that determines whether DFU-related risk factors are present in their blood
25. A method in which a strong light is shone at/through the foot so that the tissue surrounding the vasculature becomes more translucent, and the vasculature is more easily visualized
26. A method to use magnetic resonance imaging to determine the relative water content in each area of the foot to determine vascular status around the bottom of the foot
27. A method to use magnetic resonance angiography to visualize the blood vessels in the patient's foot to determine the severity of peripheral neuropathy
28. A sensor idea that relies on the presence of moisture in an ulcer for detection via sticking to the ulcer
29. A device idea in which temperature monitors are integrated into a pair of socks to detect the presence of an ulcer, while providing visual feedback to the patient via color-changing fabric on the outside of the sock
30. A device idea in which the traditional blood test has been condensed to a small test strip, either for use in the clinic or at home

31. A method of obtaining fast, user-compliant images of the bottom of the foot in which the user stands on a photocopy-like machine that scans the bottom of their feet
32. A method of imaging the patient's foot vascularization by first having them ingest a radioactive tracer substance that then emits from the blood
33. A device idea that measures relative displacements in the bottom of the foot to determine pressure distributions based on a topographical approach
34. A device that locally detects the extent (follicle density, hair length, growth rate) of hair growth, which we learned is an indicator of the extent of blood flow to a particular area.
35. Combination of “sock/foot mold” idea and “pressure sensors” idea in which a sock that fits into someone’s lower extremity has pressure sensors integrated into the fabric to measure local pressure as an indicator of risk of callous development or even the presence of a callous itself (ulcer precursor).
36. Insole with a viscous material that deforms based on the morphology of one’s foot and can be measured to get a sense of foot morphology, which may indicate presence of an ulcer or callous.
37. A device that locally detects the extent of skin shininess by measuring reflectivity, which we learned in an interview is an indicator of the extent of blood flow to a particular area.
38. Sphygmomanometer-like device with a cuff strapped around the toe and ankle that can be used to measure TBI and ABI, both of which give a sense of peripheral blood flow, which we learned are valuable quantities for detecting a non-healing ulcer and the likelihood of its healing in interviews
39. Shore durometer (device that measures hardness) used to checked for the presence of a callous on the foot based on the altered hardness of calloused tissue as opposed to regular dermis.
40. Semi electronic tissue compliance meter (a novel device used in a few studies we saw that involves monitoring of the penetration depth and exerted pressure to determine compliance) to detect altered mechanical properties of calloused tissue.
41. Indentometer (device used to measure tissue hardness/stiffness/compliance in some clinics) that is built into a shoe and measures tissue mechanical properties to differentiate a callus from regular tissue
42. OCT-based elastography can be used to characterize the tension in tissues, which may present different patterns in calloused/ulcerated tissues, based on the detected resonance frequency of oscillations.
43. Tissue stiffness, which may be variable in the presence of a callous or ulcer, can be measured with a probe that has a force sensor (measure indentation force) and image acquisition unit that can determine indentation depth with image

processing (various possible means, such as measuring contact area of a conical probe).

44. Tissue stiffness, which may be variable in the presence of a callous or ulcer, can be measured with a probe that has a force sensor and an IR laser that determines probe displacement.
45. Ultrasound elastography, a type of ultrasound elasticity imaging used in some clinics, projects ultrasound radiation into soft tissues and measures tissue movement during compression to estimate strain and can be used to detect differences in elastic properties of tissues, which may be different in calloused/ulcerated tissues
46. Another type of ultrasound elasticity imaging, shear wave ultrasound elastography, obtains the elastic modulus (which would be different in calloused/ulcerated tissue) of tissue by tracking shear wave propagation through tissue.
47. MRE (magnetic resonance elastography) combines MRI imaging with low frequency vibrations to create a stiffness map, allowing for ulcer detection based on morphology imaging and tissue stiffness.
48. Use pressure sensors and turn pressure distribution readings into a corresponding image with certain brightnesses, which may help identify areas of risk of ulcer/callus development, as well as areas in which an ulcer/callous may have already developed
49. A quantity known as oscillation logarithmic decrement (based on dampening of an oscillatory wave), commonly measured as a means to assess muscle tissue stiffness could be adapted to other soft tissues, and variations in this quantity could be used to identify callouses/ulcers
50. Small, portable, pen-sized tools that have been developed to measure soft tissue stiffness (based on buckling of a long, thin metal bar upon applied force) can be adapted to measure tissue elasticity on the bottom of the foot, which may indicate the presence of a callous/pre-ulcer if deviated from normal
51. Dynamic holography, which involves overlaying morphology images of objects in different stress states as a means to measure elasticity, can be used to determine both foot morphology and local elasticity, variations in which can be used to detect calluses and ulcers
52. Suction of skin into a probe's aperture for some time and subsequent relaxation can be measured as a means to determine both elastic (Young's modulus) and viscoelastic (creep, stress relaxation) properties, which would be locally different in callouses/pre-ulcers
53. Time-dependent change in tissue strain upon introduction of a pushing or pulling step-stress can be measured as a means of assessing the relaxation modulus, which would be different in calloused/ulcerated tissue

54. Time-dependent change in tissue stress upon introduction of a pushing or pulling step-strain can be measured as a means of assessing the relaxation modulus, which would be different in calloused/ulcerated tissue (note that this is the inverse of above and is another common viscoelastic test).
55. Dynamic rheometry, one of the three most common/standard means of assessing viscoelastic properties, can be used to measure the complex shear modulus and phase angle of tissues (which would be different for calloused tissues vs normal tissue) by applying an extensional or rotational stress in a controlled manner
56. Comparable to "shear wave ultrasound elastography" above, measuring velocities and attenuation/dampening of shear waves could be implemented with external vibration or optical microscopy to determine viscous modulus (and elastic modulus, as above), which would be different in calloused/ulcerated tissues.
57. Modification of "Non-optical, suction based measurement of tissue elasticity/viscoelasticity" that places an optical device (laser projection) to measure deformation profile of tissue within an aspiration/suction tube in order to determine local phase angle and/or elastic modulus as a means of differentiating calloused tissue from normal tissue.
58. Tissue sticks to a plate with adhesive and some stretching force is applied, which is measured and compared to displacement to determine elasticity
59. Measure elasticity of local tissue by propelling small object at it; tissue elastic properties can be determined by the nature of the collision and measured mechanical properties of projectile
60. A novel device (as of 2012) that accurately assessed Young's modulus using variable-force air flow (and deformation measurement of some form) could be adapted to determine elasticity of plantar tissues (which would be different for an ulcer/callous than for normal tissue) by projecting air onto the plantar surface
61. We could adapt a very novel (as of 2021), small, soft device was created to measure local stiffness (via an electromechanical technique in which a magnet and AC current are used to vibrate millimeter-depths of tissue, leading to variations in resistance, which can be used to determine stiffness) of tissues, which may be altered in the presence of an ulcer or callous.
62. A device could be made that compresses tissue and monitors color change over time as a means of identifying vascular abnormalities, which may be signs of the presence of an ulcer/subcutaneous hemorrhage OR increased risk of developing a chronic wound/ulcer that won't heal
63. Pulse oximetry can be used by projecting cold light and measuring penetration through tissue as a means to determine percent of oxygenated red blood cells (or other quantities related to blood accumulation) in an area, which may be different for tissues with subcutaneous hemorrhage. Can use concentrations of oxyhemoglobin and deoxyhemoglobin to assess wound progression

64. Use techniques like scanning calorimetry, skin impedance/capacitance measurement, transepidermal water loss detection, skin elasticity measurement, etc to determine how hydrated skin is locally, identifying areas of risk for callous or ulcer development.
65. IR thermometer array can be projected at foot to determine local temperature, which would be elevated at locations of ulcer and subcutaneous hemorrhage because of inflammation
66. Dr. Forouhi mentioned that nail damage is an early sign of vascular disease, so a method that quantitatively classifies nail damage optically can be useful as vascular disease is a risk factor for ulcer formation.
67. Reduced blood flow is a risk factor for ulcer formation, so tracking a consequence of reduced blood flow with tissue death or degradement from reduced nutrition could be useful.
68. As reduced blood flow is a risk factor for ulcer formation, blood flow can be quantified with a technology that adapts Doppler ultrasound blood flow measurement tools in order to quantify blood flow in the foot.
69. Poiseuille's law supports that blood flow rate is directly proportional to pressure difference, so a method to measure capillary pressure in the foot, such as with a blood pressure cuff or an expanding balloon, can quantify blood flow in the foot, allowing detection of reduced blood flow, a risk factor of ulcer formation.
70. Oxygen levels are indicative of blood flow as blood carries nutrients so adapting existing transcutaneous oxygen measurement techniques to non-invasively measure tissue oxygen levels under the skin can detect reduced blood flow, a risk factor for ulcer formation.
71. As ulcer formation likelihood is increased with reduced blood flow, radionuclide imaging methods like SPECT or other ingested or injected radionuclides can be utilized to measure blood flow by washout or other quantification methods.
72. Infrared thermographic methods can be applied as they have been for some peripheral artery disease detection applications as they measure body temperature which varies with blood flow, and reduced blood flood flow increases ulcer formation risk.
73. Microwave radiometry has used to non-invasively measure relative tissue temperature changes in humans to monitor arteriosclerotic plaque inflammation, but it could be applied to thermographically track blood flow to detect reduced blood flow, an ulcer formation risk factor.
74. Reduced blood flow is a risk factor for ulcer formation, so blood flow can be measured with thermal clearance methods which can apply heat to the foot region and then measure the localized temperature rise and dissipation
75. Dermoscopes are hand-held devices with a light source and magnifying component which are often used to identify melanomas but they can be applied

to get real-time blood flow measurements, enabling the detection of reduced blood flow, an ulcer formation risk factor.

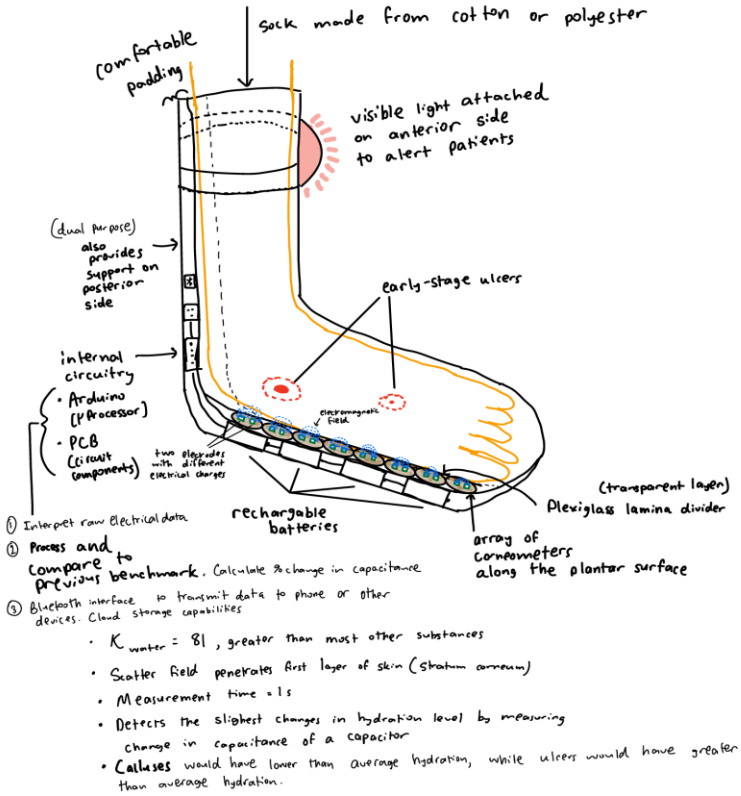
76. Although typically used to monitor blood flow in microcirculatory systems, laser Doppler flowmetry quantifies the Doppler shift of near-infrared light scattered by red blood cells to measure blood flow and so it can be adapted to measure foot blood flow to detect reduced blood flow, an ulcer formation risk factor.
77. Near-infrared spectroscopy measures blood flow through perfusion measurements based on red blood cell oxygen saturation, so it can be applied to measure foot blood flow to detect reduced blood flow, an ulcer formation risk factor.
78. The pinch test is an informal way of measuring skin elasticity by pinching the skin and then monitoring how long it takes to bounce back with dryer skin bouncing back slower, so a technology that is able to artificially pinch skin and then track the time profile of its retraction as in an elasticity test could be a formalized use of this to quantify skin dryness, which is often a sign of callous formation.
79. Resonant frequencies and their corresponding deflections in mode shapes have been utilized to get the vibrational properties of skin non-invasively to assess its health, and so this could be useful since these properties likely vary based on skin thickness and topology as they do with callouses.
80. The PRIMOS method uses digital fringe projection with micromirror projectors to quickly assess skin surface topology through an optical method, and skin surface topology can be used as irregular bumps or patches of rough, dry, or flaky skin can be indicative of a callous.
81. A previous study has used a vacuum-technology called the Cutometer MPA 580 to use suction and elongation to derive viscoelastic properties of the skin, and since these properties can be associated with callus formation if done on the foot this could be useful.
82. Dry skin can be correlated with callous formation, so quantifying dry skin in diabetic patients can be useful and this can be done with a technology such as a wearable that applies shock currents and measures the skin resistance as dryer skin is typically higher resistance.
83. Finite element analysis softwares subject real-world tissues and products to modeled forces, vibrations, flows, and more in order to predict its physical properties, so this can be used in some wearable to get the strain and stress and other properties of skin samples to estimate its roughness and other properties that could be indicative of callous formation.
84. Flaky skin can be a sign or symptom of calluses so this sock would collect and quantify the amount of flaky skin over a fixed time period to see if that amount is above the normal amount of skin shedding to see if it may be indicative of a callous.

85. This idea, motivated by the concept of thermal clearance, would involve applying water to the skin under the foot and then measuring its spreading as dryer skin, which is more correlated with callous formation, is more hydrophobic and would have less spreading than less dry skin.
86. Pulse volume recording currently uses a BP cuff and Doppler ultrasound to measure blood pressure and blood flow to diagnose peripheral artery disease, so it could be applied into some type of wearable device on the foot that could serve similar functions to detect reduced blood flow and PAD, risk factors for ulcer formation.
87. This information can be used to measure the size and depth of the wound, as well as to track its healing progress.
88. Smart bandage to monitor the wound environment and transmit data to the patient's smartphone or healthcare provider; information can be used to detect early signs of infection or other complications.
89. Embed radio-frequency identification (RFID) chips in diabetic shoes; these chips can record and transmit data about foot conditions, including pressure points and temperature, to a smartphone app or a healthcare provider
90. ML algorithms that analyze gait patterns and changes in the way a person walks can be an early sign of foot problems.
91. Nanosensor idea for detecting changes in pH or presence of bacteria on the ulcer site.
92. Design augmented reality (AR) apps that allow patients to use their smartphones or AP glasses to visualize their feet and ulcers in real-time.
93. Haptic feedback devices can alert users when they are putting excessive pressure on a particular part of their foot, thus helping them to avoid potential ulcer formation (for patients with peripheral neuropathy this could be difficult).
94. Integrate smart AI-powered voice assistants into daily life to remind patients to check their feet regularly and record observations.
95. Sock/foot mold of a patient's healthy feet can be created and patient can suspect ulcer development if protrusions on plantar surface impact the fit of the feet in the mold at subsequent timepoints
96. Molecularly imprinted polymer electrodes for point-of-care detection of tyrosine to check for greatly elevated levels within infected ulcers.
97. Addition of an enzyme or chemical to an existing ionic foot bath solution that changes color to indicate presence of ulcer.
98. Chemical strip analogous to the function of litmus paper; a person could gently rub the strip along the plantar surface of their foot and the resulting color would provide results
99. Create a footprint using a special type of paint and visually scan for any irregularities

100. A medical impact device that monitors nervous function in the foot via direct measurements inside the foot
101. Remove thin layers of the stratum corneum (the outermost layer of the skin) with adhesive tape, and an amount of natural moisturizing factor (NMF) in the tape samples can then be measured using various analytical techniques, such as high-performance liquid chromatography (HPLC) or mass spectrometry (MS).
102. Raman microspectroscopy optical method that can be used to measure the concentration of NMF and other molecules in the skin in real time; based on the principle that different molecules scatter light differently.
103. Direct analysis in real time mass spectrometry (DART-MS), a non-invasive technique that uses a stream of heated gas to ionize molecules on the surface of the skin, and then the ionized molecules are then analyzed by a mass spectrometer to identify and quantify NMFs.
104. Corneometry, a non-invasive technique that measures the hydration and barrier function of the stratum corneum, and can be used to indirectly track changes in NMF levels by measuring changes in the skin's hydration and barrier function.
105. Transepidermal water loss (TEWL), a non-invasive technique that measures the amount of water that evaporates from the skin over time, and can be used to indirectly track changes in NMF levels by measuring changes in the skin's water barrier function.
106. Obtaining skin topography directly from the skin using a special UV-A light video camera with high resolution
107. Probe that uses acoustic shockwaves to measure the anisotropy of collagen and elastin fibres in the dermis
108. After identifying the boundaries of different layers, reduction in skin thickening due to diabetic ulceration can be evaluated by calculating the distance between the demarcation echo lines from ultrasound biomocroscopy scans.

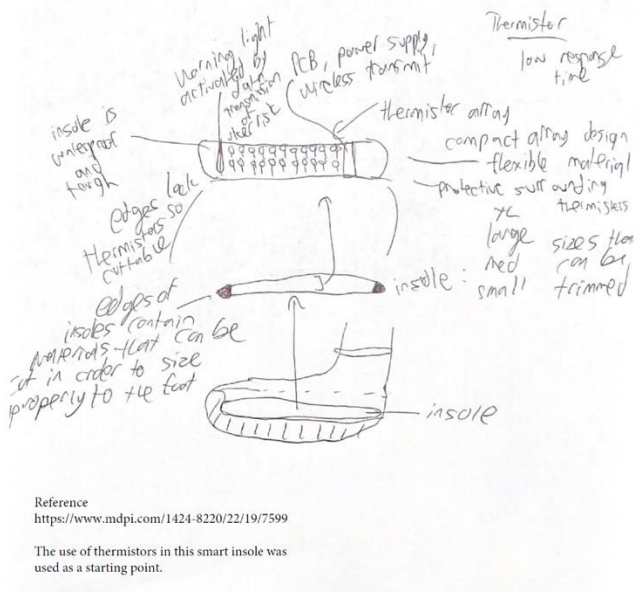
Idea Visualization

Idea 1: Sock with corneometer (measures hydration of stratum corneum)



References
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4268288/

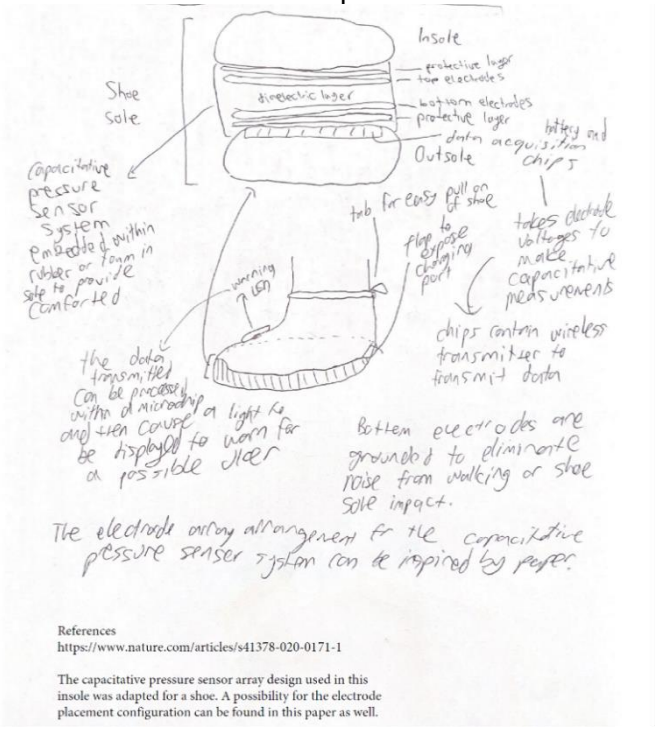
Idea 2: Insole with thermistor array



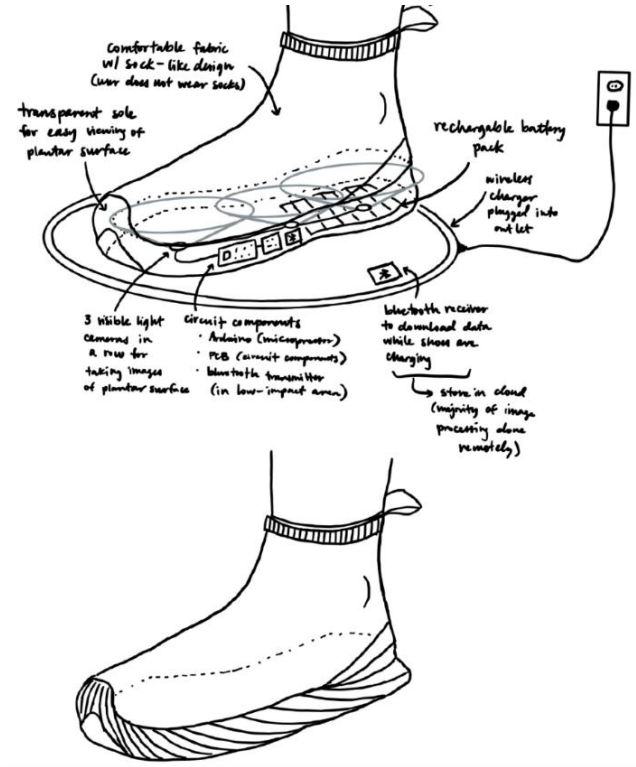
Reference
https://www.mdpi.com/1424-8220/22/19/7599

The use of thermistors in this smart insole was used as a starting point.

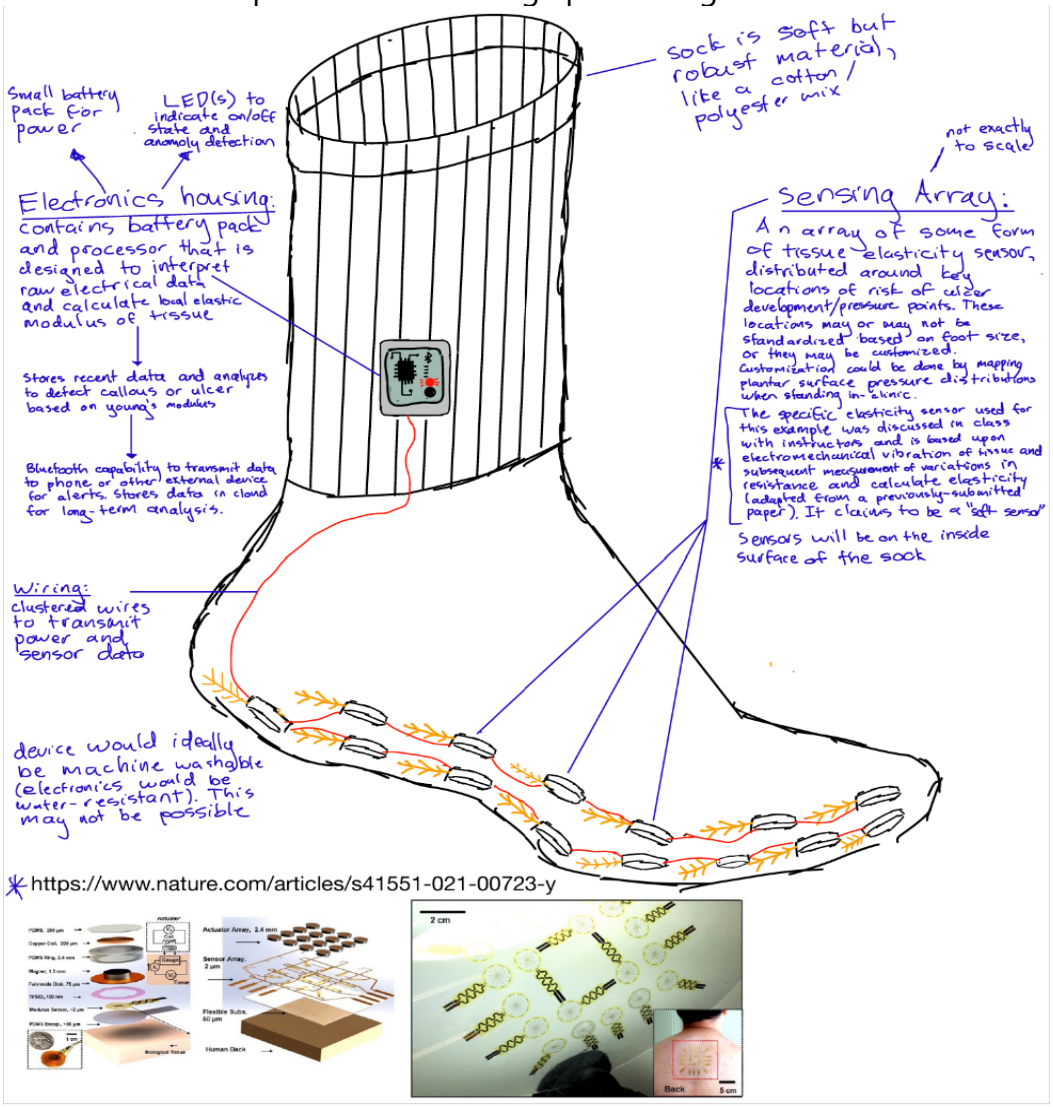
Idea 3: Shoe with contact pressure sensor



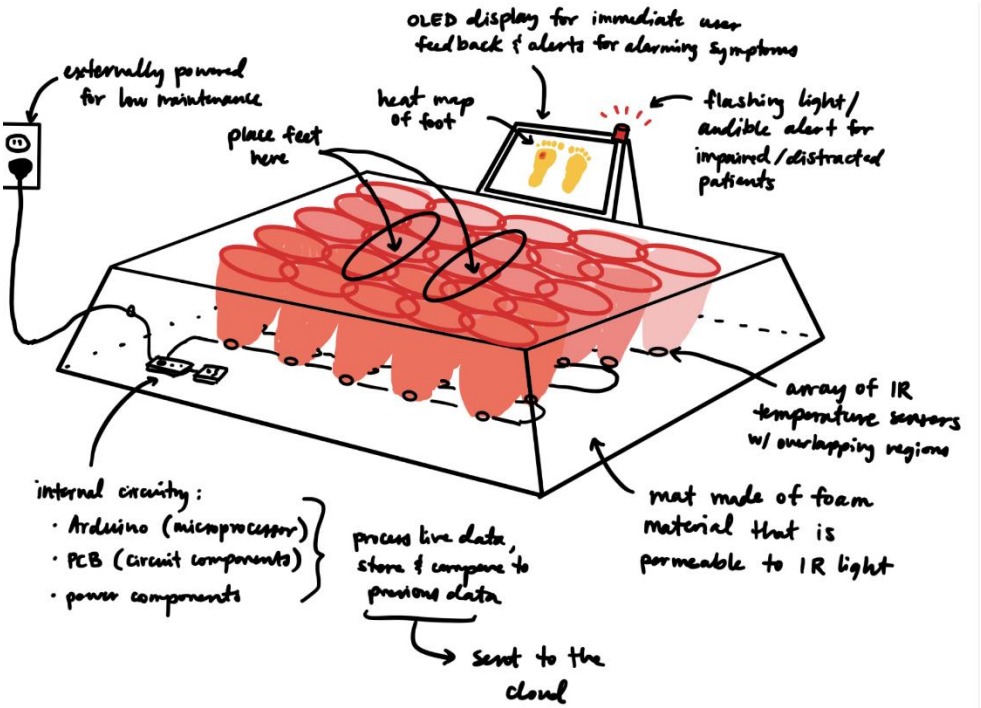
Idea 4: Sock with skin elasticity sensor



Idea 5: Shoe with plantar surface image processing



Idea 6: Mat with IR thermometer



Idea Selection

Screening

After ranking the eight established constraints above, we began the screening process by considering how easily each of the 103 ideas would integrate into a patient's existing lifestyle (5 of our original 108 ideas were identified as being duplicates or irrelevant to our detection functional requirement). At the conclusion of the first round, 50 ideas were excluded.

We then assessed the safety aspect of each of the remaining 53 solutions. 17 more ideas were eliminated due to potential undue risk or harm to the DFU patients. This left the team with 36 viable, technologically valid ideas at the end of two rounds of screening.

Upon discussion with Dr. Kyle, it was established that the appropriate next step was to evaluate how thoroughly each of the techniques have been researched in the literature. Although this is not a "constraint" per se, the approach for third round screening was imperative to ensure that our project would be more design-focused. We were able to remove another 12 ideas, reducing the pool to 24 options.

Scoring

We noticed that of the 24 remaining ideas, we could split them into two categories: device modalities and sensing techniques. Given the guidance in class to score across 5-10 ideas, the team decided to consolidate some of the sensing ideas that had similar underlying concepts. Ultimately, we were left with 6 device modality ideas and 10 sensor technique ideas that could be evaluated against the standard-of-care (self visual foot check modality with the human eye as a sensor).

We decided to score two matrices because we found it valuable to think of the modality (e.g., shoe, insole, mat) as a distinct device component than the sensor (e.g., thermistor, color sensor, pressure sensor). It should be noted that both of these sub-components are still within the same umbrella of the detection functional requirement. Note that some newly added criteria were weighted more than even some of the highly ranked constraints.

Round 1 - Modalities

We used the standard of care (foot check) as the baseline for the modality matrix shown in Table 1.

In terms of the modality, we believe that easy integration into a person's existing lifestyle (convenience) and ease of use account for 55% of the total weightage as this best aligns with the identified gaps in existing solutions as highlighted with citations at the start of this assignment. The other constraints that we thought were relevant for the modality were safety, durability/maintenance, and low cost/reimbursable potential. Durability was thought to tie in to these gaps as much as ease of use. Although safety is a higher priority for the overall functionality of the product, it was assigned a lower weightage than ease of use and durability for the purpose of this scoring matrix as we thought that safety corresponds more to the sensing technique used than for the modality. The modality or chassis of the device is more concerned with the use and wearability than safety. Finally, low cost was thought to be the least important of the included criteria.

Table 1. Device modality scoring matrix.

	Criteria	**Convenient**	**Ease of use**	**Durable (maintenance)**	**Safety**	**Low cost/reimbursable**	**Totals**
	WEIGHT (%)	**35%**	**20%**	**20%**	**15%**	**10%**	**100%**
Self visual foot check	*Score*	3	3	3	3	3	
	Weighted	1.05	0.6	0.6	0.45	0.3	**3**
Mat	*Score*	4	3	2	4	2	

	Weighted	1.4	0.6	0.4	0.6	0.2	**3.2**
Insoles	*Score*	5	4	2	3	2	
	Weighted	1.75	0.8	0.4	0.45	0.2	**3.6**
Shower Mat	*Score*	5	3	1	2	2	
	Weighted	1.75	0.6	0.2	0.3	0.2	**3.05**
Shoes	*Score*	5	5	2	3	1	
	Weighted	1.75	1	0.4	0.45	0.1	**3.7**
Socks	*Score*	5	4	1	2	2	
	Weighted	1.75	0.8	0.2	0.3	0.2	**3.25**
Interactive Mirror	*Score*	1	1	3	2	1	
	Weighted	0.35	0.2	0.6	0.3	0.1	**1.55**

As can be seen from Table 1, the highest scoring modalities were shoes and insoles in that order. Additionally, socks and the mat ideas scored above the standard-of-care in the self visual foot check. These results do align with our expectations and goals for the project. The shoes and the insoles scored significantly higher than the standard, highlighting a benefit and room for improvement on the standard from these ideas. As can be seen in our gap analysis papers cited at the start and in our visualization assignment drawings, insoles are a particular interest in current research so it would make sense that they were a relatively high scorer. Similarly, shoes are similar to insoles and would be expected to perform similarly. The fact that socks scored lower also makes sense because socks are less durable than shoes and are often subjected to additional wear-and-tear when washing or by being in direct contact with the foot. Finally, the mat ideas scoring higher than the standard make sense as they appear in existing solutions. The lowest above-standard score of the shower mat makes sense as the water would be an added risk or wear-and-tear factor that could contribute to lower scores in a couple criteria. The interactive mirror was also likely too complex or underdeveloped, and its score reflected this. Also, these expectations align with some of the ideas mentioned in our interviews, especially with Dr. Wamelink suggesting that socks and shoes would be ideal as they are already a part of an individual's life.

Round 2 - Sensing Techniques

Once again, after some debate, we decided to use the self visual foot check at the neutral for this sub-scoring as well. In this case, the human eye would be considered the "sensing technique."
Although convenience and ease of use were part of our modalities scoring, they were not included in the sensor scoring because we didn't believe these factors to be as relevant for sensing itself. Also, the human eye is obviously not compatible with any of the modalities other than the foot check.

Accuracy weighted the most for this matrix (30%) to ensure a robust, objective screening tool for in-home use. Note that accuracy is not a constraint for this project, but rather a criteria. The other non-constraint criteria that was a part of this matrix was the ability to perform frequent measurements. This ties into the continuous monitoring portion of the product, which is a goal that is not as pressing as safe, accurate, and equitable sensor measurements in our eyes. Three of the most valuable constraints selected for this matrix were safety (20%), equitable diagnostic capability (20%), and durability (10%). In this case, safety was weighted more than durability because the sensor seems to be the main determinant of the interaction of the device with the user. Finally, the general team interest was given a small weightage to factor in the design engineers' personal preferences.

The scoring matrix for the sensors considered can be seen in Table 2.

Table 2. Device sensor scoring matrix.

	Criteria	**Accurate ***	**Safe**	**Equitable in diagnosis**	**Frequent Measurements**	**Durable**	**Team interest**	**Totals**
	WEIGHT (%)	30%	20 %	20%	15%	10%	5%	**100%**
Self Visual foot check	*Score*	3	3	3	3	3	3	
	Weighted	0.9	0.6	0.6	0.45	0.3	0.15	**3**
Thermistor array	*Score*	4	4	3	5	2	4	
	Weighted	1.2	0.8	0.6	0.75	0.2	0.2	**3.75**
Contact pressure sensor/	*Score*	2	4	3	5	2	5	
	Weighted	0.6	0.8	0.6	0.75	0.2	0.25	**3.2**

Tactile Imaging								
Skin color sensor	*Score*	2	4	1	5	2	2	
	Weighted	0.6	0.8	0.2	0.75	0.2	0.1	**2.65**
Optical imaging of vasculature	*Score*	3	4	1	4	1	3	
	Weighted	0.9	0.8	0.2	0.6	0.1	0.15	**2.75**
Apply stress/strain to measure viscoelastic properties	*Score*	5	2	3	4	2	5	
	Weighted	1.5	0.4	0.6	0.6	0.2	0.25	**3.55**
IR thermometer	*Score*	4	4	2	4	2	3	
	Weighted	1.2	0.8	0.4	0.6	0.2	0.15	**3.35**
Plantar surface image processing	*Score*	2	4	2	2	1	3	
	Weighted	0.6	0.8	0.4	0.3	0.1	0.15	**2.35**
NIRS Tissue Oxygenation	*Score*	2	4	1	4	1	3	
	Weighted	0.6	0.8	0.2	0.6	0.1	0.15	**2.45**
Measure skin hydration (Corneometer)	*Score*	4	4	2	4	2	4	
	Weighted	1.2	0.8	0.4	0.6	0.2	0.2	**3.4**
TEWL	*Score*	3	4	2	4	2	4	
	Weighted	0.9	0.8	0.4	0.6	0.2	0.2	**3.1**

*Accuracy refers to whether data that are output can produce a direct, accurate diagnosis of a foot ulcer

As can be seen in Table 2, the highest scoring sensing techniques were thermistor array and then applying stress/strain to measure viscoelastic properties. Contact pressure sensing, IR thermometry, corneometry, and TEWL additionally scored higher than our standard-of-care sensor, which was the human eye used in self visual foot checks. For the most part, these results align with our expectations and goals for the project. Several sensing ideas scored higher than the standard, suggesting that there is room for

improvement and a benefit to exploring these sensor ideas in a new device. It made sense that the thermistor array, IR thermometer, stress/strain applier, and contact pressure sensor were high scoring as many current research design initiatives, as can be seen in our visualization assignment, utilize temperature and pressure mechanical measurements. Additionally, the water-based and hydration methods scored higher than the standard and this was expected as these methods were often mentioned in our interviews along with temperature and pressure to be indicators of interest that could be monitored. The ideas that scored lower than the standard were all related to imaging or were affected by skin pigmentation. For example, NIRS tissue oxygenation is the mechanism of pulse oximetry, which is affected by skin pigmentation. This trend made sense as imaging and other sensing techniques that may be affected by skin pigmentation would seem to make it difficult to supply accurate and equitable results.

Idea Research

Principle of Operation (Overall)

The development of calluses on the foot has been identified as a significant risk factor for foot ulcers, particularly in diabetic patients. Studies have reported an association between callus formation and the development of foot ulcers in diabetic patients [53]. One study examining the link between callus formation and ulceration found that, while previous ulceration is the most indicative risk factor for later ulceration, plantar callus formation was very predictive of later ulceration in the location of the callus [54]. Specifically, the study found a relative risk of 11.0 for ulcer formation beneath a callus and a relative risk of 56.8 of ulcer formation at prior ulcer locations [54]. Over the course of this study, all ulcers that developed were at locations of previous calluses. Callus formation is associated with high plantar pressures and represents an independent risk factor for the development of foot ulcers [55]. Furthermore, callus formation has been identified as a risk factor leading to *severe* diabetic foot ulcers, emphasizing the importance of preventing its formation [56].

Additionally, it has been noted that in most cases, a plantar ulcer follows callus formation, indicating a clear correlation between the two [57]. The presence of calluses on the foot has been linked to increased peak shear stress, which further contributes to the risk of ulceration [58]. Moreover, elevated foot skin temperatures, often associated with calluses, have been considered as a risk factor for ulceration due to inflammation at the site of measurement [59].

Callus formation is associated with high plantar pressures, increased peak shear stress, and elevated foot skin temperatures, all of which contribute to the risk of ulceration. Therefore, preventive measures targeting callus formation are crucial in reducing the risk of foot ulcers in at-risk populations.

Temperature is the first measurement that will be incorporated into our solution device. Studies have quantified foot temperature ranges in individuals with different conditions [60]. Specifically, significant dorsal and plantar temperature elevations were found in patients with neuropathy, a major risk factor for ulceration, relative to individuals without neuropathy [60]. Other studies have directly examined foot temperature fluctuations, finding that an elevation of 2.2℃ in one foot relative to the same region on the other foot is abnormal as these variations typically do not exceed 1℃ [61].

This relative foot region temperature difference of 2.2℃ has been used as a threshold for treatment for plantar temperature home-monitoring systems and as a relative predictor for ulcer formation [62, 63]. Such temperature differences can be observed a week before neuropathic ulcer formation [62]. Studies have found that these

temperature differences can be amplified by a factor of 4.8 a week before ulcer formation, so monitoring temperature can be very useful for ulcer prediction, prevention, and treatment [63].

The second measurement that will be included in our solution device is skin elasticity. Elasticity refers to how tissues react when subjected to outside forces [64]. Studies have characterized the biophysical properties of plantar skin as well as the skin in different conditions, ranging from calluses and corns to heel xerosis and heel fissures [64]. Lower elasticity was generally found for each of the four aforementioned conditions relative to skin in the absence of all four conditions as can be seen in Figure 3 below. The last two columns, PMA and 5th met. base, correspond to unaffected or normal skin taken from the plantar metatarsal area or the fifth metatarsal nearby to the callus, corn, fissure, or xerosis. The thickest skin usually found in the centers had less elasticity by roughly a factor of two, and the callus center was significantly less elastic than the corn center [64]. So, elasticity measurements can be used to differentiate between calluses and healthy skin.

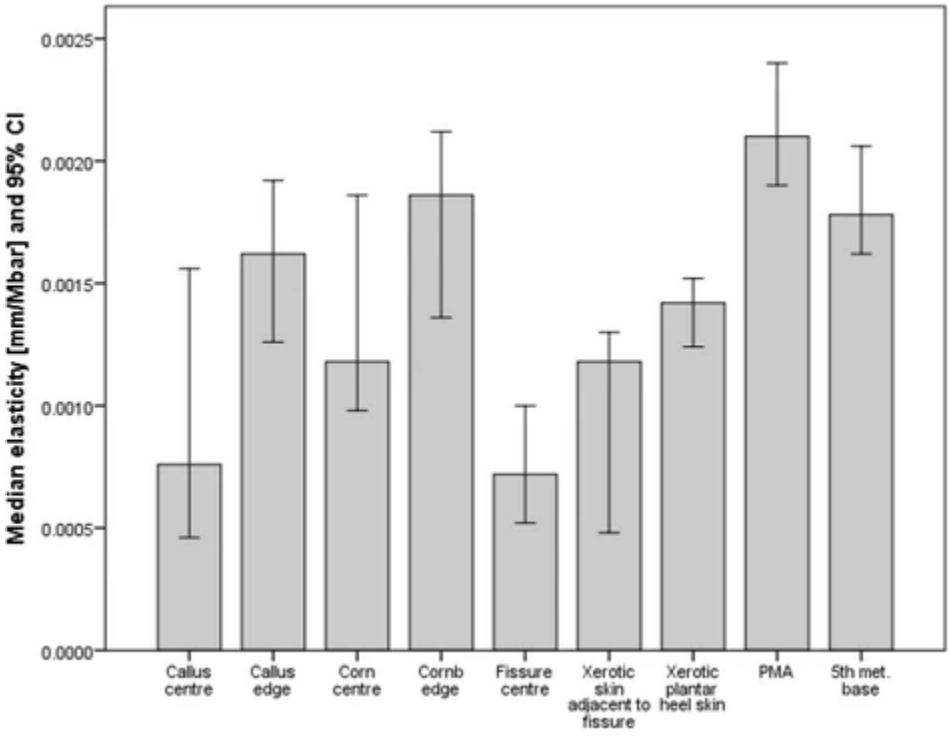


Figure 26. Elasticity of different skin sites and types (Figure 4 from Hashmi et al., 2015).

Thus, temperature and elasticity are two appropriate measurements that can be used to identify calluses and thereby predict and prevent ulcer formation or progression through early treatment.

Stiffness Sensing

Two methods, ultrasound elastography and indentometry, were considered for measuring stiffness or elasticity. Both methods and proposed solutions with each are outlined below. Then, a comparison of the two methods is included to justify the selection of indentometry as the approach that was pursued.

Ultrasound Elastography

Form

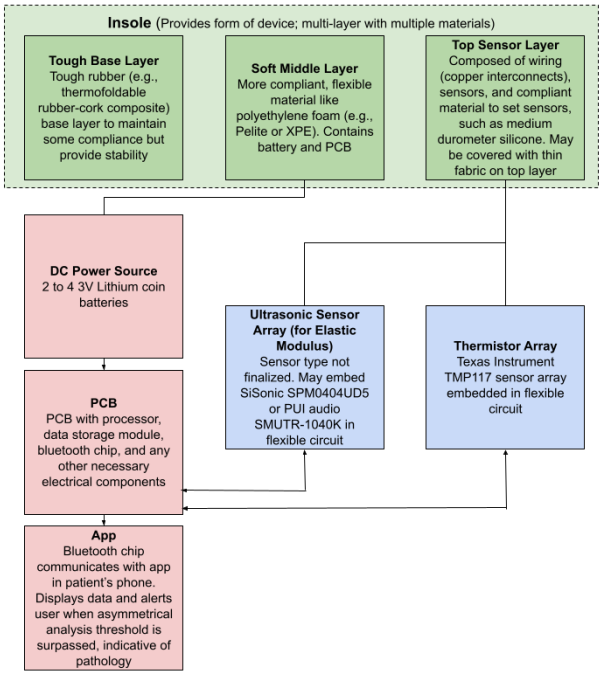


Figure 27. Ultrasound elastography solution block diagram.

The block diagram highlighting the components of the proposed solution is included above. The arrows and lines illustrate the connections between different components of the solution. Directional flow of power and information is indicated by arrows, whereas non-directional relationships between components are indicated by lines. In the diagram, unidirectional flow of electricity occurs from the DC power source to the PCB. The PCB sends electrical signals out to the ultrasonic sensor and thermistor arrays *and* receives a signal back from them associated with their data. Regardless of directionality, sensing arrays will be embedded in a top sensor layer and all other electronics will be housed in the soft middle layer of the insole. Note that some small details, such as adhesive type between insole layers (for which we may use medical-grade Loctite) were omitted.

Overall, thermistors are excellent temperature measuring sensors for the smart insole system. They are accurate, repeatable, fast, small, flexible, affordable, low-power, and durable. As stated by Khandakar et al., thermistors can also be simply connected using the same voltage divider as other sensors, making PCB circuit design easier and reducing its footprint [65]. TMP117 sensors will be used for temperature measurement [66]. These sensors return 16-bit temperatures, having a minimum error of 0.1℃. They are compliant with ASTM E1112 and ISO 80601, the key regulations on monitoring patient temperature.

Hu et al. describe a new type of ultrasound sensor that can be used to create non-invasive, three-dimensional maps of the stiffness of tissues up to 4 cm beneath the skin [67]. The sensor is made of a flexible material that allows it to conform to the body and maintain good acoustic coupling, even when the body is moving. The sensor works by transmitting ultrasound waves into the tissue and then measuring the echoes that are reflected back. The stiffness of the tissue can be determined by measuring the speed at which the ultrasound waves travel through the tissue. The sensor uses a new type of microfabrication technique to create a dense array of ultrasonic transducers, which allows it to achieve a spatial resolution of 0.5 mm. The authors used the device to map the three-dimensional distribution of the Young's modulus of tissues ex vivo. To obtain Young’s Modulus, an inverse elasticity problem is solved with the simulated strain and the reflected ultrasound wave data.

As specified in the block diagram, the array of sensors is embedded into the top layer of the insole, enabling close contact to the patient’s foot. Embedding also allows protection of the sensors. The middle layer is soft and flexible for patient comfort, and tentatively also houses the power source and processing unit, containing the PCB, processor, storage, Bluetooth chip, and other necessary electronic components. Finally, the bottom layer is rigid to provide stability to the insole. It should be noted that further investigation must be done to confirm which layer is most appropriate for housing the electronic components of this device.

Function

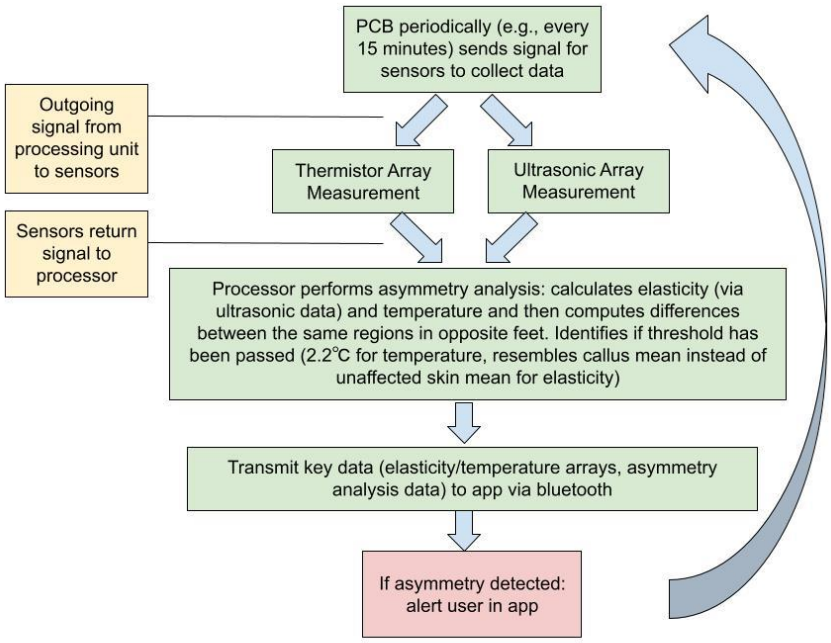


Figure 28. Ultrasound elastography solution flowchart.

Data collected by the array of sensors will be transmitted via circuitry to the PCB and processing units in the middle layer of the insole. Then, the temperature and elasticity measurement data can be processed. Relative temperature elevations and relative elasticity changes will be identified based on the aforementioned literature values and thresholds. Specifically, 2.2℃ will be used as the temperature threshold [62, 63]. The elasticity measurement will be classified as more representative of the callus elasticity mean or the unaffected PMA and fifth metatarsal skin elasticity means as seen in Figure 3 [64]. Elasticity measurements that are classified as more similar to the callus elasticity mean will be marked as abnormal. Relative measurements will consist of differences between the same regions on opposite feet. This data can also be transmitted by the Bluetooth chip for exterior analysis.

Previous studies have relied on asymmetry analysis as the primary form of data processing [68]. While many of these studies have applied asymmetry analysis to infrared imaging thermograms, the idea of asymmetry analysis can be extended to our device. By making measurements and processing them relative to measurements on the other foot, abnormalities in the temperature and elasticity can be better quantified for different individuals. Patients have unique baseline values of temperature and elasticity, but making these measurements and then using the relative differences between corresponding regions on the contralateral foot will help individualize and generalize our device.

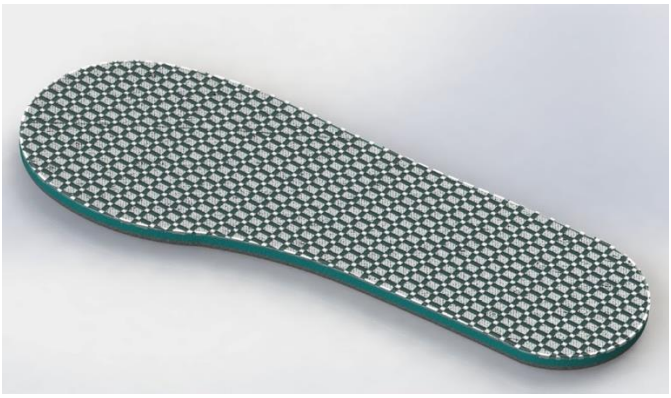
Solution Visualization

A SolidWorks CAD model was created to visualize the device described in Figure 27. The thermistor sensors were modeled using the Texas Instruments CAD models of the TMP117 Digital Temperature Sensor (Part No. TMP117AIDRVR), while the MEMS ultrasound sensors were modeled using the Knowles CAD model of the SiSonic Ultrasonic Acoustic Sensor (Part No. SPM0404UD5_KNO). All other components of the assembly were created in SolidWorks and imported to an assembly with the sourced sensors. The dimensions of the insole were selected based on a men's shoe size 10.5, which is representative of a 50th percentile male foot. The batteries were selected to represent 3 3V coin batteries and were placed in a location with relatively low impact under the arch of the foot, along with the PCB, so that they do not break under the weight of a patient.

This depiction is not perfectly representative of how our device will look in its final form. Some components that may exist in a production device are not depicted, such as wiring.

A

B



C

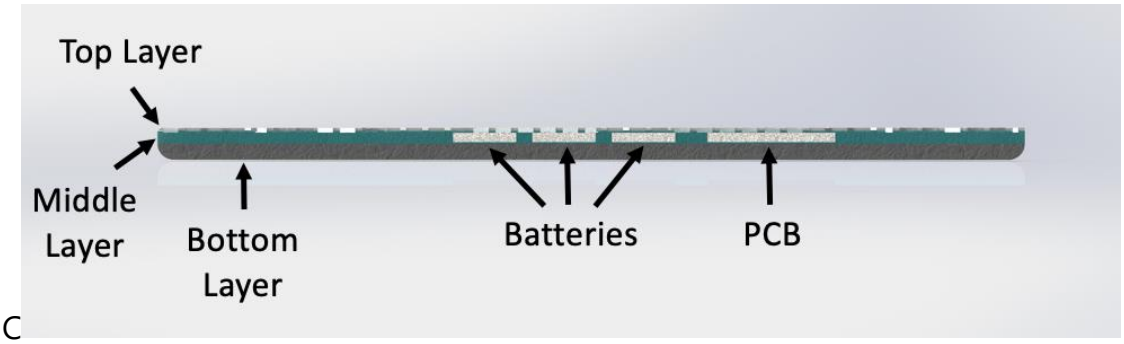


Figure 29. (A) Top view of both insoles. (B) Isometric view of one insole. (C) Side view of cut away insole, revealing inner circuitry and batteries.

Indentometry
Form

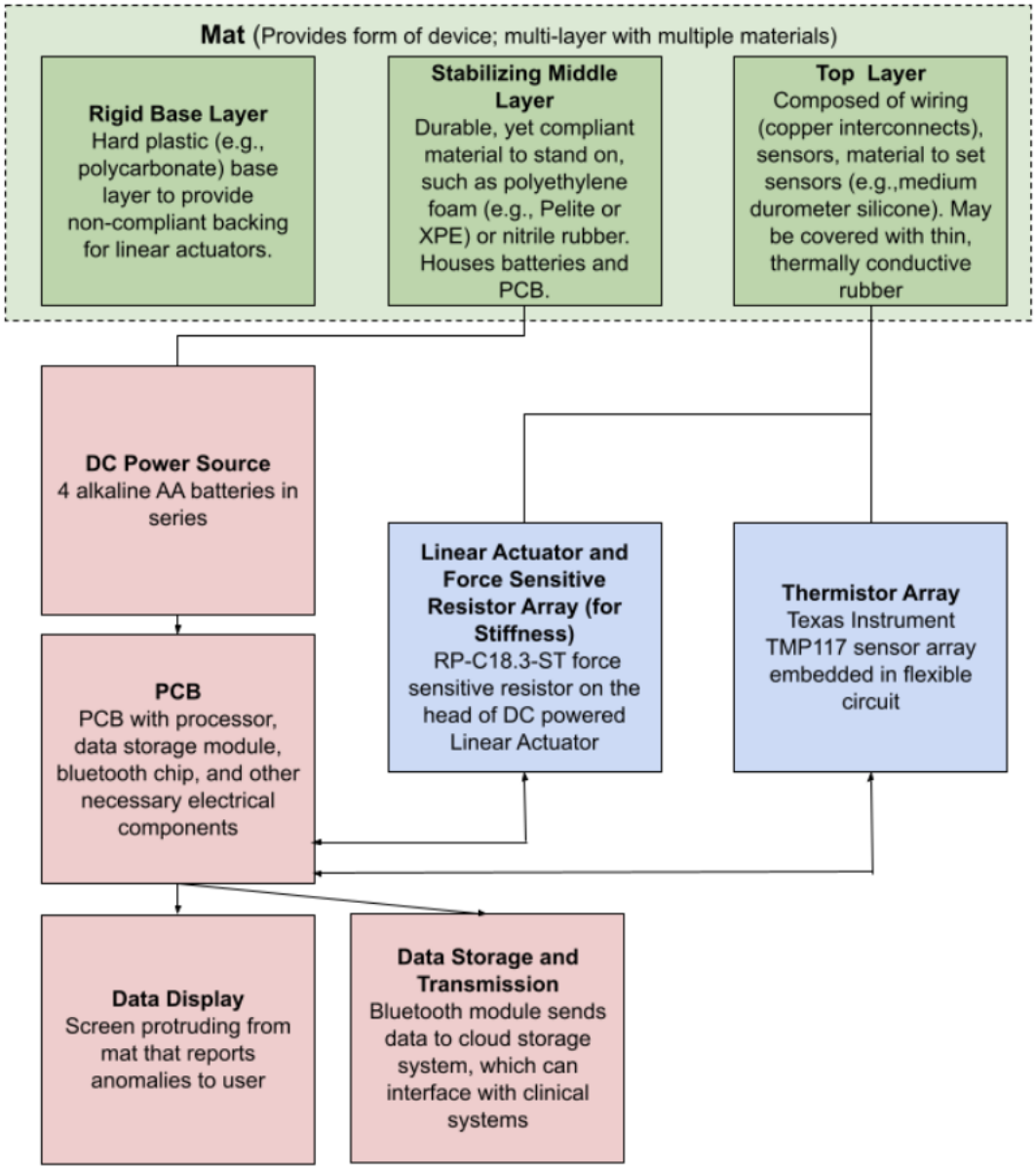


Figure 30. Indentometry solution block diagram.

Force sensitive resistors (FSRs) are often used in conjunction with linear actuators in the assessment of material stiffness, serving as a low-cost alternative to the traditional load cells used in mechanical testing. FSRs are thin, flexible sensors that measure force-induced resistance changes in a piezoresistive sheet, making them suitable for measuring the magnitude of applied forces [69]. A thermistor array is included for temperature, and all these sensors are embedded in the top layer of the proposed mat. The middle layer contains circuity components.

Function

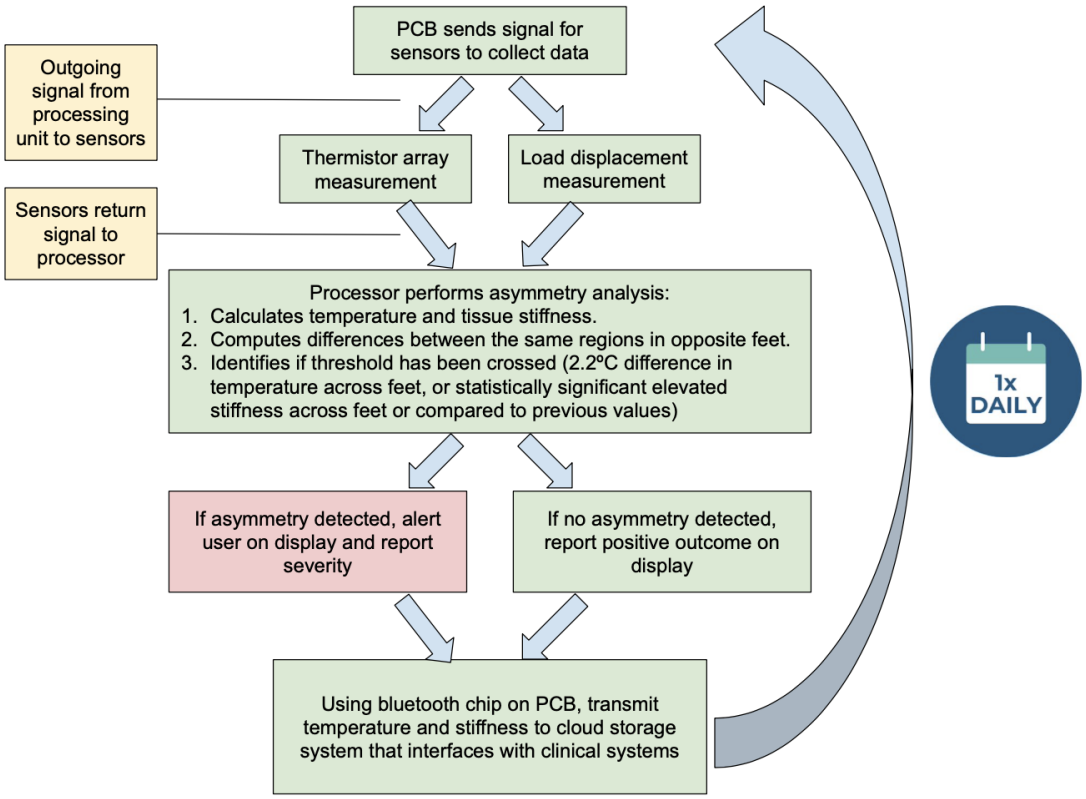


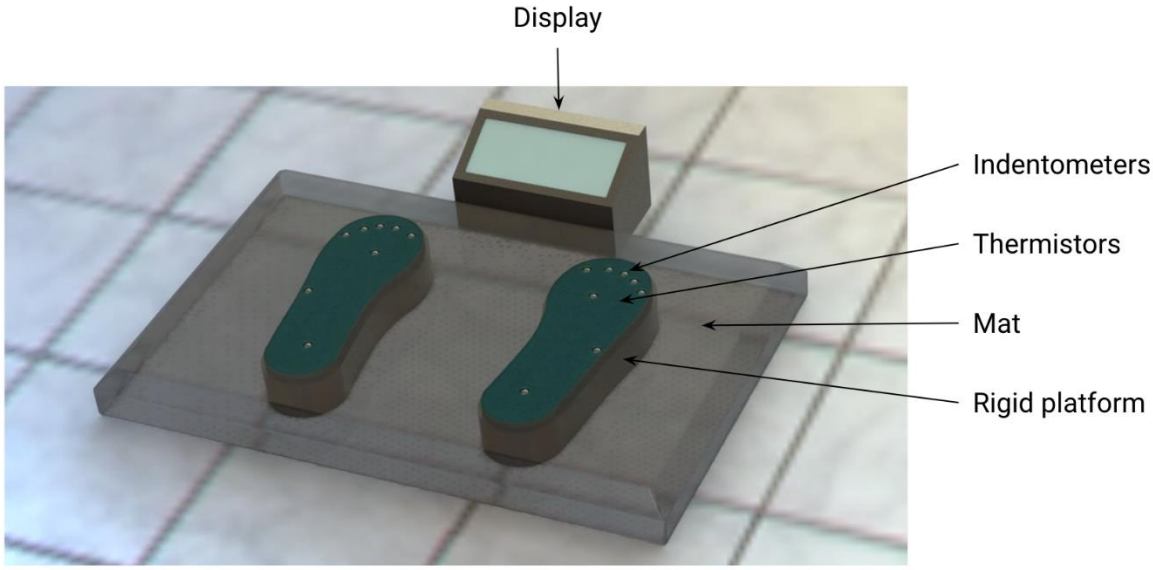
Figure 31. Indentometry solution flowchart.

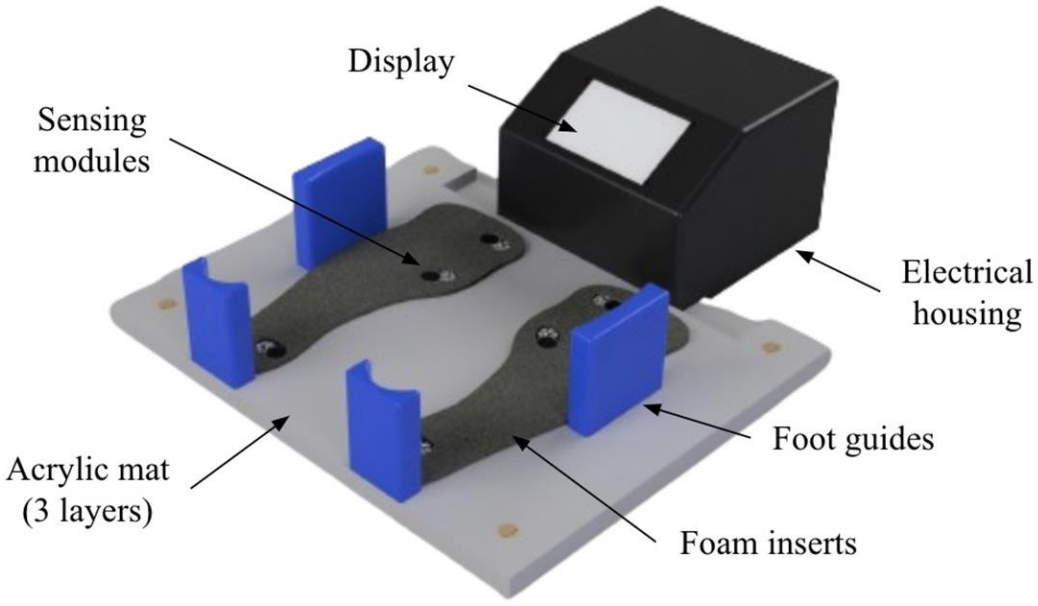
Sensing will occur daily, measuring both temperature and stiffness through the thermistor array and load displacement array respectively. Then, asymmetry analysis is conducted to classify the measurement as abnormal (indicative of an ulcer) or normal. Bluetooth enables syncing with existing clinical infrastructure.

Solution Visualization

A CAD model of the visualized solution was created and rendered using SolidWorks. Figures 32 and 33 show the visualized solution with a rendered flooring background, where the device will likely sit. Figures 34 and 35 show the device from various views.

A





B

Figure 32. Isometric view of device on the floor with labels. (A) Original embodiment and (B) Alternative newer embodiment.

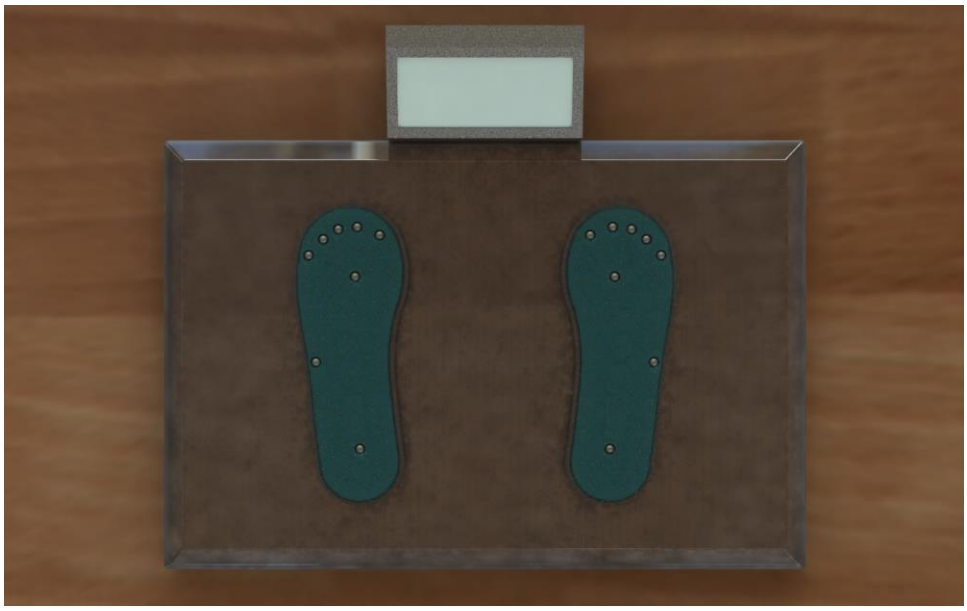


Figure 33. Top view of device on the floor.

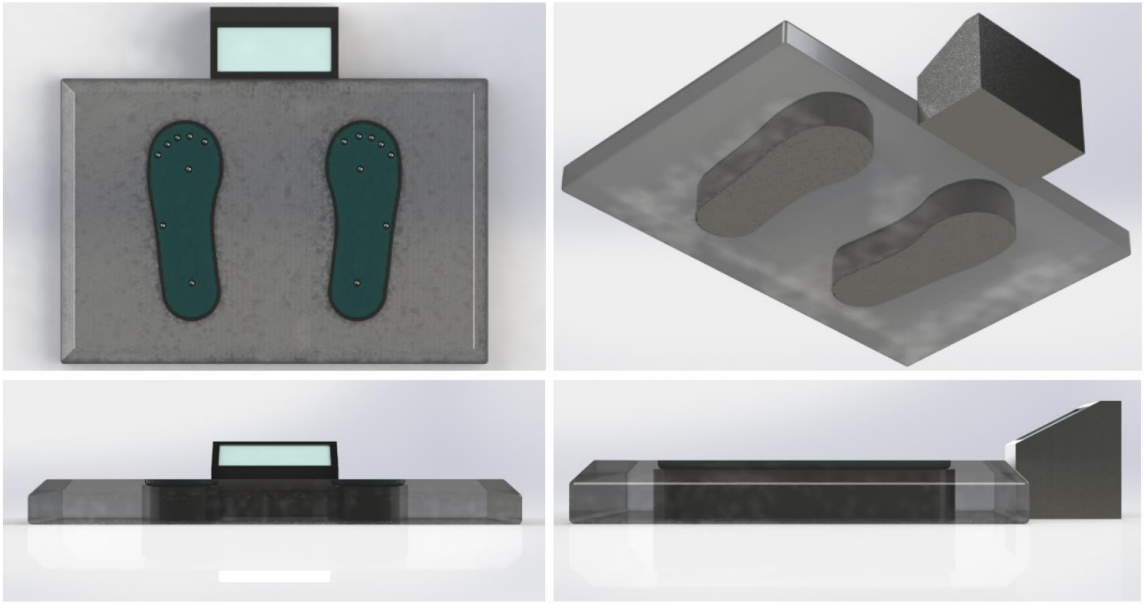


Figure 34. Top view, isometric view, front view, and side view of device.

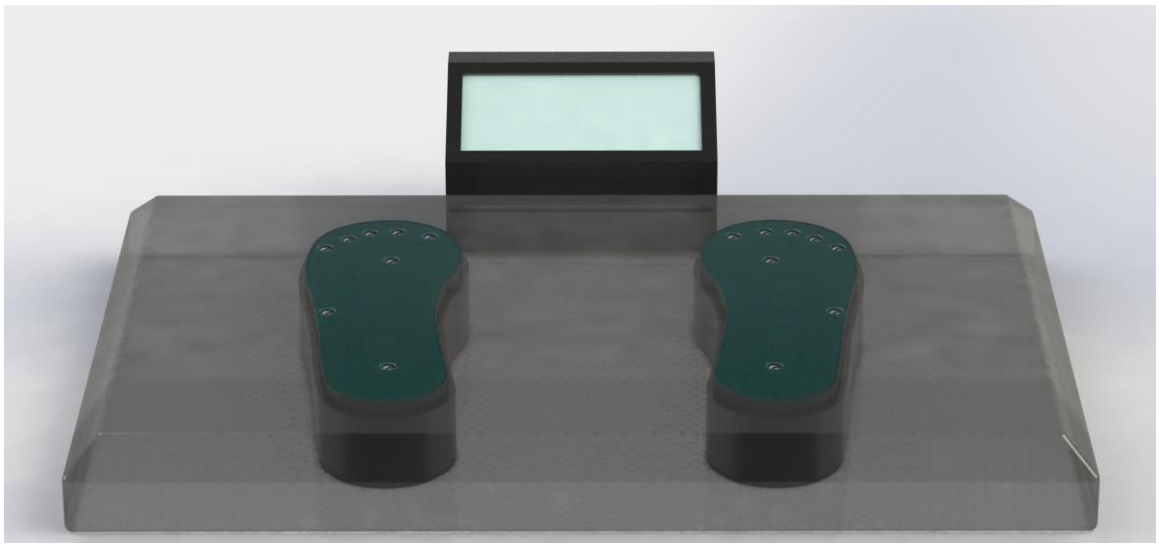


Figure 35. Elevated view of device.

The device has a colored region indicating where the user should place their foot to align it with the indentometers, as shown in Figure 36. Figure 37 shows a cross section of the device, revealing the indentometers embedded in the device. Figure 38 shows the placement of the 8 indentometers around the foot, placed on each of the 5 toes, plus the ball, side, and heel of the foot. Figure 39 shows a section view of a singular indentometer with labels, indicating how the head of the device will displace into the plantar skin.

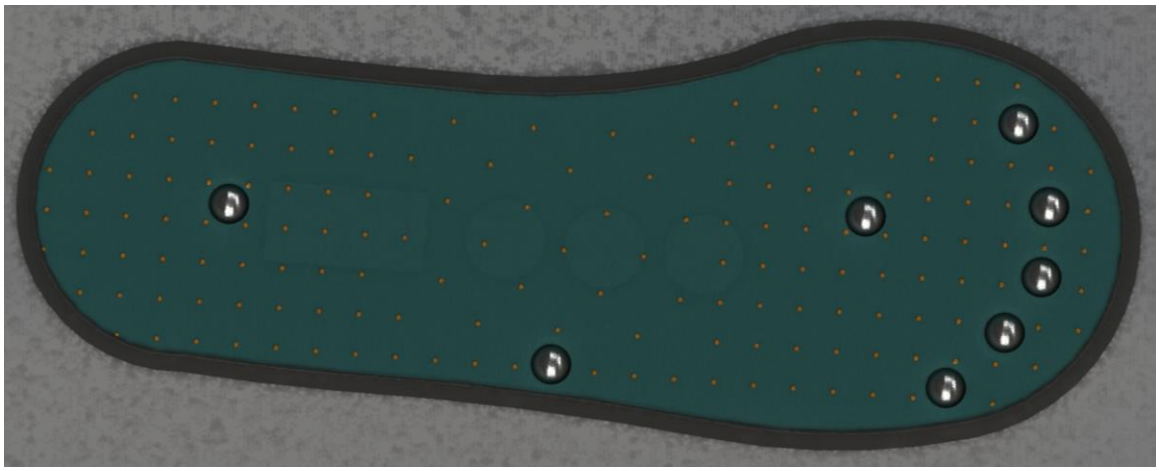


Figure 36. Close up view of foot outline with indentometers and thermistor array.

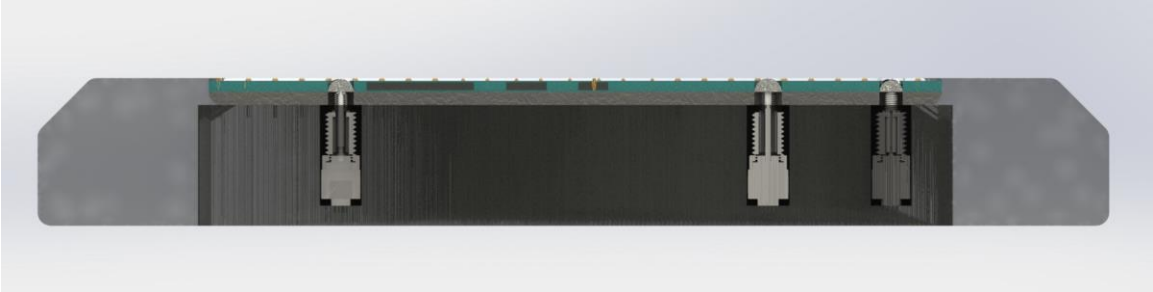


Figure 37. Section view of device revealing indentometers.

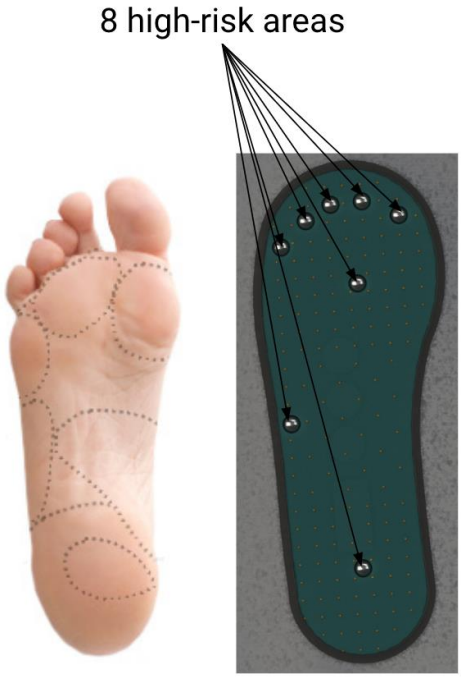
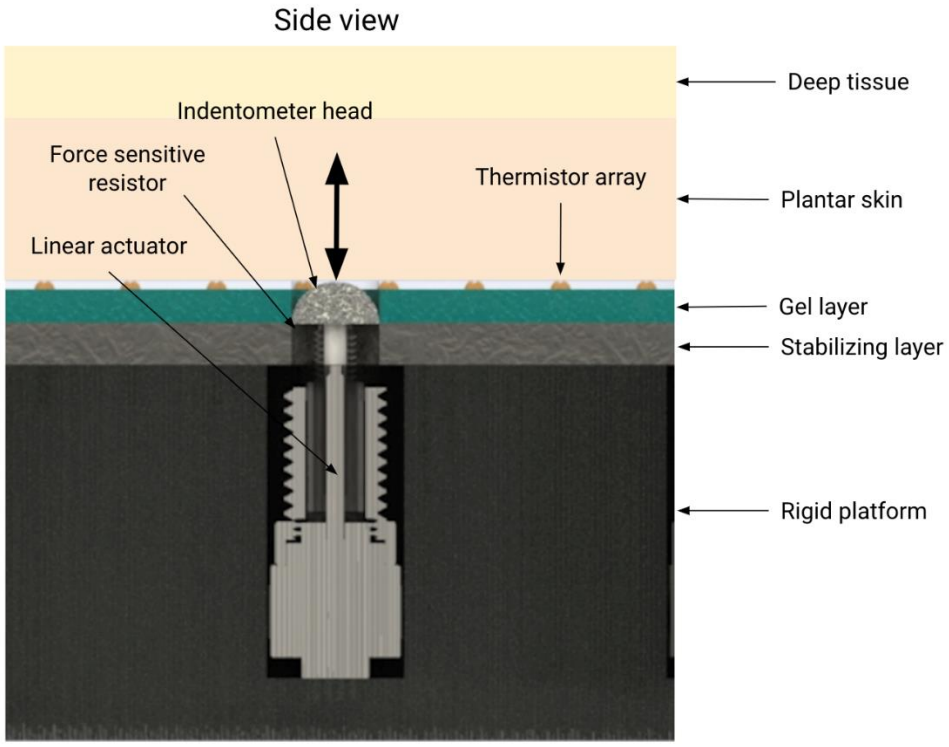


Figure 38. Indentometers located in high risk areas of the plantar surface.

A



B

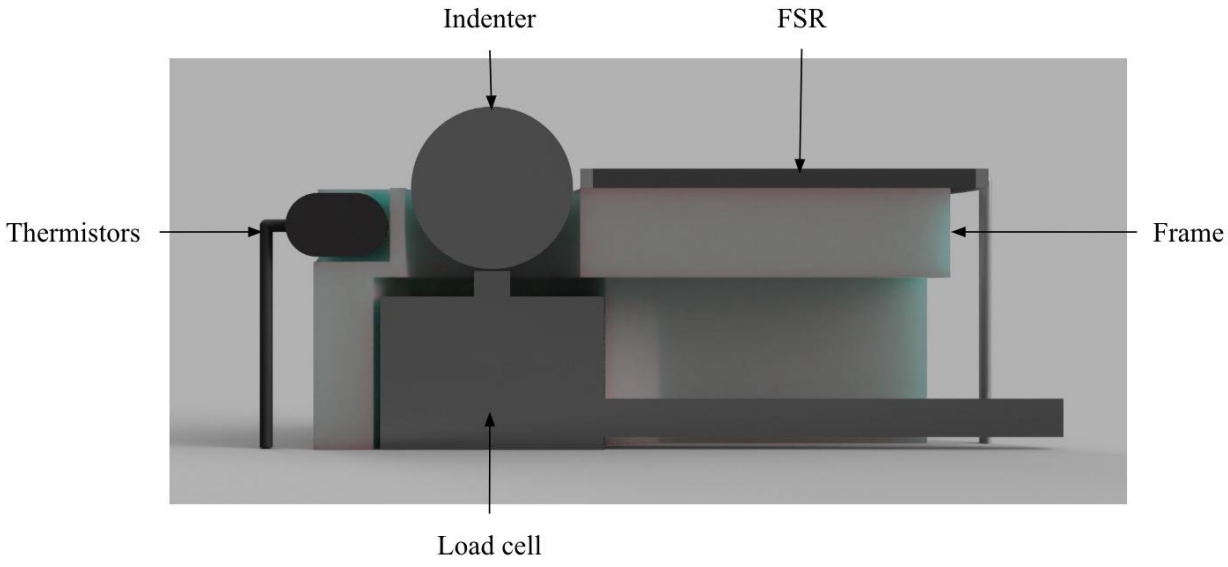


Figure 39. Section view of one indentometer with labels demonstrating how the device will displace into the plantar skin. (A) Original embodiment with linear actuator mechanism and (B) Alternative newer embodiment with use of compressive load cell.

A higher fidelity solution will involve more sensors to increase the monitoring power of the device. The plantar surface of the foot, particularly the forefoot and the areas under the metatarsal heads, is highly susceptible to the development of DFUs [70,71,72].

Approximately half of DFUs occur on the plantar surface of the foot, particularly under the metatarsal heads [70,72]. This is attributed to the high plantar pressures and increased mechanical loading in these areas, often caused by foot deformities, limited joint mobility, and sensory and autonomic dysfunction [70,71]. Figure 40 shows the high- and low-risk regions of the foot, where the high- and low-concentration sensor arrays will be embedded to monitor the state of stiffness and temperature (see Figure 41).

The high-concentration sensor array will have a spacing of approximately 0.5 cm, whereas the low-concentration array will have a spacing of 2 cm. According to the results of temperature proof of principle testing, the spacings for both high- and low-concentration arrays are within the spatial resolution of the thermistors.

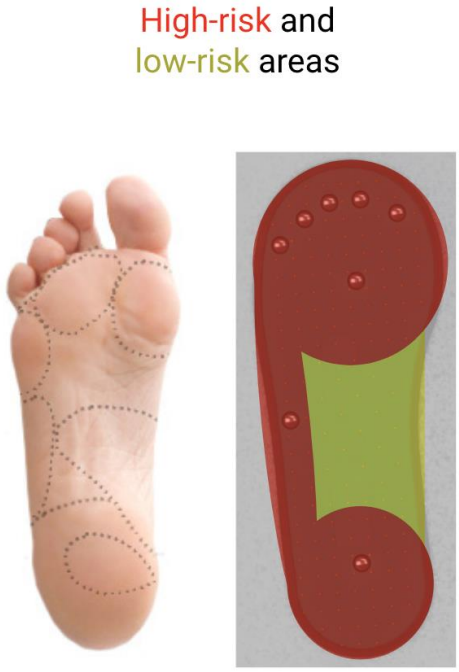


Figure 40. High- and low-risk regions of the plantar surface mapped to the device.

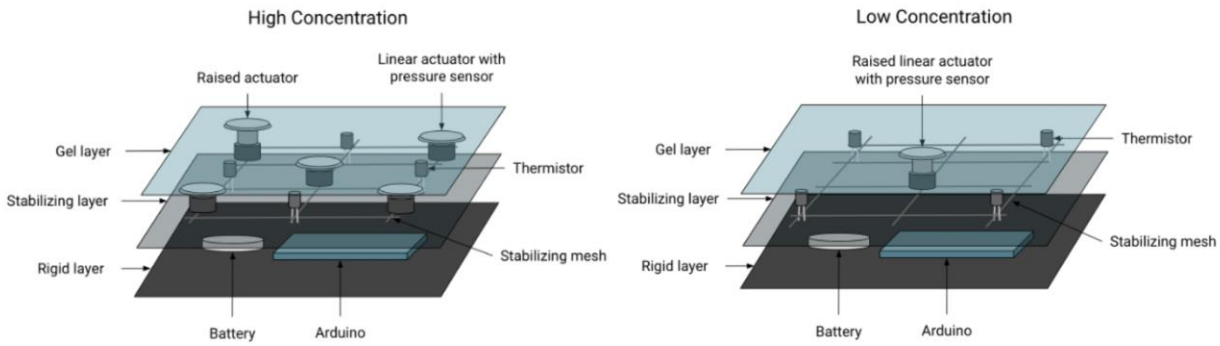


Figure 41. High- and low-concentration sensor arrays.

Comparing Efficacy

Ultrasound elastography and indentometry are both valuable techniques for assessing tissue stiffness, each with its own set of advantages. Ultrasound elastography has been widely used to visualize and quantify soft tissue stiffness and has been shown to be sensitive to tissue stiffness [73]. It is a non-invasive imaging method that can provide quantitative measurements of tissue stiffness and has been used as a valuable tool in differentiating between benign and malignant lymph nodes [74]. However, as noted from our interview with Dr. Nightingale as well as a recent article published by her team, the accuracy of ultrasound elastography in measuring tissue stiffness is heavily dependent on the accurate measurement of skin thickness, which can be challenging and operator-dependent [75]. Additionally, 3 MHz has previously been used as an ultrasound frequency for ultrasound elastography, a center frequency chosen to balance resolution and attenuation in tissue [67]. Transducers with this frequency are not very accessible, adding another challenge.

On the other hand, indentometry offers its own advantages, particularly in the assessment of skin tissue stiffness. Indentometry is an affordable way to assess tissue stiffness and has been demonstrated to be reliable for the assessment of tissue fibrosis [76]. Studies have shown that indentometry, using a Durometer, is a reliable method to assess skin hardness and stiffness [77]. Additionally, a novel measurement device based on indentometry has been used to determine skin stiffness in healthy individuals and in patients with systemic sclerosis, showing its potential in clinical application [78].
In conclusion, while ultrasound elastography is valuable for its non-invasive nature and quantitative measurements of tissue stiffness, indentometry offers affordability, reliability, and versatility in assessing tissue stiffness, particularly in the context of skin tissue. Thus, indentometry was the pursued approach.

V. Proof of Principle Testing

Proof of Principle Test #1: Load-Deflection Indentation Testing

Background
For ethical reasons, testing on human patients is not feasible for this project. One alternative solution for testing the validity of the device is to use a medical grade foot model. However, these models tend to be expensive with long shipping times, which is not ideal for rapid prototyping and proof of principle testing. In lieu of a medical grade foot model, a biomaterial with similar mechanical properties to the diabetic foot skin would be ideal for proof of principle testing.

Gelatin was investigated, as it is often used for calibration and its mechanical properties have been studied extensively in the literature [67]. However, there were difficulties preparing the gelatin due to the need for high concentrations that surpassed the saturation point at room temperature. Gelatin from different animals have been shown to have different mechanical properties, so gelatin from another animal source may have been a more viable option [82,83]. However, the need for high concentrations, compounded by long wait times to allow for proper setting at 4 ºC, made gelatin impractical, so the team began to investigate alginate hydrogels, a readily available biomaterial with similar mechanical properties. Alginate's ability to closely mimic the biomechanical behavior of the skin makes it a suitable candidate for modeling the mechanical properties of the plantar surface of the diabetic foot [78].

The prepared sample should have roughly the same elastic modulus as diabetic foot skin, which is ~1150 kPa on average, but ranges depending on the location on the plantar surface [79]. For example, the skin under the first metatarsal has an elastic modulus of ~1500 kPa for diabetic patients, while the heel skin has an elastic modulus of ~850 kPa for diabetic patients. However, calluses have been shown to be roughly 60% less elastic (as defined in units of deformation/pressure by [64]) compared to the surrounding skin, which equates to roughly a 250% increase in elastic modulus (the inverse of elasticity, normalized by equal sample heights). To encompass a reasonable range of elastic moduli that may be present on the plantar surface of a diabetic patient, the target range of elastic moduli tested will be from 850 kPa to 2125 kPa (250% of 850 kPa) [64].

Preliminary samples of alginate were prepared with different concentrations and were tested empirically in an attempt to match the target values of 850 kPa and 2125 kPa. Preliminary tests revealed that a 14.3% weight/volume mixture of alginate in deionized water yielded a modulus of ~1.1 MPa, and a 40% weight/volume mixture yielded a

modulus of ~2.3 MPa. Given that these values were in the approximate range of the target modulus, testing was done using the two aforementioned weight/volume ratios.

The thickness of the skin also affects the overall stiffness of the plantar surface [80], so it is important to account for varying skin thicknesses across the plantar surface, as well as any possible thickening of the skin due to callusing. It has been observed that individuals in Kenya who often walk without shoes develop thick callusing [81], however the thicknesses of foot calluses in the diabetic population has not explicitly been explored in the literature. Because increased skin thickness will, in theory, decrease the measured skin stiffness, it is an important parameter to test in the context of callus detection.

The average diabetic foot skin is 6.3 mm thick (which is lower than their non-diabetic counterparts) [79]. However, the thickness varies from 3 to 11 mm depending on the location of the foot [79]. The target conditions of alginate sample heights were selected to be 6 mm and 10 mm to encompass the moderate- and high-thickness regions that may be present on the different areas of the plantar surface of a diabetic patient. These thickness regions were chosen (as opposed to a low-thickness region like 3 mm), because thicker samples are easier to prepare and small within-group variations in height would proportionately have a smaller effect. In the Kenyan population described above, the average foot callus increases the thickness of the skin by less than 0.5 mm [81]. Since the 4 mm between-group difference in height is much larger than the difference seen by the presence of a callus, any effects on stiffness will be representative of measuring stiffness on different regions of the foot. Random within-group variations in sample height are more likely to be on the range of 0.5 mm, which could roughly display the extraneous effects of callus thickness on measured stiffness.
Cylindrical Teflon molds were used to make the alginate samples due to their consistent shape and size. The volume of alginate needed to achieve each sample height was calculated based on a mold diameter of 19.2 mm and assuming consistent shrinkage of the samples. These values are indicated in Table 3. Preliminary testing revealed that the lower concentration samples tended to shrink slightly more than the high concentration samples. However, without a way to prevent this from occurring, testing was continued with the intention of documenting such limitations.

The aim of this portion of the proof of principle testing is to determine whether increases in elastic modulus (which represent the presence of a callus) can be detected by measuring stiffness as a proxy for the modulus. Stiffness is an appropriate feature for the device to measure, as the dimensions of the foot are unknown. The elastic modulus is a material property that normalizes for sample dimensions via the equation $E = Fh/Ad$ (where F is axial force, h is the height of the sample, A is the cross-sectional area, and d

is the displacement). Stiffness is related to the modulus by the equation K = AE/h, which shows that stiffness is a function of both the material properties (E) and dimensions of the sample (A, h). Thus, stiffness can theoretically be derived from the elastic modulus.

Materials

- 1 Arduino Uno
- 1 force sensitive resistor (FSR, SEN0294)
- 1 small linear actuator (10 mm maximum extension)
- 1 bag of sodium alginate powder
- 1 liter of deionized water
- 10 circular molds (19.2 mm diameter)
- 4 Ziplock bags
- 1 breadboard
- 1 wire kit
- 1 2 kOhm resistor
- 1 set of calipers
- Test Resources Machine (gold standard for compression tests)

Methodology

Test Setup – Alginate Gel Preparation

1. Prepare the alginate samples according to the parameters outlined in Table 3 using the sodium alginate powder and deionized water. 10 samples should be prepared for each condition, all prepared from the same batch of alginate to minimize within-group variability. This yields 40 samples in total. Allow the alginate to set for several minutes before testing begins.

Table 3. Alginate formation parameters for each condition.

Condition	Simulated Callus State	Concentration of Alginate (%w/v)	Simulated Skin Thickness	Alginate Sample Height (mm)	Alginate Sample Volume (mL)
1	Non-callused	14.3	Moderate Thickness	6	1.7
2	Non-callused	14.3	High Thickness	10	2.9
3	Callused	40	Moderate Thickness	6	1.7

4	Callused	40	High Thickness	10	2.9

2. After the alginate has set, lightly touch the samples to ensure that they have firmed up properly. Visually inspect the samples for any fractures or imperfections and discard samples with such features. Use a caliper to measure the height of the alginate samples and for each condition, select the three samples closest to the target sample height to be used in testing.
3. Place the samples to be used for testing in Ziplock bags to minimize water loss due to evaporation. Separate the samples based on condition and label the bags appropriately.
4. Immediately before testing, remove the sample to be tested from the Ziplock bag and place it on a paper towel. Gently roll the sample on the paper towel to remove any excess moisture from the surface of the sample.
5. Then, use the calipers to measure the diameter and height of each sample to be tested. During testing, three trials of each condition will be conducted for gold standard compression tests as well as for compression tests with the PoP device. Record these values in Table 4 for the gold standard compression tests and Table 5 for the PoP device tests. After all values have been recorded, calculate the mean and standard deviation for each value. These values will not be used in the stiffness calculations but will be used to calculate the modulus of the samples, which helps to validate the alginate phantom.

Table 4. Alginate sample values to be collected during the experiment – Gold Standard

	Alginate Sample Diameter (mm)				Alginate Sample Height (mm)			
Trial	Cond. 1	Cond. 2	Cond. 3	Cond. 4	Cond. 1	Cond. 2	Cond. 3	Cond. 4
Mean	16.6	16.8	18.4	18.6	5.4	8.5	6.0	9.4
Std. Dev.	0.03	0.04	0.05	0.06	0.11	0.30	0.14	0.33

Table 5. Alginate sample values to be collected during the experiment – Device

	Alginate Sample Diameter (mm)	Alginate Sample Height (mm)

Trial	Cond. 1	Cond. 2	Cond. 3	Cond. 4	Cond. 1	Cond. 2	Cond. 3	Cond. 4
Mean	16.2	16.4	18.2	18.4	5.2	8.4	6.5	9.6
Std. Dev.	0.1	0.1	0.1	0.1	0.1	0.1	0.4	0.4

Before performing the compression tests with the PoP device, the two major components of the device (linear actuator and FSR) needed to be validated.

Device Validation – Linear actuator

The displacement rates and the force versus displacement relationships were compared for the gold standard machine and the PoP device. Figure 42 demonstrates the stepwise movement of the device. While the gold standard machine can move in a more continuous manner, the PoP device moves in increments but is still accurate in moving the intended as the linear actuator is position-controlled and moves to the distance specified. The actuator speed was 16.76 mm/s and was not directly controllable for the used actuator as it was position-controlled, but the incremental movement effectively slowed the speed. Figure 43 illustrates two behaviors of the device relative to the gold standard. First, there is stress relaxation present in the device force vs displacement whereas this phenomenon is not present in the gold standard plot. This stress relaxation behavior with repetitions of rapid increases in stress followed by gradual decreases may be tied to the incremental movement of the linear actuator as seen in Figure 42. Additionally, the stiffnesses can be seen by the slopes of the linear fits for each force vs displacement plot in Figure 43. So, the stiffness measured by the device is lower than the stiffness measured by the gold standard as will be further explored and described in the results section.

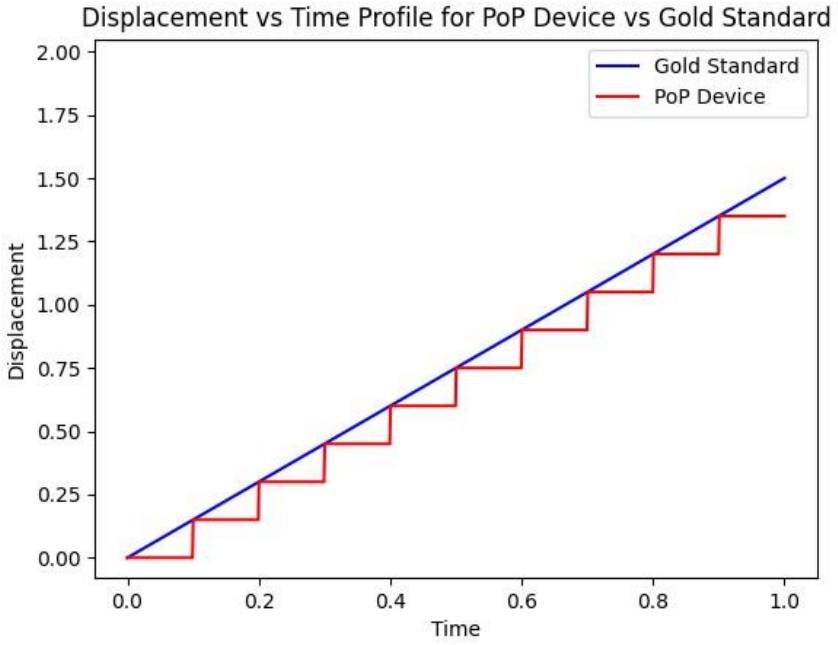


Figure 42. Displacement vs time compared between gold standard and PoP device.

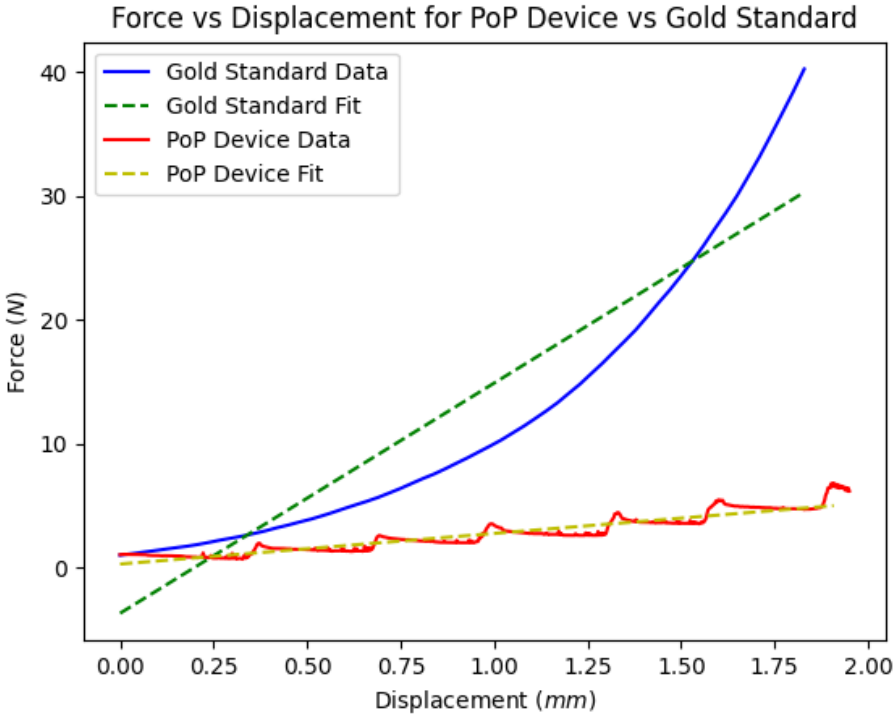


Figure 43. Force vs displacement compared between gold standard and PoP device.

Device Validation – FSR

Successfully implementing the FSR involved the development of two major equations that can be seen in the readForce() function block below from our code (located in Section VIII: Code as referred to in the appendix). The readForce() function enables the conversion of the raw ADC value to an analog FSR voltage to finally output a force reading based on resistance. Specifically, these two equations include the equation for the float fsrResistance and the equation for the float Force. The equation for fsrResistance was derived from an optimization problem and a voltage divider problem, while the equation for Force was derived from the datasheet information and subsequent calibration to the gold standard force reading magnitudes [84].

Developing the fsrResistance involved two steps. First, the optimal resistance had to be determined to get the full scale range of FSR resistances for the team's application. Second, this resistance was put into a voltage divider equation based on the structure of the circuit to then solve for resistance explicitly. This second step is a straightforward voltage divider problem, but the optimization step requires further explanation. The goal of the optimization problem was to vary the resistance to try to get the maximum range of analog voltage outputs from the FSR, therefore maximizing the team's calculated range of force outputs. As will be explained in the next section, 1 N was the desired force floor while 20 N was the observed force ceiling for the linear actuator system. The relationship on the FSR datasheet between force and resistance could be used to determine that this desired 1 N to 20 N force range corresponded to a resistance range of 6.13 kilo-Ohms down to 0.74 kilo-Ohms [84]. The output voltage with each of these resistance threshold vales could be represented with the voltage divider relationship below.

$$V_{out} = 5 * \frac{R_{FSR}}{R_{FSR} + R}$$

In the above equation, the constant 5 represents in input voltage, R_{FSR} represents the resistance of the FSR, and R represents the resistance of the additional resistor. R_{FSR} could be replaced with the 6.13 kilo-Ohm and 0.74 kilo-Ohm resistance range extremes to get the voltage outputs at the range extremes as equations dependent on the resistance R. Then, the optimization problem involved finding the value of R such that the difference between these two voltage output equations could be maximized. Ultimately, the optimal resistance was found to be 2129 Ohms. Using a 2 kilo-Ohm resistor produced a range that was approximately equivalent, so we chose this as the resistor for the FSR circuit loop in the overall circuit seen in Figure 45. When this resistance value was incorporated into the overall voltage divider equation, the FSR resistance could be derived as a function of output voltage.

Furthermore, the equation to convert FSR resistance to applied force was adapted from information in the FSR's datasheet. The division by 153180 and the exponent of -1/0.699 could be directly derived from the force versus FSR resistance relationship given in the FSR datasheet, as shown in Figure 44. Note that 153180 was used instead of 153.18 because the relation given by the datasheet took an input in kohms instead of ohms.

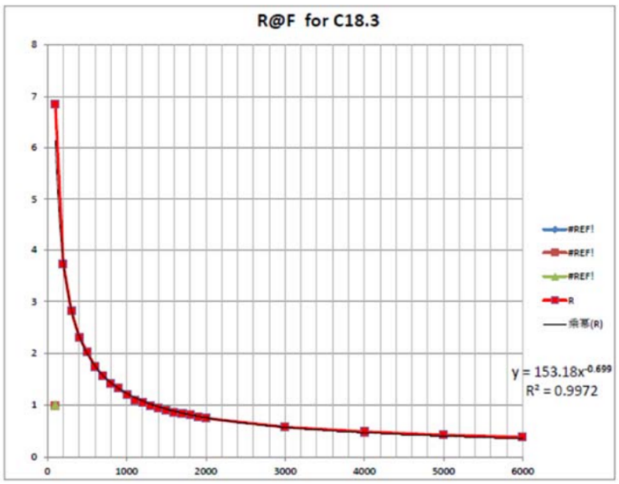


Figure 44. Conversion chart from resistance to force from FSR data sheet [84].

0.00981 was a conversion factor from grams to Newtons. We confirmed that our sensor was not behaving in perfect accordance with the provided conversion chart, so the 35.36 subtraction and division by 8 were calibration adjustments to correct for the consistent offset and magnitude scale difference between the FSR force outputs and the gold standard data. The fsr_scale variable was set to 0.625 after a series of preliminary tests and served as a final scaling factor to closely align the two sets of measurements. In the future, we may consolidate our scaling factors as to make our equations more intuitive to interpret.

"""

```
float readForce(float adc) {
  // analog voltage reading ranges from about 0 to 1023 which maps to 0V to 5V (= 5000mV)
  float fsrVoltage = map(adc, 0, 1023, 0, 5000);
  // Serial.print("Voltage reading in mV = ");
  // Serial.println(fsrVoltage);
  //this 5k seems wrong
  int resistor = 2000;  //change as appropriate
  int V_in = 5;
  fsrVoltage = fsrVoltage / 5000;                    // change fsrvoltage to volts
  float fsrResistance = 2000 * fsrVoltage / (5 - fsrVoltage);  // fsrVoltage is in millivolts so 5V = 5000mV
  // Serial.print("FSR resistance in ohms = ");
  //Serial.println(fsrResistance);
```

```
  //convert value to force using FSR datasheet [84]
  //unit conversion to get force output in N from R input in ohms
  float Force = (.00981 * pow(fsrResistance / 153180, -1 / 0.699) - 35.36) / 8;
  Force = Force * fsr_scale;
  return Force;
}
```

”””

The force readings from the FSR were compared to the gold standard Test Resources machine force readings. FSR force readings were obtained from its analog voltage values as shown in the Arduino code section below. Gold standard force readings were directly output by the machine. The scaling factor for the FSR force readings was determined so that the forces were similar in magnitude to the gold standard forces. As can be seen below in Figure 45, the general shape of the force vs time curves were similar for the FSR and gold standard tests, indicating proper functionality of the FSR. The percent errors of the FSR force readings were also low, within 7%.

A B

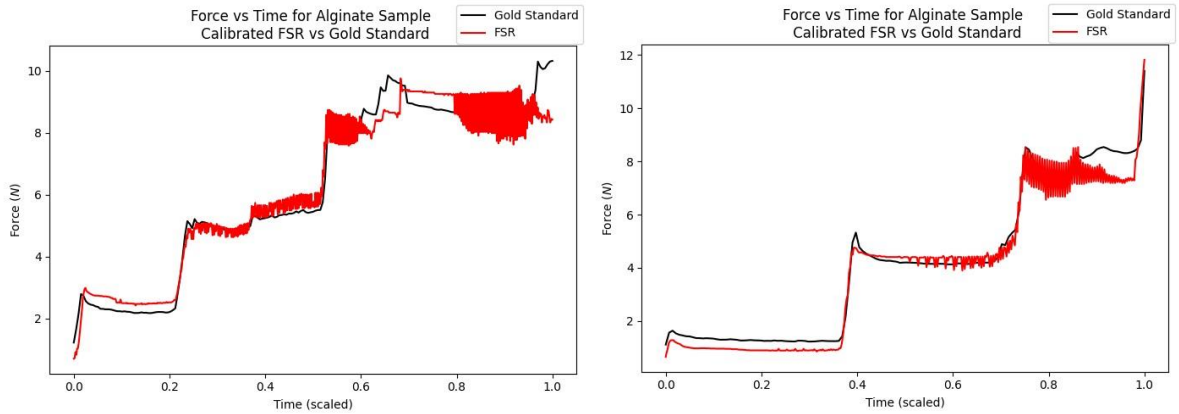


Figure 45. Calibration of the FSR to load measurements from “gold standard” compression testing machine. (A) Net percent error = 1.25%. (B) Net percent error = 6.56%.

Device Validation: Combining Actuator and FSR Function Within Arduino Code

The code utilized for the stiffness PoP testing can be viewed in Section VIII: Code. The linear actuator was controlled in conjunction with the FSR with a couple key

considerations. For both the gold standard testing and the device testing, the team chose to measure the stiffness as a linear regression between when the device reached 1N of force and then 1.95 mm after that point. The choices of a 1 N threshold and 1.95 mm distance can be justified as described below.

The force threshold of 1 N was when the data collection was initiated as it was difficult to visually tell when the top platen or linear actuator device contacted the gel. Choosing the 1 N threshold was appropriate as it was above the level of random noise and corresponded to the beginning of them rapid force uptick that was seen accompanying contact and subsequent compression. Decreasing this threshold further or incorporating more complex signal smoothing (currently, the current and previous force are averaged) to determine contact amongst the surrounding noise could be possibilities for further exploration.

The displacement of 1.95 mm was chosen as the team was aiming for 2 mm because in preliminary testing, 2 mm was the point at which the team saw samples starting to reach the maximum load made possible by the actuator. However, the actuator could only move in increments of 0.03 mm, so the team rounded down and chose the nearest round number.

Compression Testing with Gold Standard Test Resources Machine

1. Create a displacement-controlled test profile using the Newton software to control the 100 lb_f Test Resources machine. Set the maximum load to 300 N so as not to damage the machine. Set the displacement rate to 1.5 mm/s and ensure that two compressive platens are mounted on both the top and bottom of the apparatus, as shown in Figure 45. Set 3 channels to record time (s), position (mm), and force (N) at a sampling frequency of 1000 Hz and export to a .csv file for each test. Program the Test Resources machine to stop a test after a sudden 50% drop in load.

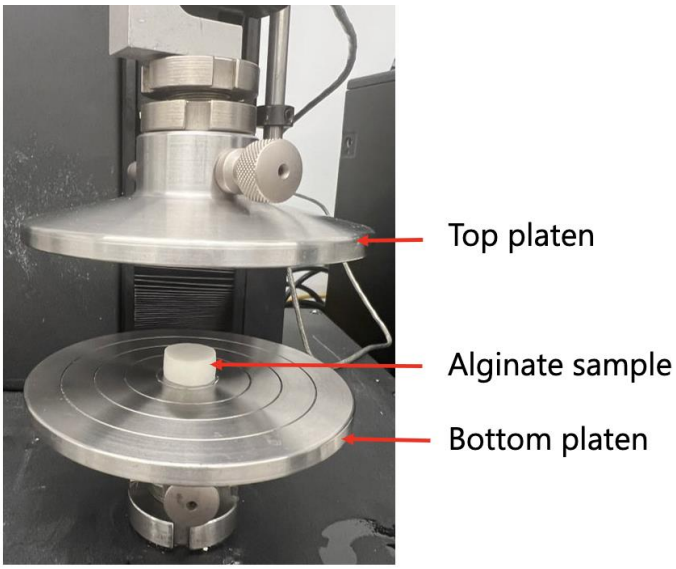


Figure 46. Test Resources Machine Setup for Gold Standard Testing.

2. Steps 3-6 below will be repeated for each of the 4 conditions listed in Table 3. Three trials of each condition shall be performed. Following this, data analysis with steps 7-10 should be performed on each of the 4 conditions as well.
3. Place the alginate sample in the Test Resources testing apparatus such that it rests on the center of the bottom platen, as shown in Figure 46.
4. Tare the machine with the platen well above the sample, then jog down the top platen until it is barely touching the top of the sample, creating a force of ~0.01 N.
5. Press the play button on the Newton software and watch the sample be compressed. In case of emergency, be ready to hit to red stop button on the Test Resources remote. The machine should automatically stop the test after the sample reaches failure.
6. Import the force and position data to Python. Calculate the second derivative of the force data and determine where full contact with the sample was made by finding the maximum concavity within the first 0.05% of the data. Subtract the force and displacement values at this point from the rest of the force and position values so that they are effectively zeroed at contact.

To calculate the stiffness of the linear region:

7. Determine the point at which there is a second maximum in concavity (after the first ~40% of data), indicating the start of the linear region. Verify visually that this is the point at which the force versus displacement curve is starting to be most linear. Calculate the slope at this point and determine the point at which the slope drops below 50% of the initial slope, indicating the start of yield stress and the end of the linear region. Perform a linear regression on the force versus displacement data in this range and report the slope of the regression as the

stiffness of the linear region. This is shown by the equation below with the spring constant, k, defined as the change in force over the change in displacement.

$$k = \frac{\Delta F}{\Delta x}$$

To calculate the modulus of the linear region:

8. Calculate stress and strain using the equations below. Note that h is the height of the sample and A is the cross-sectional area of the sample, which can be calculated from the measured diameter in Table 4.

$$Stress = \frac{\Delta F}{A}, Strain = \frac{\Delta x}{h}$$

9. Using the previously described linear region, perform a linear regression on the stress versus strain data and report the slope of this regression as the modulus of elasticity, E, as shown in the equation below.

$$E = \frac{Stress}{Strain}$$

To calculate the stiffness of the low-displacement region:

10. Determine the point at which the force first exceeds 1 N, and the point 1.95 mm of displacement after that. Perform a linear regression on the force versus displacement data in this range and report the slope of this regression as the stiffness of the low-displacement region.

Compression Testing with PoP Device (Linear Actuator and FSR)

1. Build the circuit outlined in Figure 47 using the Arduino, linear actuator, controller, force sensor, and a 10 kOhm resistor. Use a USB computer cable as the power supply for the Arduino, which will power the linear actuator. The SEN0294 sensor has a thickness of 0.4 mm with a pressure measuring range of 20g to 6kg.
2.

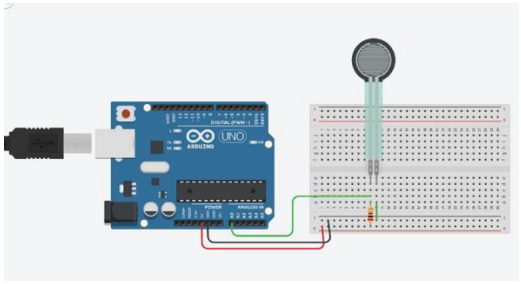
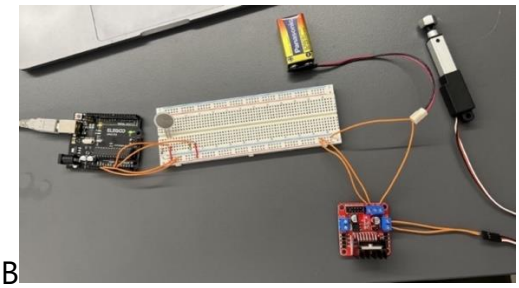
A  B 

Figure 47. FSR and Motor Driver Module with Arduino. (A) Schematic made in Tinkercad and (B) Physical Setup

3. Attach the FSR to the end of the linear actuator, perpendicular to the direction of motion. The FSR should be mounted firmly and in a way that it is compressed when the linear actuator extends.

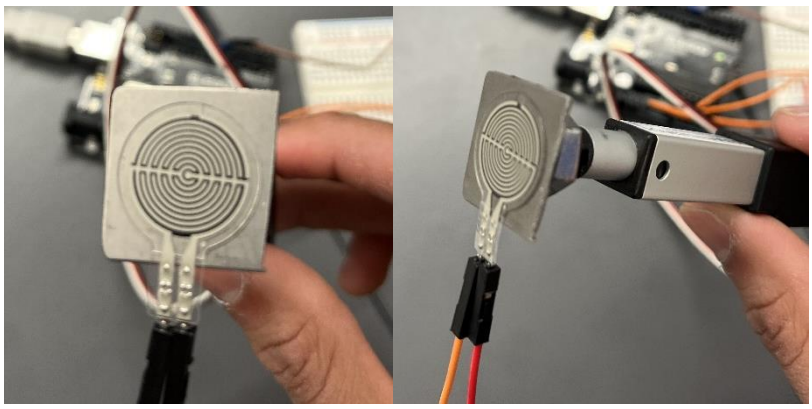
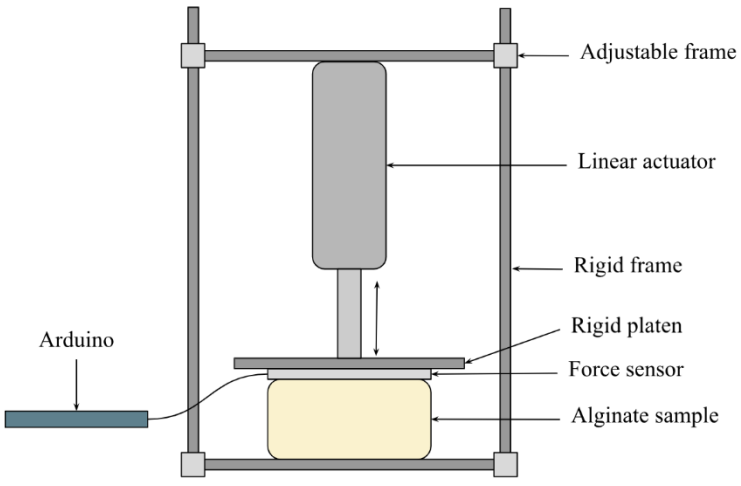


Figure 48. Adhesive side of the FSR attached a custom cut sheet metal, which was Gorilla Glued to a hex nut connected to the linear actuator.

4. Construct the experimental setup shown in Figure 49, with a tensile clamp holding the linear actuator in place. Adjust the clamp so that it firmly holds the linear actuator perpendicular to the center of the bottom platen and will prevent backwards movement once the actuator extends.

A



B

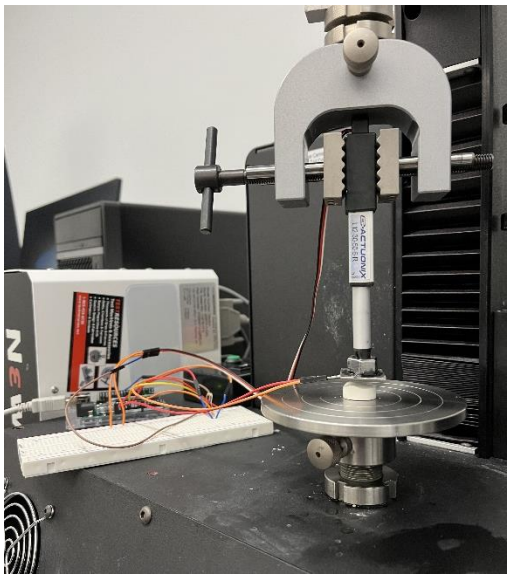


Figure 49. Test setup for compression tests of alginate samples using the linear actuator and FSR. (A) Schematic diagram and (B) Experimental setup.

5. Upload code to the Arduino to perform the desired task. The Arduino code for stiffness PoP testing is listed in section VIII with the code as referred to in the appendix. The main functional components of the code were described in the validation section within methodology. Force data and displacement data were recorded at a sampling frequency of ~3380 Hz and printed between increments of the linear actuator. Incrementing the movement allowed reduction of the usual 16.76 m/s speed of the actuator, and position was controlled due to the position-control nature of the chosen actuator.
6. Steps 6-9 below will be repeated for each of the 4 conditions listed in Table 3. Three trials of each condition shall be performed.
7. Place the alginate sample in the center of the bottom platen. Jog down the tensile clamp using the Newton software so that the bottom of the FSR is within a few millimeters of the top of the sample.
8. Press the reset button the Arduino to allow the linear actuator to retract to its initial position, return to the halfway position, tare itself, and then start incrementing. The force and displacement values will print to the Serial monitor as the actuator extends. When initial contact is made (≥1 N), the displacement values are zeroed, and the actuator extends for another 1.95 mm before the test ends.
9. An optional validation step is to have the Test Resources machine collect force versus time data in dwell mode. The force values can then be compared between the FSR and gold standard for validation.
10. At the end of the test, copy the printed results from the Serial monitor and paste them into an Excel sheet. Import the force and displacement data to Python for further analysis.

To calculate the stiffness:

11. The first recorded data point occurs when 1 N of force has been reached, so no cropping of the data needs to be done on the front end. Determine the point at which the maximum force was reached and exclude data after this point, since this is where the maximum displacement is first reached. Perform a linear regression on this region of the data and report the slope of the regression as the stiffness, as shown by the equation below.

$$k = \frac{\Delta F}{\Delta x}$$

Analysis

Gold Standard Force vs Displacement Plots

Two graphs are included for each of the four conditions tested in the gold standard testing. The first graphs (Figures 50, 52, 54, 56) are the stress vs strain curve for that condition, following the expected shape with an initial linear region and then a nonlinear region. The slope of the linear region is used to find the elastic modulus. The second graphs (Figures 51, 53, 55, 57) apply a linear fit for the linear region of each sample's stress vs strain plot, therefore representing the elastic modulus of the sample through the fit's slope. These slopes corresponding to the elastic moduli could be used to verify that the alginate concentrations were in the physiological target range for elastic modulus.

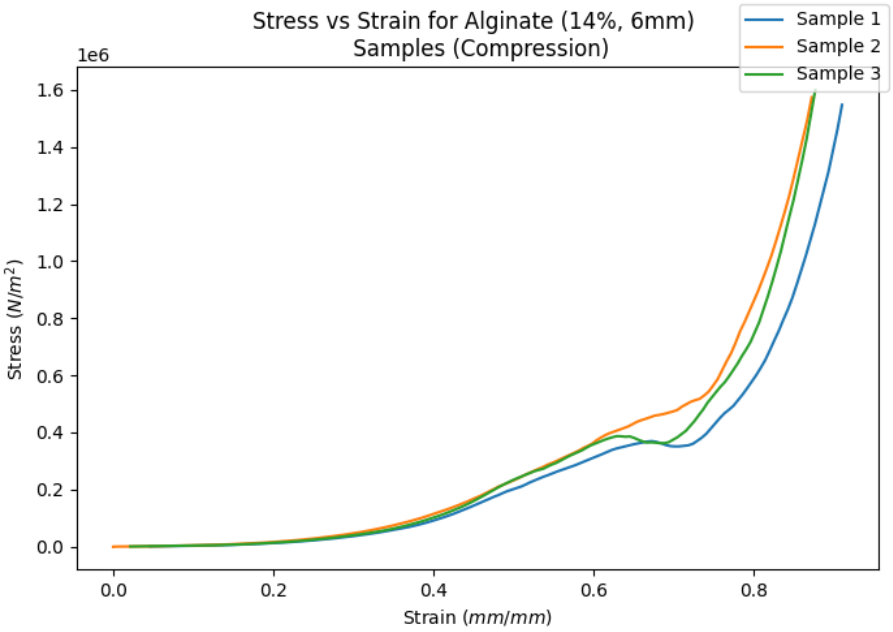


Figure 50. Stress vs strain plot for Condition 1.

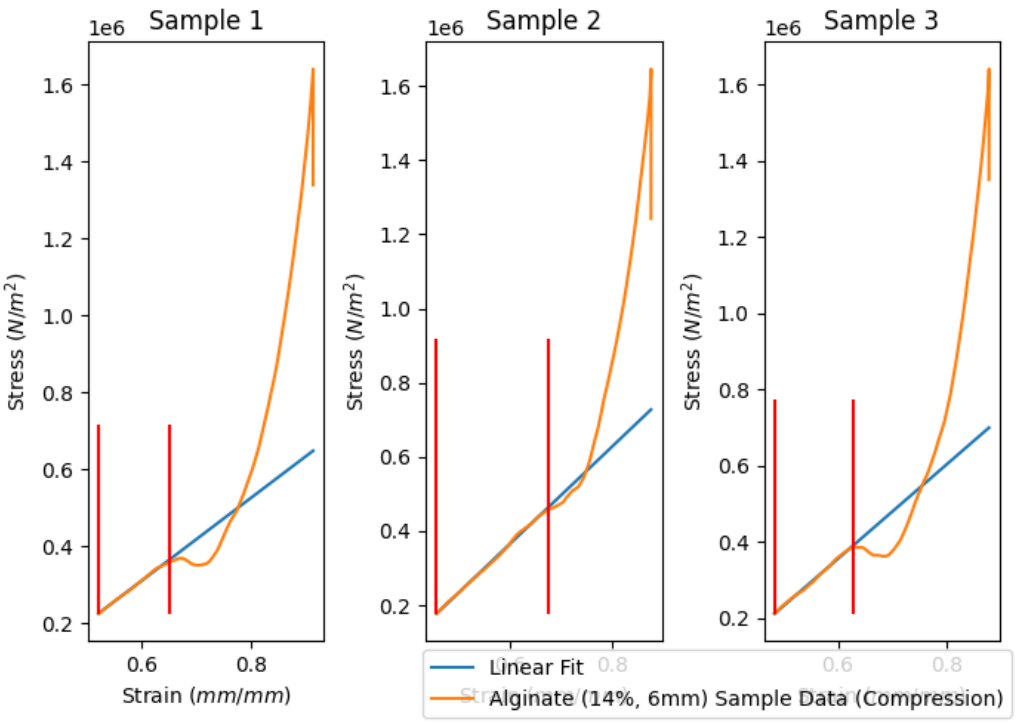


Figure 51. Linear Regression for Condition 1.

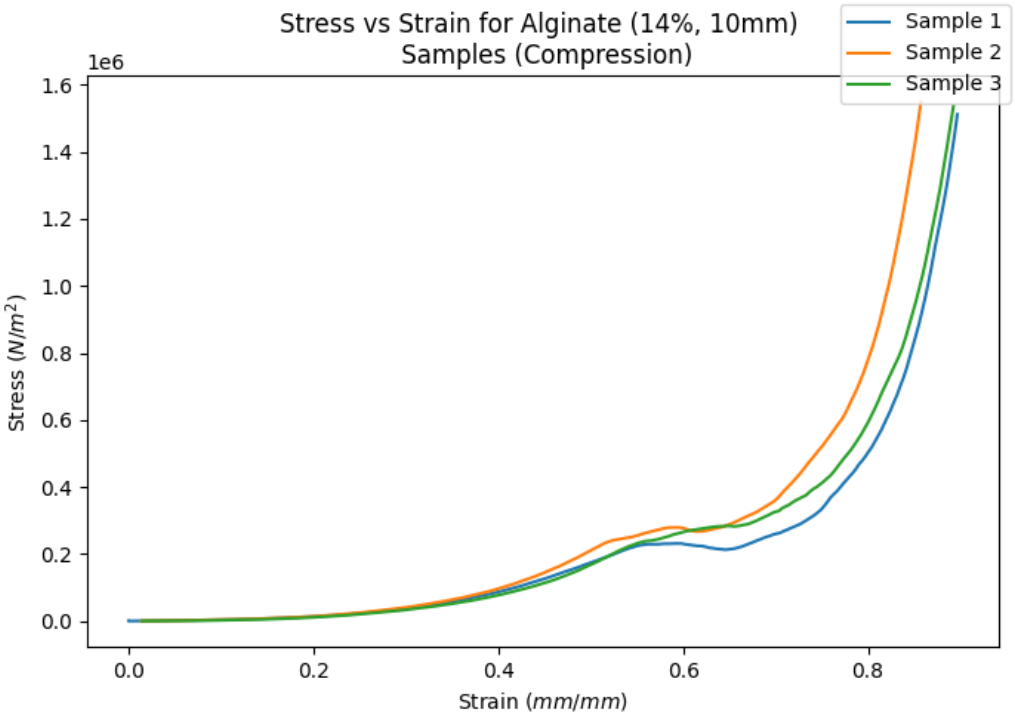


Figure 52. Stress vs strain plot for Condition 2.

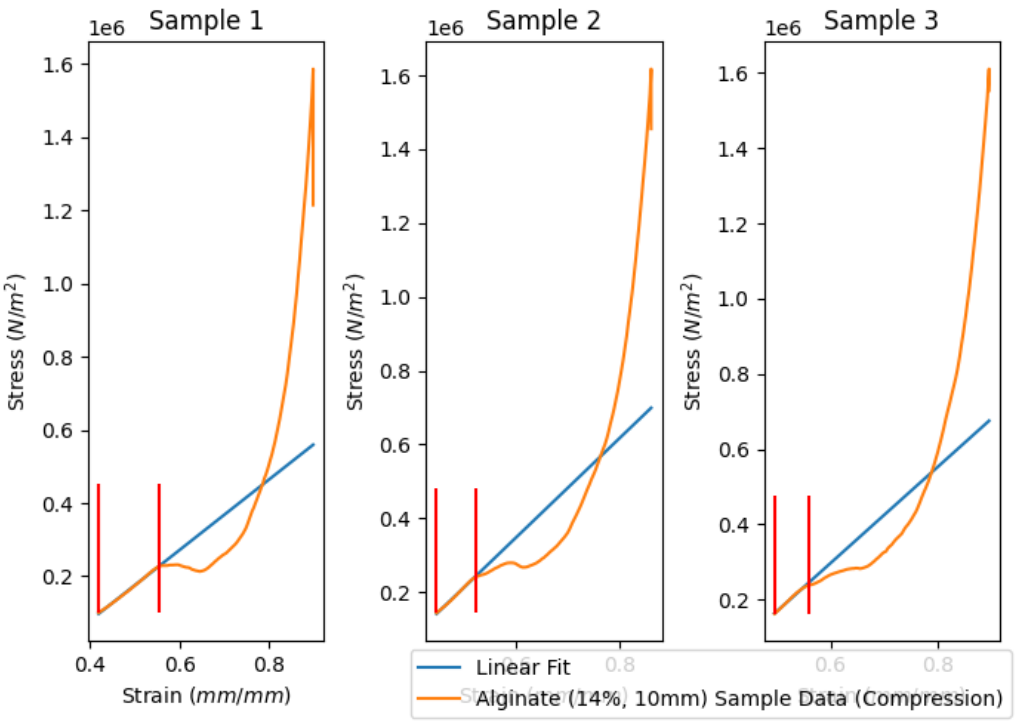


Figure 53. Linear Regression for Condition 2.

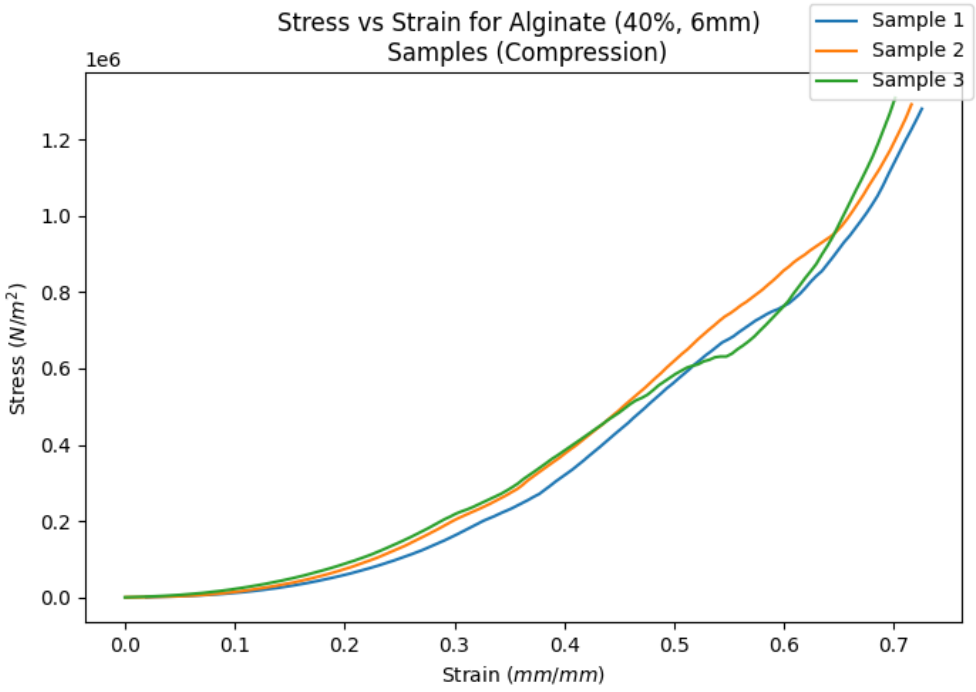


Figure 54. Stress vs strain plot for Condition 3.

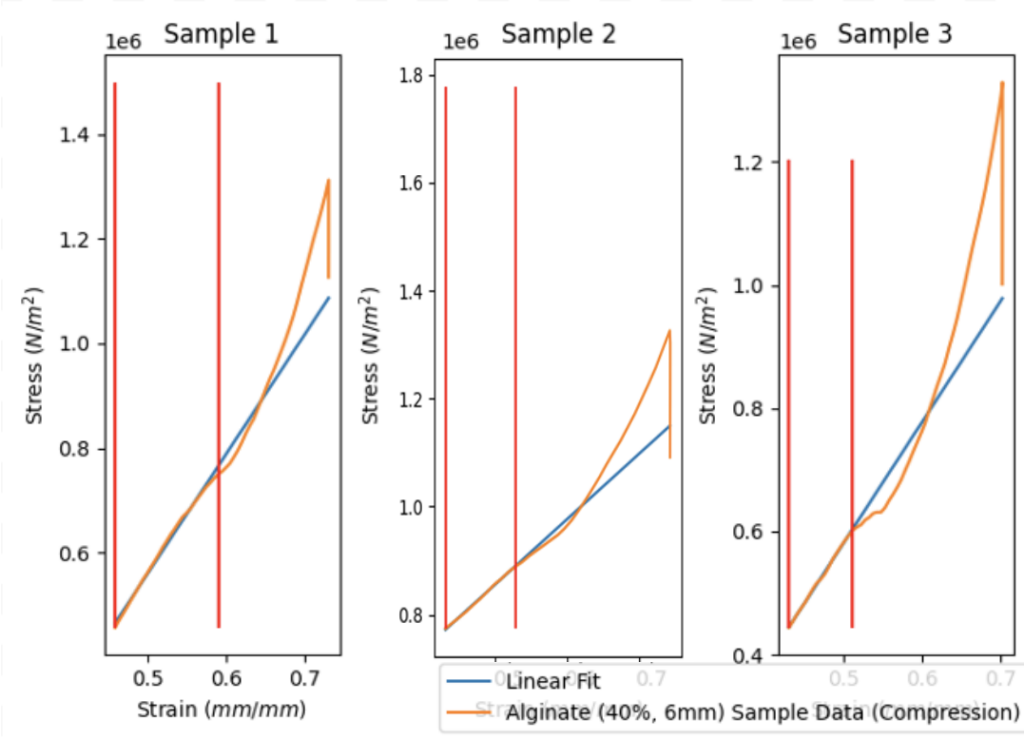


Figure 55. Linear Regression for Condition 3.
Note: Sample 2 required a separate script due to its small dip in yield stress.

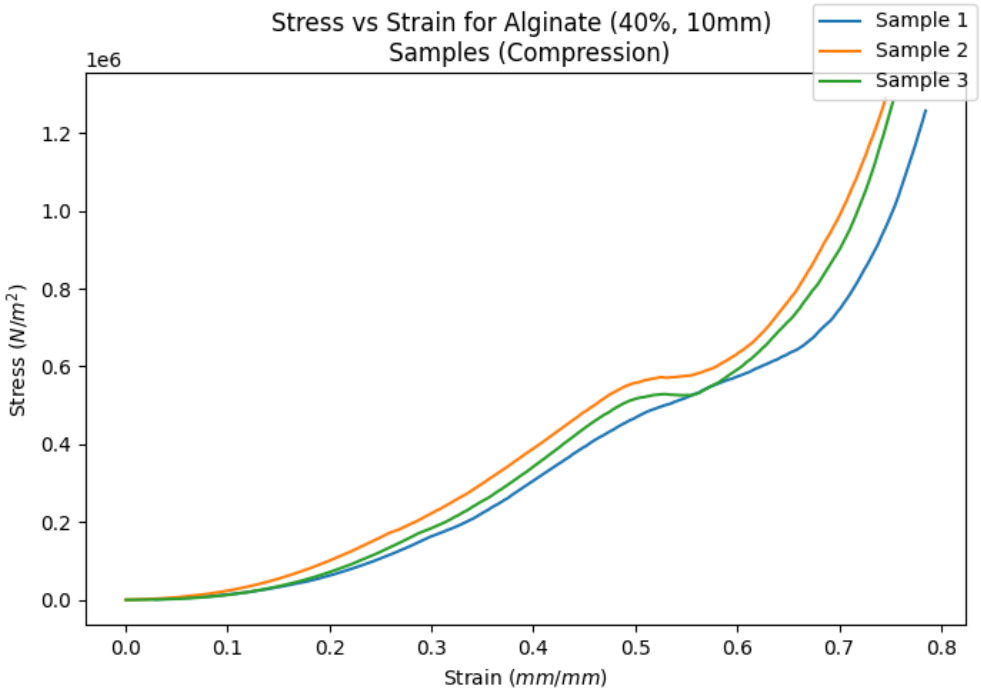


Figure 56. Stress vs strain plot for Condition 4.

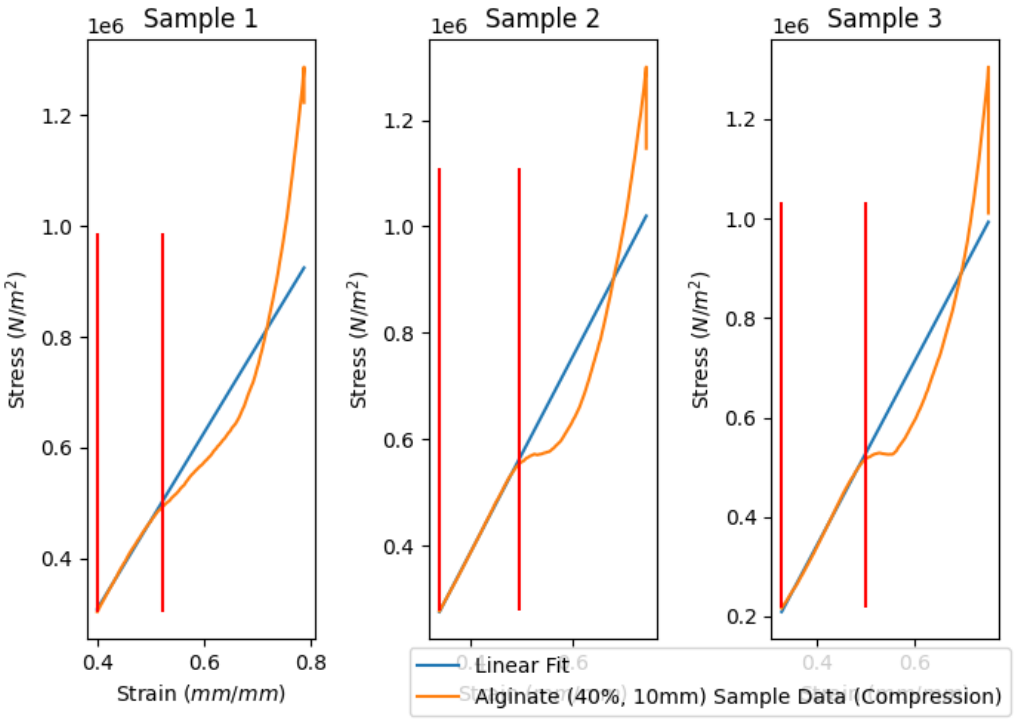


Figure 57. Linear Regression for Condition 4.

Linear Actuator Device Force vs Displacement Plots

Generated force vs displacement graphs for all conditions (Figure 58) and then for each condition individually are included for the device testing. The graph of linear fits for the samples for each condition is included in Figure 63. These linear fit slopes correspond to elastic moduli, which are then used to calculate stiffnesses. All plots were cropped to stop at the maximum load to standardize all trials to end at max deformation. As observed in the linear actuator validation testing, the presence of stress relaxation can be seen in each of the force vs displacement curves for each condition.

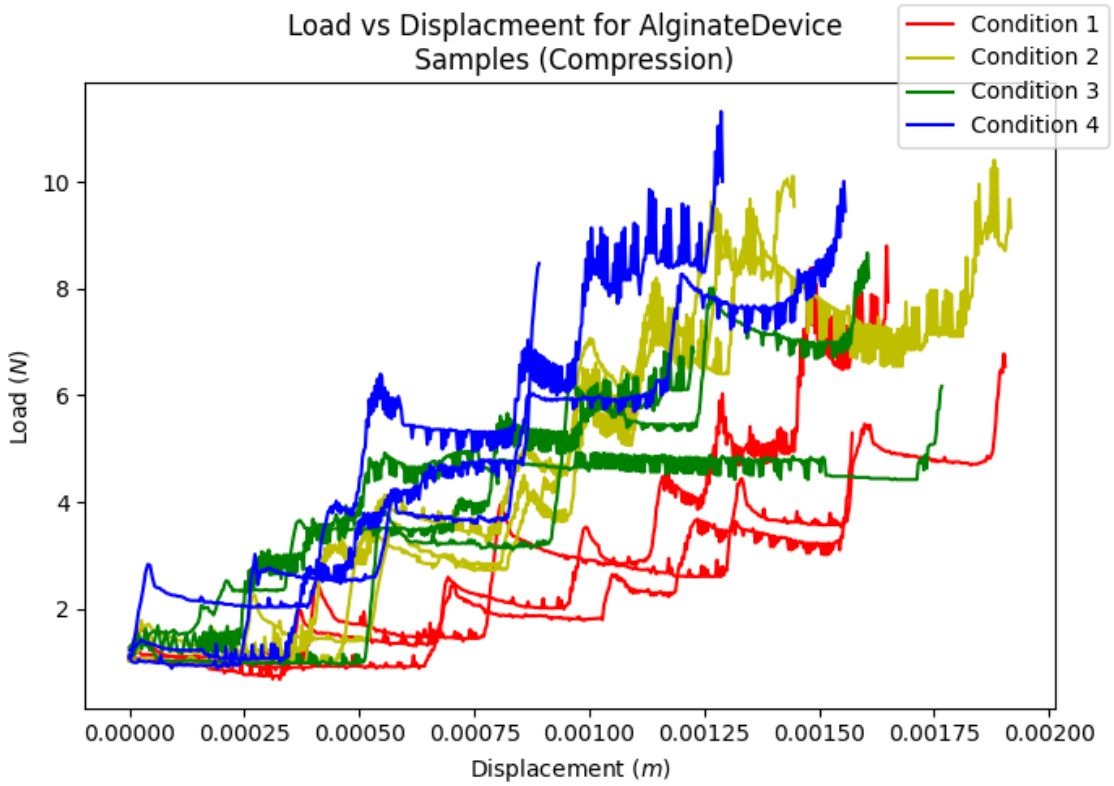


Figure 58. Load vs displacement plots for all trials of all four conditions.

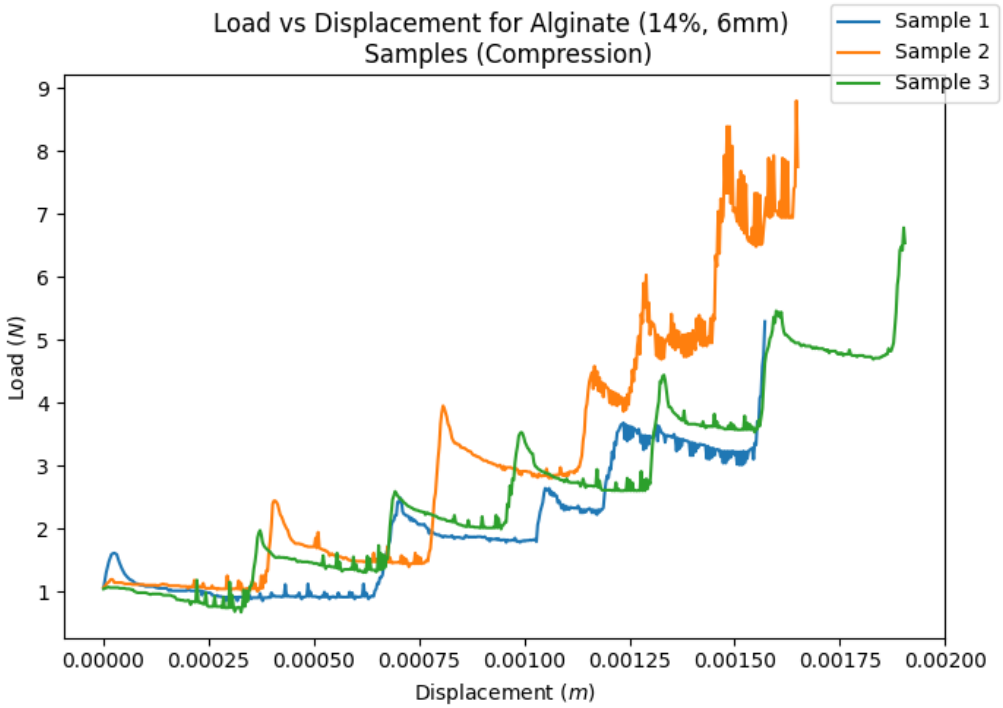


Figure 59. Load vs displacement for Condition 1.

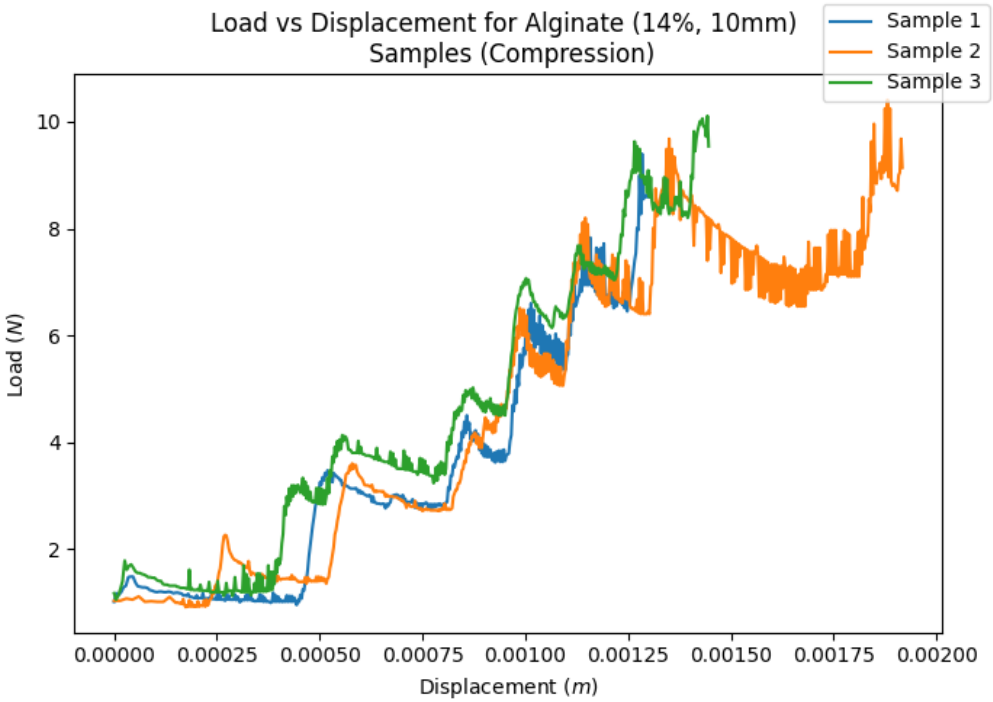


Figure 60. Load vs displacement for Condition 2.

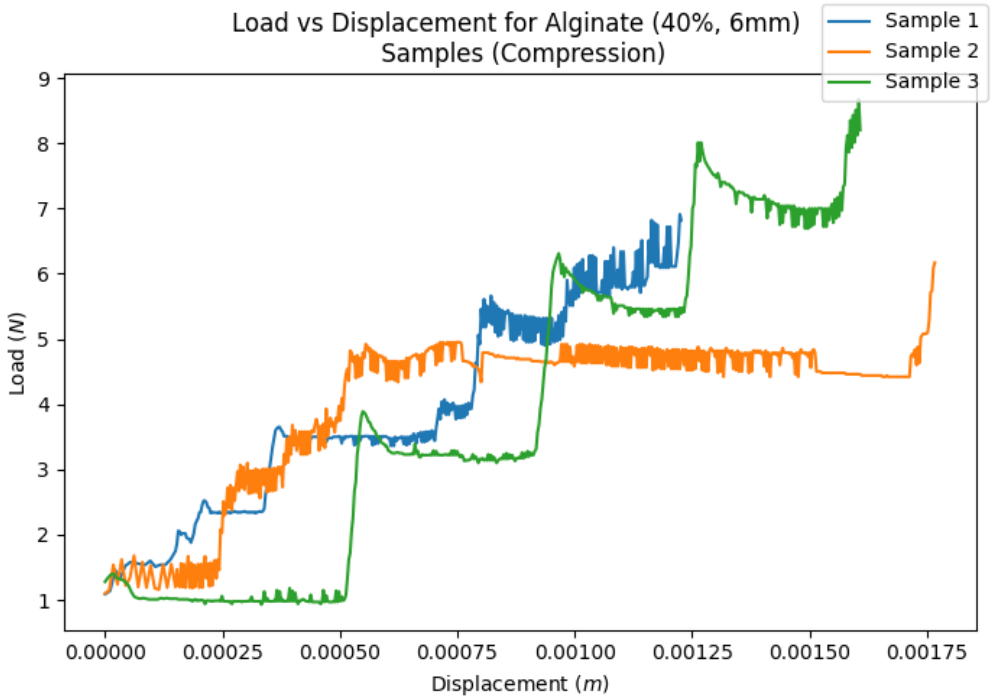


Figure 61. Load vs displacement for Condition 3.

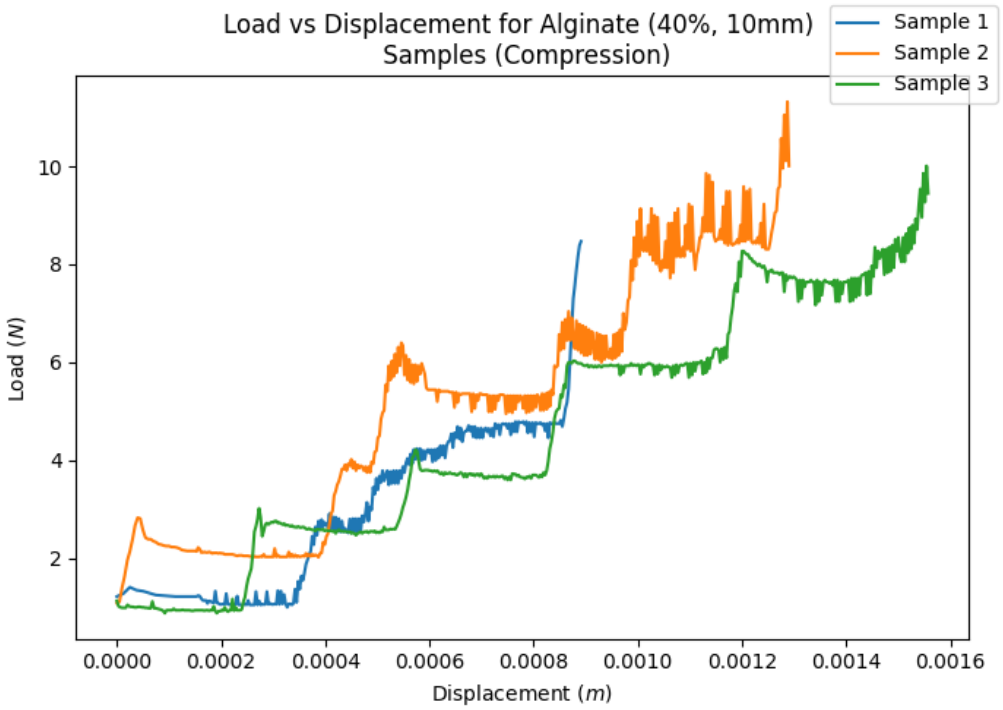


Figure 62. Load vs displacement for Condition 4.

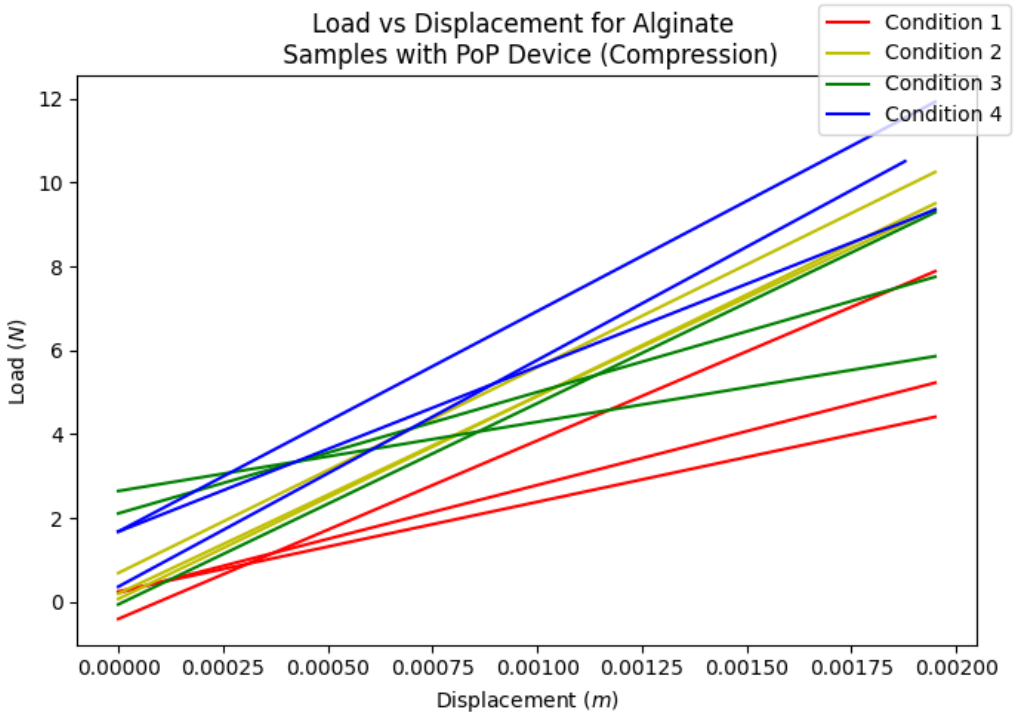


Figure 63. Linear fits for the 3 samples tested in each condition. Slopes represent stiffness.

Results

As described in the methods section, stiffness values were extracted from the linear regression slopes in the force vs displacement plots for each condition.

Gold Standard – To Failure

The stiffness calculations can be seen in Table 6. The elastic modulus values of each of the three samples across the four different conditions are reported in Table 7.

Table 6. Alginate sample stiffnesses – Gold Standard.

	Calculated Stiffness (kN/m)			
Trial	Cond. 1	Cond. 2	Cond. 3	Cond. 4
1	43.69262743	24.58068057	102.85490442	48.22788083
2	53.95215744	34.26463156	103.89997547	52.14744956
3	48.41996928	34.94540804	88.6891412	50.33869519
Mean	48.6883	31.2636	98.4813	50.238
Std. Dev.	4.1927	4.7337	6.9373	1.6017

Table 7. Alginate sample elastic moduli (calculated from Gold Standard data).

	Calculated Modulus (MPa)			
Trial	Cond. 1	Cond. 2	Cond. 3	Cond. 4
1	1.07071414	0.96231766	2.28274907	1.58554782
2	1.32340153	1.35905801	2.43061054	1.81766295
3	1.24017559	1.28144723	1.95544417	1.82898291
Mean	1.2114	1.2009	2.2229	1.7441
Std. Dev.	0.1051	0.1717	0.1985	0.1122

A two-way ANOVA fixed effects model with alginate concentration and sample height as the independent variables was performed for both stiffness and elastic modulus. Alginate concentration and sample height were found to yield statistically significant differences in stiffness ($p<0.001$ and $p<0.001$, respectively). Post-hoc Tukey HSD test

A

revealed that there was a significant increase in stiffness when alginate concentration was increased from 14.3% w/v to 40% w/v for both the shorter samples ($p<0.001$) and taller samples ($p=0.0058$). Post-hoc Tukey HSD test also revealed a significant decrease in the stiffness for the taller samples at both the 14.3% and 40% alginate concentration ($p=0.017$ and $p<0.001$, respectively). Furthermore, a significant interaction action was found between the two independent variables ($p=0.0018$). The antagonistic relationship between concentration and thickness is evident in Figure 63A. The combined effect of a higher alginate concentration and a taller sample is much less than each of their individual effects. Hence, Condition 4 has a statistically similar average stiffness compared to Condition 1.

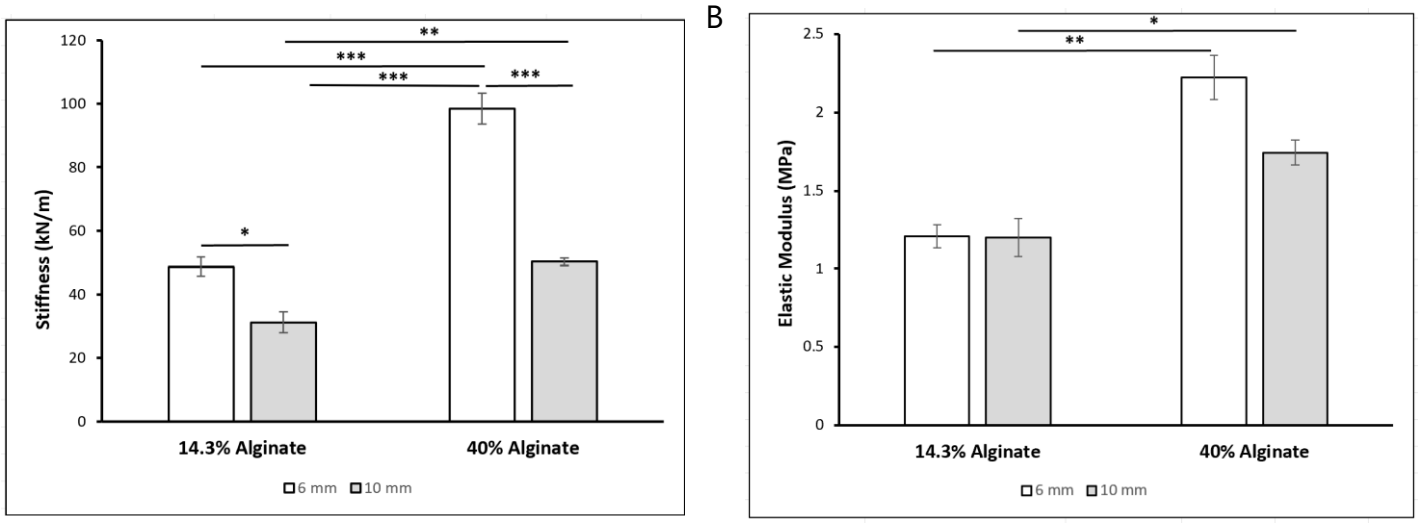


Figure 64. Differences in (A) stiffness and (B) elastic modulus across alginate samples with varying concentrations and heights. Error bars represent SE, *p<0.05, **p<0.01, ***p<0.001

In terms of the elastic moduli, only the alginate concentration was found to yield statistically significant differences in stiffness ($p<0.001$). The average elastic moduli at the 14.3% w/v alginate concentration was about 1.2 MPa and the average elastic moduli for the 40% w/v alginate concentration was about 2 MPa, in the range of the target physiological values reported earlier in the Background section. Post-hoc Tukey HSD tests indicated that increasing the alginate concentration universally leads to higher average sample stiffnesses ($p=0.003$ for shorter samples and $p=0.020$ for taller samples). No significant interaction effect was found between the two independent variables ($p=0.061$). From a biomechanical context, the results are justifiable. The elastic modulus remain approximately the same across different sample thicknesses because it has effectively normalized for the effects of sample dimensions. On the other hand, stiffness

does not account for these values because it is simply K = F/d. Hence, the elastic modulus is an intrinsic material property and is independent of a sample's size or shape.

Gold Standard – Small Deformation Region

In the context of foot indentometry, the small deformation region is more relevant for several reasons. Firstly, foot tissues are soft and easily deformed. Unlike bone or other rigid materials, the foot consists of soft tissues like muscles, fat, and connective tissue that deform readily under pressure. Therefore, measurements within the small deformation region, where the stress-strain relationship is linear, provide more accurate information about the initial elastic response of these tissues. From a clinical standpoint, the small deformation region reflects the initial, sensitive response of the tissue to pressure, making it ideal for detecting these early-stage changes. Finally, considering our team plans to focus on indentometry, this technology typically measure small displacements within the small deformation region to minimize discomfort on the patient.

As discussed earlier, we chose to assess the stiffness after the sample had been displaced 1.95 mm from the initial point of contact with the platen. The results for the three samples in each of the four conditions is shown in Table 8.

Table 8. Alginate sample stiffnesses – Low strain region Gold Standard (<1.95mm).

	Calculated Stiffness (kN/m)			
Trial	Cond. 1	Cond. 2	Cond. 3	Cond. 4
1	21.75539893	5.38277403	40.39133766	18.27033346
2	20.29695905	5.78328469	43.53731926	20.76648199
3	20.51885281	6.78693808	44.34357569	17.81298638
Mean	20.8571	5.9843	42.7574	18.9499
Std. Dev.	0.6416	0.5906	1.7051	1.298

The same trends were preserved in this scenario, with alginate concentration and sample height leading to statistically significant differences in stiffness ($p<0.001$ and $p<0.001$, respectively). Again, post-hoc Tukey HSD test revealed that increasing alginate concentration yielded a significant increase in stiffness for all sample thicknesses ($p<0.001$ for both shorter and taller samples). This can be visualized by comparing

Conditions 1 and 3 as well as Conditions 2 and 4 in Figure 65. Lower stiffnesses were observed with the thicker samples across both alginate concentrations ($p<0.001$ for both). The interaction effect action was still present between the two independent variables ($p<0.001$).

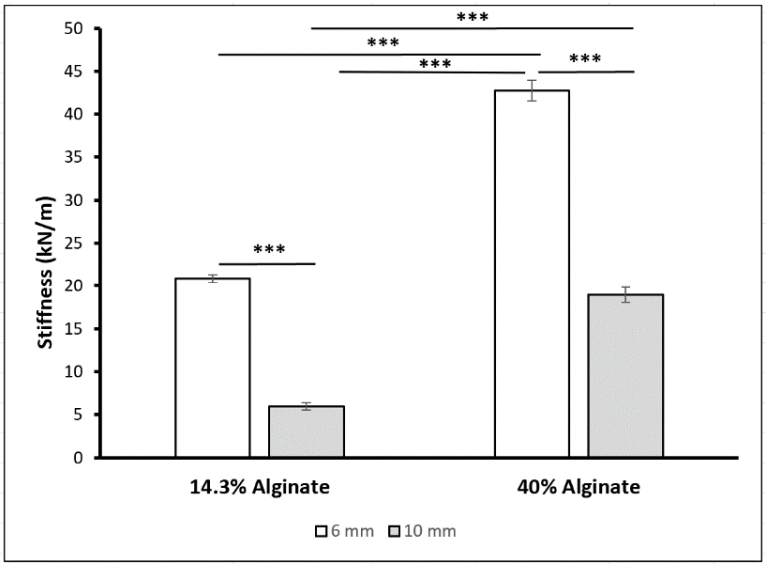


Figure 65. Differences in stiffness across alginate samples with varying concentrations and heights in the small deformation region. Error bars represent SE, *p<0.05, **p<0.01, ***p<0.001

Linear Actuator Device – Small Deformation Region

This portion of the compression testing was performed on a different day than the "gold standard" compression tests. The batch of alginate samples initially prepared was used, as they had been stored in sealed Ziplock bags. The calculated stiffness values are shown in Table 9.

Table 9. Alginate sample stiffnesses – Low strain region Linear Actuator Device (<1.95mm).

	Calculated Stiffness (kN/m)			
Trial	Cond. 1	Cond. 2	Cond. 3	Cond. 4
1	2.02526614	5.68758124	4.22541514	6.86413011
2	1.54572022	4.85004676	3.94697235	6.84506581
3	2.46870161	6.31053288	5.1555013	6.72366998

Mean	2.01323	5.6161	4.4426	6.8109
Std. Dev.	0.3769	0.5984	0.5167	0.07619

Two-factor ANOVA suggested that both the alginate concentration and sample thicknesses played a significant role in the final stiffness values ($p<0.001$ and $p<0.001$, respectively). As expected, post-hoc Tukey HSD test revealed that increasing alginate concentration yielded a significant increase in stiffness for all sample thicknesses ($p=0.005$ for shorter samples and $p=0.048$ for taller samples). However, contrary to either of the gold standard collected data, the thicker samples were found to be stiffer across both alginate concentrations ($p<0.01$ for both). While not intuitive initially, there are some possible explanations for this trend after consideration of the limitations of our methodology.

Interestingly, interaction effect between alginate concentration and sample thicknesses was not found to be statistically significant ($p=0.082$). This indicates that the relationship between one independent variable and the dependent variable is not influenced by the level of the other independent variable. Nevertheless, there is likely to be some extent of interaction but too weak to be detected.

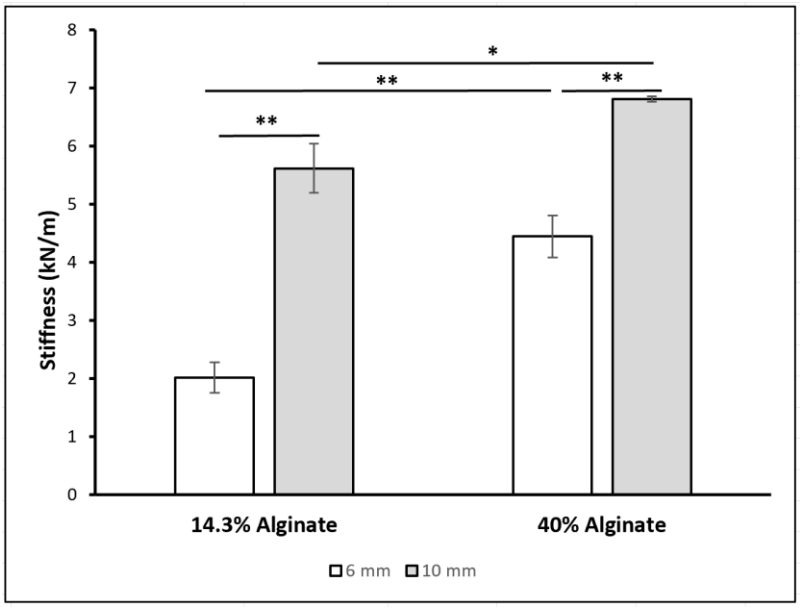


Figure 66. Differences in stiffness across alginate samples with varying concentrations and heights in the small deformation region. Error bars represent SE, *p<0.05, **p<0.01, ***p<0.001

Limitations

Alginate hydrogel serves as a reasonable model for the diabetic foot skin, as evidenced by its measured Young's modulus values. A more precise representation of callused and non-callused conditions could be achieved by further modulating the concentration of the samples to dial in the Young's modulus. A viscoelastic material like the skin has other important factors, such as the Storage and Loss moduli, which are both measured using rheology. To further validate the use of alginate as an appropriate model of the foot, it would be ideal to perform rheological testing on alginate samples, as well as explore possible additives, such as gelatin from various animal sources, to make the phantom more skin-like [78]. For the purposes of this experiment, however, alginate served as a decent phantom for the callused and non-callused diabetic foot skin.
Prior groups have discussed how the curvature of samples leads to lower measured stiffnesses—and the difference is particularly noticeable for shorter samples [85]. We noticed that some of the alginate samples, especially the shorter ones, were slightly convex/asymmetrically sloped on top but hadn't considered the implications during testing. Our "gold standard" tests took place a few days before our PoP device tests.

During that period, we stored the samples in Ziplock bags so that they wouldn't dry out. Upon revisiting pictures in our camera roll, we observed that all the shorter samples fell to the bottom of the bag (and ended up sitting in a pool of water that was lost over time). However, the taller samples remained in the middle of the bag and were more spread out (but still lost some water over time). This led to slight degradation of the small samples on the side closest to the edge of the bag, which led to sloped tops. This could potentially explain why the shorter samples had a drastically lower stiffness during the second batch of testing with the PoP device. Overall, the samples experienced water evaporation, making the samples slightly smaller (as shown in Tables 4 and 5), and therefore more concentrated for PoP testing. This would have the effect of increasing the measured stiffness for the PoP device, but the large effects from stress relaxation appear to have dominated in the opposite trend.

Looking at the data between the two days of testing, the 6 mm samples showed a huge decrease in stiffness, whereas the tall samples only showed a moderate decrease in stiffness relative to the gold standard (presumably due to the stress relaxation). The stepwise motion of the linear actuator (due to its position-controlled nature and non-programmable displacement rate) is likely what caused the observed stress relaxation phenomenon. Due to the stress relaxation with the decreasing force after initial spikes, the cumulative force over displacement was less for the device than the gold standard, resulting in lower stiffness values for the device relative to the gold standard. The combination of these factors led to the short samples being even less stiff than the tall samples, which is why the opposite trend was observed in the PoP data. As can be seen,

there are many confounding sources of error for our data. We believe that the provided explanation is logical and supported by the literature. Going forward, it would be best to make a fresh batch of alginate samples immediately before testing. If the samples are stored, they should be placed in a Tupperware container and not be touching other samples.

A challenge that we will have to navigate is the interaction effect between the variables of height and concentration, as observed in the gold standard experiments, both to failure and in the small deformation region. Although a statistically significant interaction effect was not present with the PoP device data, the aforementioned factors regarding experimental conditions could have contributed to this deviation. For the gold standard compression testing data, the effect of increased alginate concentration was negated by a greater sample thickness. This may pose a challenge in the context of callus detection if analysis is solely performed on two different points on one foot (as various regions have differing thicknesses). However, with our proposed asymmetric analysis, this issue is mitigated as we plan to interrogate the same point on two different feet.

Another confounding variable that may have led to interaction effects between sample concentration and height was the variability in cross-sectional area of the alginate samples. Tables 4 and 5 show that sample dimensions slightly increased with higher concentrations, both for the gold standard and PoP testing. This may have been due to a more rapid degradation of the lower concentration samples from sitting in a Ziplock bag. This increase in cross-sectional area for the higher concentration samples lowered the average force exerted on the sample, which lowered the measured stiffness of the high concentration samples relative to the low concentration samples. If this variable had been controlled, the trend in stiffness as a function of sample concentration would have been even more pronounced. In indentometry, the cross-sectional area of the probe is controlled for because it is the same for every interrogation of the foot. So, although this variation in sample dimensions is a limitation within compression testing, we believe the issue will be corrected for with indentometry, and the principle behind detecting calluses based on stiffness will be even stronger.

Interestingly, the increase in height between low and high concentration groups was roughly the same height that is added by the formation of a callus, ~0.5 mm. It was previously unknown to what extent the increase in skin thickness due to a callus would cause a decrease in stiffness, negating the increase in stiffness due to the hardening of the skin. However, through this erroneous increase in sample height, it has been indirectly shown that the slight increase in skin thickness due to a callus will not prevent

the measured stiffness values from being statistically higher than the non-callused group, which matches the observed trend in the literature [64].

A more thorough analysis would have reduced the effects of some of these confounding variables. For example, increasing the number of gel concentrations tested or increasing the number of gel heights tested would have allowed for a clearer representation of the relationships between concentration, height, and stiffness. When combined with sample preparation just prior to testing to limit the effect of curvature, the sample morphology would be better controlled, and the relationships would be better seen with more than two gradations in the independent variables to account for possible variation in one or more gradation.

Proof of Principle Test #2: Temperature Testing

Background

Plantar surface temperature is widely variable and differs from what is considered the standard physiological body temperature of 37 ℃. The mean awake foot temperature was found to be 30.6 ℃, with a standard deviation of 2.6 ℃ [86]. Another study on foot temperature in diabetic patients reported the range of temperatures measured to be between 27 ℃ and 35 ℃ [86].

We've previously chosen an elevation of 2.2 ℃ in one foot relative to the same region on the other foot to be considered abnormal [87]. Our solution proposes the use of a thermistor array embedded in a device to measure plantar surface temperature and detect this difference in temperature via asymmetry analysis. Accordingly, we developed a testing protocol to determine if a thermistor array can detect special differences in temperature with sufficient accuracy. Testing was done within the range of physiological plantar surface temperature values.

This proof of principle test is composed of two substeps: a well spacing variation test and a temperature offset variation test. In both tests, 5 thermistors were submerged in an array of water wells, in which the temperature of the water in the central well was higher than the peripheral wells. This was intended to replicate the pathophysiology associated with an ulcer, in which local temperature would be elevated.

In the well spacing variation test, we attempted to hold the temperature offset (defined as the difference between the central and peripheral wells) as close to 2.2 ℃ as possible. Then, we take 3 iterations of measurements in wells that were spaced out by different distances. This was repeated for 3 different well spacings. This test was intended to determine if thermistor spatial resolution impacts measurement accuracy for spacing distances that we may select.

In the temperature offset variation test, we held the distance between wells constant. We then varied the temperature offset between the central and peripheral wells. We collected data for 3 different ranges of offsets, including 0 ℃ to 1 ℃, 1 ℃ to 2 ℃, and 2 ℃ to 3 ℃. For each bin of temperatures, we obtained three data replicates. This test was intended to determine the minimum temperature at which our thermistor array could detect a temperature difference without being overly affected by error.

Both procedures are explained in more detail below.

Materials

- 1 Microcontroller (Arduino Uno)
- 5 Thermistors (Vishay NTCLE100E3103JB0)
- 5 resistors (10 kohm)
- 1 breadboard
- 1 FLIR IR Camera (to serve as gold standard)
- 1 or more laboratory hot plates (e.g., LabGenius 3388-01)
- Beakers
- Disposable Hand Pipet
- Water
- Styrofoam to fabricate insulated wells for heated water
- Tape to hold thermistors in place within water

Methodology

1. Fabricate Styrofoam wells with desired well spacings
    a. Using calipers, create markings that are 5 mm apart in a plus shape (see below) to ensure that the 4 peripheral wells are equally spaced from the center well

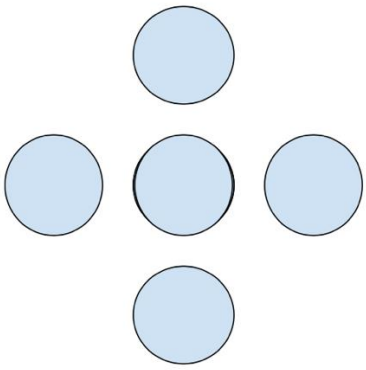


Figure 67. Well Array Layout.

b. Using the same tool for all 5 wells (e.g., 2.5 mm drill bit or 2 mm mandrel), puncture or drill holes over all markings created in step a. Create wells of a constant depth. Make wells much deeper than they are wide to minimize heat loss. Make wells wide enough that thermistor heads can be placed centrally in well without touching walls of well. Make sure holes are centered over markers created in step a
c. Repeat a and b for well distances of 10 mm and 15 mm on separate pieces of Styrofoam

2. Construct thermistor circuit and code
   a. Circuit is composed of 5 thermistors in voltage dividers with 10k resistors. An analog pin probes the node between the resistor and thermistor (see below)

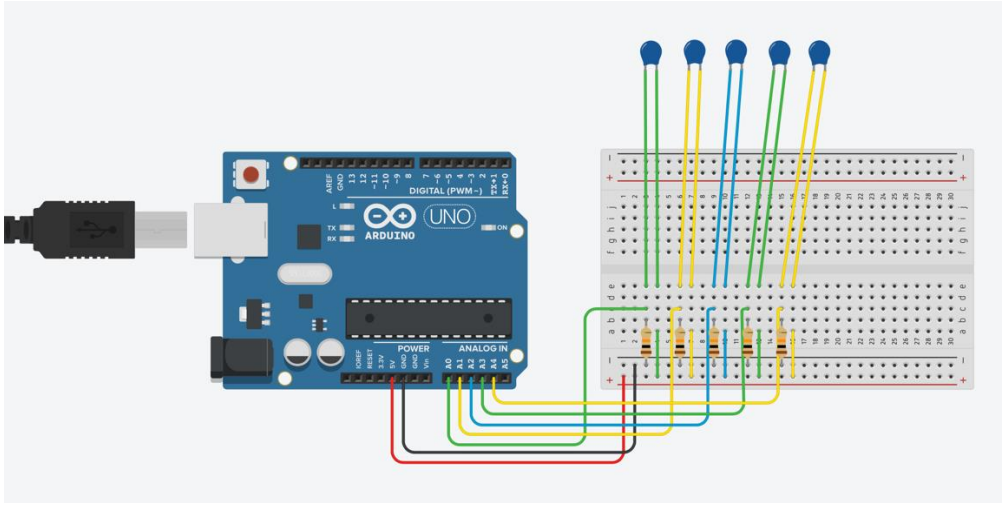


Figure 68. Thermistor Circuit Diagram in Tinkercad.

   b. Construct code (See "VIII Code" Section). Key steps explained below
      i. For each analog pin used, convert analog reading to voltage reading
      ii. Convert voltage reading to resistance reading using the voltage divider equation, given the circuit setup above: $R = 10k\ (\frac{5\ V}{V_{reading}} - 1)$
      iii. Convert resistance to temperature using the Steinhart-hard equation (below) and parameter values for the Vishay NTCLE100E3 (readily available in datasheet; R_{ref} = 10k)
         1. $T(R) = (A_1 + B_1 \ln\left(\frac{R}{R_{ref}}\right) + C_1 \ln^2\left(\frac{R}{R_{ref}}\right) + D_1 \ln^3(\frac{R}{R_{ref}}))^{-1}$
      iv. Report temperature on serial monitor for each thermistor
   c. Further calibrate thermistors (ideally would not be necessary, but Steinhart-hart from data sheet yielded a reading that was not correct)

i. Using liquid/surface of known temperature, place thermistors in contact with material. Contact thermistors with material and allow to reach temperature (~5 min)
ii. Determine discrepancy between thermistor reading and material temperature. Repeat for all thermistors for three trials. Using the average discrepancy across all thermistors and trials, add or subtract the proper scaling factor from the Steinhart-hart equation in the code, such that thermistor readings are now approximately correct
iii. Repeat I and ii at least once more, ideally reaching a point at which calculated scaling factor is less than 0.1 ℃

For Well Spacing Variation Test

3. Begin heating water in beakers to ~33 ℃ (center of physiological range + 2 ℃). Meanwhile, tape each of 5 thermistors into desired well of selected Styrofoam well construct. Start with 5 mm wells. Ensure that they are at equivalent depths within the well and not in contact with the well walls
4. Once water has reached a physiological temperature + 2 ℃ (shoot for approximately 33), use disposable pipet to completely fill central well with warm water. Pipet quickly and use large volumes to minimize heat loss
5. Using the FLIR to confirm temperature, wait until the water in the well has dropped ~2 ℃ below the water on the heat plate. Quickly and immediately, pipet water into the 4 peripheral wells
6. Ensure the code is outputting readings to serial monitor. Immediately upon output of a reading to the serial monitor, focus FLIR above each well and record temperature. Record FLIR readings for all 5 wells and thermistor outputs at a corresponding time point
7. Repeat 4-6 for 3 iterations
8. Repeat 3-7 for the 10 mm and 15 mm Styrofoam constructs. Throw out the data for a trial if IR readings for peripheral wells are not within the physiological range of values or "offset" between peripheral wells and central well is not approximately 2.2 ℃ (± 0.35 2 ℃). Note that controlling all these temperature parameters presents a significant challenge. Make sure to transfer water and take measurements quickly. Pipet water at a slightly higher temperature than you would expect, allowing for heat transfer. You may have to complete many extra iterations of the trial to get good data

For Temperature Offset Variation Test (where offset refers to the difference in temperature between the central and peripheral wells)

9. Use the Styrofoam construct with 10 mm spacing. Begin heating water in beakers to ~33 ℃ (center of physiological range + 2 ℃). Meanwhile, tape each of 5 thermistors into desired well of selected Styrofoam well construct. Ensure that

they are at equivalent depths within the well and not in contact with the well walls

10. Once water has reached a physiological temperature + 2 ℃ (shoot for approximately 33 ℃), use disposable pipet to completely fill central well with warm water. Pipet quickly and use large volumes to minimize heat loss
11. Using the FLIR to confirm temperature, wait until the water in the well has dropped ~0.5 ℃ below the water on the heat plate. This represents the middle of the "low offset" bin of temperature offsets that will be tested. The low offset bin spans [0 ℃, 1 ℃]. Quickly and immediately, pipet water into the 4 peripheral wells
12. Ensure the code is outputting readings to serial monitor. Immediately upon output of a reading to the serial monitor, focus FLIR above each well and record temperature. Record FLIR readings for all 5 wells and thermistor outputs at a corresponding time point
13. Repeat 10-12 for 3 iterations
14. Repeat 10-13 for the other temperature offset bins. For the medium offset bin, shoot for an offset of ~1.5 ℃. This represents the middle of the "medium offset" bin, which spans (1,2]. For the high offset bin, shoot for an offset of ~2.5 ℃. This represents the middle of the "high offset" bin, which spans (2,3].
    a. Throw away data in which the mean temperature offset doesn't fall into any of the predetermined bins.

A B

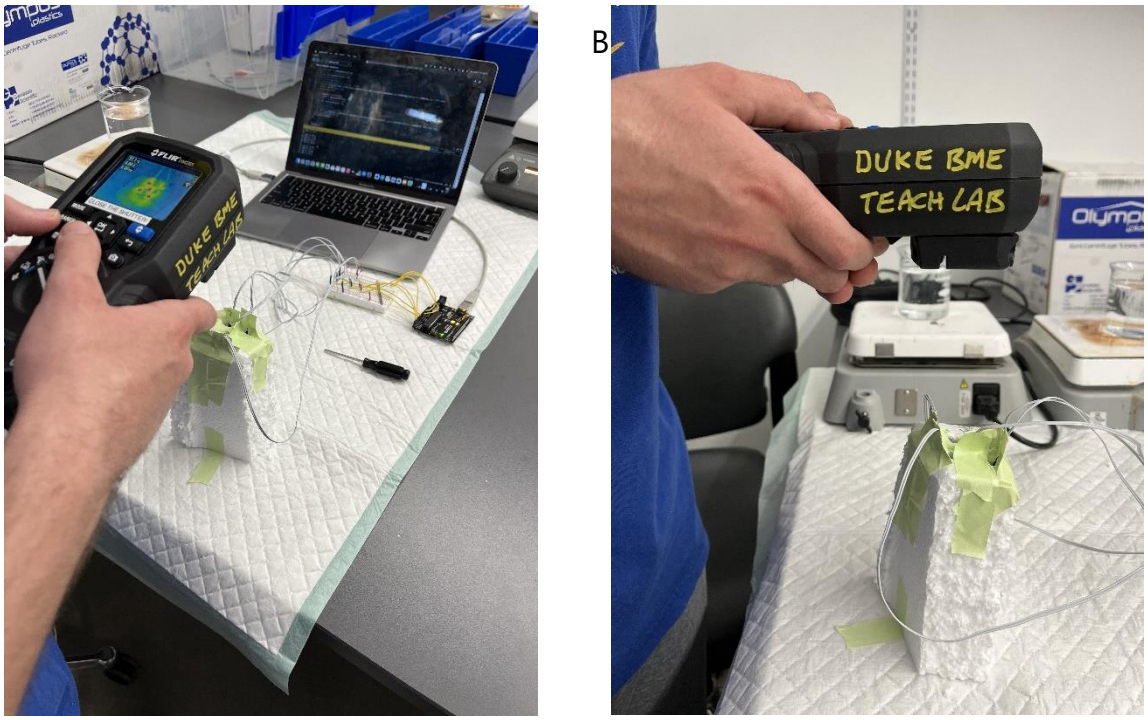


Figure 69. Experimental setup for temperature offset variation test using Styrofoam construct. (A) Isometric view and (B) side view.

Data Processing

15. For each iteration of iteration of the experiment, ensure that key parameters are within acceptable range (e.g., peripheral temperatures are within physiological range, temperature offsets between central and peripheral wells are acceptable for a given test, etc.)
16. For each iteration of the well spacing experiment, calculate the magnitude of the mean error between the central and peripheral wells. Use the equation below
    a. Mean error = $|(\sum_{i \in peripheral\ wells}(\left(T_{C,g} - T_{Pi,g}\right) - (T_{C,t} - T_{P,ti})))/4|$
        i. $T_{C,g}$ is the central well temperature, as obtained by the gold standard
        ii. $T_{P,g}$ is the well temperature for the gold standard in peripheral well i
        iii. $T_{C,ti}$ is the central well temperature, as obtained by the thermistor
        iv. $T_{P,ti}$ is the well temperature for the thermistor in peripheral well i
        v. Note that division by 4 is done because all iterations of the experiment had 4 peripheral wells
17. For each iteration of the temperature variation experiment, calculate the percent error in measurement between the central and peripheral wells
    a. Percent error = mean error/mean offset = |experimental – actual|/actual
        i. Mean error = $|(\sum_{Pi \in peripheral\ wells}(\left(T_{C,g} - T_{Pi,g}\right) - (T_{C,t} - T_{Pi,t})))/4|$
            1. $T_{C,g}$ is the central well temperature for the gold standard
            2. $T_{P,g}$ is the peripheral well temperature for the gold standard
            3. $T_{C,ti}$ is the central well temperature, as obtained by the thermistor
            4. $T_{P,ti}$ is the well temperature for the thermistor in peripheral well i
        ii. Mean offset = $|(\sum_{Pi \in peripheral\ wells}(\left(T_{C,g} - T_{Pi,g}\right)))/4|$
        iii. Thus, percent error = $\frac{|(\sum_{Pi \in peripheral\ wells}(\left(T_{C,g} - T_{Pi,g}\right) - (T_{C,t} - T_{Pi,t})))/4|}{|(\sum_{Pi \in peripheral\ wells}(\left(T_{C,g} - T_{Pi,g}\right)))/4|}$
    b. If we divide by the average offset (difference between central wells and peripheral wells according to the gold standard), we can understand the size of the error relative to the temperature difference we are trying to detect. This gives us an idea of what percent of the overall resolution the error represents.
       In the space variation experiment, the mean offset was held relatively constant (whereas it was a key parameter that we varied in the temperature offset variation test), so it became more intuitive to look at mean error. Nonetheless, dividing by mean offset to get percent error would have been a reasonable alternative metric to what we selected.

Results

<u>Well Spacing Variation Test Results</u>

We received feedback that it would be valuable to provide a map of the temperatures showing what we detected and where. To address this, we created a visualization of the data for all trials and all conditions. For each peripheral well, we calculated the difference between the central well reading and the peripheral well reading. This was done for both the thermistors and IR camera. Then, in the third column, we calculated the difference between theses measured differences for the FLIR and the thermistors. These are presented below for both the well spacing test and the temperature offset test. Note that the detected differences for the IR camera and thermistor (column 1 and 2) use a different color gradient than the calculated difference between the two (column 3)

Table 10. Spacing Variation Test Data
("difference" is between central and peripheral wells unless otherwise indicated)

	Thermistor Detected Difference			IR Camera Detected Difference			Difference Between IR and Thermistor		
		1.85			1.9			0.05	
5 mm, Trial 1	2.22		2.02	2		1.8	-0.22		-0.22
		2.32			1.9			-0.42	
		2.48			2.5			0.02	
5 mm, Trial 2	2.93		2.67	2.5		2.1	-0.43		-0.57
		2.44			2.4			-0.04	
		2.22			2.1			-0.12	
5 mm, Trial 3	2.55		2.01	2.2		1.7	-0.35		-0.31
		1.91			2			0.09	
		1.71			2.2			0.49	
10 mm, Trial 1	1.58		1.72	1.9		2.3	0.32		0.58
		2.29			2.2			-0.09	
		2.29			2			-0.29	
10 mm, Trial 2	1.95		2.31	2.6		1.8	0.65		-0.51
		2.16			1.7			-0.46	
		2.34			2.2			-0.14	
10 mm, Trial 3	2.58		2.5	2.4		2.2	-0.18		-0.3
		2.27			2			-0.27	
		2.11			2.1			-0.01	
15 mm, Trial 1	2.38		2.5	1.8		2.1	-0.58		-0.4

		1.94			1.7			-0.24	
		2.43			2.2			-0.23	
15 mm, Trial 2	2.18		2.71	1.9		2.8	-0.28		0.09
		2.26			1.8			-0.46	
		1.76			1.8			0.04	
15 mm, Trial 3	2.03		2.08	2.1		1.7	0.07		-0.38
		2.12			1.8			-0.32	

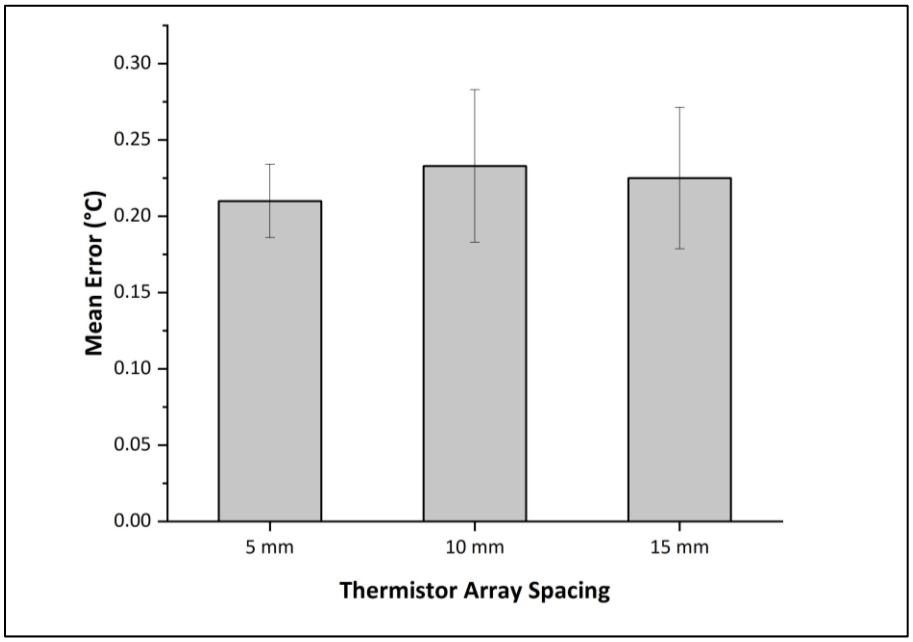


Figure 70. Mean Error Outcomes for Well Spacing Variation Test ($\pm SEM$)

One-way ANOVA revealed no statistically significant differences in mean error (as calculated in procedure step 17) between the different well spacing groups (p=0.92). This supports the notion that – at the tested spacings – temperature readings are not significantly impaired by thermistor spacing. Thus, this component of the PoP test supports that we can create an array of thermistors to detect temperature without spatial resolution impeding measurement accuracy, at least for spacings between 5 and 15 mm.

Temperature Offset Variation Test Results

Table 11. Temperature Offset Variation Test Detection Data
("difference" is between central and peripheral wells unless otherwise indicated)

	Thermistor Detected Difference			IR Camera Detected Difference			Difference Between IR and Thermistor		
		1.71			2.2			0.49	
High Offset, Trial 1	1.58		1.72	1.9		2.3	0.32		0.58
		2.29			2.2			-0.09	
		2.29			2			-0.29	
High Offset, Trial 2	1.95		2.31	2.6		1.8	0.65		-0.51
		2.16			1.7			-0.46	
		2.34			2.2			-0.14	
High Offset, Trial 3	2.58		2.5	2.4		2.2	-0.18		-0.3
		2.27			2			-0.27	
		0.95			0.7			-0.25	
Low Offset, Trial 1	0.52		0.62	0.4		0.4	-0.12		-0.22
		0.67			0.8			0.13	
		1.37			0.8			-0.57	
Low Offset, Trial 2	0.82		1.43	0.6		1.1	-0.22		-0.33
		1.03			1			-0.03	
		0.81			0.3			-0.51	
Low Offset, Trial 3	0.67		0.63	0.6		0.3	-0.07		-0.33
		1.13			0.5			-0.63	
		1.56			1.9			0.34	

Medium Offset, Trial 1	1.43		1.57	1.6		2	0.17		0.43
		2.14			1.9			-0.24	
		1.77			1.6			-0.17	
Medium Offset, Trial 2	1.28		1.65	1.2		1.6	-0.08		-0.05
		1.55			1.3			-0.25	
		0.83			1.1			0.27	
Medium Offset, Trial 3	1.16		1.05	1.5		1.1	0.34		0.05
		1.17			1.4			0.23	

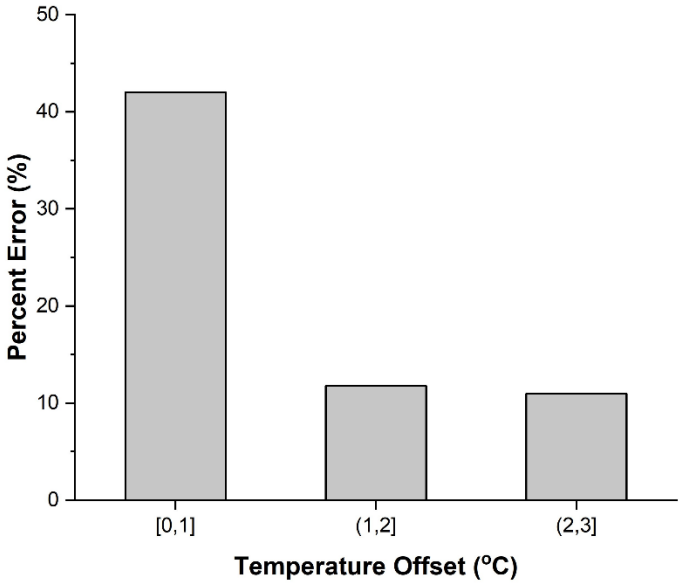


Figure 71. Percent Error Outcomes for Temperature Offset Variation Test.

Note that a high offset is considered a temperature difference between the central and peripheral well (according to the gold standard) belonging to the set (2, 3]. A medium offset belongs to the set (1, 2]. A low offset belongs to [0, 1].

The temperature offset variation test revealed that measurement of temperature differences less than or equal to 1 ℃ had a very high percent error. In other words, the error in measurement was a very large percentage of the offset between the central and peripheral wells. This suggests that detection of differences this small may not be

feasible with the thermistor setup that we used. Even detection of differences between 1 and 3 ℃ could only be completed with approximately 10% error, which we deemed to be high. If we set our detection threshold to be 2.2 ℃, we would have a reasonable amount of confidence that the true value is within 0.22 ℃ upon triggering of this threshold. Ideally, we would want our thermistor array to be able to detect a threshold value with less than 5% percent error.

Given that our results were not satisfactory, we need to explore other options. Thermistors like the TMP117 are rated for measurements with $\pm$0.1 ℃ accuracy, meaning that they could detect differences greater than 2 ℃ with the desired percent error, in theory. It may be valuable to explore the option of using a thermistor like the TMP117. Alternatively, we could attempt different calibration techniques for our current thermistor. As seen in the data, the difference between the IR and thermistors was skewed in the negative direction on average, meaning that thermistors may not have been scaled to the optimal value. Nonetheless, a large amount of variability was observed in the data, suggesting the thermistor setup needs to be improved. It may also be valuable to determine whether allowing thermistors to read for a longer amount of time improve measurement error. This would complicate the procedural design because we would have to prevent heat dissipation over time. However, given the thermal time constant of 15 s for the thermistor that we tested, it may be a factor.

The minimal difference in the medium and high condition is an unexpected outcome. It is expected that the medium temperature difference condition would have a higher percent error in detection relative to the high temperature condition, given that the mean offset is smaller (see step 17 in procedure). If we assume that error did not play a significant role in this outcome, it may be possible that there is a nonlinear relationship between temperature difference and percent error. This trend may be necessary to explore further by increasing the number of data replicates obtained and decreasing the bin size to increments smaller than 1 ℃. Perhaps testing another thermistor or an updated version or our previous circuit may provide insight into whether this trend is the result of experimental error, as we expect.

Temperature Offset Variation Test Results – Updated

In our further analysis, we used the same data but examined a different metric. In this metric, we determined the measured difference between all central and peripheral wells recorded by our gold standard and thermistors, regardless of the iteration of the experiment. Then, for each peripheral well (again, regardless of iteration), we subtracted the difference obtained by thermistors from the difference obtained by the gold standard and divided this difference by the difference recorded by the gold standard.

This can be thought of as a well-by-well percent error. This can be summarized by the equation below:

$$\frac{(T_{C,g} - T_{Pi,g}) - (T_{C,t} - T_{P,ti})}{(T_{C,g} - T_{Pi,g})}$$

For all measurements (n = 36 = 3*3*4), we then binned values into groups defined by the difference between the central and peripheral wells, as obtained by the gold standard. Initially, we took the absolute value of our metric for all wells in each of these groups then found the in-group mean of these values. This produced the following graph:

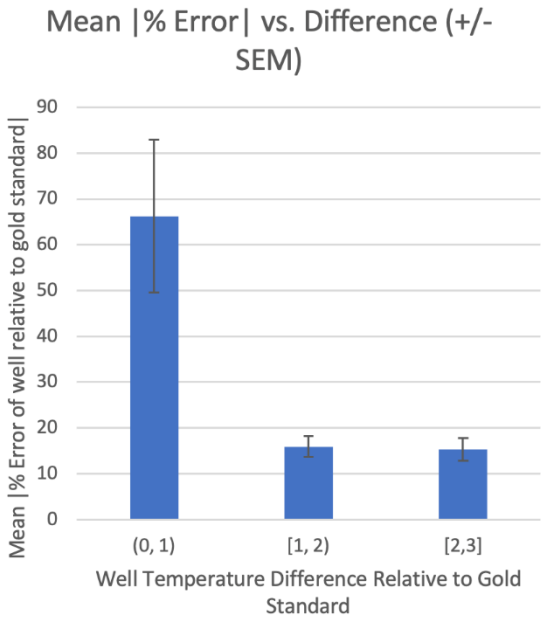


Figure 72. Mean percent errors in-group means with absolute values.

Then, we found the in-group mean without taking the absolute value, producing the following:

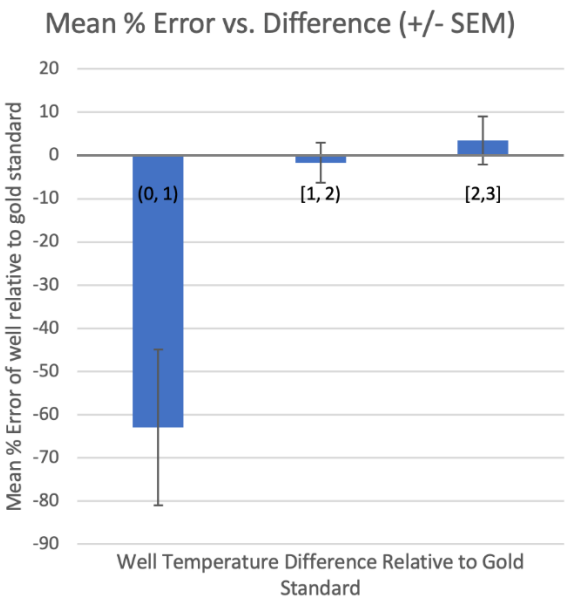


Figure 73. Mean percent errors in-group means without absolute values.

Summary

The original experimental analysis was conducted in light of a desire to determine whether an array of thermistors could accurately detect a local difference in temperature. This initial metric appealed to us because it represented a relatively straightforward way to assess the percent error (relative to a gold standard) of our entire sensor array on an iteration-to-iteration basis.

In our further analysis, we considered each well individually, which decoupled our measurements from the "iteration" of the experiment, as defined above. This metric has upsides, including that it may be more reflective of the largely independent nature of thermistor readings in different wells. Also, it increases the number of distinct data points that can be used to analyze variability. It also may have drawbacks – one being that it does not assess the capabilities of our sensors in an array (i.e., >=3 thermistors), which we established was a goal of the experiment.

Importantly, when we avoided taking the absolute value of our measurements, we learned that the well-by-well percent error relative to the gold standard was very low (i.e., ~5%) for temperature offsets between 1 and 3 °C. Despite a somewhat high mean magnitude of percent error for all peripheral wells in these conditions, we saw that thermistor readings were (on average) correct. This may suggest that thermistor reading precision (as opposed to accuracy) presented a component limitation. Ultimately, choosing to take the absolute value of our measurements during our initial analysis may have caused us to miss an important trend. However, we are confused by how extreme

the negative trend was for the condition in which temperature offsets between central and peripheral wells within the range of 0 and 1. We expected the magnitude of the percent error for this condition to be higher than other conditions, but not to the extent that it was. We believe this is due to experimental/human error. Nonetheless, our experiment provided valuable insights.

The thermistors we used may have significantly impaired our results. Beyond the data/analysis described above, we discovered the following about individual components:

On average, individual thermistors (regardless of the iteration of the experiment) had ~2% percent error relative to the gold standard. This quantity was derived using the absolute value of individual measurements.
Individual thermistors had an average error magnitude of 0.6 ^{o}C.

All tests were conducted between 29 and 33 ^{o}C. This is not compliant with the standard we selected for temperature measurement (ASTM E1112-00(2018) 4.1).

Thus, it may be valuable to test thermistors with more rigorous accuracy ratings and/or refine our calibration methods (described in DHF). The thermistors used in proof of principle testing were obtained from BME teaching labs and accuracy ratings were not known. We have ordered thermistors with more rigorous accuracy ratings, which we plan to use henceforth.

Limitations
There are a few limitations involved in this temperature proof of principle procedure. First, there may be confounding errors involved with the gold standard FLIR camera. Specifically, it is possible that the FLIR might be picking up the surface temperature of the water as opposed to the temperature at the depth of the thermistor. As the surface of the water is in contact with the room air and involves more thermal exchange with the cooler room temperature air, the temperatures that the FLIR reads may therefore be lower than they would be if the FLIR was measuring at the same depth as the thermistors. Therefore, there may be inherent differences between the FLIR and thermistor temperatures, though this would likely change the nominal temperature readings and maintain the relational values due to the consistent offset introduced by the differential depth measurement. The above difference may have contributed to the observed skew during calibration. The measurements were precise when both conducted in air, but the skew between the two was observed when in the water.

A second issue to consider would be with the generalizability of the procedure. Specifically, performing the same process with a different thermistor would be needed to better generalize these results. With only one thermistor type, there may be trends that are particular to the properties and behaviors of that one thermistor type. Additionally, an increased number of array components, as well as different structures, could be tested for a more thorough investigation. Finally, measurement may be challenged by the presence of thin, thermally conductive material over the sensor.

Proof of Principle: Conclusions

Stiffness was shown to be a reliable indicator that could be differentially measured. The FSR force readings were comparable to the gold standard force readings, suggesting its utility and justifying the team's decision to move forward with the FSR component of the system. The linear actuator component of the stiffness testing device, however, was challenged by stress relaxation apparent in the generated force plots. Further exploration with the linear actuator and overall general displacement design is needed to mitigate these effects of stress relaxation, so the team will not move forward with the linear actuator used in proof of principle testing. Through conversations with Dr. Ni and reading the literature, we are also brainstorming feasible indentometry approaches, which are distinct from compression testing. In terms of the skin model gels, alginate served as an appropriate skin model, but further optimization of the gel to match more rheological properties of skin would be valuable. So, alginate will be moved forward with at this point, although other concentrations and gelatin insertions should be considered. In terms of temperature, the special resolution identified was appropriate at less than 5 mm. However, there was a relatively high percent error in differential temperature detection. So, there is uncertainty as to whether the existing setup of the thermistor array will be moved forward. In later prototyping stages, we plan to explore alternative thermistor options and layouts. Concurrently, we will need to think about strategies for improving the calibration process.

Tested Component	Status
Force-Sensitive Resistor	
Linear Actuator	
Thermistor Array	
Alginate Callus Model	

Figure 74. Proof of Principle Components Future Outlook.

VI. Design Iteration #1: Frankenstein Prototype

Prototype

Design

The Frankenstein prototype was implemented as a single multimodal sensing module.

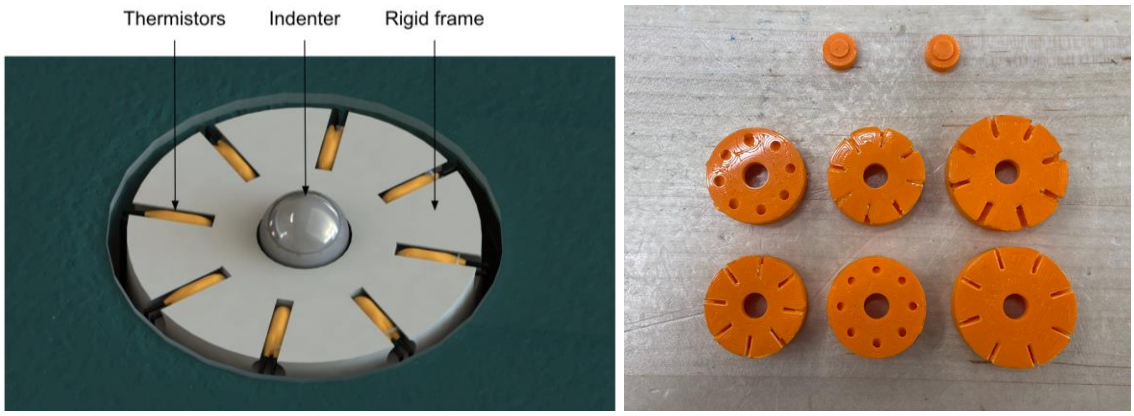


Figure 75. Multimodal Sensor – Indenter Frame.

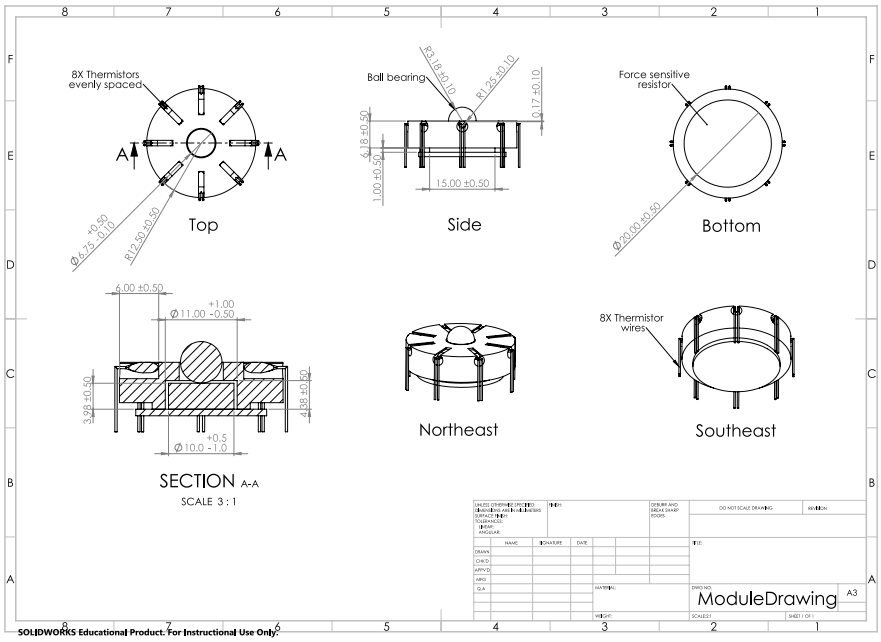


Figure 76. Multimodal Sensor Engineering Drawing.

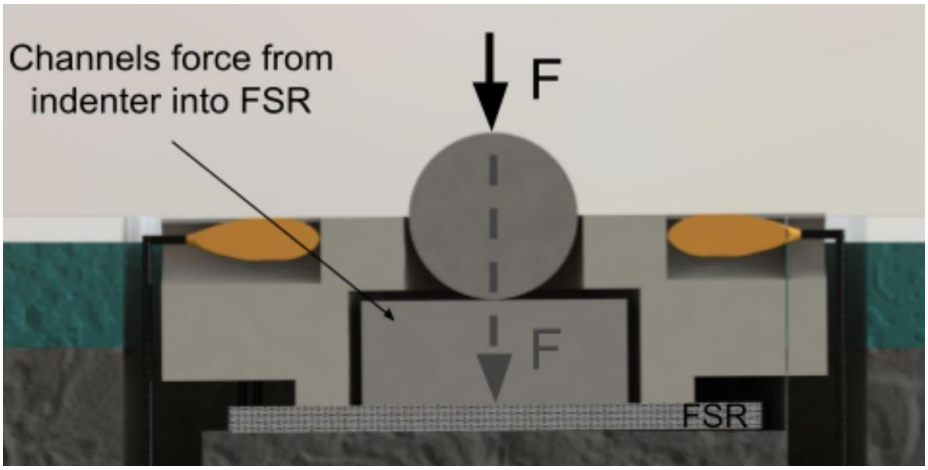


Figure 77. Multimodal Sensor Force Detection Mechanism.

A 3D printer is used with PLA to fabricate the frame and piston of the multimodal sensor. A thermally conductive epoxy is placed in each of the frame's thermistor holes. Then thermistors are placed within the epoxy and held as close to the upper surface of the device as possible while the epoxy sets.

The assembly is then placed on top of a force-sensitive element (i.e., FSR, strain gauge, or load cell). In the first iteration of this prototype, an FSR was used as the force-sensitive element. Note that the piston is placed above the force-sensitive element in its pocket beneath the indenter frame. It moves freely within this pocket. An aluminum bearing ball is then placed freely in the center of the indenter frame, resting on top of the piston. Thus, when a body makes contact with the ball, the force it exerts on the ball is transferred through the piston and into the FSR. Ideally, this would be a rigid junction such that minimal force is lost to the surroundings. However, as shown later through testing, this was not adequately achieved via the piston and FSR setup.

Circuitry

In our physical Frankenstein prototype, the circuitry for the thermistors and FSRs both consisted of voltage dividers connected to analog pins of the Arduino. Separate voltage dividers were used for each thermistor and FSR. However, given that we needed to expand our sensing capacity beyond just a single sensing module, we knew we needed a more robust sensing circuit. Thus, we implemented multiplexing, which allowed us to use one Arduino to read the analog inputs from a large number of sensors. Below is an early schematic of our integrated sensing array circuit, given our single-module design and multiplexing implementation. Note that this layout is theoretical and was never actualized because some elements of the circuit were changed between the Frankenstein prototype and the final prototype.

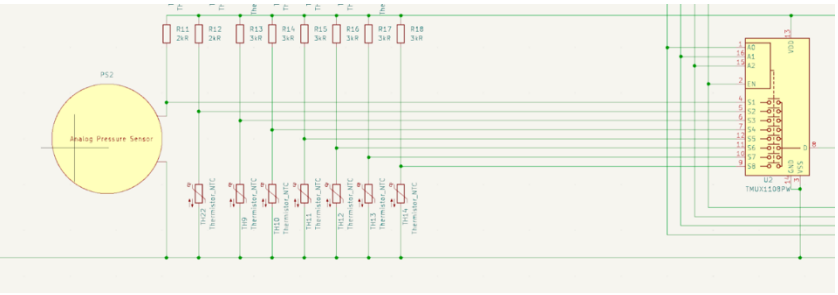


Figure 78. Theoretical Multiplexing Circuit Layout for a Single Sensing Module.

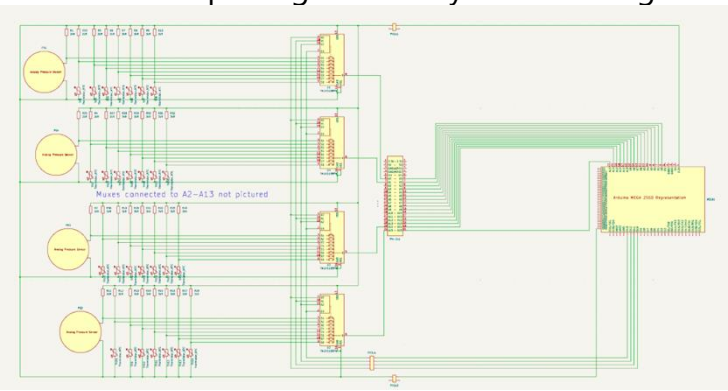


Figure 79. Theoretical Multiplexing Circuit Layout for Several Sensing Modules.

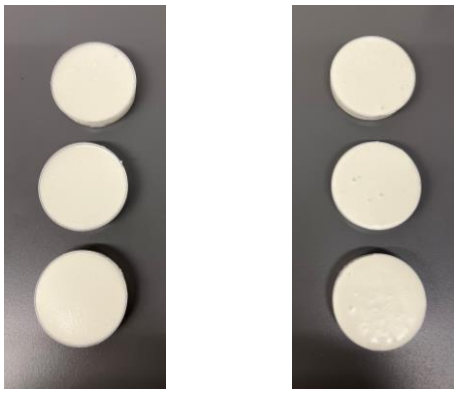
Testing

Objectives

The objectives of early testing with the Frankenstein prototype were 1) to determine whether the modulus of different alginate samples could be accurately determined, and 2) if temperature data could be simultaneously monitored accurately. A sub-goal was to determine whether the point at which contact was made with the surrounding indenter frame could be determined via the inflection point method described below.

Materials

Alginate samples were created using the 14% and 40% concentrations that were determined to be representative of non-callused and callused skin during Proof of Principle testing. Petri dishes were used as molds for the samples to create a larger surface area for contact. Alginate was held on the top platen of a Test Resources mechanical testing frame by a custom-designed PLA adapter.



Non-Callused (1.2 MPa) *Callused (2.3 MPa)*

Figure 80. Alginate Samples with Different Moduli.

For temperature testing, a hot plate, 1/8-inch sheet of silicon, and FLIR thermal imaging camera were used.

Methodology

The alginate samples were placed in a 3d-printed holder that was attached to the top compression platen of a Test Resources machine, suspending them over the sensing module, which sat on the bottom compression platen, as shown below.

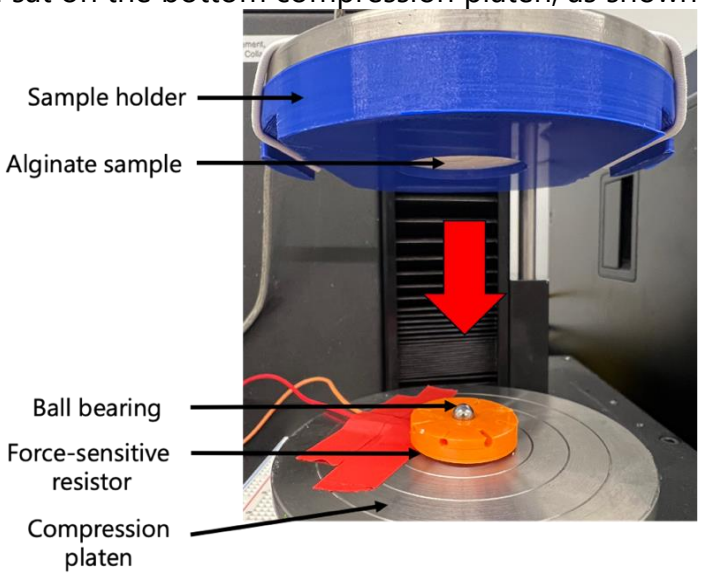


Figure 81. Test Setup for Frankenstein Prototype.

Compression tests were then performed at a displacement rate of 10 mm/s and a maximum load of 100 N. This test setup simulates the lowering of a patient's foot onto the sensing module once it is integrated into its final form factor. This testing was performed with and without thermistors wired into the sensing module to determine whether both measurements could be accurately recorded simultaneously.

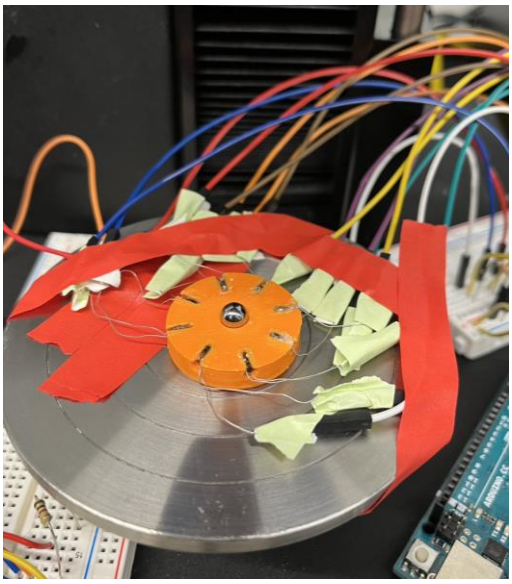


Figure 82. Test Setup with Integrated Sensing Module.

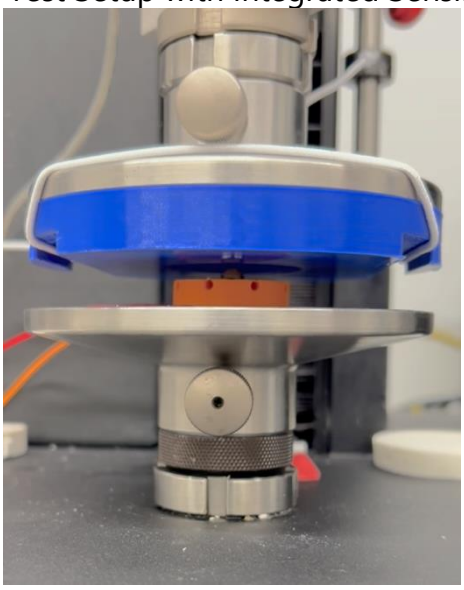


Figure 83. Compression Tests for Frankenstein Prototype.

A video of the testing setup and execution can be seen here.

The Hertz Contact Theory was used to calculate the modulus of the sample in terms of the force applied upon contact of the alginate sample with the indenter frame. The Hertz Contact Theory math is shown below, which uses the Poisson's ratio of the sample, the radius of the indenter, and the vertical deformation of the sample to outline a simple proportional relationship between modulus and force.

$$E = \frac{3F(1-\nu)}{4R^{1/2}\delta^{3/2}}, \qquad where: \; F = force\ applied,$$
$$\nu = Poisson's\ ratio\ of\ sample,$$
$$R = radius\ of\ indenter,$$
$$\delta = vertical\ deformation$$
$$E = 66500 * F, \qquad where: \; F = force\ applied\ at\ Contact\ 2$$

Figure 84. Mathematics for the Hertz Contact Theory.

The Poisson's ratio of the sample was selected to be 0.45 based on diabetic foot models in the literature [88]. The radius of the indenter was set equal to the vertical deformation of the sample based on the hemispherical protrusion of the spherical indenter, which is represented by *Contact 2* in the cross-sectional view below.

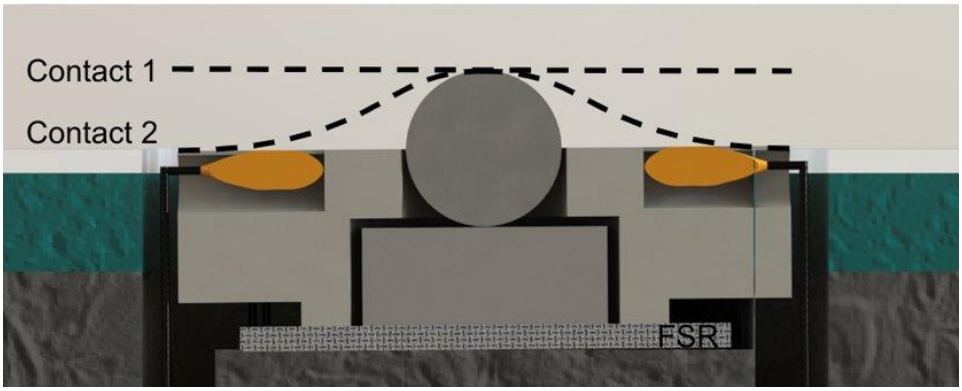


Figure 85. Cross-sectional View of Hertz Contact Theory.

The point at which *Contact 2* was made was determined by plotting the force (as read by both the FSR and the gold standard Test Resources machine) over time. At both *Contact 1* and *Contact 2*, there are inflection points in the force versus time graph which indicate when the surface area of contact increased instantaneously. The inflection points were determined systematically by taking the second derivative of the force versus time data and finding the maxima in a Python script. This method was referred to as the inflection point method and would have been ideal for determining the exact point at which the force should be captured to calculate the modulus of the sample. Isolated temperature testing was performed using a silicone skin phantom and a hot plate setup that allowed for real-time validation with the gold standard FLIR camera. The new set up was used so that we could verify that our combined sensor could accurately detect temperature, specifically at the physiological plantar surface temperature, given that our previous testing had confirmed that we could measure a range of temperatures. The temperature was measured with our sensing circuit as well as with the gold standard FLIR camera, as shown in the diagram below.

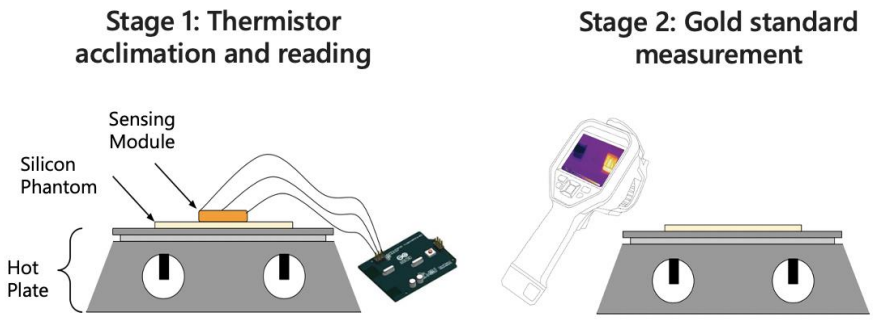


Figure 86. Test Setup for Temperature Testing.

Combined testing of the phantom was attempted, where the alginate phantoms were heated on the hot plate, then placed in the holder for compression testing. However, the alginate samples cooled quickly, as their temperature was not being maintained by the hot plate, which made it difficult to measure their temperature. The fact that the alginate holder surrounded the sample also made it difficult to validate the surface temperature of the sample with the FLIR, so combined testing was postponed with a need for a better integrated test setup. However, the individual tests were sufficient at this time, given that they validated the functionality of the device separately.

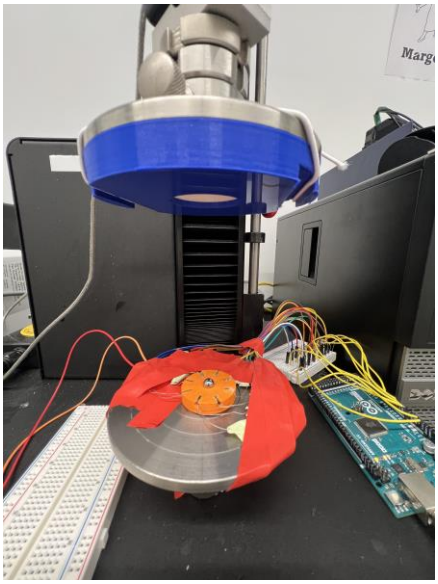


Figure 87. Test Setup for Combined Testing.

Results

The inflection point method proved to be an accurate method for determining the two contact points as shown in the cross-sectional view in Figure 88. As shown in the plot below, the two inflection points are clearly visible in both the gold standard and the FSR.

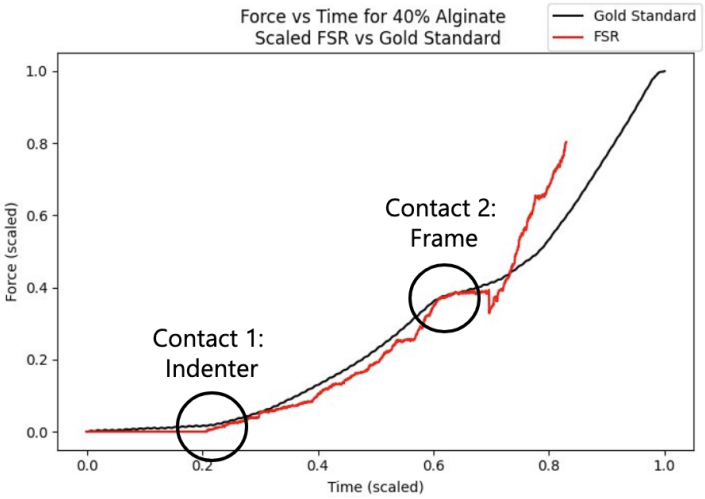


Figure 88. Force vs Time Data for Gold Standard and FSR.

Unfortunately, this method required several steps of data processing (smoothing and derivates) which made it difficult to automate reliably. A safer backup solution was devised, which relied on a separate sensor placed next to the frame, which would detect contact at the exact moment which the frame was contacted. Despite the promising results of the inflection point method, the contact sensor method was implemented into the final prototype due to its simplicity. However, the inflection point method could be implemented in a future prototype.

The calculated modulus of the samples is shown in the plot below under "FSR Indentometry". As a comparison, the modulus of the samples as determined from gold standard compression tests was included under "Gold Standard".

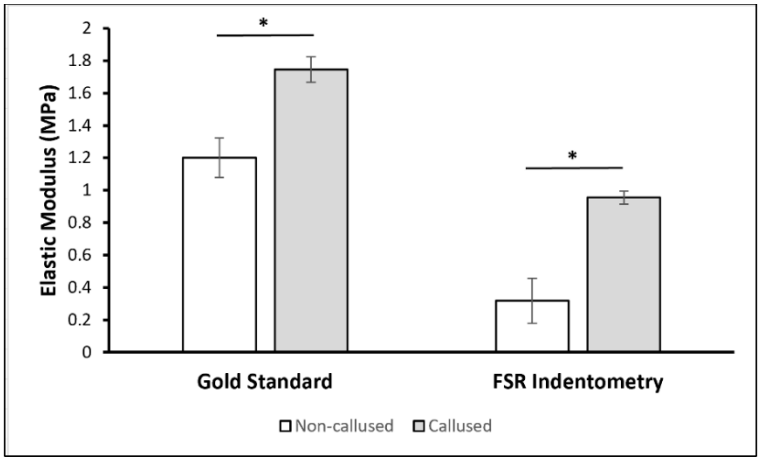


Figure 89. Calculated Modulus for Gold Standard and FSR Indentometry. Error bars represent the SEM; *p < 0.05.

Significant differences in the calculated modulus were achieved for the callused and non-callused conditions. These were promising results, which showed that the Hertz Contact Theory did work in practice with the Frankenstein prototype. Because the same trend was observed for both methods, it was shown that with proper calibration, our device could work to detect the presence of a callus.

The magnitude of the FSR Indentometry approach was approximately 2-3 times lower than that of the gold standard, which showed that there may have been some errors with the test setup. It was hypothesized that this was caused by an error in the FSR's force detection abilities. Even after the FSRs were calibrated to match the force detection of the gold standard, their readings were found to be incorrect. The plot below shows traces of the force versus time data, as obtained by the FSR and the gold standard, which revealed that the FSR values were far too low.

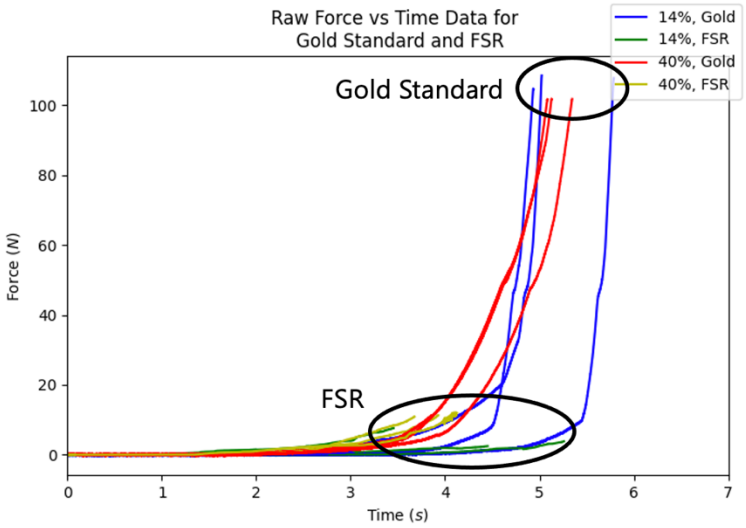


Figure 90. Force vs Time Plot for Gold Standard and FSR.

We hypothesized that this was due to the inefficiencies in the FSR and piston setup in Figure 90 which may not have channeled the full force on the ball bearing through the piston and into the FSR. These insights motivated a change in the force-detection method from an FSR to a load cell. A load cell was already being used in the gold standard Test Resources machine and is known for being more accurate than an FSR. Additionally, the use of a load cell would eliminate the need for a piston below the ball bearing, which would help to reduce the amount of energy lost in translation of the forces. The combination of these reasons made the load cell a logical choice for the final prototype.

As shown in Figure 91 below, our thermistor array measured temperatures slightly higher than the gold standard FLIR camera. The smaller standard error bars on the thermistors suggest that they had a lower sensitivity than the FLIR.

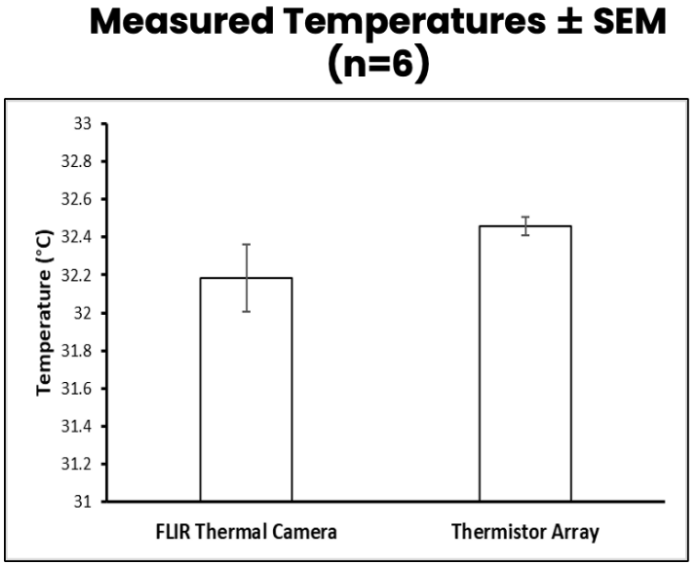


Figure 91. Measured Temperature for the FLIR Camera and Thermistor Array.

Figure X shows the difference in temperature measurement between the thermistors and the gold standard, again showing that the thermistors read temperatures of ~0.35 ºC higher than the FLIR on average. The standard ASTM E-1112 dictates that devices measuring the surface temperature of the skin on peripheral parts of the body should have an absolute error of 0.3 ºC or less, which is indicated by the dashed line in Figure X.

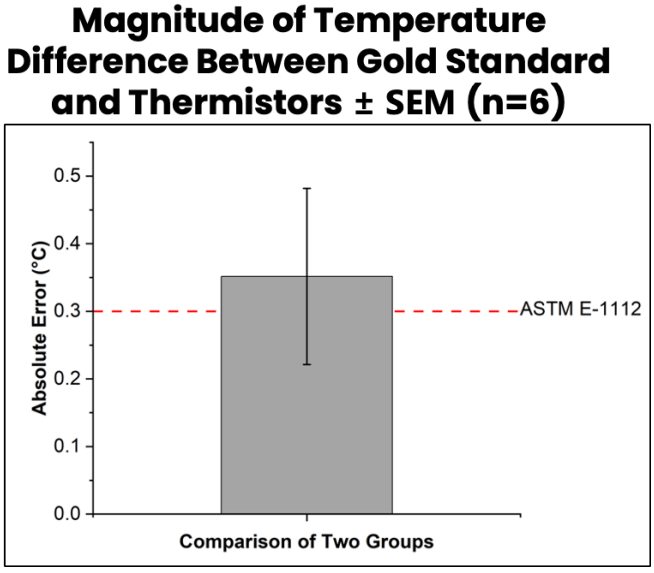


Figure 92. Magnitude of Temperature Difference Between the Gold Standard FLIR and Thermistors.

Although the mean temperature difference was above this threshold, the standard error bars show a considerable overlap with the requirements of standard ASTM E-1112. Given the changes that had to be made in the indentometry part of the device, it was decided that most of the team's focus should be diverted towards improving the modulus detection, rather than further improving temperature detection to fully comply with the standard.

VII. Design Iteration #2: Final Prototype

Prototype

Design

Given our previous issues with consistency amongst FSR force readings, we began prototyping with a load cell. Calculations were made based on the Hertz model to determine the resolution (1.5 N) and range of forces (5 N to 55 N) needed from a load cell, and an appropriate item was ordered for testing.

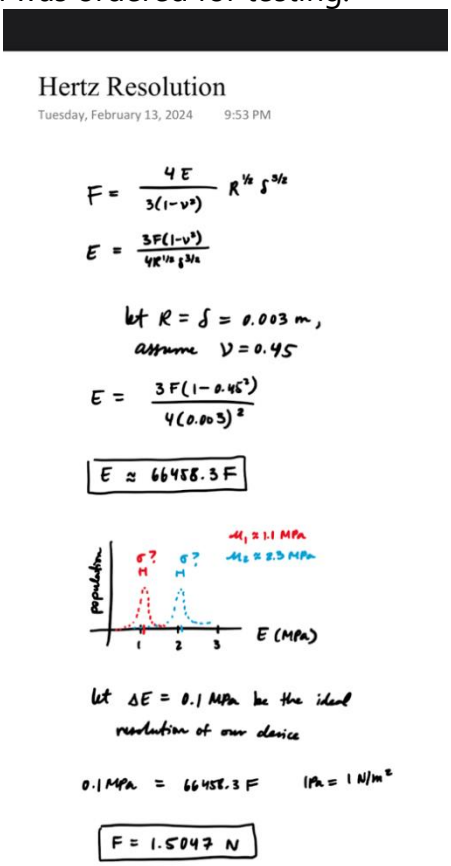


Figure 93. Scratch work for determining required resolution of load cell.

Because of natural variability in foot structure amongst patients, we plan to make the layout of the sensors in an industry-ready, manufacturable product variable based on the size and morphology of the patient's foot. We have established a plan for manufacturing and customization that enables production of a device that measures key biomarkers in high-risk areas of the plantar surface for all foot structures. To do so, we plan to create size groups based on the shoe size of patients. The entire range of possible shoe sizes will be binned into subgroups (e.g., US men's 10-12) for which we will define outer dimensions of sensing areas that are big enough to fit all feet within the range of possible foot sizes for that group. Then, we will decide the anatomical

regions in which we will choose to place high-density sensing regions for our industry-ready device (which, importantly, would include more regions than our current device). We will account for morphological/anatomical diversity amongst patients by expanding the size of our high-density sensing regions. Essentially, this means that we will include as many sensors as is required to maintain high spatial resolution across a sufficiently large *area,* such that all possible anatomies within 4 standard deviations of key anatomical dimensions will be compatible with our device. As mentioned, these key anatomical dimensions will be defined by the areas we define as high risk, which require greater resolution. For example, in a hypothetical device that defines the 1st metatarsal head and heel as the only two high-risk regions, we would make sure that the minimum distance between sensors in the high-density regions associated with these anatomical features is less than the reported distance between the feature on patient anatomies (say, for 4 standard deviations from the mean). If a solution adheres to all of these characteristics, it will be functional for the strong majority of anatomies, easily prescribable, and limit the need for customization (which may be challenging from a manufacturing standpoint). Like all possible manufacturing solutions, this approach comes with tradeoffs. In this case, a solution may require a relatively large number of sensors, in comparison with a fully customized solution, which may drive up the price.

In the span of this semester, the final prototype aimed to accurately monitor DFUs for the average male foot. Based on literature values in the U.S., the length, width, and heel width of the target foot should be 27.0 cm, 10.2 cm, and 6.7 cm, respectively [89]. The distance between the back of the heel to the calcaneus, first metatarsal head, and hallux will be defined as 15%, 65%, and 80% of the total length of the foot, respectively, based on literature values.

Furthermore, we have established key locations of importance for DFU screening based on existing solutions and known statistics regarding areas of increased risk on the plantar surface. Based on the figures below from the existing solutions and literature along with the fact that ulceration sites tend to be associated with the plantar points of highest pressure, the locations of the modules for this device was determined [90]. Specifically, we have decided to implement at least 3 sensing locations per foot in our prototype. One will be on the hallux, the second will be on the metatarsal head, and the third will be on the heel.

(a) High risk regions (b) Force readings (lbs) from two different subjects

Figure 94. Key locations from existing solutions. Left is Podimetrics mat [43]. Right is pressure monitoring device [91]

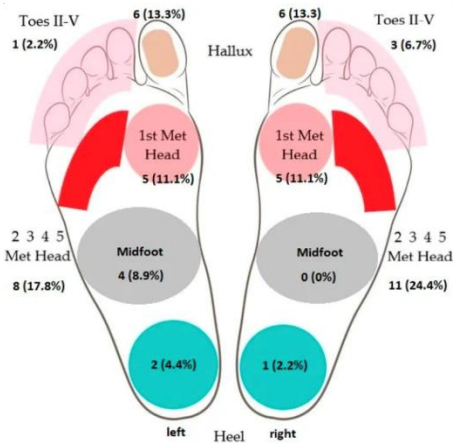


Figure 95. High Risk locations for Ulcer Development [92].

Using these key locations, a comprehensive integrated prototype was developed as shown in the figures below.

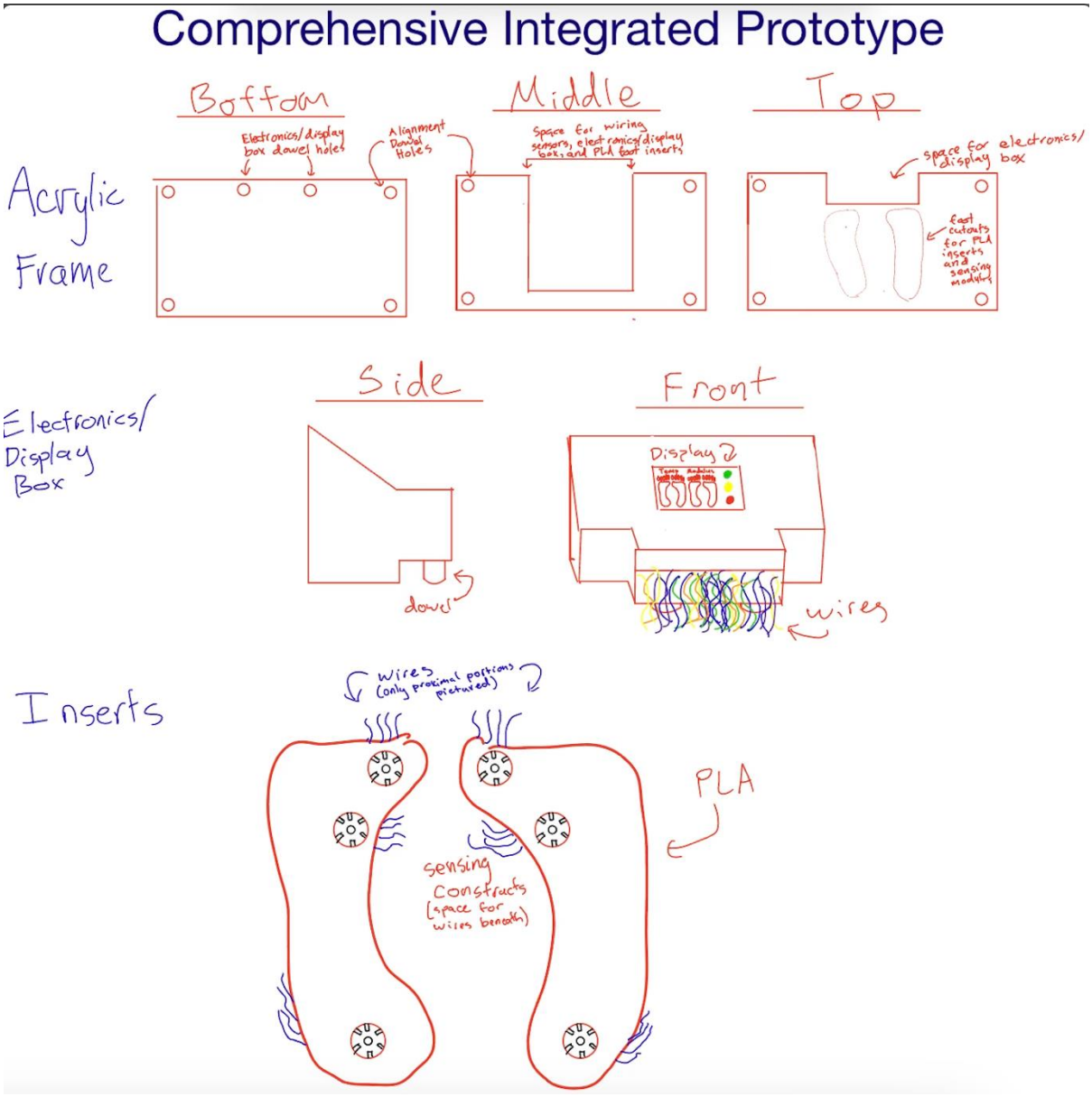


Figure 96. Breakdown of laser cut acrylic mat and integration with circuit.

A mat/board was laser cut out of acrylic according to the 3-layer design above. Integrated sensing modules were mounted in their proper locations and initial testing was performed. Temperature and elasticity values could be obtained in a single iteration of testing, and the values obtained in this setup were like those obtained when the integrated sensing module was tested alone.

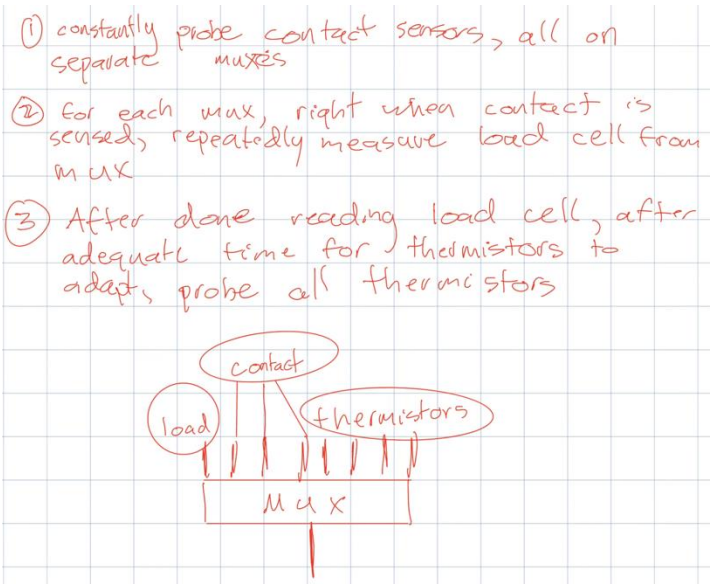


Figure 97. Single sensing module design.

A modular design was implemented to arrive at the prototype seen in Figure 96. The design and logic of a singular module can be seen in Figure 97. Three modules will be used per foot at the key locations. Each module consists of one multiplexing unit encompassing the three sensor types: a load cell for modulus measurements, thermistors for temperature measurements, and FSRs for contact sensing. Specifically, it has one load cell, three FSRs, and four thermistors as the total number of input channels in the multiplexers we will use is ideally eight. Three FSRs were incorporated to detect planar contact. If any additional thermistors are deemed necessary, they will be added from a separate (or chained) mux.

Over the course of the semester, the above ideas were implemented to arrive at the final realization of the designs as can be seen in Figure 98 below.

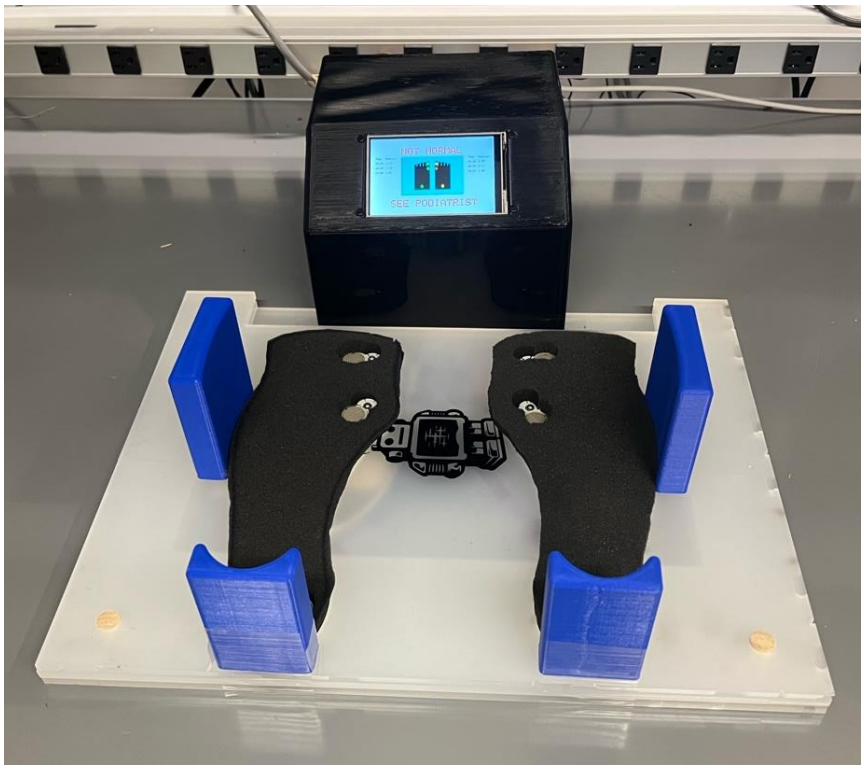


Figure 98. Realization of mechanical design.

Shown above is a final product form factor. The physical design is well-aligned with the solution visualization created earlier. A three-layer mat was prepared using laser cut acrylic. PLA “boosters” were inserted into the feet-shaped cutouts. The six modules were added on top of that layer. Note that the most recent version of the modules implements the FSRs adjacent to the ball indenters, along the same plan rather than beneath. Foam of optimal hardness was cut using a foam cutter and added as the top layer. PLA guides were also 3D printed to support the user with foot placement using the heel and lateral side of the foot. A custom enclosure was 3D printed to house all electrical components and mount the TFT display. The back side of the enclosure could be screwed and unscrewed to access the hardware as needed for troubleshooting purposes.

CAD Components

For the sensing modules present in the figures above, the frames holding the sensors were 3D printed. The CAD images of the sensor containing modules are included below.

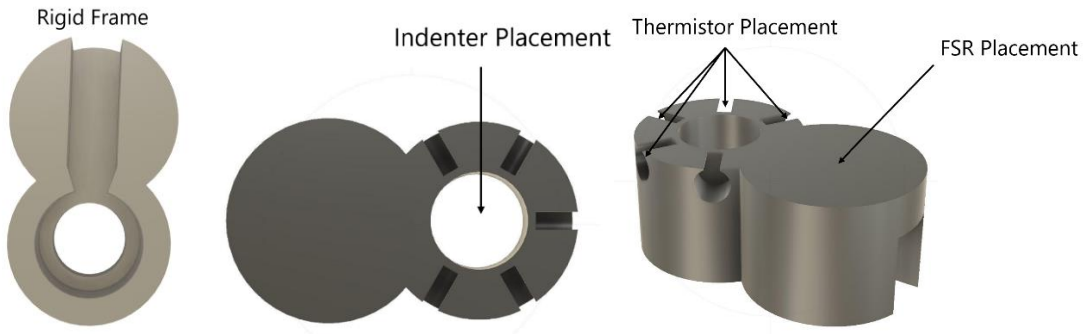


Figure 99. Decomposed single module diagrams of 3D-printed frames.

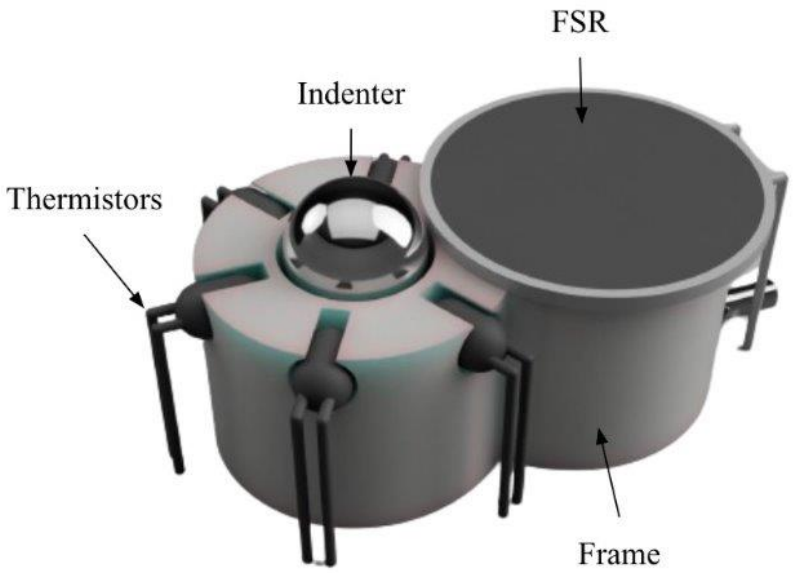


Figure 100. Combined single module CAD diagram of 3D-printed frame.

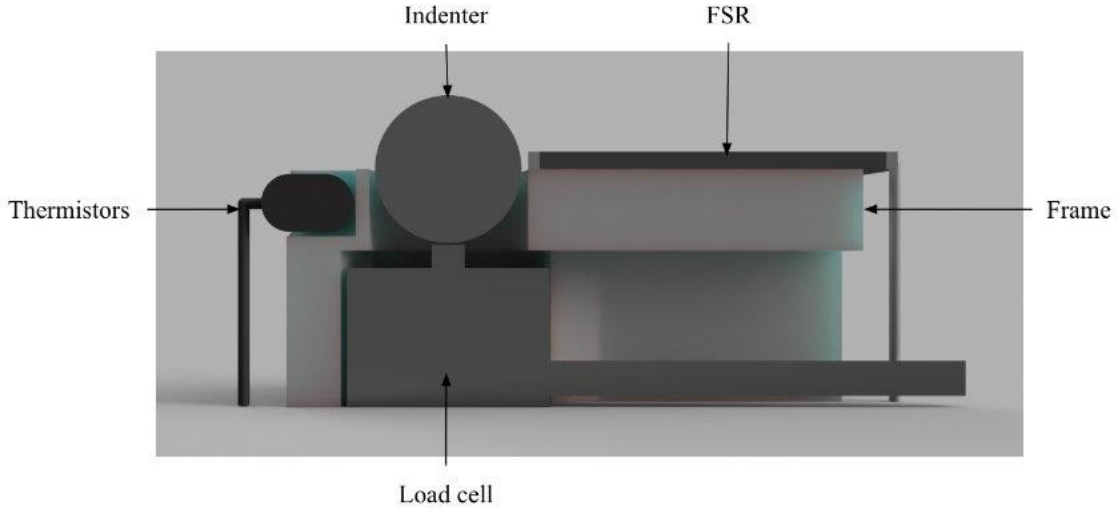


Figure 101. CAD cross-section of a single module.

After 3D-printing the modules above, the sensors were incorporated into the frames to form the sensing modules. Then, these sensing modules were then incorporated into the larger mat to arrive at the final product.

Circuitry

Load Cell Signal Processing Circuit

A signal processing circuit for the load cells was created as depicted below. The circuit obtained the differential signal, removed noise, and scaled the output. The gain was set such that it mapped our full scale range to the desired load values (https://youtu.be/3-fgPKqFyXw). Note that the system in the video was powered by an Arduino.

Prior to this, we created and implemented a signal processing circuit for the FX29 load cell (https://youtube.com/shorts/qop9WFbjGEI). This was much less consistent and effective, so we will not be using it. The setup video for that effort can be seen (https://youtube.com/shorts/hjbJnY6EydU).

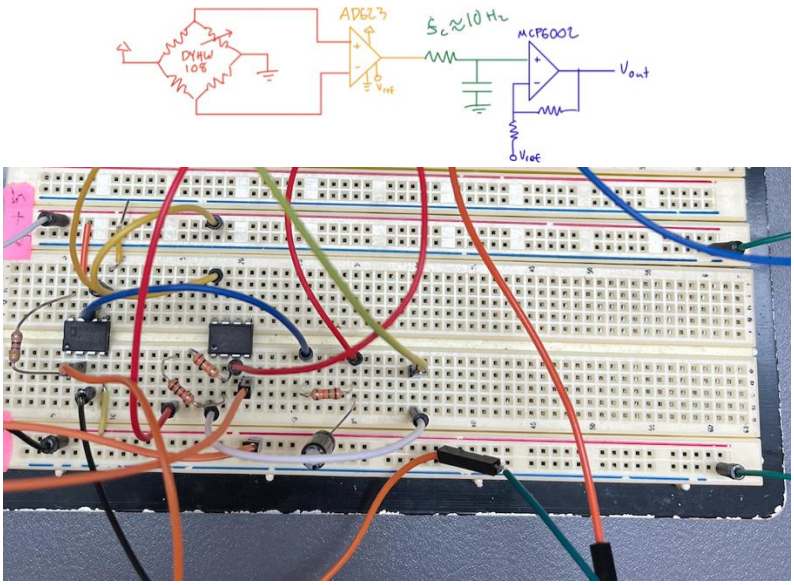


Figure 102. Single signal processing circuit for the load cell.

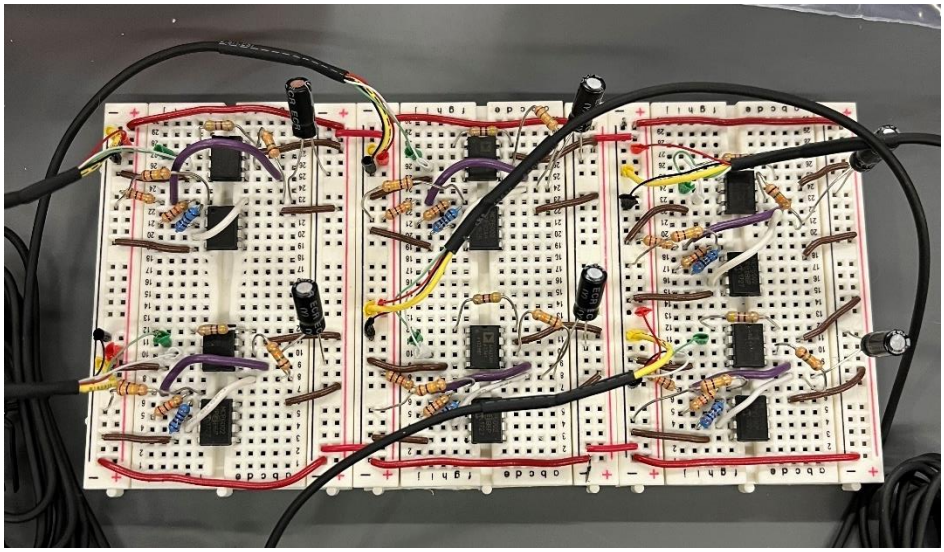


Figure 103. Load cell signal processing circuits for all six modules.

Multiplexing Circuit

Using the simple voltage divider circuits for the other sensors and the multiplexing circuit design specified by Figure 97, the below circuit was developed. Six multiplexers were used, utilizing one multiplexing unit per module.

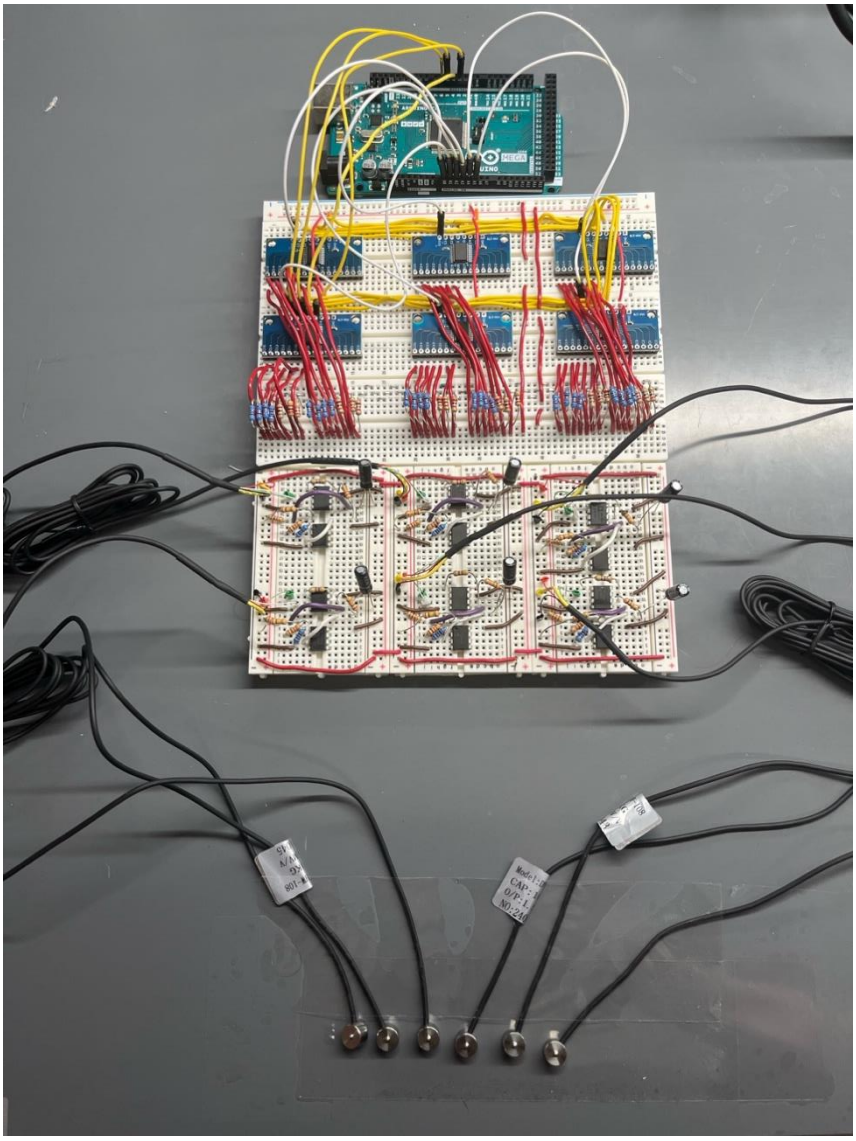


Figure 104. Multiplexing circuits for the load cells of all six modules.

Integrated Circuit

All of the circuit components were gradually combined and implemented into the mat as shown by the progression below in Figures 105-107. The overall multiplexing circuit was combined with the load cell signal processing circuit and all of the thermistors were wired.

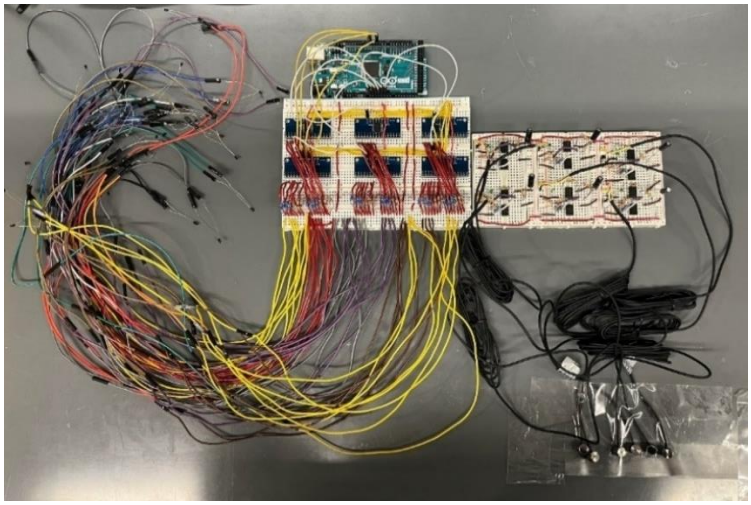


Figure 105. Integrated circuitry with the load cells and thermistors not in the mat.

After all of the thermistors had been wired, the load cells and the thermistors were incorporated into the module frames and placed where they belonged on the mat.

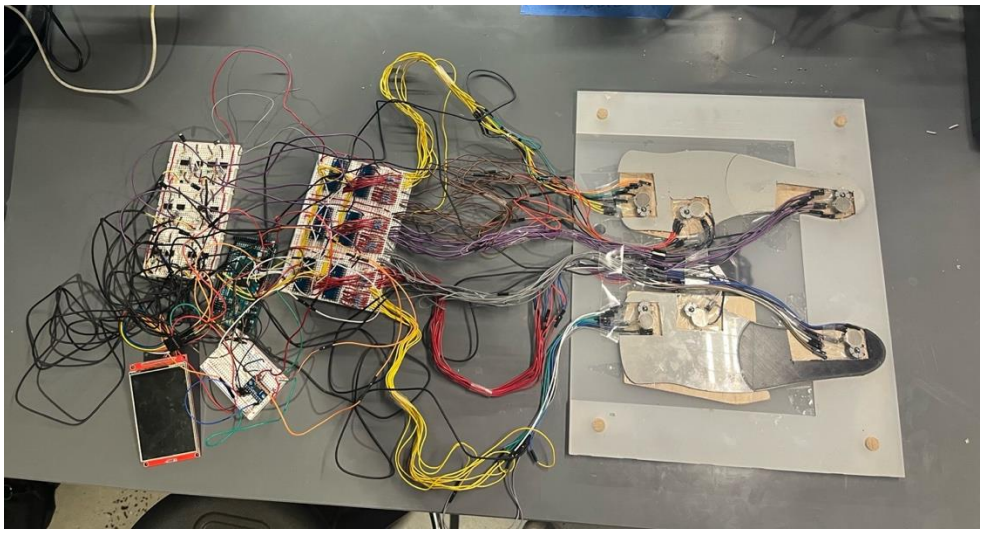


Figure 106. Integrated circuitry with the load cells and thermistors connected to the mat modules.

After the module frames had their sensors placed into them, the mat was covered with its top layer and foam layers over the feet.

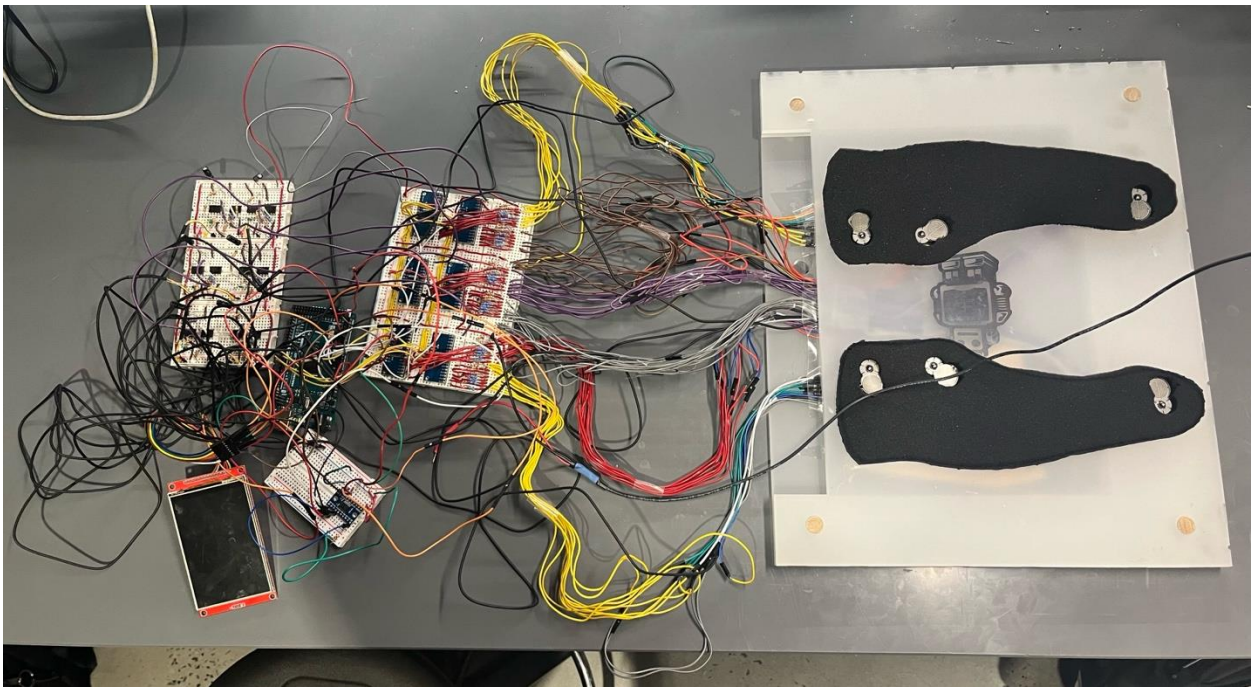


Figure 107. Integrated circuitry with the load cells and thermistors connected and within the mat.

Software

The procedural logic underlying the code for the device is specified in the figure below.

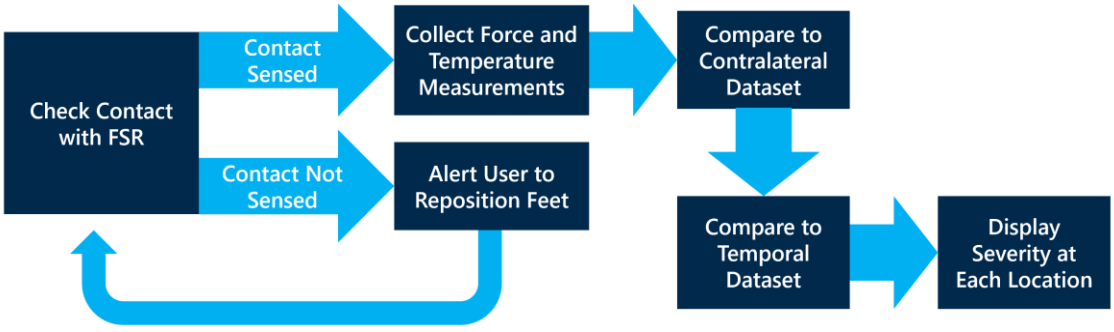


Figure 108. Solution Workflow.

The integrated version of the code (see Appendix) implemented the logic specified in the above solution workflow. However, the evaluation was solely based on contralateral comparisons and did not yet incorporate temporal comparisons. Furthermore, the

stored data structure named data would be used for temporal comparisons as it holds the data from the last 28 measurements.

User Workflow
Physical Workflow

The physical workflow of the device is outlined below. Together with the code, it outputs on the LCD as shown on Figures 111 and 112.

- Patient sits down and places their feet on the ground on either side of the mat. The mat should be sitting directly in front of the patient, positioned under their knees.
- Patient turns the device on with a button.
- Device screen displays the following instructions:

    a. Perform the following steps one foot at a time: left foot, then right foot.
    b. Lift your foot in the air and place your heel firmly against the backing.
    c. Rotate your foot laterally until the inner side of your foot is firmly against the backing.
    d. Slowly lower your foot down into the cut out, being careful to lower it at a steady rate. The device will record force vs time data, and if it is too noisy, will tell the patient to repeat this step.
    e. Rest your foot on the mat for 30 seconds, being sure to hold it still. During this time, the device will display a countdown graphic showing the time remaining. At the end of 30 seconds, the device will tell the user to remove their foot from the device.
    f. Lift your foot straight up from the device and set it back on the floor. Repeat for the other foot.

- The device processes the data and determines the severity of the warning for the patient based on the chart below, where red is an alarming symptom, yellow is a cautionary symptom, and green is a clear symptom. Descriptions of the symptoms are provided in the case of cautionary and alarming symptoms.

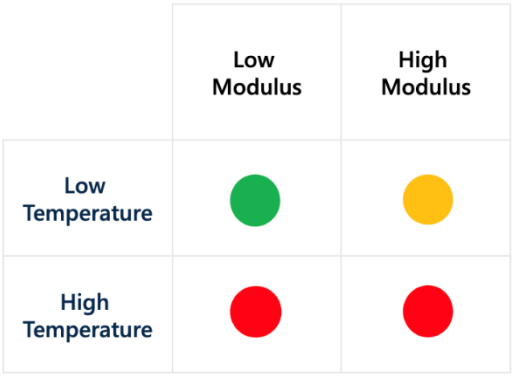


Figure 109. Decision matrix implemented in our device. Red is concerning results, while yellow is actionable results and green is normal results.

- The device stores the data for that day in its database. If the patient requires a doctor's visit, they can access their data history via a USB drive.

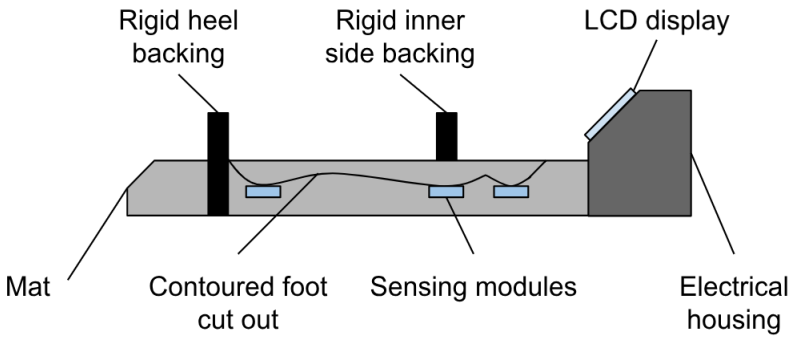


Figure 110. Side view drawing of final prototype.

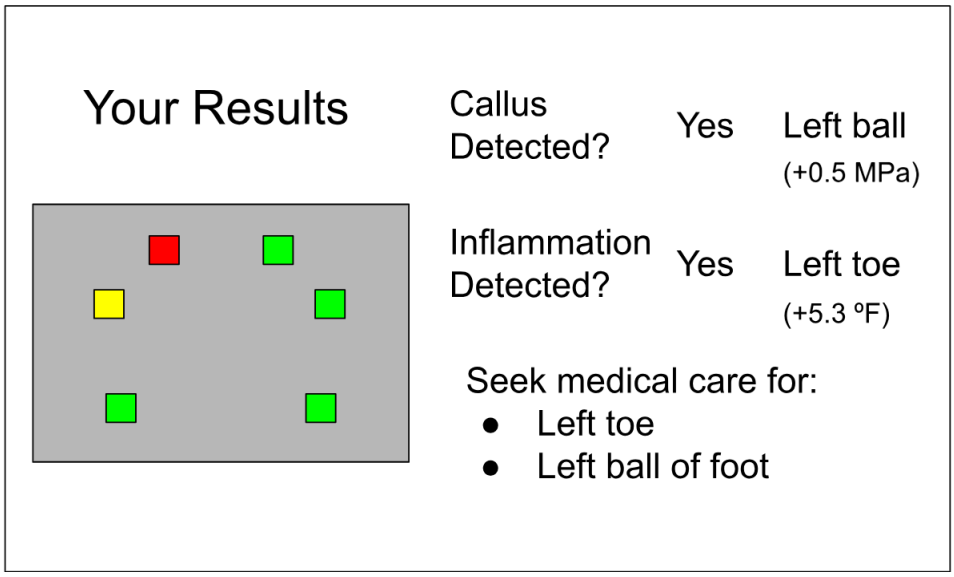


Figure 111. Example theoretical output on LCD display to user.

We considered graphic LCDs, OLEDs, and TFT LCDs for the LCD display shown to the user. We landed on TFT LCDs because of their low price, low power consumption, availability, and growing popularity. Their growing popularity is particularly important because robust prior use ensures that adequate development resources will exist, such as Arduino libraries to interface with their display drivers and implementation tutorials. The display drivers ILI9341 and ILI9488 seem to be commonly used with Arduino, so we began working with devices that incorporate these drivers. Note that ILI9488 requires 3 V logic, so we plan to use SPI-compatible logic level converters.

Figure 112. Implementation of TFT screen.

The physical implementation of the TFT screen is shown above. The code outputs the results as green, yellow, and red at the locations of the modules. Green corresponds to normal results, yellow corresponds to actionable results, and red corresponds to abnormal results. As previously discussed, all comparisons were made based on contralateral measurements for this iteration of the device. In other words, the results were determined through comparisons to the corresponding module temperature and modulus measurements on the other foot.

Simulated user interaction with the device can be seen here.

Testing

Objectives

Using the fully integrated prototype, the objective was to determine the rates at which the device could accurately distinguish temperatures and moduli. Specifically, four cases were to be assessed: low temperature, low modulus; high temperature, low modulus; low temperature, high modulus; and high modulus, high temperature.

Materials

The materials used were the device itself, the heated socks, and the phantoms of differing moduli. One phantom set was representative of the normal diabetic foot, while the other sets were representative of stiffened skin of varying degrees.

Methodology

Load Cell Calibration

The new compression load cell did not have an ADC to force calibration curve in its datasheet, so one had to be created empirically with the use of a gold standard Test Resources machine. The load cell, frame, and ball bearing were stacked vertically in the Test Resources machine, and a load of 70 N was gradually applied. The gain of the load cell had to be tweaked by changing the gain resistor value, and then 3 trials were recorded at the optimal gain. Force and time data from both the gold standard and the load cell were time-synced in Python, and scipy.optimize was used to perform a 2-dof least squares optimization to transform the load cell data onto the gold standard data. The optimal parameters were 16.4 (slope) and -1.55 (intercept). The following comparative plot was produced after scaling, which shows a very accurate fit.

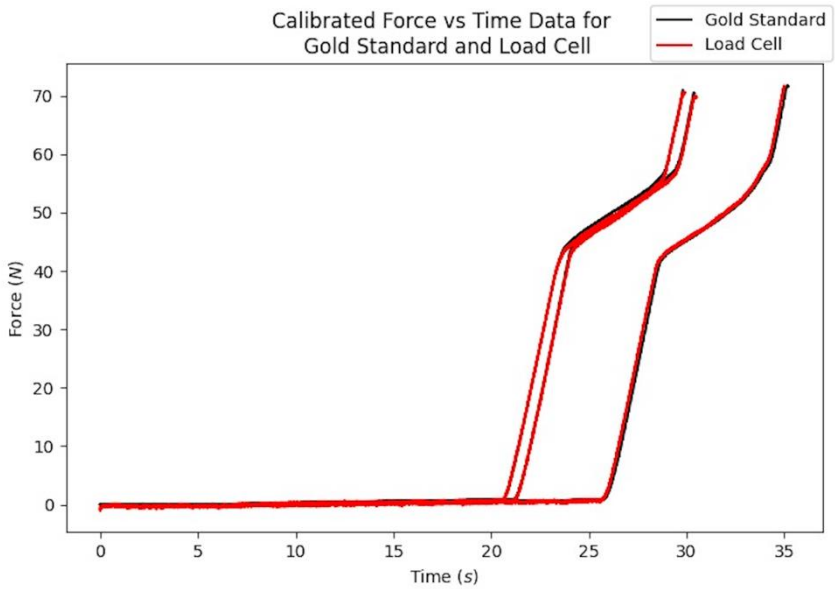


Figure 113. Load cell calibration relative to test resources gold standard.

After performing integrated testing (https://youtu.be/oSLw5aIOPmQ) on both some A-60 silicone and some softer ~A-20 silicone, the following populations of elastic modulus were determined, with errors bars illustrating the standard error.

Once the load cells had been calibrated, the device could be properly tested.

The four conditions (low temperature, low modulus; high temperature, low modulus; low temperature, high modulus; and high modulus, high temperature) were tested as follows. Moduli were varied by placing the phantom with normal diabetic foot modulus on one foot of the device, while placing stiffened phantoms on the other foot of the device. Temperature was varied by placing the heated sock on one foot of the device, while placing normal skin on the other foot of the device.

To conduct the testing, eight trials of each of the four combinations were tested. High modulus and high temperature were obtained as specified above. Testing was deemed successful if the LCD output indicated that there was a difference between the contralateral regions as would be expected for that scenario combination.

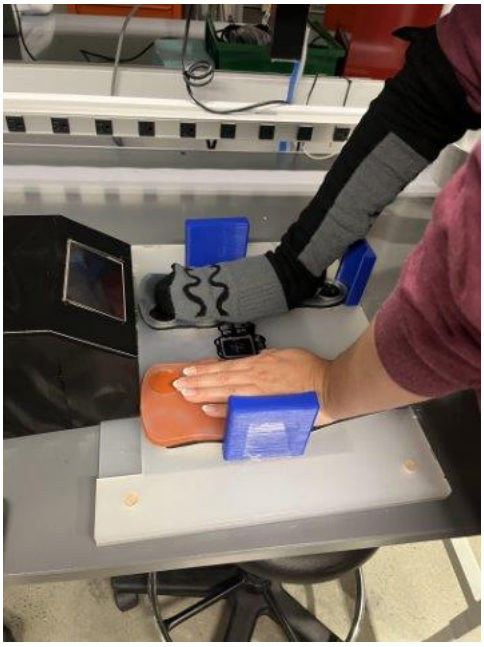


Figure 114. Preliminary device testing with silicone foot phantoms to simulate different moduli and heated socks to simulate different skin temperatures. In this examples, the phantom for the right foot is stiffer than that of the left foot. Additionally, localized heat is being applied toward the right 1st metatarsal head. Uniform/consistent load applied by arms during each trial to ensure repeatability.

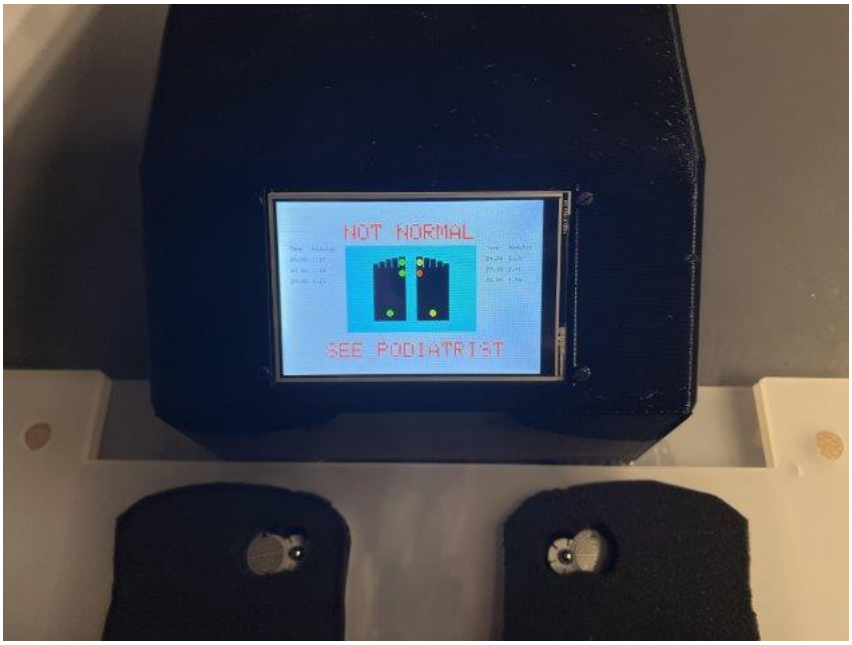


Figure 115. Example screen output.

Results

The plot below (Figure 116) shows a clear difference between the two populations, with minimal variation, which is very promising.

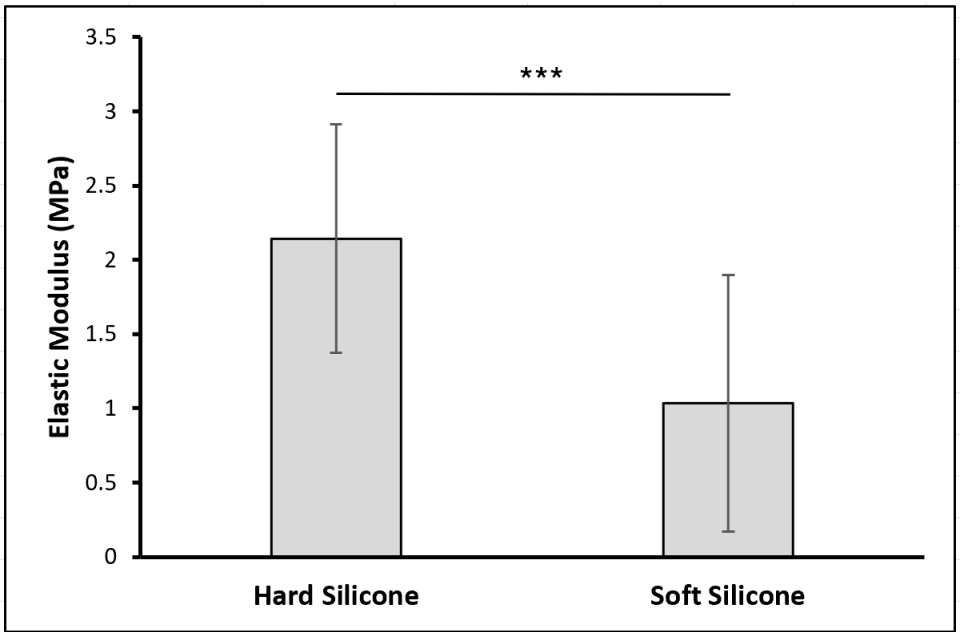


Figure 116. Load cell test after calibration.

After conducting eight trials of each condition, the success result percentages can be visualized below.

	Low Modulus	High Modulus
Low Temperature	**100%**	**100%**
High Temperature	**87.5%**	**87.5%**

Figure 117. Testing results.

As can be seen in the figure above, the only mistakes that the device made resulted in the high temperature cases. Next steps would include larger-scale testing.

VIII. Design Ethics

Continuous monitoring of DFUs offers tremendous potential for improving patient care, but it also raises significant ethical dilemmas. These concerns fall into several key areas, including accessibility and equity, data privacy and security, patient autonomy, and patient safety.

The broad umbrella of accessibility entails consideration of cost, power consumption, and storage of data. Home monitoring systems can be expensive, potentially excluding low-income or uninsured patients [93]. Furthermore, the additional features and complexity of our proposed multi-modal sensing mats will likely lead to a higher price point compared to standard temperature monitoring mats such as Podimetrics' SmartMat. The additional series of linear actuators beyond the array of thermistors sensors adds to the cost of materials and manufacturing. Integrating multiple sensor types and processing their data requires more complex hardware and software. The mat needs to be able to collect, analyze, and interpret data from various sensors, which increases the cost of development and production. Strategies to mitigate this include cost-sharing programs and insurance coverage for high-risk patients. Durable medical equipment (DME) products are more likely than direct-to-consumer (DTC) products to receive insurance coverage or reimbursement, making them more affordable for patients. Hence, DME coverage may be relevant in the case of remote monitoring devices. Types of insurance payers that cover durable medical equipment (DME) include Medicare Part B, Medicaid, and private insurance plans (to different extents). With regards to the power source, batteries can be expensive and require frequent replacement, posing a burden in resource-scarce settings. One avenue that can be explored to address this issue is alternative power sources like solar panels or energy harvesting technologies. Lack of internet access can limit access to home-based monitoring platforms, particularly for rural or underserved communities. App-based monitoring such as MyFootCare exacerbate the digital divide, as not everyone has access to smartphones or consistent internet connections. Patients are also required to be comfortable with using the technology and troubleshooting app issues. We plan to navigate this challenge by providing offline data storage options. Bluetooth modules can function independently, and data can be stored directly offline. Additionally, this module will have a simple interface with fewer buttons and screens, hopefully making it easier to use for individuals with limited technical skills.

Home-monitoring systems collect sensitive health data, requiring robust security measures to protect against unauthorized access, breaches, and data misuse [94]. Ensuring patient data privacy and security is paramount. This requires transparent data ownership policies, limited data sharing, and patient notification. Apps may raise concerns about data security and privacy, requiring robust measures to protect patient

information. In our device, the data will be stored directly on the monitoring device, eliminating potential cloud security risks. However, it should be noted that Bluetooth devices typically have limited storage capacity, requiring data to be transferred or deleted regularly to avoid overwriting. Achieving an optimal balance will be critical for ensuring accurate early detection and intervention of DFUs. Additionally, our system will need to appropriately incorporate alert mechanisms to notify both patients and healthcare professionals of stiffness or temperature differentials that may indicate DFU onset risk. From our stakeholder interviews with healthcare providers such as Dr. Adams, we have learned that implementing a targeted data collection approach based on risk factors and wound progression is preferred over continuous data transmission. Healthcare workers already receive a large volume of data from various sources, and continuous monitoring could overwhelm them. Analyzing and interpreting endless data streams can lead to alert fatigue, where they might miss important alerts due to desensitization. Dr. Adams had also expressed concerns surrounding liability, as the provider would not want to be held responsible for information that is potentially sent to them while they are not working. Hence, the functional requirements of interfacing properly with clinical systems will require further conversations with providers. Nevertheless, implementing robust data governance policies and adhering to relevant privacy regulations like HIPAA and GDPR are crucial for building trust and ensuring compliance.

Finally, our monitoring system must give patients enough information and autonomy to make informed decision about their own care. The regular updates on the data collected by the monitoring system must enable end-user empowerment. Users should be able to understand and interpret the data collected by the system. The design should promote health literacy and engagement rather than creating a passive relationship between users and their health data. In other words, the goal is to have a shared decision-making model and the right to refuse or withdraw. Another aspect from the lens of the patient is safety. The indentometer sensors should be designed to distribute pressure evenly and avoid causing additional tissue damage to the already fragile wound area. Even in the case of neuropathic patients, the indentometry measurement process should not cause any pain or harm. Recently, a group reported the use of spherical-tip indentation to measure the apparent elastic modulus of cortical bone [95]. We have had preliminary discussion about translating this concept over the application of the plantar surface of the foot.

Additional considerations for our product include transparency of device capabilities and clear instructions for use. The EZStepper device aims to identify individuals at increased risk of developing a foot ulcer. This at-home risk screening tool is distinct from a diagnostic device which serves to confirms the presence or absence of a disease

in individuals already experiencing symptoms. Given that the target population of end-users would generally be asymptomatic individuals or those with no immediate symptoms. The tool's sensitivity and specificity must be clearly communicated to users, along with the potential for false positives and the need for further medical evaluation. The EZStepper would prioritize high sensitivity (not missing potential cases) even if it leads to some false positives requiring further investigation. The potential of overestimating risk could lead to unnecessary anxiety and distress in patients. As device developers, it is our responsibility to provide clear instructions and training materials to properly guide users in interpreting results and seeking appropriate follow-up care.

By addressing the above items and developing a comprehensive strategy for data integration and utilization, continuous monitoring can become a valuable tool for improving diabetic foot ulcer care – but only if it enhances, not burdens, the workflow of healthcare workers as well.

IX. Regulatory

Distinguishing between a medical device and a general consumer product hinges on their intended use and the claims made about their function. Since our team makes specific claims about monitoring a medical condition, the device is subject to FDA regulation. For various reasons, the EZStepper would be categorized as a Class 1 medical device category. While the device is able to measure elastic modulus and temperature of tissue, it doesn't directly diagnose DFUs. This device identifies "hot spots" and "stiff spots" that could indicate inflammation and callus formation, respectively. Next, the device poses minimal risk to the user as there are no invasive procedures or potential for harm. The spherical shape of the balls used in indentometry, paired with the foam padding layers, ensure safety and comfort of the user. Finally, this device monitors non-critical physiological parameters and doesn't directly treat or support vital bodily functions. In fact, Podimetrics, one of the main competitors in the market described in an earlier section, legally market the RTM mat in the U.S. as a class I medical device for its intended use of "periodic evaluation of the temperature over the soles of the feet for signs of inflammation" [96].

Furthermore, this multi-modal DFU risk screening device would fall under the category of a "daily activity assist device" as defined in 21 CFR 890.5050. This section of the Code of Federal Regulations defines these as modified adaptors or utensils intended for medical purposes to assist a patient in performing specific functions related to daily activities like dressing, grooming, recreational activities, transfers, eating, or homemaking. It should also be noted that the Podimetrics RTM mat product code is registered as a OIZ Daily Assist Device. These devices are exempt from 510(k) premarket notification procedures prior to marketing [97]. This exemption simplifies the process from the manufacturers standpoint, making it easier to bring these assistive devices to market.

While exempt from premarket notification, daily activity assist devices are still subject to some quality system requirements. Specifically, manufacturers of Feet Guys' EZStepper product must comply with § 820.180 and § 820.198 of the Quality System Regulation [98]. Section § 820.180 outlines general requirements concerning records that manufacturers must maintain. Section § 820.198 deals with complaint files, mandating that manufacturers have a system for handling and tracking customer complaints.

X. Business Plan

Market Overview

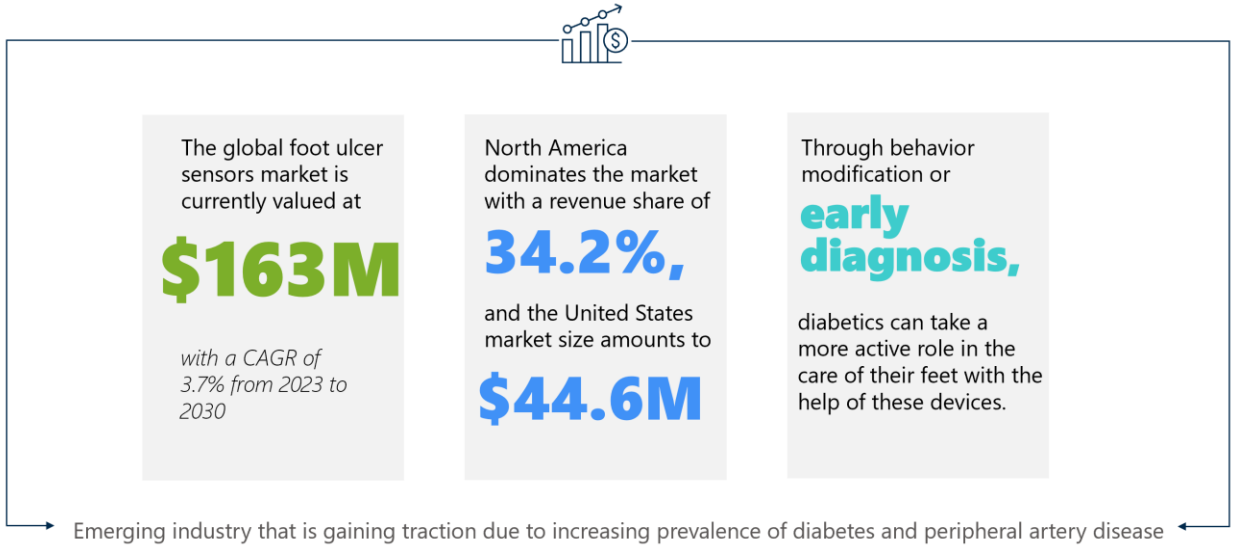


Figure 118. Market overview.

The foot ulcer sensors market is poised for significant growth, with projections estimating it to reach over USD 200 million by 2032 [99, 100]. This expansion is driven by several factors, including the rising prevalence of diabetes, a major risk factor for foot ulcers, and the growing elderly population, who are more susceptible to this condition. Advancements in sensor technology, wearable devices, and personalized healthcare solutions are further fueling market growth by enabling continuous monitoring, early detection, and improved patient outcomes. This market comprises various medical device manufacturers specializing in diabetes management and wound care, offering solutions that utilize pressure, temperature, or imaging technologies to detect and monitor foot ulcers, ultimately leading to better patient care and potentially reducing the burden of diabetic complications.

Given that DFUs affect about 1.6 million in the US annually (serviceable obtainable market), even a five-year 6.25% market penetration would enable EZStepper to reach the “feet” of ~100,000 patients per year.

Our EZStepper mat is primarily sold through a prescription approach with potential for reimbursement. It's not intended for general consumer use but is recommended for specific high-risk patients with diabetes, often determined by a podiatrist or other healthcare provider. Certain healthcare systems, like the US Department of Veterans Affairs (VA), will adopt the mat and may directly reimburse the company for the device and associated monitoring services provided to eligible patients. Some private insurance

providers will ultimately also began to cover the cost of the mat and its monitoring services if it falls within their coverage policies for DFU prevention.

Finaly, it should be noted that Medicare CPT code 99454 specifically covers the costs associated with remote patient monitoring (RPM) services. This code reimburses healthcare providers for supplying patients with remote monitoring devices, collecting and transmitting patient data over a period of at least 16 days within a 30-day timeframe. The existence of this code plays a crucial role in driving the adoption of RPM technologies. It provides a standardized mechanism for billing and receiving reimbursement, incentivizing providers to utilize these tools for improved patient care and potentially reducing overall healthcare costs in the long run.

XI. Future Work

The next major step for this device would be two-fold. First, a system would have to be designed for exporting data, such as an SD card, USB, or Wifi. This storage aspect had become low-priority as the semester passed, but it is necessary to implement in the next step. Once this storage aspect of the data and evaluations has been established, it will secondly need to interface well with clinical systems. A protocol must be established for this process of seamlessly interfacing with existing clinical systems that podiatrists and other care providers utilize.

Next, a major part of the manufacturing considerations would revolve around designing for adaptability of different feet anatomies as discussed previously. An increased number of modules could be added to each foot to increase the density of the sensors. Mats could then be created for different ranges of shoe sizes, incorporating these modules at the proportional locations dependent on shoe size. A major consideration in creating this range of mat sizes would be having a high enough density of modules such that a continuous distribution of foot anatomies can be served. After these considerations are decided, the go-to-market strategies can be developed.

As for the team, the next steps involve making some of the above steps while preparing for design competitions and potential patent processes. Specifically, the team is interested in participating in the DEBUT competition among others. As for the patent processes, the team submitted an invention disclosure form to Duke OTC in April 2024 and will continue discussions to assess IP potential. The long-term goal beyond these short-term endeavors would be licensing the technology, registering EZStepper as a FDA Class 1 medical device, and to going to market as a competitor to the Podimetrics mat.

XII. Poster

Daily Diabetic Foot Risk Screening Device

Sarah Glomski[1], Kishen Mitra[1], William Temme[1], Joshua Tennyson[1]

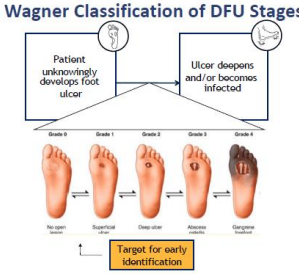
[1]Department of Biomedical Engineering, Duke University, Durham, NC, USA

FEET GUYS

BACKGROUND

- Due to loss of sensation, individuals with diabetic neuropathy may not notice pathological abnormalities on their feet. Callouses and injuries go undetected, eventually developing into open wounds called ulcers.
- Ulcers affect approximately 30% of diabetics in their lifetime.

Wagner Classification of DFU Stages



Clinical Outcomes of Diabetic Foot Ulcers (DFUs)

12 weeks	40%	60%	~20%
AVERAGE HEALING TIME	1-YEAR ULCER RECURRENCE RATE	SUSCEPTIBLE TO INFECTION	LIFETIME AMPUTATION RISK

DFU Monitoring Technology Gap Analysis

	Smart Socks	Ulcer Monitoring App	RTM Mat	Biosensing Insoles
Early-stage ulcer detection	—	x	—	✓
Frequent measurements	✓	x	x	✓
Comprehensive bioanalysis	x	x	x	—
Convenient	—	x	—	✓

***Need Statement:** Diabetes patients need a convenient and effective method to monitor early-stage neuropathic ulcer development to minimize necessary invasive treatments.*

DESIGN INPUTS
Functional Requirements

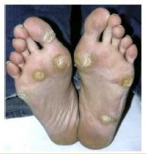
Detect Early-stage Ulcers	Identify ≥ 90% of ulcers at or before Grade 1 on the Wagner scale
Alert Patients	≥ 3 different levels of risk severity are considered
Interface with Clinical Systems	Score > 4 on user-defined scale to assess provider perception of device data integration

Constraints

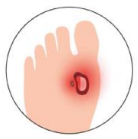
Convenient	Score > 4 on user-defined scale
Safe	User-defined scale and IEC 60601 for medical device electrical safety
Easy to Use	Score > 4 on user-defined scale
Equitable	Score > 4 on user-defined scale

PROPOSED SOLUTION: EZ STEPPER

Pathophysiology of Early-Stage Ulcers

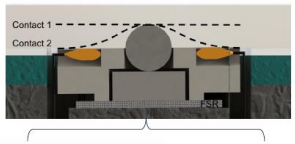


Pre-Ulcer Skin
- Calloused skin is 2-3 times stiffer than normal skin.



Inflammation
- DFU inflammation causes locally elevated skin temperature - 2.2°C is considered abnormal.

Principle of Operation – Multimodal Biosensing

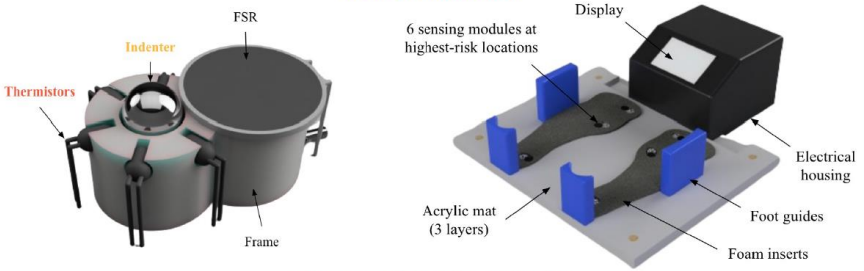


Pre-Ulcer Skin
- Spherical indentation measures Young's modulus through Hertz Contact Theory

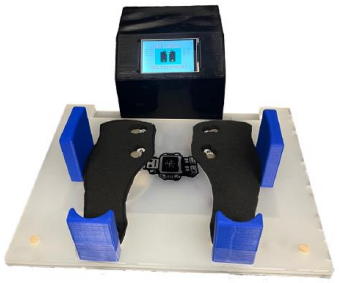
$$E = \frac{3F(1-\nu)}{4R^{1/2}\delta^{3/2}}$$

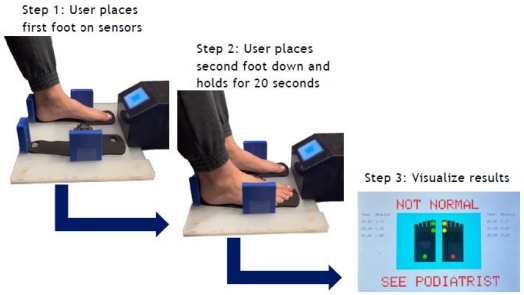
Inflammation
- Thermistors measure Temperature.

Solution Visualization

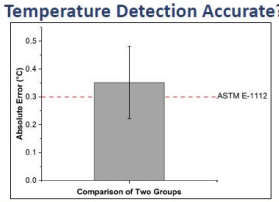


Prototype, Workflow, and Testing

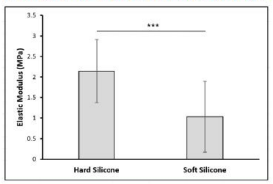




Is Temperature Detection Accurate? ✓



Is Modulus Detection Accurate? ✓



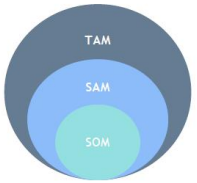
Can we Detect Ulcer Risk? ✓

	Low Modulus	High Modulus
Low Temperature	100%	100%
High Temperature	87.5%	87.5%

BUSINESS PLANNING

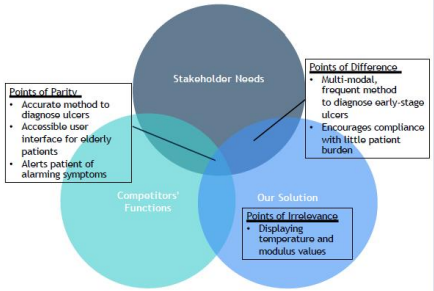
Regulatory Pathway	• Attain Class I (low risk) clearance from the FDA • No 510(k) required, as the CFR predicate is also 510(k) exempt (21 CFR 890.5050)
Reimbursement	• Device will be prescribed by podiatrists • Coverage by payer mix of Medicare and commercial insurance (CPT Code 99454)

Foot Ulcer Sensors Market Size



Total Addressable Market
18.6 million people worldwide
$163 million with CAGR of 3.7%
Serviceable Available Market
1.6 million people in the U.S.
$44.6 million per year
Serviceable Obtainable Market
5-year projection: 100,000 patients
$2.8 million per year

Value Proposition



CONCLUSIONS

Our multi-modal solution monitors tissue stiffness and local temperature fluctuations as early indicators of DFU formation.

- Next steps:
  - Establish protocol to interface with clinical systems
  - Design for manufacturability and adaptability
  - Obtain approval as a Class A medical device
  - Go to market as a competitor with the Podimetrics mat

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Duke UNIVERSITY | PRATT SCHOOL of ENGINEERING

XIII. Feet Guys Final Pitch Slides

FEET GUYS

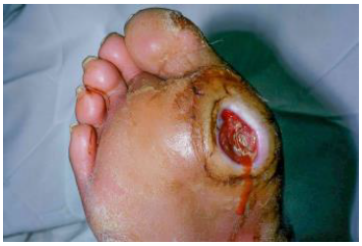
Daily Diabetic Foot Risk Screening

APRIL 2024

1

2

Diagnosis – Late-stage diabetic foot ulcer (DFU)



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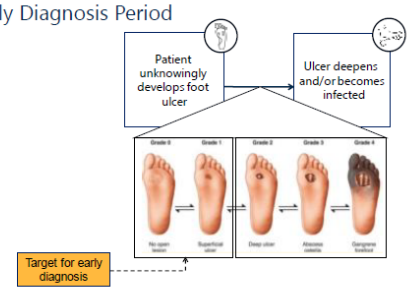
Clinical Outcomes

12 weeks	40%	60%	~20%
AVERAGE HEALING TIME	1-YEAR ULCER RECURRENCE RATE	SUSCEPTIBLE TO INFECTION	LIFETIME AMPUTATION RISK

4

Early Diagnosis Period



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Current Landscape

	Smart Socks	Ulcer Monitoring App	RTM Mat	Biosensing Insoles
Early-stage ulcer detection	—	x	—	✓
Frequent measurements	✓	x	x	✓
Comprehensive bioanalysis	x	x	x	—
Convenient	—	x	—	✓
Accessible	x	✓	✓	x

6

Need Statement

We need a way to monitor **early-stage neuropathic ulcer development** in diabetic patients to **minimize necessary invasive treatments** and **promote faster healing**.

8

Design Inputs

Functional Requirements

Detect Early-stage Ulcers	≥ 2 pre-ulcerative biomarkers are assessed
Alert Patients	≥ 3 different levels of risk severity are considered
Interface with Clinical Systems	> 4 on user-defined scale to see how integrated the device data is for healthcare providers

9

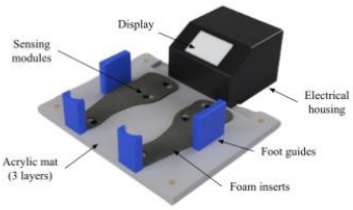
Design Inputs

Constraints

Convenient	Score > 4 on user-defined scale
Safe	User-defined scale and IEC 60601 for medical device electrical safety
Easy to Use	Score > 4 on user-defined scale
Equitable	Score > 4 on user-defined scale

10

Proposed Solution – Multi-Modal Mat



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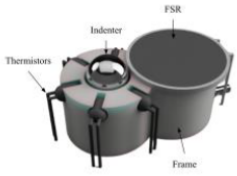
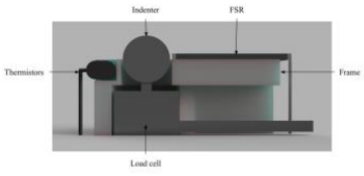
Sensing Modules





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Principles of Operation

- Elevated temperature → inflammation response (pre-ulcerative state)
  - ASTM E-1112 and Literature: Detect 2.2 °C difference with ±0.3 °C max error
- Elevated modulus → callus formation (further upstream pre-ulcerative state)
  - ASTM E2546 and the Hertz force-indentation relation

	Low Modulus	High Modulus
Low Temperature	🟢	🟡
High Temperature	🔴	🔴

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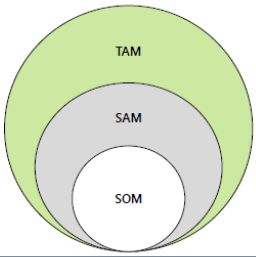
DFU Market Size



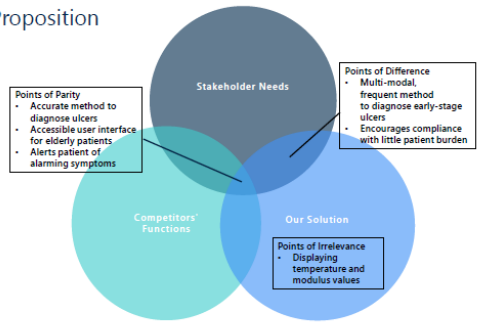
Serviceable Available Market
- 1.6 million people in U.S.
- $44.6 million per year

Total Available Market
- 18.6 million people worldwide
- $163 million with CAGR of 3.7% between 2023 and 2030

Serviceable Obtainable Market
- 5-year projection: 100,000 patients
- $2.8 million per year

22

Value Proposition



Points of Parity
- Accurate method to diagnose ulcers
- Accessible user interface for elderly patients
- Alerts patient of alarming symptoms

Points of Difference
- Multi-modal, frequent method to diagnose early-stage ulcers
- Encourages compliance with little patient burden

Points of Irrelevance
- Displaying temperature and modulus values

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Team

Kishen Mitra
Business Development Lead

Sarah Glomski
R&D Lead

Will Temme
Manufacturing Lead

Josh Tennyson
Software Development Lead

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Aaron Kyle, PhD	Eric Richardson, PhD	Lokesh Kumar Manivannan	Paris Brown
Liz Feeney, PhD	Matt Brown	Xiaoyue Ni, PhD	Chenhang Li

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Appendix

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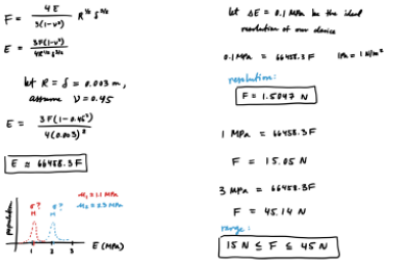
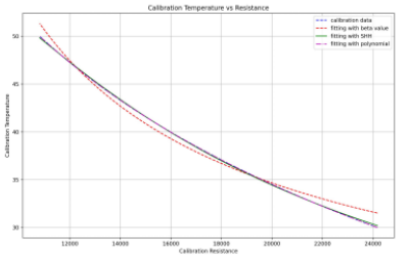
Hertz Contact Theory & Calculations



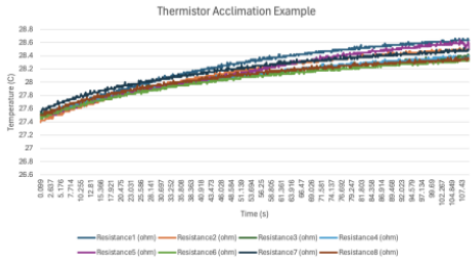
29

Calibration Curve for Thermistor



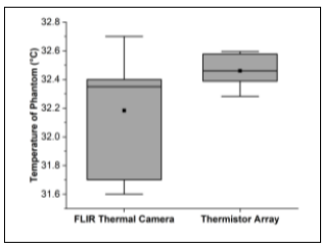
30

Thermistor Equilibration Time



31

Thermistor Array Data



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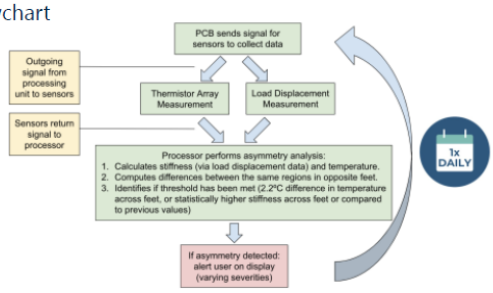
Flowchart



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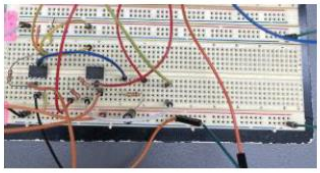
Load Cell Signal Processing Circuit



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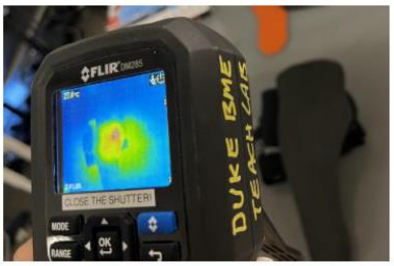
Integrated Test Phantom



- Heated socks were used to warm specific region of foot phantom
- FLIR gun "gold standard" to verify onset of inflammation

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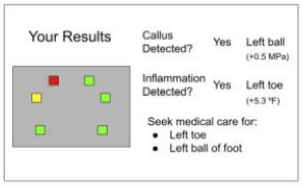
User Interface



Podimetrics mat software

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XIV. Stakeholder Interviews
Healthcare Providers
Meeting Title: **Interview with Dr. Sam Quesada**
Stakeholder Role: **Podiatrist at VA Palo Alto Health Care System (VAPAHCS)**
Date: **9/19/2023**
Format: **Offline Q&A, Virtual Zoom Discussion**
Facilitator: **Will Temme**

Attendance:

Sarah Glomski, Will Temme, Dr. Sam Quesada

Q&A:

- How long do patients typically take to notice an ulcer?
    - Depends, highly variable, multiple factors. Do patients perform foot checks daily? Do they have neuropathy? Have they experienced an amputation before? Compliance?
    - Tell patients to perform daily visual foot checks, but many patients do not
    - People will look at shoes/socks/carpets and notice blood, drainage, wet socks
    - Red hot and swollen foot with open wound (signs of infection)
- What tends to cause a patient to notice an ulcer?
    - Usually feeling pain, noticing drainage in shoes/socks, remembering that they kicked/scratched themselves
    - Numb feet and can't feel when step or kick things
    - Foot is red, hot, and swollen
- Have you noticed any trends in what patients identify as the cause of their ulcers?
    - Also highly variable, some patients come to clinic knowing they had an event which caused a wound and others will say it's from neuropathy and noticing it later on.
    - Neuropathy from having diabetes, from therapeutic agents, agent orange exposure, carcinogenic chemical exposure
- How much time typically passes between a patient noticing an ulcer and it getting reported to you?
    - <1mo for 95%, typically 1-2 weeks, between ulcer development and clinical presentation
    - Generally more common checking of foot leads to sooner diagnosis
- Do you typically take preventative measures to avoid ulcers (or be more proactive in their detection) in patients with diabetes and/or peripheral neuropathy prior to the development of their first ulcer?

    - Yes, we instruct patients to perform daily foot checks, prescribe RTM mats, orthotics/diabetic footwear, prevalon boots for those bedridden, regular appointments in clinic to check in, monitoring A1C, also recommending regular follow ups with PCP.
- What methods have you found successful in preventing initial amputation?
    - RTM mats, monitoring glucose/A1C levels, patient needs to be compliant with their care and closely monitor themselves or have someone monitor their feet (daily foot checks), regular appointments with PAVE clinic or regular Podiatry clinic
- What factors contribute most to the necessity of successive amputation?
    - Vascular status (poor ABIs). We work closely with Vascular Surgery to ensure good bloodflow in order to heal wounds. Diabetic status (are pt's diabetes well-controlled? If not = longer healing times = higher chance of infection). Patient compliance.
- What existing techniques do you use most to avoid successive amputation after initial amputation?
    - Local wound care, grafts, negative pressure wound therapy, working with Vascular Surgery to revascularlize patients
- In your experience, how frequently do patients with an ulcer avoid infection?
    - It really depends on a multitude of factors. The longer a wound is open vs patient's personal health and compliance to care.
- What would you consider the most effective/benchmark existing solution for ulcer detection and prevention, regardless of cost/novelty/clinical prevalence?
    - Daily foot checks, diabetic/vascular management, and RTMs
- Are patients typically compliant with RTM mat usage requests?
    - Yes, though some patients get lost to follow up, patients are usually pretty consistent with the mat because I believe they get notifications/calls/frequent check ins.
- Have you ever heard of RTM insoles/orthotics on the market (or prescribed them)?
    - Nope! I imagine the hook-up would be similar to Walkasins or haptic feedback insoles for neuropathic patients/balance issues/lack of proprioception
    - Call center monitors when patient's temperature goes up ~1 degree, then contact patient and doctors → watchpoint (ie. watch metatarsal head)
    - Able to integrate remote temperature monitor (considers labs, glucose, vascular status, pressure points) into an insole with haptic feedback → very helpful in prevention of amputation
    - Monitor symptoms and/or send message to podiatrist over time

- Do you often use topical solutions for ulcer treatment? Are they effective? Do you use them alone?
    - Yes. The main ones used here are iodosorb which is an iodine cadexomer and silver sulfadiazine. It depends on the wound base. Santyl, aquacel, prisma, grafting (neox)
- Do you find using total contact casts effective in healing ulcers?
    - Absolutely. It is the gold standard for ulcer treatment. The next best is offloading with a CAM walker (97% effectiveness).
- Do you frequently identify the specific pathogen that infects ulcers?
    - Staph aureus
- Other than temperature and pressure/shear stress, are there any notable biomarkers that you can think of to help observe the development of ulcers and/or infection?
    - ABIs/Waveforms, Glucose/A1C levels, SWMF/Neuro section on clinical exams
- In your experience, what does the VAPAHCS's diabetic care team typically do for patients regarding amputation/reamputation avoidance?
    - PAVE clinic, regular foot exams, follow-up appointments
- Do you see a need for additional development of tools for prevention/detection of ulcer development?
    - Yes, a significant portion of the population either has or will deal with diabetes later in life
- Do you think any of the following areas have a greater need of solution development than the others: ulcer detection in pre-amputation feet, infection detection in ulcers on pre-amputation feet, ulcer detection in post-amputation feet (or lower limbs), infection detection in post-amputation feet (or lower limbs)? Would an exhaustive (covers all aforementioned spaces) solution be desirable?
    - Either ulcer detection or post-amputation care due to higher risk of successive amputations, but honestly they are all important
    - Yes because I have seen so many people with existing amputations and there is a large portion of the population dealing with diabetes and/or vascular disease.
- Are all existing tools accessible to underserved clinics?
    - No and at the VA we have access to cutting edge technology that other clinics may not have access to.
- Do you have any suggestions regarding areas to begin researching or products to explore to help our design process?
    - Temperature with RTMs is one factor. Existing deformities/pressure points are another. Ideally something that uses AI or an algorithm as well as the Risk Assessment for diabetic ulcers

- What factors have you noticed cause patients to avoid using podiatric devices (devices include diagnostic tools, topical medications, prosthetics, shoe inserts, etc)?
    - Noncompliance, lack of ease of use
- What sort of technologies do you think patients would comply with vs not comply with (e.g., socks, insoles, shoes, shoe interior linings, mats, manual scanning probes, picture-taking devices, etc)?
    - Hard to say because patients become noncompliant for many reasons. Ideally it would be something with a regular reminder and it would be annoying!
- Can you think of any common comorbidities (along with diabetic foot ulcers) that would be important to design around?
    - Neuropathy, not vascularly intact/CAD, existing amputations, arterial/venous insufficiency, lymphedema
- In your eyes, what are the most important design criteria (e.g., comfort, size, diagnostic speed, accuracy, usability, interfacing with medical records) when developing a podiatric diagnostic tool?
    - Interfacing with medical records, usability, comfort, and frequency
- In your eyes, what are the most important design criteria (e.g., comfort, size, longevity, convenience, etc.) when developing a podiatric wearable or corrective/preventative device?
    - Convenience

Discussion Notes:

- Other than RTMs, there is a haptic feedback insole (walkathins)
    - A lot of the factors involved in these complications are vascular status, PCP things (glucose testing, labs, etc)
    - If you're able to integrate remote temperature through some sort of algorithm - also taking into account lbs, glucose, pressure points, etc. to output a "risk assessment"
    - Haptic feedback
    - Would be really helpful in the prevention of amputation
    - Send message to PCP or podiatrist
    - Raise in temperate 1F is usually a sign of ulcer formation
- Mat is used because it's reliable, patients use it at the start of the day
- Vascular status (arterial insufficiency with perpetuate ulcers getting larger, increase risk of amputation)
    - Highest risk for ulcers, non-healing ulcers, amputations
- ABI (Ankle Brachial Index) -> check for peripheral artery disease

    - Toe brachial index (TBI) tends to be larger; index or pressure monitor. Related to microvascular disease vs greater arterial insufficiency. TBI is for forefoot. Ankle applies to anything distal to ankle joint. Other indices may exist.
    - ABI waveforms are marker for how well something is gonna heal.
    - Also A1C monitoring. If too high chances of healing ulcer goes down.
    - TCPO2 transcutaneous oxygen perfusion was used a lot by attendings. Just sorta uses a camera.
    - Would be valuable to have some sort of sensor for this out of clinic
    - If less than .7 typically at decreased rate of healing
    - Less than .3, chances of healing are next to none
- Ulcer monitoring design space
    - Prevention is most important space
    - Up to 50% mortality in next 5 years after amputation
    - Prevention of ulcers
    - Local wound care (more of a research project) → also existing solutions exist
- Intraoperative tech helps determine vascular of an amputation
    - "Spy-fi"
- Post-amputation
    - Preventing re-amputation: vascular is biggest factor, glucose levels (a1c's > 6.5/7 → chances of healing are low)
    - Hyperglycemic, diabetes, high a1c will make ulcer healing take much longer
    - Fasting glucose is monitored multiple times per day → insulin levels are adjusted
    - Medicine co-management
    - Below-knee amputation patients have very poor vascular status → bilateral BKA
    - Failed angiogram with intervention, failed bypass
    - Non-compliance is also a lesser problem
    - Amputations beyond 1 digit rips off insertion points of many tendons → biomechanical standpoint, causes varus deformity (not intact tendon → inverts foot) → bones move because tendons aren't attached
    - All performed in the clinic: Dorsalis pedis (can we feel your pulse?), capillary fill time, gross edema, venous insufficiencies
    - Monophasic blood flow from Doppler ultrasound → referral to vascular
    - Markers are same pre- and post-amputation
    - Usually you would revascularize before/during amputation
- ABI/TBI

    - Does continuous monitoring help?
        - Only tested once
        - Only asked to do multiple when they have amputations months apart
    - Rare to have ABI before showing up to clinic (unless you have known coronary artery disease)
    - Predictive measure on whether something heals (<0.3 → next to 0 chance of healing, small range of what is expected to heal)
    - Ankle/toe brachial index (ABI, TBI) (comparison to arm)
    - TBI ranges from 0 to 1 (pressure doesn't need to be as high for it to not heal)
    - Valuable to have inside of insole (patients typically comply with insoles unless they are uncomfortable)

Major Findings:

- Prevention of amputation is the most important space for device design, and has a large market in the future.
    - "A significant portion of the population either has or will deal with diabetes later in life."
    - "Up to 50% mortality in next 5 years after amputation."
    - However, post-amputation ulcers form from the same pathophysiology (largely due to poor vascularization) and they make up a large portion of the population.
- If caught early enough, the gold standard for ulcer treatment is to prescribe a total contact cast.
    - The next best is offloading with a CAM walker.
- Vasculature and temperature are the two most important biomarkers for indicating ulcer formation.
    - Currently, vasculature is evaluated exclusively in the clinic (ie. dorsalis pedis (can we feel your pulse?), capillary fill time, gross edema, venous insufficiencies, or during amputation surgery).
    - ABI, TBI, and A1C are valuable and reliable metrics for predicting whether an ulcer will heal.
- If we could develop some sort of sensor or device as a metric for ABI for patients to check at home (outside of clinic), it would be very helpful.
    - Sock/insole/similar (compressive)
    - Monitoring would help in prevention
    - Hard to tell which branches are occluded without angiogram first
    - Pulse oximetry could potentially help

    - TCPO2 (transcutaneous pulse oximetry, camera that showed level of oxygenation in foot area)
    - Other indices for spinal-related ulcers (for bedridden patients)
- Most important design criteria are: interfacing with medical records, usability, comfort, and frequency.

Follow Up/Referrals:

- Upon request, referred to Faranak Pourghasemi, DPM – Podiatrist for PAVE clinic
- No scheduled follow up but indicated intent to provide additional help, referrals, talk to attendings, and provide resources for us to study

Meeting Title: **Interview with Dr. Samuel Adams**
Stakeholder Role: **Orthopedic Surgeon, Foot & Ankle Specialist at Duke Health**
Date: **10/2/2023**
Format: **In person**
Facilitator: **Will Temme**

Attendance:

Will Temme, Kishen Mitra, Dr. Adams

Notes:

- What is Dr. Adam's role ?
    - DFU patients have foot deformation and overloading of a particular part of foot
    - People are there to see him for correction of foot deformity
    - People often come to him then they refer to vascular surgery
- What are demographics of DFU patients?
    - Majority of cases I see are neuropathic
    - People are often too obese to see the bottom of their feet
    - Many people are so incapacitated that they can't put shoes on alone
    - From a socioeconomic background where they don't know about fundamentals
    - Don't know to or care about checking bottom of foot
    - "Sometimes they know they have an ulcer, but they don't give a crap because they think it's going to heal."
    - Particularly because in the South, people tend to be obese, lower education, multiple comorbidities, hypertension, heart issues
    - Seems about "50/50" white/black
    - Not necessarily racial issue, just diet
    - Probably differences in pathophysiology for different socioeconomic statuses
    - A lot of people live alone and don't have a spouse to look at their foot. People in higher class typically have better care (someone else to help them organize and get through care process).
    - Root cause is lack of care and coinhabitant for socioeconomic disparity
    - "Most patients that I operate on also have PAD". Not 100%.
- What is the tmeline of the patient care cycle?
    - Very variable—in the weeks range
    - Ulcer healing can take weeks
    - Healing doesn't happen on own, must intervene
    - Total contact cast, revascularization, offloading tend to be interventions

    - Can never restore sensation but can heal ulcer then alter foot structure (fix charcot foot)
    - Can be charcot midfoot, hindfoot, ankle
- What are standard biomarkers to track for screening/diagnosis?
    - If truly a vascular related ulcer: “In my mind it's about pressure and temperature.”
    - Moisture could be valuable to monitor
        - High moisture environment plus rubbing equals wound
    - The more variables you have, the better predictions you can make
    - “What exists right now is not sufficient for my purposes. If it was an awesome product, it would have invaded our clinics.”
    - Shear stress vs normal is also good marker
        - Shear stress is an important biomarker
- What are other real world considerations in DFU monitoring?
    - Big issue preventing distribution of existing solutions is “Who's gonna pay for this?” Insurance only pays for one every so many years
    - Foot shape changes
    - Insurance needs to step up and pay for monitoring up front instead of 50-100k surgery ahead of time
    - Sometimes things have to be built into a custom orthotic
    - Dealing with compliance in lower socioeconomic status is a major factor
    - Continuous monitoring (and sending data to care team) when the care team is not there adds a responsibility for them to provide care at ALL TIMES, which adds liability to them. More data is more of an inconvenience. Receiving more data is out of the question. They don't make money and have more risk.
    - User themself needs to be incentivized to go to the provider immediately

Major Findings:

- Pre-amputation is the space with the most need.
- The major socioeconomic factors that affect DFU cases include: diet (and subsequently, hypertension, obesity, etc.), access to co-inhabitants, and education.
- Dealing with compliance in lower socioeconomic status is a major factor to consider in the design.
- Continuous monitoring of biomarkers and sending large amounts of data to clinical systems adds liability for the care team, which is not ideal.
    - Instead, patients need to be incentivized to seek treatment based on the screening results they see.

Follow Up/Referrals:

- Referred to Kyle Wamelink, DPM – Podiatrist
- Attempted to connect us with a patient for formal interview – not yet successful

Meeting Title:	**Interview with Dr. Souren Forouhi**
Stakeholder Role:	**Geriatrician at VA Palo Alto Healthcare System and Urgent Care Doctor at Multiple Systems**
Date:	**10/6/2023**
Format:	**Zoom Call**
Facilitator:	**Will Temme**

Attendance:

Will Temme, Kishen Mitra, Josh Tennyson, Dr. Forouhi

Notes:

- Can you explain how you fit into the cycle of care with respect to diabetic foot ulcers?
    - In general (doctor/geriatrician) because I did primary care as my first residency, I do get to see a lot of patients who have diabetes. And I do see a lot of patients who have some sort of infection (this is referring to outpatient). The problem is that once it gets to the point that you have a diabetic ulcer it switches to podiatry and surgeons. I do an initial assessment. I also work urgent care. I look, I get some x rays, I start at antibiotic. If its extensive I send them to a specialty clinic. Regarding extensiveness, if I see someone with a small ulcer with minimum discharge, they gave good sensation on feet, they dont have elevated white count, they have good flows and pulses. Then I deal with it in outpatient setting. So I get anX-ray and blood. If X-ray doesnt show any osteomyelitis then I deal with it as an outpatient. If they're diabetic, I do send them to get checked out. Also, you dont necessarily have to be diabetic to get peripheral vascular. If they have ulcer and they have a vascular disease I will send them to podiatrist. Podiatrists are surgeons, so opening and draining is better to be done by them. If someone has a small opening, I just do my own thing.
    - In the inpatient setting, I deal with the afterward of whatever is done. After they get some sort of surgery or debridement. I deal with them here with woundcare and antibiotic.

- How often do you send a patient with a DFU to podiatry? How often do they send one to you?
    - Referral no matter what if they ulcer
    - If podiatry needs to see the patient a few time a weeks if they a wound wack/rag?, if they need to have a change in dressing, or if they need to have antibiotics
    - Second question hard to answer from his perspective; only sees the 10 that come to him
- Have you noticed significant demographic (race, age, rural living setting, homeless, etc) of patients with DFUs or DFU-related amputations.
    - Majority of the patients are white (at VA as a whole), but in population Hispanics have a higher rate of diabetes and ulcers
    - Low socioeconomic populations are at a higher risk for diabetes from lower access to healthcare, lower access to nutritious foods, more
- Have you noticed any trends in what patients identify as the cause of their ulcers?
    - It's a vascular disease
    - Diabetes, hypertension, high cholesterol can all cause vascular disease
    - Lack of movement
    - Diabetics do not get the nutrients and care that tissues need so tissue damage does not heal as for non-diabetic individuals
- If applicable, in your experience, how frequently do patients with an ulcer avoid infection?
    - Ulcers are infected most of the time when they present
    - Much lower infection rate if caught early; depending on how bad vascular disease and diabetes is
    - 25% if caught early (in callous phase and treated very properly) progress negatively
- What would you consider the most effective/benchmark existing Have you ever heard of RTM insoles/orthotics on the market (or prescribed them)?
    - I'm not too familiar with RMTs.
- Other than temperature and pressure, are there any notable biomarkers that you can think of to help observe the development of ulcers and/or infection?
    - Anything that can detect low flow of blood to the foot
    - Temperature can be a sign of low blood flow. Low hair growth shows low nutrition. Shiny skin is sign of lack of nutrients from blood flow.
    - Checking the sensation of the bottom of the feet. Some devices are currently used to detect low sensation
    - Damage happens from top to bottom (most superficial to least). Nail damage could be early sign of vascular disease.

        - Is vascular efficiency valuable to monitor (BTI, ABI)
    - Measuring this would be one of the most important things. 100% would be valuable.
        - Detecting this earlier would be a great preventative thing
        - Even for measuring tissue injury, it will have to do with the blood flow to that area.
            - Normal people will get an ulcer and it will heal naturally (from previous question).
        - Something that can measure redness of skin possibly
            - Non-blanching areas are a sign of tissue injury
        - Cold = lack of blood flow
    - Familiar with ABI
        - Risk factors
            - Smoker
            - Poor mobility
            - Chronic disease (vascular disease, diabetes)
            - Severe pain causes lack of movement
            - History of trauma to that area
            - Autoimmune disease like rheumatoid arthritis
- Do you see a need for additional development of tools for prevention/detection of ulcer development?
    - It would be great to have something for sure. It definitely would be. Most of the time when we see our patients we are backpedaling. We want to detect injury before infection.
    - There is nothing that can indicate you're in great danger of ulcer.

- I know you see a lot of noncompliant patients – what factors have you noticed cause patients to avoid using podiatric devices (devices include diagnostic tools, topical medications, prosthetics, shoe inserts, etc)?
    - Access, cost (covered by insurance (is it fancy and costs a lot of money))
    - How often can they get a resolution – will it really help or will it just detect
    - How long will they have to wear it
    - Is it comfortable
- Does it prevent from doing daily activities

  What sort of technologies do you think patients would comply with vs not comply with (e.g., socks, insoles, shoes, shoe interior linings, mats, manual scanning probes, picture-taking devices, etc)?
    - Should be part of habit. Should be easy to integrate into lifestyle.
    - Socks: good

    - Insoles: sure
    - Shoes: sure
    - Shoe interior linings: sure
    - Mats: below everything above, thought for much longer than the previous ones
    - Manual scanning probes: still compliance issues
    - Photos: I highly doubt they would be compliant. Patients wont even look at feet without a picture.
    - Only very small amount of patients do foot checks every day
- In your eyes, what are the most important design criteria (e.g., comfort, size, longevity, convenience, etc.) when developing a podiatric wearable or corrective/preventative device?
    - Comfort
        - Second place.
    - Cost
        - Very important because if you have to pay out of pocket and its a lot, not everyone will do it. People get free stuff and dont even do it
    - Ease of use
        - People tend to be older

Major Findings:

- He refers patients with a DFU to a podiatrist if they have an ulcer no matter the severity of the ulcer
- In his practice (bay area) demographics are skewed, but he does see a disproportionate number of Hispanic patients and patients of a low socioeconomic status with DFUs
- Vascular disease is a key player in the incidence and healing of chronic DFUs. It would be valuable to monitor this
    - Measuring blood flow in the foot would be "one of the most important things." He provided various ideas regarding how to do this
- Catching an ulcer very early – in the callous stage – is valuable for improving clinical outcomes and altering treatment plans
- He views socks, insoles, shoes, and shoe liners as the most likely solutions to induce compliance. Mats and all other solutions that we have analyzed thusfar are less likely to induce compliance
- Comfort and cost are the two most important factors to consider in designing a solution

Follow Up/Referrals:

- He requested to be kept up to date on project
- No follow up scheduled; indicated availability to answer questions over text/call in future if desired

Meeting Title: **Interview with Dr. Kyle Wamelink**
Stakeholder Role: **Podiatrist at Duke Health**
Date: **10/12/2023**
Format: **Phone call**
Facilitator: **Kishen Mitra**

Attendance:

Will Temme, Kishen Mitra, Dr. Wamelink

Notes:

- What do you see in the clinic and what is your typical treatment plan?
    - Pretty broad question: I also see the same type of patient in the same stage as Dr. Adams, but I also see them early
    - Sometimes management is conservative and sometimes its surgical
    - Sometimes diabetic cases are compared to cancer – catching diabetic ulcers at an early stage leads to a better outcome
    - If you find a patient in the late stages, you will often see them in the hospital. They have advanced to a stage where they have sepsis, need IV antibiotics and surgery
    - Once you get an amputation, the chances of another amputation go up because of a number of reasons
    - Amputation means diabetes is poorly controlled. High risk patient
    - Also, losing great toe (or other) causes altered mechanics because rest of foot needs to compensate. Walking differently leads to another wound that leads to the need to amputate.
    - Many people have jobs that require them to work on their feet – hard to adhere to the requirement set for them
    - I try to get infection cleared then work to make sure it never happens again
    - Sometimes there is preventative reconstructive surgery, depends on their foot type and mechanics
- Where is your primary patient base?
    - Duke regional
- What are the techniques your team at duke regional uses to monitor occurrence of DFUs?
    - Im very familiar with a lot of the products that are available
    - In general, I don't use those for my patients. I just educate them on how to perform foot checks. Tell them wear white socks.

    - I dont use because of access. Getting patients access to some of these technologies is nearly impossible. It is very widespread that monitoring ulcers is done by inspection
    - Indicating heat or high pressure would be very helpful
- What are challenges other than accessibility with existing solutions?
    - Demographic is important to consider
    - The need is there
    - The issue is compliance
    - Sock is most feasible because they are worn all the time
    - May not wear same shoes all the time, may take them off in the house
    - Even if available and works well, its difficult to get people to use. Its a combination of this and getting patients access to them
- Regarding wearing same socks for a long time:
    - It can be difficult to reach your feet, which makes it hard to take socks off
    - Some people dont have significant other or family to take socks off for them
    - Poor hygiene is associated with the patient population in many cases
- If you get an alert, what would you do about it?
    - Some patients (or loved ones) are highly interested in preventing something negative from happening to feet. Some patients may appear to care less, but their wife may be super on top of stuff. If there was an alert of an ulcer, they would take action. There are these patients that are proactive. These are the ones that would probably be our target market.
    - This is about 50% of patients
    - In my old practice we used to provide 1 pair of shoes and 3 inserts. You have to also bee seen by a primary doctor and then have to write a letter. Not everyone’s insurance covers diabetic shoes.
    - Custom inserts, heat molded inserts
    - Of the 50%, only 50% has coverage (the diabetic shoes and inserts are like $400; diabetic shoes are different than ulcer detection devices – these diabetic shoes are meant to prevent ulcer formation). Medicaid patients don't have coverage.
    - There is also group that is so limited in ability to care for self that it is outside of their scope to monitor. These people likely wouldn't be targets for this kind of tech

- Existing solutions. Have you had experience with them
    - Only used insoles. I wouldn't know how to get my patient a mat. I don't know other colleagues who are using them.
    - Which insole did he use?

    - Used dr comfort insole. Common diabetic shoe option. No monitoring capabilities.
- How could we solve this accessibility issue?
    - Sock is most reasonable way to address compliance. Sock seems like an easy solution for someone to get access to. There are already compression socks, garments, stockings, etc. Its just another garment that has a different function.
    - Incorporating it into the existing diabetic shoe program. Issue here is getting insurance to cover it.
- You mentioned catching it early leads to better outcomes – just like cancer. How early might be too early? Callous formation? Or detect once it first becomes ulcer? Diagnosis at what stage would be clinically valuable to you?
    - If they have a callous, its a sign of increases pressure. Related to foot mechanics. It could be knees, hips, shoulders, spine, etc. Callous gets thicker and presses on tissue more profound then causes subcutaneous hemorrhage. Bacteria cause infection of skin, it begins to progress and becomes an ulcer
    - When I see a callous, that means a pre ulcerative lesion. THis is a high risk area that we need to watch. We look for this as high risk; could become a problem.
- So it would be valuable to catch ulcer early – callous stage. Would you intervene (and would there be better outcomes) if we caught it at this point???
    - Yes, once it gets into the bone, the standard of care is amputation. If you catch it then, you have to amputate.
    - If you catch it early. Say its under 5th toe, you can do a surgery to lengthen the achilles. You can modify shoes, inserts, activity letter, small bone surgery to alter mechanics, all of which will improve outcomes.
    - Similar to above. Callous vs early ulcerative stage – it is valuable to clinical outcomes to catch it in callous stage as opposed to ulcer.

Major Findings:

- Catching a diabetic ulcer early leads to better outcomes
    - Preventing amputation (and osteomyelitis) by catching early is key to preventing grave prognosis for patient
    - Catching it in its callous stage is very valuable
- He is very familiar with existing monitoring solutions, but he only tells patients to use foot checks
    - Doesn't use others because of lack of accessibility and compliance
    - Existing solutions are often too expensive and don't fit into framework of insurance

- He sees socks as the most viable solution (though this is not necessarily an opinion that is relevant to our process at this point). He thinks its important that the tool we develops would lead to positive insurance coverage outcomes
- Only 50% of patients would be inclined to care about DFU prevention
    - Of those, only 50% are capable because of various reasions. This would be our target market

Follow Up/Referrals:

- Indicated that we can reach out with future questions as this process continues
- Indicated desire to be kept up to date with logistical interactions with companies that we may interact with in developing a solution (say, we needed a podiatrist to affirm need for device in talking to a sock manufacturing company)

Academics

Meeting Title:	**Interview with Dr. Eric Richardson**
Stakeholder Role:	**Professor in Dept. of Biomedical Engineering at Duke, Co-Director of Duke Design Health**
Date:	**11/13/2023**
Format:	**Zoom**
Facilitator:	**Kishen Mitra**

Attendance:

Kishen Mitra, Josh Tennyson, Dr. Richardson

Notes:

- What techniques were used by the abdominal stiffness group that you advised in the past?
    - That group was not directly measuring "stiffness" per say, whereas we are looking for more localized tissue stiffness
    - The group aimed to estimating interior pressure of a spherical vessel, therefore using a surrogate for pressure as opposed to stiffness
        - How far finger will go into balloon if you press into it => more pressure than stiffness
- Varying skin displacement methods for stiffness measurement:
    - Optical
        - Tissue would spread out when stepping on glass; can look at squishing or spreading out of the skin to quantify pressure distribution through displacement
    - Bubble wrap approach
        - When looking underneath the surface of bubble, can tell what pressure is inside bubble and how much the bubble has displaced/collapsed
    - Poke and probe
        - Look at how far the pins are going into the foot. Put uniform pressure and see how far the pins poke back up.
    - Shore scales
        - Replicate measurement system that is basically a spring scale
        - Mount upside down, get reading from each point
- Alternate measurement methods
    - Visual imaging and light imaging
    - Ultrasound based- elastography
        - Frequency has to be in the MHz scale for our purposes

        - Referred us to several individuals noted in the follow up section at the bottom
    - Colorimetric pulse-ox approach
    - Temperature measurements
    - Pressure sensors
    - Mechanical indentation techniques
        - Durometry with custom development of a linear actuator and load cell
- Analogous project besides the abdomen stiffness from last year
    - Preventing bed sores for bedridden patients in hospitals by monitoring pressure ulcers
        - Smart pads
        - Scanning patients on their backs with robes on

Major Findings:

- The methods used by the abdomen stiffness group from last year are not directly applicable to our goals as that group was more focused on pressure while we are more focused on stiffness
    - Projects focused on preventing bedsores for hospital patients are more analogous to our direction
- There are various skin displacement approaches that we can experiment with to measure stiffness or even pressure. Mechanical indentation is one such promising method.
- Imaging methods are an alternative to displacement methods. Ultrasound elastography is particularly promising.

Follow Up/Referrals:

- Dr. Richardson referred us to Dr. Mark Palmeri in the BME department to ask him who to talk to for imaging approaches. Also, Dr. Richardson specifically named Dr. Gregg Trahey and Dr. Kathy Nightingale as contacts that we could ask about elastography.

Meeting Title: **Interview with Dr. Kathy Nightingale**
Stakeholder Role: **Professor in Dept. of Biomedical Engineering at Duke**
Date: **11/27/2023**
Format: **In-person**
Facilitator: **Sarah Glomski**

Attendance:

Will Temme, Sarah Glomski, Dr. Nightingale

Notes:

- How would elastography work if we did it?
    - shear wave elastography is a possible method (not necessarily good choice)- speed of shear wave can be related to stiffness of tissue
    - Transducers can be fragile, which may pose an issue
    - In tensile testing
        - Most materials are nonlinear for getting the modulus during stress strain testing
        - If you compress too much with the transducer the relationship becomes nonlinear
- Is elastography feasible for our solution?
    - Challenge would be
        - Can someone stand on transducer and not damage it
            - Static pressure on the transducer could be problematic
            - Sitting on chair and gently resting feet on transducer could be okay
                - Would need force to be consistent across trials; this could be a challenge
        - Shear wave elasticity technology has lower resolution, does not take as fine of images
            - Need to let it propagate for a certain time before you estimate how fast its moving
        - Need really high contrast changes in stiffness for devices we make to be able to detect
        - Cost would be really high; wouldn't work with an at home device
        - Tissue sensor interface
            - Need some gel to get good resolution
        - Medical ultrasound devices are very high frequency (MHz range) so this won't propagate through air
            - kHz range will propagate through air

                - They would have terrible resolution. Picture is size of source. You just get a surface contour.
                - Could put patients' foot in water bucket for good matching layer
            - Flexible ultrasound array
                - Far off from being feasible, still in research phase
    - She doesn't see us moving past these hurdles
- Could other imaging methods be used to do elastography?
    - Most successful quantitative stiffness imaging systems has been shear wave elastography, though this has not been great
        - Other way is to take a picture then press the tissue and take another picture. In the picture you can look at where things moved a lot and where things didn't move as much
            - This is called strain imaging. You don't get a modulus because you don't know how much force is applied (maybe you do based on patients weight)
                - If pattern changes too much, it decorrelates completely
                - For breast imaging, a new idea is to hold the transducer on the person and the person's breathing will apply enough strain to avoid too much pattern changing
            - Use cross correlation to look at structural (lines, planes, etc) movement and how it changes across the images.
            - Not sure how this works with tougher tissue like the bottom of the foot. Worked well for soft tissue
            - Would be complicated to make that work
- Can you elaborate on the mechanical properties we would be measuring
    - Acoustic impedance depends on bulk modulus (compressibility) and density, not directly Young's modulus.
    - There's structural stiffness and material stiffness, which are different things. Material stiffness would be different for scars and probably callouses.
        - Any abnormality you can feel has a material stiffness change.
        - Size affects structural stiffness
        - These are the two things that contribute to stiffness and hardness.
        - Both of these contribute to the strain response (material and how big it is)
- We are currently pursuing a linear actuator-FSR system. Do you believe this is more feasible?
    - For load cells
        - You would need an array of load cells, you can't just have one

        - This will get expensive (the more load cells you have, the better it will be, but the more expensive it will get).
- Other ideas
    - What if you sheared the callouses? Would they get trapped, so you could detect them? Would you feel more load if you dragged something across them?
    - Do more research on readily available Indentometry/durometry sensors. I believe they exist and could be integrated

Major Findings:

- **Ultrasound elastography is not a feasible solution for our device**
    - Expensive, fragile, low resolution, flexible version are early in development, SNR would be low, interfacing with foot is hard
- Other imaging techniques are possible, but she doesn't see them as the best solution
- Using a load cell instead of a FSR would be too expensive

Follow Up/Referrals:

- Indicated that we can reach out with future questions as this process continues, but did not directly refer us to anyone else

Meeting Title:	**Interview with Dr. Xioayue Ni**
Stakeholder Role:	**Professor in Dept. of Mechanical Engineering and Materials Science at Duke**
Date:	**11/22/2023 (Follow-up Meeting on 12/8/2023)**
Format:	**Zoom**
Facilitator:	**Will Temme**

Notes:

- How does your acoustic device for monitoring elastic modulus function?
    - The device is about half the size of my palm
    - It is flexible and has some sort of silicon coating
    - It is based upon propagation of acoustic waves and the measurement of how these waves propagate by a MEMS accelerometer that is at different locations relative to the transducer
    - It is intended for use on large, flat surfaces, such as the arm and abdomen. It can be used for a number of applications, such as detecting water/edema via measurement of skin hydration
- Is the device that she is developing appropriate for adaptation into our device?
    - Likely not
        - This device is intended to make contact with a flat surface
        - Applying pressure to an acoustic transducer and the tissue that receives the signal alters the math behind how elasticity is calculated. It would not be feasible to do this math
            - Our device is weight bearing, so this would become an issue
        - Even if the device were not weight bearing (e.g., patient just rested feet on device), she is not confident that problem would be resolved
        - The device may not perform as well with the complexity of the plantar surface (not flat)
        - The device is intended to function with an air gap interface. The form of the foot and applied pressure would make this behave unpredictably
        - The device is fairly big
- Do you think Ultrasound transducers would be possible to use?
    - Likely not
        - Stretchable ultrasound transducer arrays are in fairly early-stage development and do not perform well
        - Ultrasound transducers that we would use are expensive

        - Ultrasound transducers pose the same issues mentioned above for her device
            - Applied pressure
            - Fitting to form of foot surface
- What are your suggestions for sensors to use in a new device?
    - Instead of ultrasound, use something that has a mechanical displacement
        - This wont damage the tissue because you can do it on a very small scale
    - Indentometer is a good solution
        - Indentation can be done with many different methods
            - We could explore something like we are doing with a linear actuator
            - If we work with her lab (see below) she would want to look into a device that involves magnetic vibration
- Dr. Ni's proposal for the future
    - She wants to understand what our goals are and the level of commitment we can provide
        - Is our goal to make a production device? Or work for one semester? Or produce a research paper?
        - We should schedule a follow up meeting after Thanksgiving break with her and the rest of the team so that we can collectively discuss how far we want to take the project and the amount of time we will commit (need to message team after meeting)
    - If we agree to creating a manuscript at the end of the semester, she will treat us like one of her PhD or master's students in her lab. She will provide guidance and resources.
    - If we don't want to produce a manuscript, she will still provide guidance but will have to take a step back in terms of the amount of time she spends on this
    - She may be able to set us up with a grad student to provide mentorship for this project.

Major Findings:

Major findings from original meeting

- Her device cannot be incorporated into our solution
- Ultrasound elastography is not a feasible solution for our device
- Indentometry seems like the most viable approach in her eyes
- Our group may be able to explore a collaboration with her lab, obtaining feedback and using some of her resources

Major findings from follow-up meeting (retrospective summary)

- IP
    - We must be careful about using resources funded by the university and/or government, as well as machinery licensed from industry
    - We must also consider how much of the intellectual property is generated by us vs a grant-funded grad student
    - We should continue to discuss our collaboration with the tech transfer folks
- Compressive testing/indentometry
    - Contact surface angle/curvature certainly could be a factor in error in stiffness measurements we observed. You need a flat contact to accurately do compression testing.
    - Toe region extrapolation of modulus from low deformations has been attempted, is a topic in research right now
    - She has flat phantoms that she uses. Models skin in the kPa range (need to verify this)
    - She has an indentometry setup that she used for mechanical testing of skin phantoms. We can use her setup and phantoms
- Sensor Development
    - Many other possible techniques could be explored (triboelectric, piezoelectric, magnetic coil that vibrates, etc.)
    - She suggests we explore a displacement-controlled strain sensor
        - Next steps involve replicating the results of the self-locked stretchable strain sensor in Chen *et al*
- Research outcomes
    - Our primary goal is to create a device compliant with the expectations of BME 473/474. We could also pursue an IEEE type research paper on the sensor/system we develop.
    - It would be possible to explore the question of: "can we develop a self-locked stretchable strain sensor that is used to monitor the stiffness of diabetic plantar surface tissue as a means of ulcer detection?"

Follow Up/Referrals:

- Collaboration with Dr. Ni will continue in the coming semester
    - We plan to use her lab's phantoms and indentometry testing gold standard device
    - We will attempt to replicate components of the self-locked stretchable strain sensor in Chen *et al.*, possibly using her resources and guidance

Meeting Title: **Interview with Dr. Jonathan Viventi**
Stakeholder Role: **Professor in Dept. of Biomedical Engineering at Duke**
Date: **12/01/2023**
Format: **Zoom**
Facilitator: **Kishen Mitra**

Attendance:

Kishen Mitra, Josh Tennyson, Dr. Viventi

Notes:

- Measurement methods (impedance electrical tomography, non-contact thermal imaging, thermistor arrays)
    - Impedance electrical tomography (EIT)
        - Tracks tissue morphology changes
            - Tumor vs non-tumor tissue application
                - Tumors have different propeorties than health tissues so detection can be driven by EIT
        - Differences in hydration, tissue properties => differences in impedance
        - Implementation
            - Flow current between two points and measure voltage for each sensor
            - Mesh of sensors to measure voltage at different points along the foot to reconstruct an image
            - Impedance heat map generated; absolute measurements will change a lot based on hydration and other properties, sweat, etc.
                - Relationship differences are preserved, so methods like asymmetry analysis can then be applied
    - Non-contact thermal imaging
        - Take 2D image of temperature of foot
        - Tenth of degree accuracy and relatively low-cost
        - As opposed to thermocouples which require good contact, this method is more like a thermal imaging camera that does not require contact
            - Fleer thermal imaging camera can be the gold standard
        - Android plug-in thermal imager
            - https://www.amazon.com/FLIR-One-Thermal-Imager-Android/dp/B0728C7KNC/ref=asc_df_B0728C7KNC/?tag=&li

nkCode=df0&hvadid=344120837477&hvpos=&hvnetw=g&hvrand=67466125915966866 72&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9009748&hvtargid=pla-358812752856&mcid=516493f76c973bcc8bf1d98aa5f6c800&ref=&adgrpid=72147117987&gclid=CjwKCAiApaarBhB7EiwAYiMwqqrMJKa5Q0a-Xnh-KPWqVR3TygbYE51WI4JFegM0GI2sEfh--XOrfxoC68wQAvD_BwE&th=1

- Implementation and challenges
  - FOV and angle of lenses need to be monitored and optimized, especially when getting the camera under the feet
  - Placing the camera 1-2 inches below the foot would make it low enough to image the entire foot
  - IR-transparent materials can be used between the camera and the foot
    - If the foundation was a scale that the patient could step on, certain types of glass or plastic could be used as IR-transparent base materials
- Thermistor array: 2D grid of passive thermistors
  - Arrays of thermistors for temperature sensing have previously been implemented
    - https://www.researchgate.net/figure/Screen-printable-temperature-sensors-a-Photograph-of-a-12-6-passive-matrix-array_fig1_329369019
    - Micro or nano sized NTC thermistors
    - 12x6 array of thermistors
      - Connect to one column and one row at a time and then run a current through it; only sensor at intersection will have current through it so can get temperature at each thermistor passively
      - Custom manufacturing not necessary, can just buy from mouser for any size array
        - Have it machine assembled with 1000 of these small thermistors below
- Thermistors: Extremely small surface mount thermistors
  - https://eu.mouser.com/c/circuit-protection/thermistors/ntc-thermistors/?package%20%2F%20case=0201%20%280603%20metric%29&product%20type=NTC%20Thermistors&termination%20style=SMD%2FSMT

        - https://www.mouser.com/c/circuit-protection/thermistors/ntc-thermistors/?package%20%2F%20case=0201%20%280603%20metric%29&product%20type=NTC%20Thermistors&termination%20style=SMD%2FSMT
            - **0201** is 2 cents each in large quantity
            - 0.3 mm high and some other random numbers probably on datasheet
- General implementation
    - Spacing and general framework
        - Advised us to put thermistors into a flexible circuit, solder them, and then cover it in insulating material
        - One column wire and one row wire
        - Flexible circuits placed inside an insole or other container
            - Flexible PCB manufacturing
                - https://www.pcbway.com/
                - These guys can assemble all the thermistors too
        - If using thermal imaging camera
            - Just imaging IR light continuously; relative numbers rather than absolute numbers are what matter
- Combination of sensing approaches
    - Thermistor based approach would be straightforward to combine with other forms of modalities. Can embed other types of sensors within flexible substrate
    - Combining optical with other modalities is doable but maybe more challenging. More transparent circuit boards (polyimide? he mentioned) polyimide are yellowish, transmit some visible light; copper traces are not transparent
        - Paralene/graphene conductor for totally transparent circuits
            - Unreliable, very research focused, expensive
    - Thermal imaging camera (easier than thermistors) and machine learning
        - ML deep leaf algorithms
        - Pairs with cellphone
        - Image when
            - Click image when person is standing on it
            - Automatically takes image when foot stops moving
                - He made analogy to mobile deposit? When check in FOV?
                - Classifier of this is a foot and this is not a foot; learns feature differences as a classic machine learning problem

    - Cold air pump and thermal imaging to take breast tissue imaging by one of his colleagues
        - Chill or heat the foot
        - Cancer detection: normal extremity tissue in response to cold air restricts blood vessel and flow, tumor tissue does not do this
        - Change in vasculature with respect to a change in temperature. Interesting
- Challenges
    - Reliability: must go through many cycles and not break the thing
        - Would be easier to do optically
            - EIT more compatible with the optical approach
        - Can you instead get people into a clinic or stand on a scale?
    - Melanin levels
        - Need to see whether there is an effect of deep IR region in different levels of melanin

Major Findings:

- Electrical impedance tomography was a method that he was particularly fond of
    - Tracks changes in tissue morphology by flowing currents and measuring voltages gathered by a sensor array to generate impedance maps
    - Hydration and other properties change the absolute values, but the relative relationships should hold
- Thermal imaging cameras may be more easily implemented than thermistor arrays or other thermocouples as they do not require good contact
    - IR-transparent material would need to be used and the camera would need to be placed 1-2 inches below the foot
- Several good NTC thermistors are available for purchase on Mouser, and thermistor arrays have previously been implemented
- Flexible circuits can be customized online to then be manufactured and sent to us. We will likely utilize this second semester.
- Combing thermistor arrays with other sensors is fairly straightforward, but combing optical methods with other sensors is more challenging
    - An additional challenge with optical imaging methods would be accounting for different levels of melanin in different people

Follow Up/Referrals:

- Referred us to Matt Brown for more information on thermistors and the implementation or purchase of a 2D array of thermistors that we desire

- Additional follow-ups could ask or investigate the projects that he mentioned, especially the tumor distinction project and the cold air pump/thermal imaging breast tissue imaging project

Patients

Meeting Title: Interview with DFU Patient at Durham VA

Date: 11/28/23

Facilitator: **Kishen Mitra and Dr. Kyle Wamelink**

Questions:

- How long have you been living with neuropathy?
    - 11 years
    - In what ways would you say neuropathy has most affected your daily life?
        - Multiple doctors appointments with different specialists for my feet
- Who is your support system and/or group of people that you can lean on?
    - My wife
- Are you able to live independently at home or do you require assistance from a caregiver?
    - Independent
- How frequently do you perform foot checks at home?
    - My wife helps me multiple times a week
    - What is your general process for conducting foot checks? Do you think foot checks are effective? Do you have any concerns or challenges with foot checks?
    - She looks at the bottoms of my feet and my heels
- How did you first become aware of the diabetic foot ulcer (i.e. family member, blood on sock)?
    - My sock had blood on it
    - Did you feel any pain from the region around that ulcer before noticing it or shortly after recognizing it?
    - No pain associated with the wound
- How long have you been living with diabetes?
    - 15 years
- Did you see a podiatrist before coming here to the VA today? If so, when?
    - I've seen different podiatrists on and off

- What initiatives have you taken, if any, to monitor the diabetic foot ulcer?
    - None
- In your current situation, on a scale of 1-10, how much of a priority is foot care?
    - What (if anything) would make it easier to make foot care a higher priority for you?
        - High priority / Nothing that I can think of to make this process easier
- A team of biomedical engineers at Duke is developing a device that would enable you to autonomously detect/monitor foot ulcers.
    - On a scale of 1-10, how likely are you to use a device that is placed in your shoe?
        - 8-9 likely
    - On a scale of 1-10, how likely are you to use a device that is embedded in fabric (like a sock)?
        - 8
    - On a scale of 1-10, how likely are you to use a device that you would have to manually use once a day (e.g., camera, RTM mat, etc.)?
        - 8
    - What are the most important criteria for you (i.e. cost, ease of use, etc.)?
        - Ease of use. I'd pay anything for something like this
    - If the device were to personally alert you to see a podiatrist or foot and ankle surgeon, would you do so?
        - yes
- Is ulceration a recurring problem?
    - If so (and if applicable), what factors contributed most to successful healing last time?
        - Seeing my doctor
- Did your podiatrists educate you about your options regarding foot ulcer monitoring?
    - If so, at what point (e.g., just after diabetes diagnosis, just after neuropathy diagnosis, just after first callous, etc.) did they educate you and/or prescribe a monitoring device?
        - N/A
    - How confident are you in your understanding of how and why ulceration occurs and what steps that you can take to prevent or treat those ulcers?

        - Pressure on my feet causes the ulcers
- Do you think that most diabetic patients with peripheral neuropathy would want a device to monitor ulcer occurrence?
    - Not sure
- What part of the care process (if any) has been most challenging/frustrating for you? Why?

    - Having to depend on my wife to help me with my feet

Major Findings:

- Many patients use visual foot checks as their home monitoring method, done especially by someone in their support network.
    - This often requires dependence on someone else to do the checks.
- However, many ulcers are caught at a later stage, such as when bleeding in the sock is observed as in this case.
    - Pain is often not observed with the wound, further complicating early detection.
- Many patients are unaware of current technologies on the market that can be used to monitor their feet for ulcers. Ease of use is a stressed desire.

Follow Up/Referrals:

- Dr. Wamelink indicated that we can reach out with future questions as this process continues.

Meeting Title: Interview with DFU Patient at Durham VA

Date: **11/29/2023**

Facilitator: **Kishen Mitra and Dr. Kyle Wamelink**

Questions:

- How long have you been living with neuropathy?
    - 20 years
    - In what ways would you say neuropathy has most affected your daily life?
        - It caused me to have an amputation
- Who is your support system and/or group of people that you can lean on?
    - My daughter and family
- Are you able to live independently at home or do you require assistance from a caregiver?
    - Independent
- How frequently do you perform foot checks at home?
    - I am able to do them a couple times a week
    - What is your general process for conducting foot checks? Do you think foot checks are effective? Do you have any concerns or challenges with foot checks?
    - I use a mirror. It can be difficult to look at my ankle and in between my toes
- How did you first become aware of the diabetic foot ulcer (i.e. family member, blood on sock)?
    - The top of my feet turned red and I went to the hospital
    - Did you feel any pain from the region around that ulcer before noticing it or shortly after recognizing it?
    - I can't feel my feet
- How long have you been living with diabetes?
    - 20-25 years
- Did you see a podiatrist before coming here to the VA today? If so, when?
    - Yes
- What initiatives have you taken, if any, to monitor the diabetic foot ulcer?

    - Nothing
- In your current situation, on a scale of 1-10, how much of a priority is foot care?
    - What (if anything) would make it easier to make foot care a higher priority for you?
        - It is very important. Diabetic shoes and socks have been helpful. I m not aware of any monitoring options
- A team of biomedical engineers at Duke is developing a device that would enable you to autonomously detect/monitor foot ulcers.
    - On a scale of 1-10, how likely are you to use a device that is placed in your shoe?
        - 10
    - On a scale of 1-10, how likely are you to use a device that is embedded in fabric (like a sock)?
        - 10
    - On a scale of 1-10, how likely are you to use a device that you would have to manually use once a day (e.g., camera, RTM mat, etc.)?
        - 10
    - What are the most important criteria for you (i.e. cost, ease of use, etc.)?
        - Cost
    - If the device were to personally alert you to see a podiatrist or foot and ankle surgeon, would you do so?
        - yes
- Is ulceration a recurring problem?
    - If so (and if applicable), what factors contributed most to successful healing last time?
        - The antibiotics and surgery saved my foot
- Did your podiatrists educate you about your options regarding foot ulcer monitoring?
    - If so, at what point (e.g., just after diabetes diagnosis, just after neuropathy diagnosis, just after first callous, etc.) did they educate you and/or prescribe a monitoring device?
        - N/A
    - How confident are you in your understanding of how and why ulceration occurs and what steps you can take to prevent or treat those ulcers?
        - Confident

- Do you think that most diabetic patients with peripheral neuropathy would want a device to monitor ulcer occurrence?
    - Absolutely
- What part of the care process (if any) has been most challenging/frustrating for you? Why?
    - All of the doctors I have to see

Major Findings:

- Foot checks can be done by the patients themselves in their homes by using mirrors. Mirror checks can still restrict vision between toes and around the ankles, so they can be limited.
- Early detection can be a challenge as can be seen by how this patient only realized the ulcer after the top of the foot turned red, and by how there was no pain.
- While patients may be aware of how ulcers progress, they may not be actively doing anything to monitor them. Patients recognize the importance, so a big reason for this is because many patients are not aware of current ulcer monitoring technologies on the market.

Follow Up/Referrals:

- Dr. Wamelink indicated that we can reach out with future questions as this process continues.

Other

Meeting Title: **Interview with Russell Sanchez**

Stakeholder Role: **Pathology Supervisor at VAPAHCS**

Date: **9/27/2023**

Format: **Phone call**

Facilitator: **Will Temme**

Attendance:

Will Temme, Sarah Glomski, Russell Sanchez

Notes:

- How many lower extremity amputations do you receive?
    - Weekly rate can vary from ~3/week to 1/week
    - Monthly average 7-9 limbs (varying from above knee to below knee to ankle) just from his facility (VAPAHCS)
    - At least 90% of these lower extremity amputations are diabetic
- What factors affect the frequency at which you receive amputations in pathology?
    - Communication between patient with family members about how to take care of illness
    - Veterans live alone, no family communication, don't take care of themselves properly bc don't have ability to do that → very unaware of what result can be if they don't take care of their diabetes
    - Take care of feet, stop smoking, better diet, no drinking
    - Nobody following up with veterans → they leave podiatry and go home and smoke, don't follow through with aftercare
    - Veterans don't care: at the point (50-60 years old) where they think "why should I change now?"
    - Lack of education about diabetes, what are the results if they don't follow instructions
    - Eating habits are poor, lots of saturated fats, fast food, live alone so don't cook
    - Leave podiatry with supplies they need: meds, insulin, etc
- Are veterans given a foot monitoring mat from the start after they are diagnosed with diabetes? At what point do they receive socks/mats/insoles?

    - Right when they see it needs to be monitored more frequently. Tends to be when they get an ulcer with a certain level of severity
    - Tends not to be too late
    - People wait too long to present symptoms to doctor
- Has there been an increase in amputations over career?
    - Yes, as years go on, people get older (aging population)
    - Medicare soldiers have lots of injuries, PTSD was recently brought up
    - Homelessness increasing, can't see doctor, found or go to ER → leave and return to dirty environments with little personal hygiene
- Specific to homeless people, how to address issue?
    - Figure out how to set up stations regularly for monitoring
    - No ability to travel to hospital
    - Need to focus on education and the future
    - Lack of ability and resources to get medical care and supplies. They can give them gauze, tape, etc, but not more complex tools (including diagnostic tools) to prevent these ulcers. They don't provide resources to clean wounds
    - Have a limited budget. Have to pick and choose regarding who can get it. Then people lose faith in organizations because they don't do anything for them.
        - "As far as I know, the resources that they get are limited." Also depends on progression of injury/infection. Only might give things like mats to people with more severe injury and infection.
        - If you can come up with some device they can use to clean wounds, (administrate medication to help infection) where they don't have to take dressing off that would be good.
        - "Once you have an open wound, you're removing the first line of defense. If you don't have that cleaned and taken care of, you'll develop an infection in an ulcer. You're putting down a welcome mat for bacteria"
        - Need to put some fear into people. Show them what it's like to walk around with diabetes. A hardcore approach is needed. People don't care about the outcomes before they happen
- What are challenges in monitoring?
    - People don't have other people that can help them care for and monitor wounds
- He calls podiatry the "Chop shop" -- amputations move progressively up the leg
- Are amputations that you receive disproportionately from certain groups
    - Absolutely yes

    - African Americans, hispanics, etc are big contributors to the population that is at highest risk for amputations and diabetes
    - "Most of the amputations I see are in that population. Very strong majority of amputations I receive in pathology are from population of color" (he estimated around 90%, though this may vary widely)
    - Don't have resources to get healthy diets and properly address diabetic condition
    - Food intake patterns is very significant.
    - A lot of people are Spanish speaking only, so doctors are unable to explain what needs to be done to care for ulcers and diabetes.
    - Lower income people tend to have more difficulty managing situation
    - Lower education amongst disadvantaged communities

Major Findings:

- Significant discrepancies observed in underserved populations.
    - Veterans – noncompliant, live alone, often don't care about treatment
    - Homeless – don't have access to transportation for regular testing, financial burden of treatment, unclean living conditions lead to high infection rate
    - African American – lack of resources for healthy diet and diabetic care
    - Hispanic – communication issues between patients and doctors
    - Lower income and education – lack of resources and education about dangers of DFUs
- Mats are only given to patients after they develop an ulcer to a certain degree of severity due to limited budget.
- Overall, there is a strong need for an accessible device that can detect early-stage ulcers.

Follow Up/Referrals:

- No follow up scheduled, but offered to help if we have additional questions
- Offered referral to PAVE clinic and anyone else we wanted but is out of work right now because of a surgery he had done

XV. Design Review Meeting Agendas

Meeting Title: Design Review Meeting

Date: 9/25/2023

Scribe: Kishen Mitra

Invitees and Attendance:

Kishen Mitra	☒	Will Temme	☒
Sarah Glomski	☒	Josh Tennyson	☒
Aaron Kyle, PhD	☒	Paris Brown	☒

Agenda and Meeting Notes:

Topic Leader	Discussion Points	Follow-up/Action Items

Will Temme	• Top Problem #1: Ulcer development monitoring for the purpose of amputation prevention in diabetic patients
	  ○ Brief disease fundamentals overview
	  ▪ Progression from diabetic symptoms to ulcers to osteomyelitis to amputations
	  ○ Assess biggest gap seen in existing solutions that we can try to address; which problem space he sees as most viable
	  ○ Discuss directions from preliminary interviews
	  ○ Specific feedback from Dr. Kyle
	  ▪ Focusing on things device directly does vs. indirect benefits
	  ▪ Functional requirements vs. constraints
		• Learn more about the clinical treatments that occur upon detection
		  ○ Stakeholder interviews
		• Steer clear from the treatment side of things
		• Detecting or tracking peripheral vascular disease
		• Vascular efficiency before and after amputation (could be interesting)
		• Decide on foot ulcer route vs. vascular efficiency route
		• Functional requirements are what it actively has to do (what can be controlled);

Topic Leader	Discussion Points	Follow-up/Action Items
		constraints are limitations • What can the device "do" rather than "be"

Kishen Mitra	• Top Problem #2: Early diagnosis of bruxism
	  ○ Findings from literature
	  ▪ Much larger gap in the awake bruxism space
	  ○ Specific feedback from Dr. Kyle
	  ▪ Review the role of each stakeholder
	  ▪ Functional requirements vs. constraints
	  ▪ Develop set of functional requirements
	  ○ Discuss insights from preliminary interviews
	  ▪ Existing diagnostic devices are not widely used in the clinic
	  ▪ Our device would have to be very easy to implement (Dr. Messenger)
	  ▪ Another route is to explore the treatment avenue/orofacial pain (Dr. Westmark)
	  ▪ Generic monitoring device for multiple diagnoses (Dr. Messenger)
		• More stakeholder interviews
		• Can present on this next week if needed

Sarah Glomski	• Top Problem #3: IBD symptom monitoring
	  ○ Discuss current state of research/knowledge
	  ▪ IBD biomarker research (CRP, FC)
	  ▪ At-home and in-clinic biomarker detection technology
	  ○ Discuss best market gap to fill	

Topic Leader	Discussion Points	Follow-up/Action Items
	▪ Acute symptom monitoring (speed) vs. chronic symptom monitoring (quality) ▪ Accessibility: cost, education level, tech savviness, equipment ▪ Compliance: non-invasive, painless, passive use o Specific feedback from Dr. Kyle ▪ Develop set of functional requirements	
Josh Tennyson	• Other prospective need areas (if time permits) o Adapting color-blind glasses to people who suffer from ophthalmic issues ▪ Mention existing solutions and gaps ▪ Assess possible points of intervention as well as their feasibility	
All	• Midterm Presentation Questions o "Initial market quantification" ▶ TAM SAM SOM? • Other? o Had some obstacles with the economic impact research	•

Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 11/6/2023
Scribe: Kishen, Josh

Topic Leader	Discussion Points
Will Temme	• Summary of screening and scoring process • Top solutions were generated by considering the compatibility of sensing techniques with device modalities • Prospective Solution #1: Sock that measures skin elasticity ○ **Principle of Operation** ▪ General info: elasticity sensor array embedded within the fabric of a soft sock such that it contacts high-risk areas on plantar surface of foot. Any necessary wiring and hardware (processor, battery pack, etc) would also be embedded into the fabric. ▪ Measure Young's Modulus of soft tissue at depths from 1-8 mm by providing a sine wave voltage to a coil, generate a magnetic field that uses time-dependent forces to cause vibration of the magnet ▪ Transmits a certain amount of pressure to the tissue surface that is in contact with the actuator. The metal traces of an adjacent strain gauge record the amplitudes of periodic variations in tissue resistance, indicating deformation and allowing elastic modulus to be calculated. ○ **How you decided on this idea:** Sock was our 3rd highest scoring modality. Strong points were its convenience and ease of use. Weak points were durability and safety. Tissue elasticity measurement was the 2nd highest scored sensor. Strong points were accurate, frequent measurements, and team interest. Weak points were safety and durability. ○ **How you intend to create device:** Design a PCB that allows for data storage, processing, and transmission. Design a small housing for battery power source and PCB. Connect wiring to array of whatever sensor type we decide to use. Stitch all components into interior of crew sock – sensor array on plantar surface and electronics/housing on ankle area.
Kishen Mitra	• Prospective Solution #2: Sock that measures hydration of stratum corneum

Topic Leader	Discussion Points
	○ **Principle of operation – corneometry** ▪ Overview: array of corneometers (potentially nano-sized?) arranged along the plantar surface of the fabric of a durable crew sock. Layer of plexiglass separates the sensors from the foot. Appropriate wiring and hardware components would be fit within a layer of padding on the posterior side of sock. • Exploring the possibility of implementing a foot brace type look to address sock's weak point of durability ▪ Electrical properties of the skin are dependent on the water content of the stratum corneum of the epidermis ▪ Non-invasive technique that measures the hydration and barrier function of the stratum corneum, and can be used to indirectly track changes in natural moisturizing factor levels by measuring changes in the skin's hydration and barrier function. ○ **How you decided on this idea:** Sock scores 3rd highest in terms of modality ideas. Corneometer also scores 3rd highest in terms of sensing technique options. We thought it was a relatively novel idea to leverage this technology for DFU applications, as it has primarily been used in the dermatology space rather than podiatry ○ **How you intend to create device:** Overarching concept of fabricating a basic PCB that enables data storage, processing, and transmission. Initially considered storage on a microchip but concerns with safety and washing capability. Design a foam pad cushion layer that can be integrated within a sock and house electrical components. Test what materials (i.e. plexiglass) and layer thickness are optimal for corneometer functionality. Assess the fit of these sensors within a sock…
Sarah Glomski	• Prospective Solution #3: Shoe with image processing ○ **Principle of operation:** The sensor modality is (visual light) imaging via a camera with remote image processing. Several of these sensors would be arranged in the transparent sole of a shoe to construct a view of the entire plantar surface. Image data would be downloaded and processed remotely using a

Topic Leader	Discussion Points
	convolutional neural network (CNN) or similar image processing technique. ○ **How you decided on this idea:** Image processing is a valuable tool for diagnosing ulcers once they break the skin (at or beyond Grade 1). Image processing essentially mimics the human eye and brain in terms of classification, so it could likely be trained to screen for ulcers at a similar level to a professional clinical (given the proper training set). This is a promising idea because it would be very convenient for a diabetic patient to be able to incorporate into their daily lifestyle. They would simply have to buy the shoes and charge them wirelessly at night. ○ **How you intend to create device** ▪ An off-the-shelf shoe with compressive fabric on the top could be purchased to eliminate the need for the user to wear socks. The sole of the shoe would likely have to be removed and replaced with a clear material such as acrylic so that the plantar surface can be viewed from down below. ▪ The circuitry components would have to be designed via a breadboard and Arduino originally, but could eventually be reduced onto a PCB for easier storage and a low profile design. An optimal user alert system would have to be designed so that the patient can be alerted when they have alarming symptoms. ▪ The image processing model would have to be trained to classify images based on the presence of an ulcer, and to be able to determine the severity of the ulcer based purely on appearances. This training set may need to be augmented specifically to not be sensitive to light levels, as the view from the sole of the foot may not be well lit without the presence of a light to illuminate the plantar surface.
Josh Tennyson	• Prospective Solution #4: Shoe with contact pressure sensor ○ **Principle operation**: Peripheral neuropathy can promote muscular atrophy, resulting in atypical high pressure regions. High pressure regions are at risk of forming ulcers. So, monitoring pressure of the foot can inform ulcer risk.

Topic Leader	Discussion Points
	○ **How you decided on this idea**: Shoes were the highest scoring device modality. Cost and durability were the main weaknesses. Contact pressure sensor was the 5th highest scoring sensing technique. Durability and accuracy were the lowest scoring areas. Shoes are a daily part of life for most people, so they would be easily integratable into daily life. Foot pressure patterns have also been mapped in previous research. ○ **How you intend to create device:** Previous research has developed pressure systems embedded in insoles. For example, pressure could be measured through capacitance in an elastic layer with a dielectric separation. This system could be transferred to replace the sole region of a shoe. A data acquisition chip, a wireless transmitter, and a power source could be coupled with the sensor array to ultimately alert users with a light. It would be imperative to design a shoe that does not require socks as socks could get in the way of accurate measurements.
All	• Preliminary Proof of Principle ○ What we test will depend on if we intend to detect pre-ulcerative lesions or only early-stage ulcers ○ Testing plans: validate the accurate detection of irregularities on foot ▪ Implementation depends on specific sensor we are testing ▪ E.g., callous detection; place glue dots on silicon skin model and confirm sensor can identify normal vs calloused skin ○ Specific parts/supplies: foot model, sensors discussed above

Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 1/25/2024

Meeting Lead: Will Temme
Meeting Scribe: Kishen Mitra

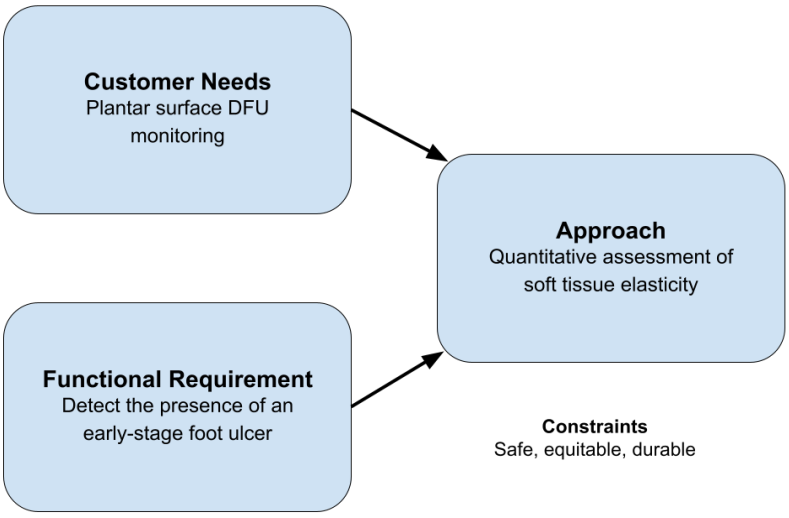
RECAP:
Charge from previous meeting (Team's & Instructors')
Action items

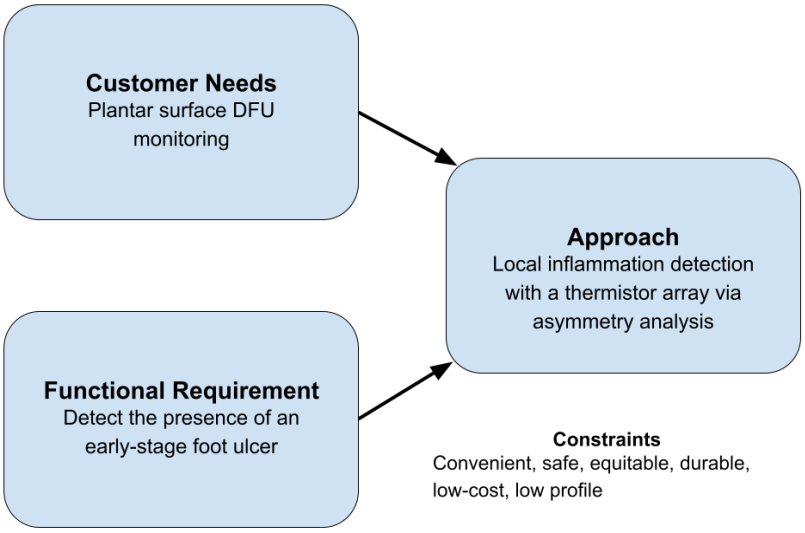
Visited the Ni Lab and checked out their equipment.
Researched force-indentation models to measure stiffness of soft tissues

- Identified the Hertz contact theory model

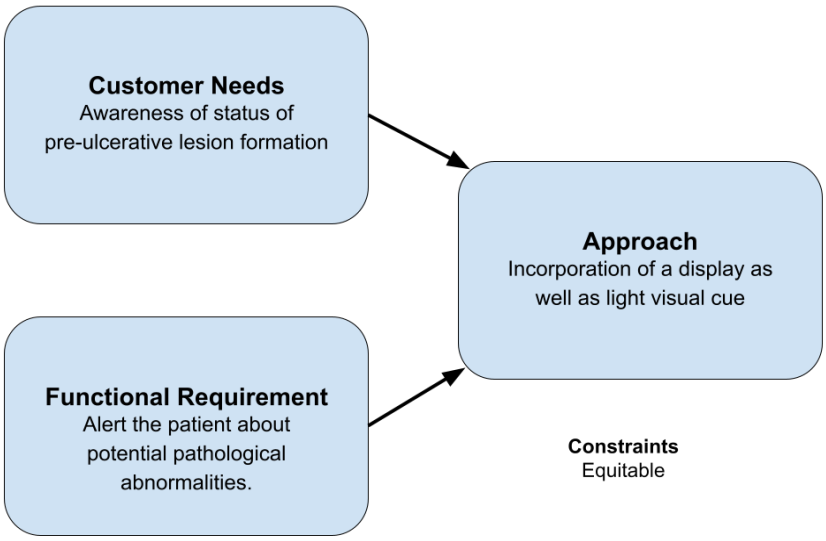
WEEK'S ACTIVITIES:
What's been done and why
Experiments, prototypes (photos, videos, live demos)

Ranked Block Graphics
Functional Requirement #1: Detect the presence of an early-stage foot ulcer.

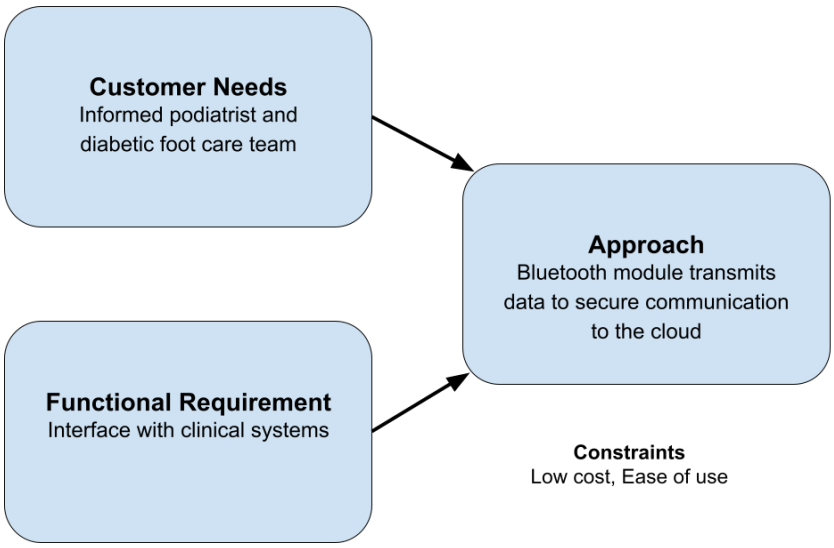




Functional Requirement #2: Alert the patient about potential pathological abnormalities.



Functional Requirement #3: Interface with clinical systems to alert the podiatrist and/or diabetic care team about symptoms.



Specifications for Functional Requirement #1:

- Temperature measurement
    - Standard: ASTM E1112-00(2018) 4.2 (and possibly ISO 80601-2-56:2017(en) part 2-56)

TABLE 1 Maximum Error Temperature Ranges

Temperature	Maximum Error
Celsius Scale:	
Less than 35.8°C	±0.3°C
35.8°C to less than 37°C	±0.2°C
37.0°C to 39.0°C	±0.1°C
Greater than 39.0°C to 41.0°C	±0.2°C
Greater than 41.0°C	±0.3°C
Fahrenheit Scale:	
Less than 96.4°F	±0.5°F
96.4°F to less than 98.0°F	±0.3°F
98.0°F to 102.0°F	±0.2°F
Greater than 102.0°F to 106.0°F	±0.3°F
Greater than 106.0°F	±0.5°F

- Specification: Accuracy

        - Although the above standards are for thermometers, they are the closest things our team could find in terms of what was needed from a regulations standpoint.
        - Note that the mean awake foot temperature is 30.6 ℃, with a standard deviation of 2.6 ℃.
    - Standard: ASTM E1112-00(2018) 4.1
        - Specification: Temperature range
            - "the instrument shall display temperature over the following range: 35.5 to 41.0°C [96.0 to 106.0°F]"
            - The range from the above regulatory document doesn't seem suitable for measuring foot temperature, given physiological values
    - Standard: Literature
        - Specification: Accuracy
        - Detect a difference in temperature of 2.2 ℃ with a maximum error of ±0.3 ℃
        - https://www.sciencedirect.com/science/article/pii/S0002934307007395?via%3Dihub
          "Studies of dermal thermometry have suggested that variations in temperature >4°F (2.2°C) could be helpful in skin surveillance"
        - https://diabetesjournals.org/care/article/27/11/2642/23780/Home-Monitoring-of-Foot-Skin-Temperatures-to
          Both of these showed significantly improved outcomes (DFU prevention) using a threshold of 2.2 ℃

- Stiffness / Elastic modulus measurement
    - There isn't a specific ASTM standard that is widely recognized for the measurement of soft tissue stiffness using indentometry testing. ASTM standards related to indentation or mechanical testing of materials, though not tissue-specific, may offer insights.
    - Standard: ASTM E2546 - Standard Practice for Instrumented Indentation Testing
        - Specification: Radius of curvature of spherical cap
            - The instantaneous radius of curvature (R(h)) of the spherical cap at any indentation depth h measured from the point of first contact should not vary by more than a factor of two from the average radius, that is, 0.5 < R(h)/Rav < 2.
    - Standard: Literature
        - Specification: Elastic modulus calculations

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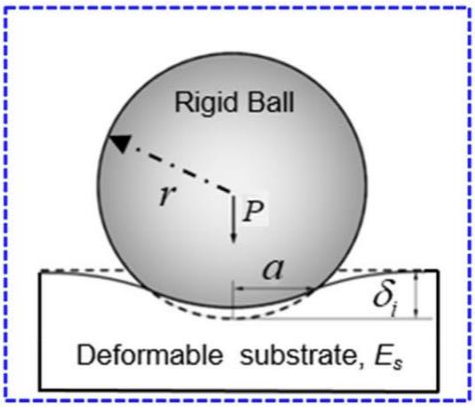


Hertz force-indentation relation:

$$P = \frac{4}{3} E_s \sqrt{r} \delta_i^{3/2} \Big/ \left(1 - \nu^2\right)$$

- The contact force P would be the load from the foot. We would back-calculate Es, or elastic modulus of the tissue
- Poisson's ratio between 0.4 and 0.5
- Displacement would be fixed
- Calculated elastic modulus with small error (5-10%). We believe this is considered a good target for many medical applications, especially when dealing with sensitive tissues.
- Could not find relevant ASTM, ISO, or FDA guidelines regarding this topic.

DATA:
Charts, figures, tables w/ stat analysis
NEXT STEPS
From Team:
Short-term goals:

- Researching flexible PCB designs
- Researching strain gauge fabrication techniques
- Re-creating CAD from paper for strain-based sensor
- Literature review of FSR/sphere systems
- Order more FSRs and/or thermistors as necessary

Milestones:

- Early to mid-February: Deciding which avenue to pursue for the indentation component
- February 12: Deadline for submitting application to the JHU Healthcare Design Competition (send draft to instructors the week before)

Kanban board: https://trello.com/b/wjGsrVLe/team-6-josh-will-sarah-kishen

From Instructors:

- Connecting team with appropriate folks at OTC (do we need to file IDF prior to working at Ni Lab..?)

BREAKDOWN OF WORK:

Who did what
There are three main "arms" involved to address the top FR

- Designing a thermistor array - Josh, Will, and Sarah
- Fabricating a strain sensor - Kishen, Will, and Josh
- Developing a FSR-based system - Sarah and Kishen

Ultimately, we will need to decide whether to pursue the strain sensor or FSR sensor based approach for the indentation component of the device.

OTHER REMARKS:

- Should we invest time into calibrating alternative FSRs that may be more suitable for this project?
- How much do we need to account for the surrounding tissue stiffness in areas of high contact pressure? Also, do we need to account for people standing on the device in different positions?
- Should our device adapt to different users? Or should we target a one device fits all approach?
- Sarah discussed the idea of potentially shifting the position of indentometers as necessary to fit the contact pressure distributions of each patient.

Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 2/1/2024

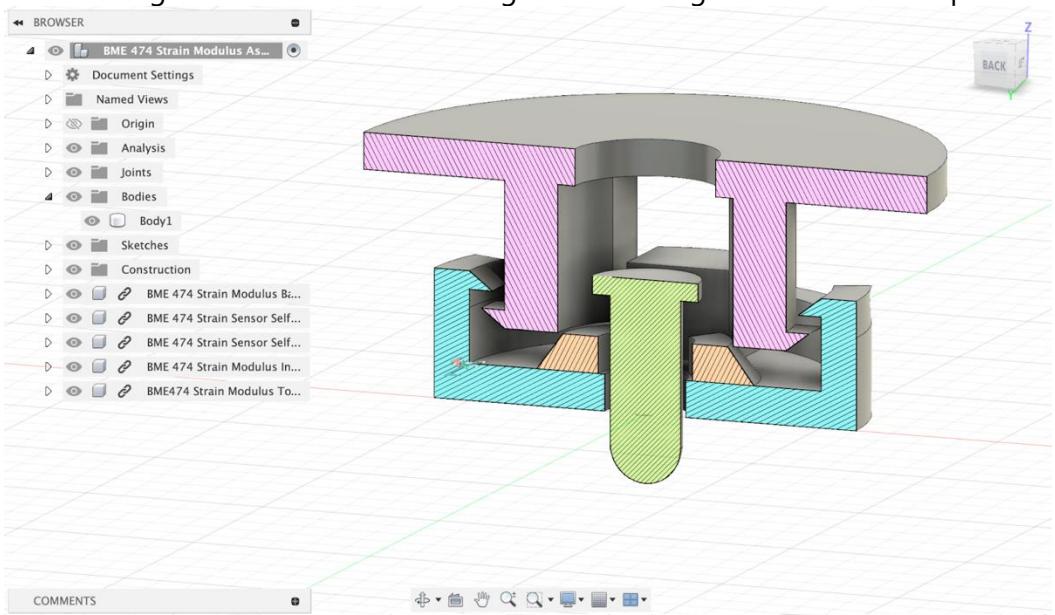
Meeting Lead: Will Temme
Meeting Scribe: Kishen Mitra

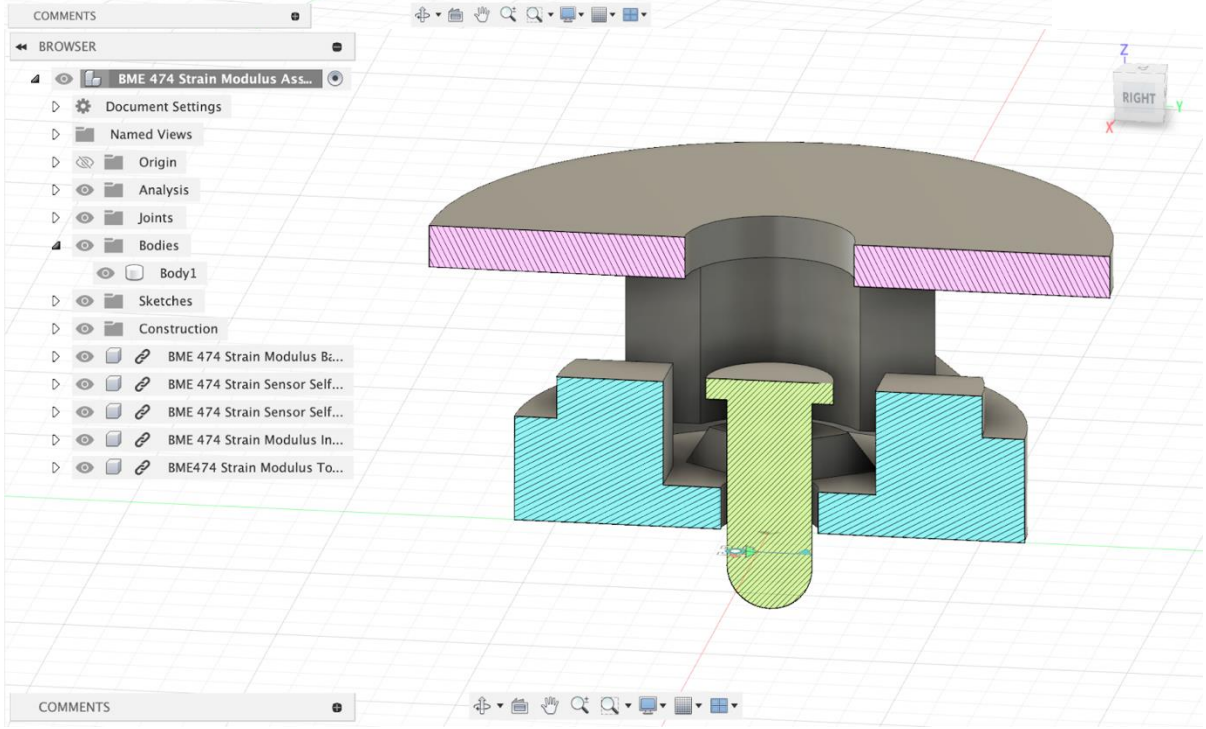
RECAP:
Charge from previous meeting (Team's & Instructors')
Action items

- Contact sensor array companies to learn about price and procurement
- Conduct ball indentation tests to compare this performance against gold standard for E determination
- Discuss thermography testing results from Fall 2023

WEEK'S ACTIVITIES:
What's been done and why
Experiments, prototypes (photos, videos, live demos)

- Six more FSRs have been ordered to have a net of eight FSRs to perform preliminary testing
- Ordered CD74HC4067 CMOS 16 Channel 16 CH Digital Analog Multiplexer Breakout Module for Arduino
    - This breakout module can be used for multiplexing of information from eight FSRs for now
- Ordered flexible protoboards and skin model

- Conducted literature review on flexible sensors/sensor array/electronics
    - Done for correspondence with Ni lab. Grad student (Chenhang) provided papers to read
- Iterated self-locking strain sensor CAD and began researching fabrication techniques
    - 

    - 

DATA:
Charts, figures, tables w/ stat analysis

Discuss thermography testing and outcomes

NEXT STEPS

From Team:

Short-term goals:

- Prototype small scale sensor array with multiplexor
- Print strain sensor shell and continue to iterate
- fabricate strain sensor electrical components (not necessarily within the next few weeks)
- Obtain data for validation of single FSR-based indentor
    - make phantoms, assemble ball-bearing system, etc

- FSR experiments
    - Josh and Kishen: work on multiplexing experiment to confirm ability to process force information from 8 FSRs. Prepare circuit and code to enable and test multiplexing approach for FSR force data to see how accurate the measurements can be from an FSR array
        - Next step would be to do the same for the thermistor array and then to integrate the two multiplexed signals
    - Sarah: ball indentation tests
        - purchased small ball bearings (6mm diameter)
        - perform PoP testing similar to last semester in which we validate the ability of the ball bearing setup to perform indentation tests
- Flexible sensor literature review: Will

Milestones:

- Early to mid-February: Deciding which avenue to pursue for the indentation component (FSR vs locking strain sensor)
- February 12: Deadline for submitting application to the JHU Healthcare Design Competition (send draft to instructors the week before)

Kanban board: https://trello.com/b/wjGsrVLe/team-6-josh-will-sarah-kishen

From Instructors:

-

BREAKDOWN OF WORK:

Who did what

There are three main "arms" involved to address the top FR

- flexible sensors and thermistors - Josh, Will, and Sarah
    - flexible sensor array and thermistor literature review - Will
- Fabricating a strain sensor - Kishen, Will, and Josh
    - strain-based sensor CAD iteration and printing research - Will

- Developing a FSR-based system - Sarah and Kishen

Meeting Notes:

- Multiplexing
    - Is the array part of a voltage divider or a bridge circuit?
    - Does each cell have its own sensing circuit? Or is there one cumulative sensing circuit?
        - how do they design the downstream circuit? is that something we could design ourselves or would we have to separately purchase the circuit?
    - multiplexer: digital switch
    - hardware switch: instability and lot of noise into the system unlike multiplexer
    - multiplexing shouldn't be an issue as there are many ICs that we can build with
    - TO-DO: ORDER either fsr array or thermistor array
- Ball bearing fsr
    - 3D print holder of the sample or attach to top platen to get initial contact
    - is the hertz contact theory the same if the tissue is coming down to the fsr setup or if the fsr setup is coming down to the tissue?
        - top down with the sensors: removes residual forces from weight of the foot so can isolate the responses of the tissue
    - Size of the ball
        - size of the ball would influence engagement with the foot
    - pressure profile across the feet is highly variable and may differ from day to day so that adds to the residual forces from the weight of the foot
    - Unloading effects from ground surrounding ball: opposite forces to the fsr ball force we are measuring
        - maybe sitting will make these unloading effects consistent and controllable. ideally, want 0 force from unloading effects so it can serve as a reference frame
    - switches, touch capacitors, or springs to control how much indentation there is so that unloading effects can be minimized by minimal contact at locations besides the sensor
    - can get force and distance right when it touches?
    - TODO: flip the fsr setup to the top to flip the movement to eliminate unloading effects. or attach the sample to the top platen
    - Todo: can isolate just the ball by bringing it down and having FSRs on the side away from the ball to experimentally see when there is a difference to identify contact

Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 2/8/2024

Meeting Lead: Sarah Glomski
Meeting Scribe: Will Temme

RECAP:
Charge from previous meeting (Team's & Instructors')
Action items

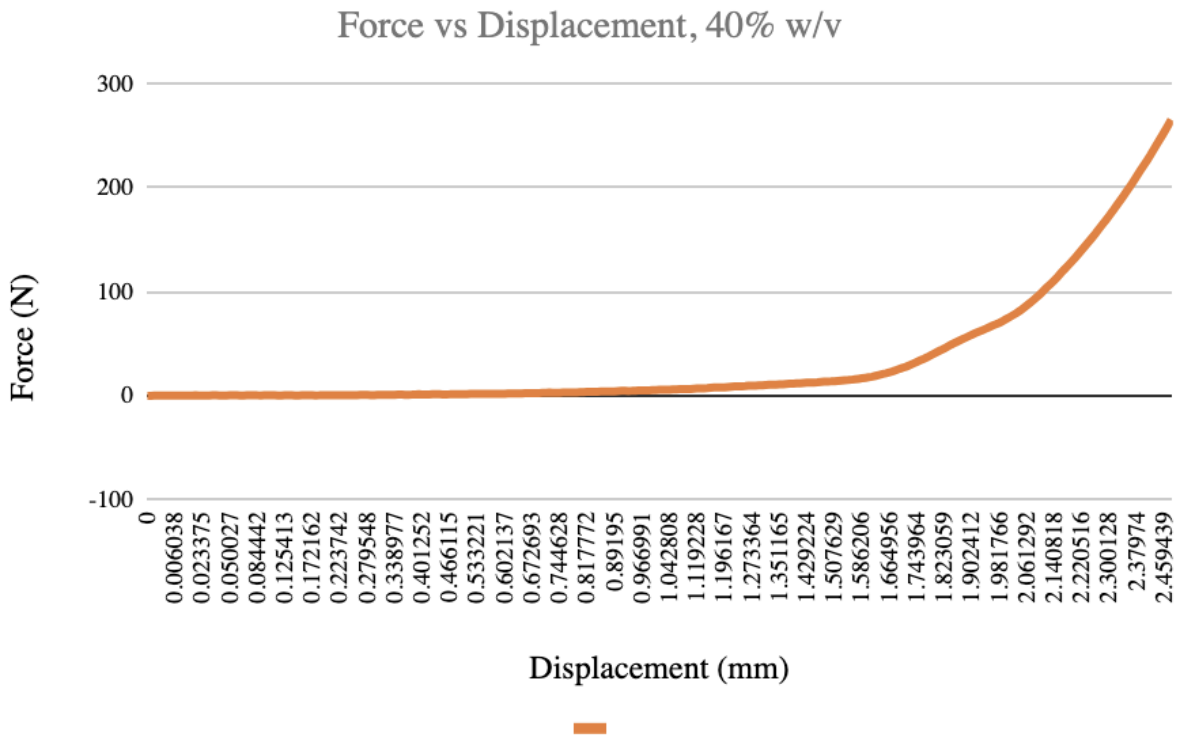
- Discuss thermography testing results from Fall 2023
- Continue ball indentation tests with 3d printed parts to compare the performance of the FSR against gold standard
- Order FSR array
- Construct multiplexing circuit and test if data can be converged

WEEK'S ACTIVITIES:
What's been done and why
Experiments, prototypes (photos, videos, live demos)

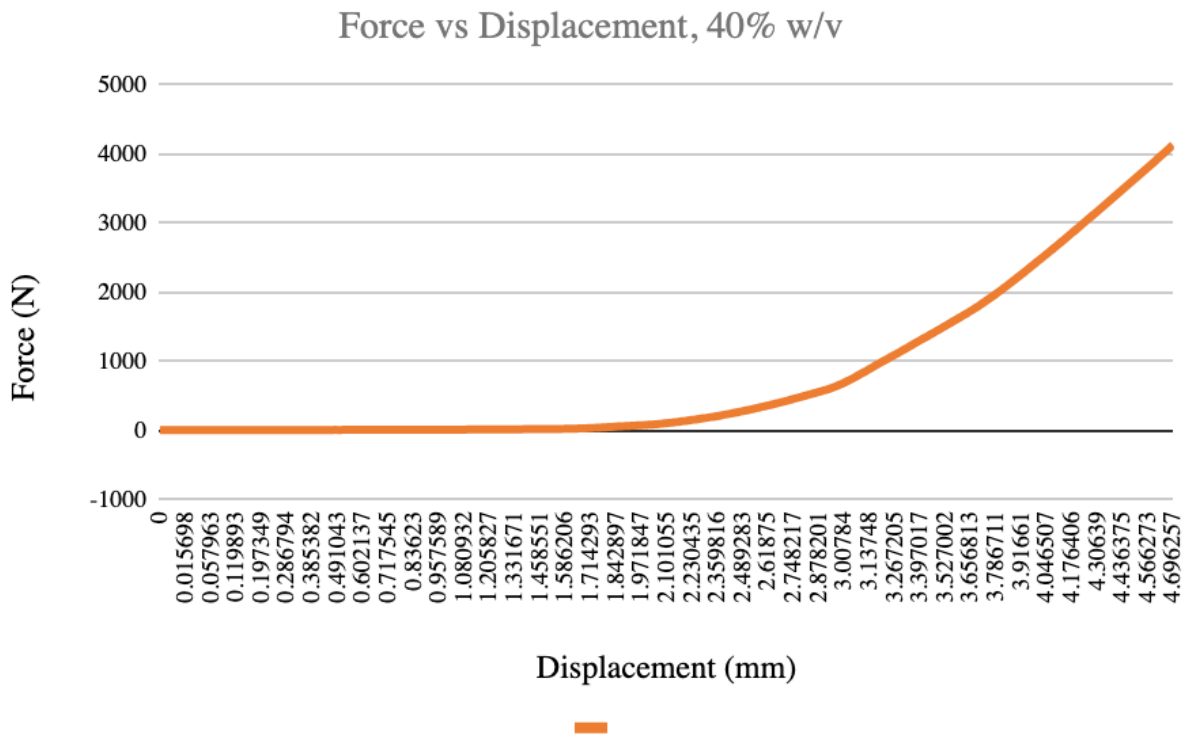
- Met with Dr. Kyle to discuss thermography results from last semester. Major takeaways were that our statistical approach was valid, but that it could be simplified to make it easier for an audience to comprehend quickly.
- The multiplexer circuit was constructed using 6 FSRs.
    - Replicated voltage divider circuit from last semester for each FSR and integrated the multiplexing module
    - Need to debug code to properly obtain the analogReads for the FSRs
    - Might add more FSRs to test if adding another bit level will still work; will it scale properly?
- Met with Dr. Ni's grad student and discussed next steps for flexible strain gauge fabrication. Next steps include determining the electrical properties that will be needed from the strain gauge, selecting a metal to build the strain gauge, and meeting with Dr. Ni to confirm our proposed approach.
- Met with a Bluesmith employee and discussed advanced 3d manufacturing options for the self-locking frame for the strain sensor.
- Conducted fit tests with the 3d printed indenter holders with different tolerances.
    - The best tolerance was a 0.5 mm increase in diameter surrounding the ball bearing and a height of 2.7 mm for the part under the ball bearing (responsible for channeling force into FSR).
- Conducted 2 tests using the 3d printed alginate holder and a 3d printed indenter holder placed over an FSR.
    - Had trouble getting the FSR data to write to a CSV file. Force data was therefore only processed from the gold standard.
    - Had issues with the Test Resources machine where it was moving very slowly and then maxed out the load after the test ended. This created large permanent indentations in the alginate samples.

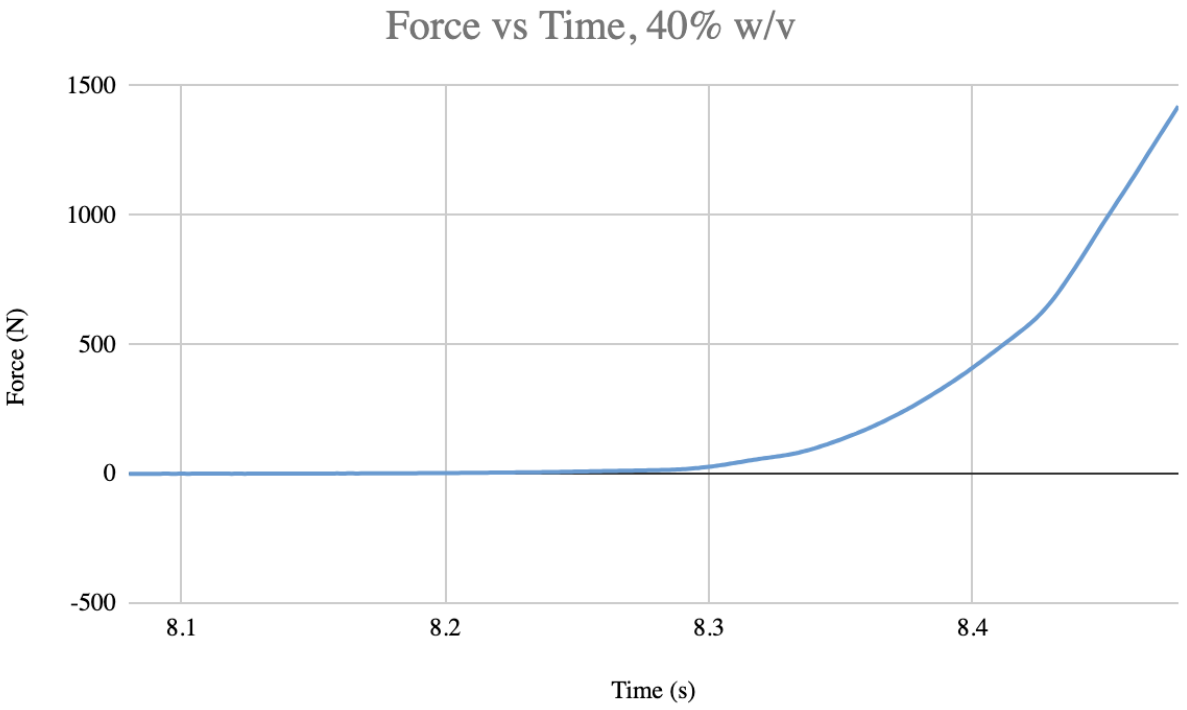
DATA:
Charts, figures, tables w/ stat analysis

It was expected that there would be a steady increase in force while only the indenter was in contact with the alginate sample. Then, once the surrounding material around the indenter made contact with the alginate sample, a sharp increase in force was expected to be seen. The figure below shows force vs displacement for an alginate sample being indented. 2 inflection points can be seen around 1.6 mm and 2.0 mm of displacement. It is important to note that there was a 0.5 N preload defined on the test profile, which means that the displacement is offset by an unknown amount. Given that the ball bearing tested was 5.56 mm in diameter, a full indentation would occur around 2.78 mm of displacement. It is unclear whether the inflection points seen in the force vs displacement curve were a result of the surrounding material making contact with the alginate sample.



The figure below is from the same test as the one above, but is zoomed out to include all the way up to 4.7 mm of displacement. A slight inflection point can be seen around 3 mm of displacement, which could be where the alginate sample made contact with the surrounding material. However, the forces seen in this region exceed 600 N, which are higher than expected.


Force vs Displacement, 40% w/v
Force (N)
5000
4000
3000
2000
1000
0
-1000
0
0.015698
0.057963
0.119893
0.197349
0.286794
0.385382
0.491043
0.602137
0.717545
0.83623
0.957589
1.080932
1.205827
1.331671
1.458551
1.586206
1.714293
1.842897
1.971847
2.101055
2.230435
2.359816
2.489283
2.61875
2.748217
2.878201
3.00784
3.13748
3.267205
3.397017
3.527002
3.656813
3.786711
3.91661
4.046507
4.176406
4.30639
4.436375
4.566273
4.696257
Displacement (mm)


Force vs Time, 40% w/v
Force (N)
1500
1000
500
0
-500
8.1
8.2
8.3
8.4
Time (s)

NEXT STEPS

From Team:
Short-term goals:

- Print strain sensor shell and continue to iterate
- Fabricate strain sensor electrical components (not necessarily within the next few weeks)
- Continue to collect data for validation of single FSR-based indenter
    - Write new Arduino code to export FSR data to CSV for easy visualization

- Work on multiplexing experiment to confirm ability to process force information from 6 FSRs. Troubleshoot circuit and code to enable and test multiplexing approach for FSR force data to see how accurate the measurements can be from an FSR array
    - Next step would be to do the same for the thermistor array and then to integrate the two multiplexed signals
- FSR/indenter indentation tests

Milestones:

- Early to mid-February: Deciding which avenue to pursue for the indentation component (FSR vs locking strain sensor)
- February 12: Deadline for submitting application to the JHU Healthcare Design Competition (send draft to instructors the week before)

Kanban board: https://trello.com/b/wjGsrVLe/team-6-josh-will-sarah-kishen

From Instructors:

-

BREAKDOWN OF WORK:
Who did what
There are three main "arms" involved to address the top FR

- flexible sensors and thermistors - Josh, Will, and Sarah
    - flexible sensor array and thermistor literature review - Will
- Fabricating a strain sensor - Kishen, Will, and Josh
    - strain-based sensor CAD iteration and printing research - Will
- Developing a FSR-based system - Sarah and Kishen

Meeting Notes:

- buy a packaged load cell if having trouble with the FSR?
    - FSR: pressure averaged over a whole area; when there's inconsistencies then you can get drifts and more
    - FSR has a lot of drift based on contact and average force and such
    - take a video (sharpie approach that Sarah mentioned)
- Load cells: what Dr. Richardson recommends
    - point load cells
    - strain gage based approach
        - pretty cheap
    - email him to look for load cell
- take derivative of data to figure out where to threshold out
- Consider getting a commercially available strain gauge customized to our desired size. All shapes and sizes available off-the-shelf
- Would need to characterize the relationship of change in resistance per unit displacement of a custom-designed strain gauge. This could pose challenge
- Off-the-shelf strain gage might be possible for this project
- Thermistors take a while to equilibrate, most things in the body you probably want a faster response time. Consider thermocouplers?
- Need to decide between FSR and strain gauge approach soon
    - Reach out to chenhong and ask for specific strain gauge parameters, learn more about methodology, realistically how long it will take to get trained and fabricate sensor
    - Set up a meeting with Dr. Ni with Dr. Richardson
- Will to email Dr. Richardson, send Cui et al paper

Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 2/15/2024

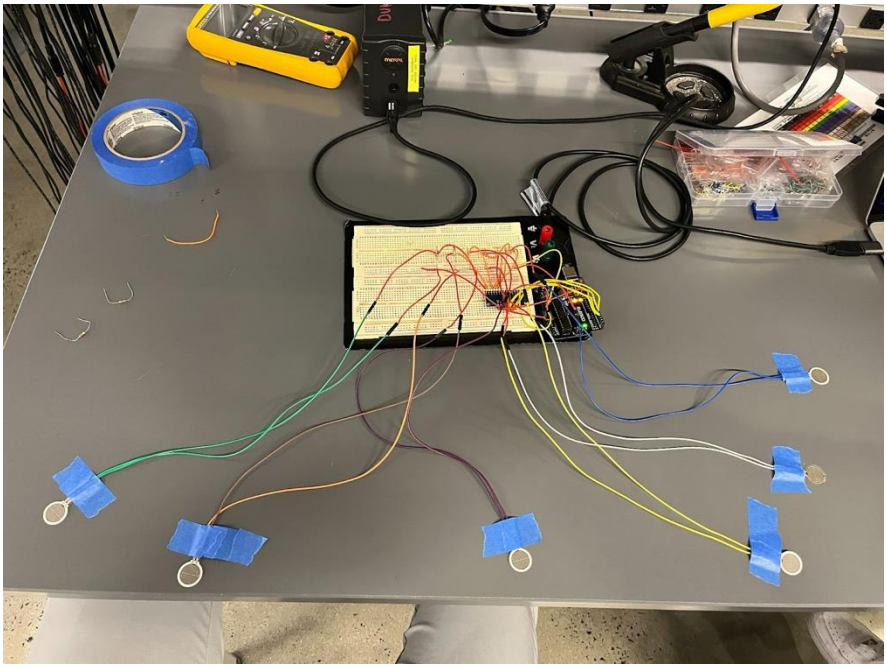
Meeting Lead: Will Temme
Meeting Scribe: Josh Tennyson

RECAP:
Charge from previous meeting (Team's & Instructors')
Action items

- Continue ball indentation tests with 3d printed parts to compare the performance of the FSR against gold standard
- Construct multiplexing circuit and test if data can be converged
- Set up a meeting w Dr. Ni, Dr. Richardson, and Dr. Kyle to identify the strain gauge design parameters

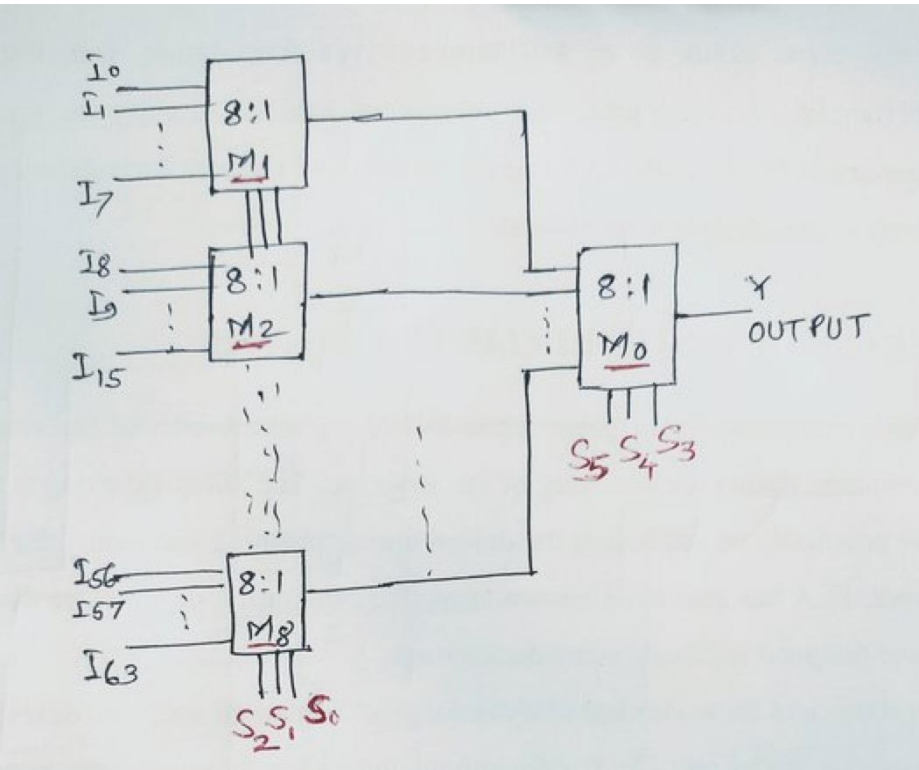
WEEK'S ACTIVITIES:
What's been done and why
Experiments, prototypes (photos, videos, live demos)

- Nano-indentation testing
  - 
- The multiplexer circuit was constructed using 5 FSRs.
  - Replicated voltage divider circuit from last semester for each FSR and integrated the multiplexing module
  - photos of setup are below (also took videos showing function)
  - Multiplexing will form the basis of our sensing pathway



Multiplexer setup. Connecting all of the S pins for each layer of multiplexers will allow group control of which channels to switch on. However, can specify which FSR to read through the analog pin control.

- Explored circuit design for the system and created an Eagle file with the circuit design
    - Stacking multiplexors for both temperature and stiffness measurements
    - Researched different microcontrollers suitable for our design
        - One example: https://www.ti.com/product/MSP430FR6005#order-quality
    - RF signaling



- Ordered more multiplexers (IC MULTIPLEXER 1 X 8:1 16DIP)
- Wrote new Arduino code to export FSR data to CSV for easy visualization. Beneficial to data processing for subsequent experimentation.
- Submitted JHU Design Healthcare Proposal (2/12 deadline)

- As per Dr. Richardson's recommendation, we used the delta stiffness values to back calculate the delta force measurements observed from our earlier experiments. This derivation can hopefully give us an idea of the necessary resolution for a load cell.

[redacted]

Hertz Resolution

Tuesday, February 13, 2024 9:53 PM

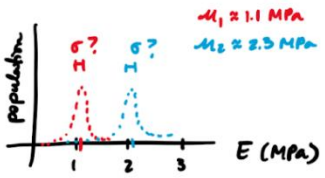
$$F = \frac{4E}{3(1-\nu^2)} R^{1/2} \delta^{3/2}$$

$$E = \frac{3F(1-\nu^2)}{4R^{1/2}\delta^{3/2}}$$

let $R = \delta = 0.003$ m,
assume $\nu = 0.45$

$$E = \frac{3F(1-0.45^2)}{4(0.003)^2}$$

$$\boxed{E \approx 66458.3F}$$



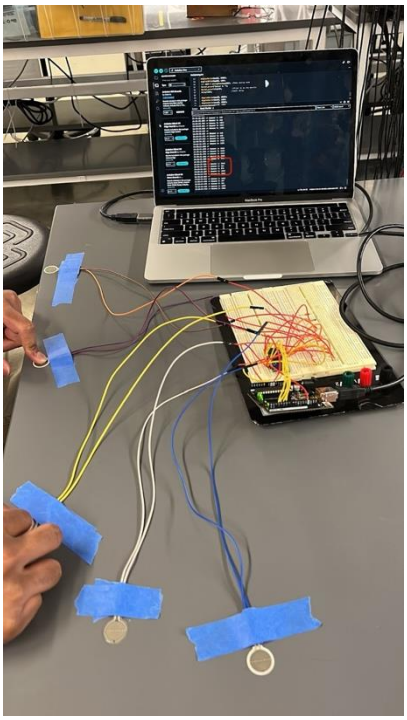
let $\Delta E = 0.1$ MPa be the ideal resolution of our device

$0.1 \text{ MPa} = 66458.3F$ $\quad 1\text{Pa} = 1 \text{ N/m}^2$

$$\boxed{F = 1.5047 \text{ N}}$$

DATA:
Charts, figures, tables w/ stat analysis

- The multiplexer circuit
    - Ensured that the setup could be used to obtain analog resistance values from each FSR and that these values could be backed out to force measurements
    - Code has already been developed to output force measurements directly
    - Multiplexing will form the basis of our sensing pathway



- Revised temperature analysis from last semester as per Dr. Kyle's suggestions over our Zoom meeting

NEXT STEPS

From Team:

Indentometry:

- Prepare more alginate molds
- Conduct proper ball indentation tests with FSR
- Order low-cost load cell and perform preliminary testing with it.

Strain gauge fabrication:

- Spoke with Dr. Richardson on 2/13 and he provided some insights for optimal strain gauge parameter selection. We are coordinating a meeting with Dr. Richardson and Chenhang to learn more about the fabrication process. We need some more information to establish what parameters need to be considered (i.e. gauge factor).

Thermistor array and overall Circuit:

- Solder thermistors onto a flexible PCB, potentially coat thermistors with silicone. Arrange thermistor circuit with multiplexing layout.
- Lokesh mentioned that the thickness of the solder mask is really low on these flexible PCBs and they can easily melt even at a temperature that is a degree Celsius too high sometimes. Hence, we will need to look into the optimal temperature for the specific boards we have ordered.
- We will share and look over the schematic prepared on KiCad with Lokesh.

Milestones:

- Within next week: Deciding which avenue to pursue for the indentation component (FSR vs locking strain sensor)
- Late February: Frankenstein prototype

Kanban board: https://trello.com/b/wjGsrVLe/team-6-josh-will-sarah-kishen

From Instructors:

Indentometry:

- Dr. Kyle suggested we explore a quarter Wheatstone bridge circuit layout as opposed to a voltage divider circuit for the FSR layout in order to achieve higher accuracy and better dynamic range.
- Dr. Kyle also seemed to be concerned about ensuring force measurements are read across the entire cross section of the FSR
- In terms of the load cell route, Dr. Kyle also brought up an idea of using a singular load cell that can interrogate across different points one at a time.
- Dr. Richardson will hopefully be able to guide us in the direction of a suitable load cell that has a 1.5 N resolution

Strain gauge fabrication:

- Dr. Richardson reiterated his suggestion of purchasing an off-the-shelf strain gauge with similar desired properties to at least use in the short-term if we would like to explore that arm or the project.

Breakdown of work:
Who did what
2/9-2/10: Kishen and Josh met to work on designing multiplexing circuit.
2/10: Josh and Will met to brainstorm PCB layout for thermistors
2/13: Team work session; developing plan of action for thermistor array arm of project.

Meeting Notes:

- Figure out a way to get a hemisphere shaped bearing

Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 2/21/2024

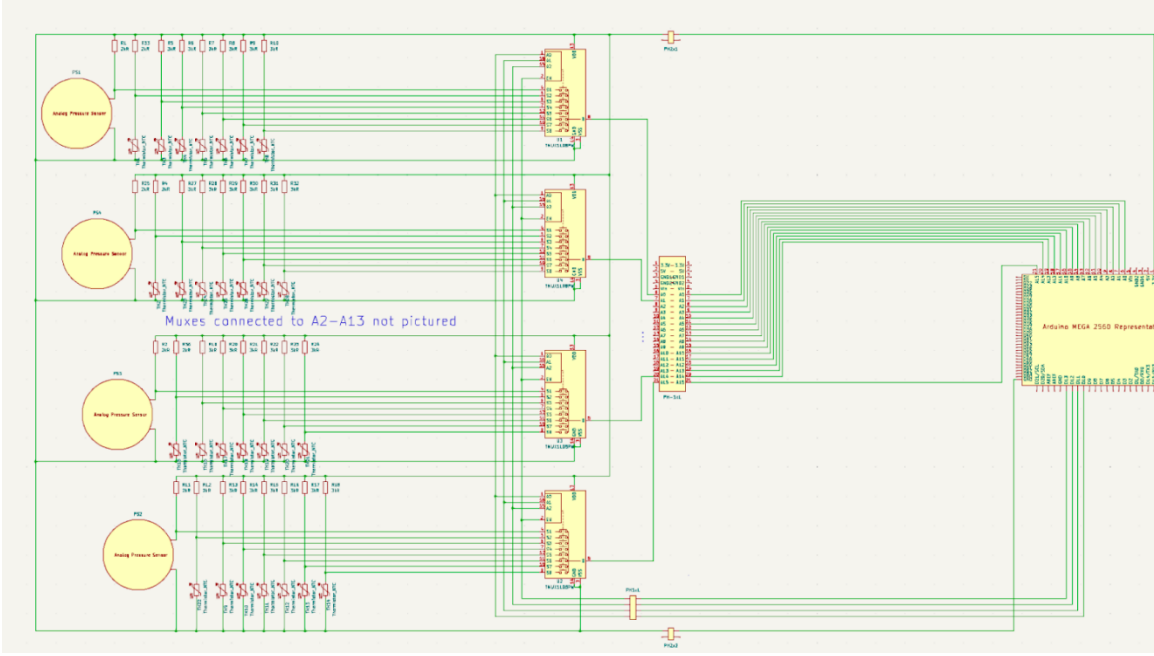
Meeting Lead: Will Temme
Meeting Scribe: Sarah Glomski

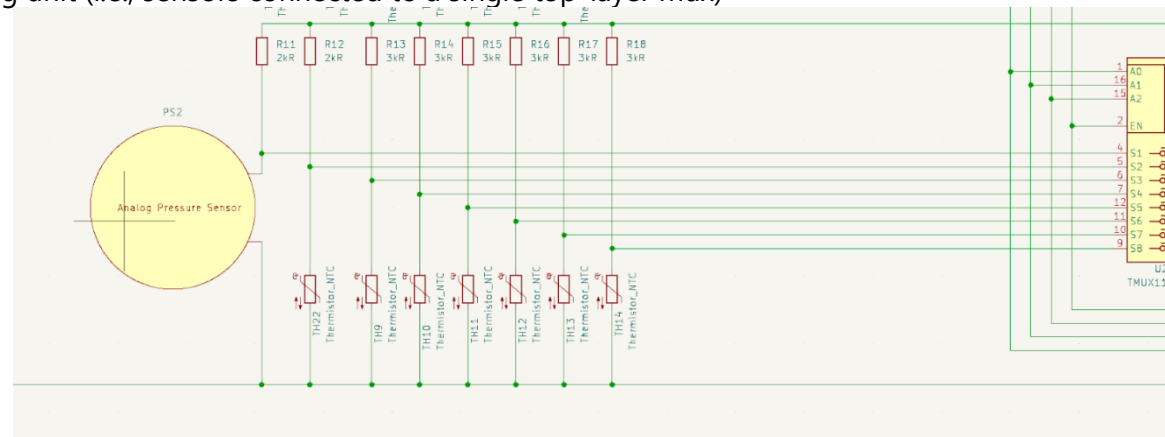
RECAP:
Charge from previous meeting (Team's & Instructors')
Action items

-

WEEK'S ACTIVITIES:
What's been done and why
Experiments, prototypes (photos, videos, live demos)

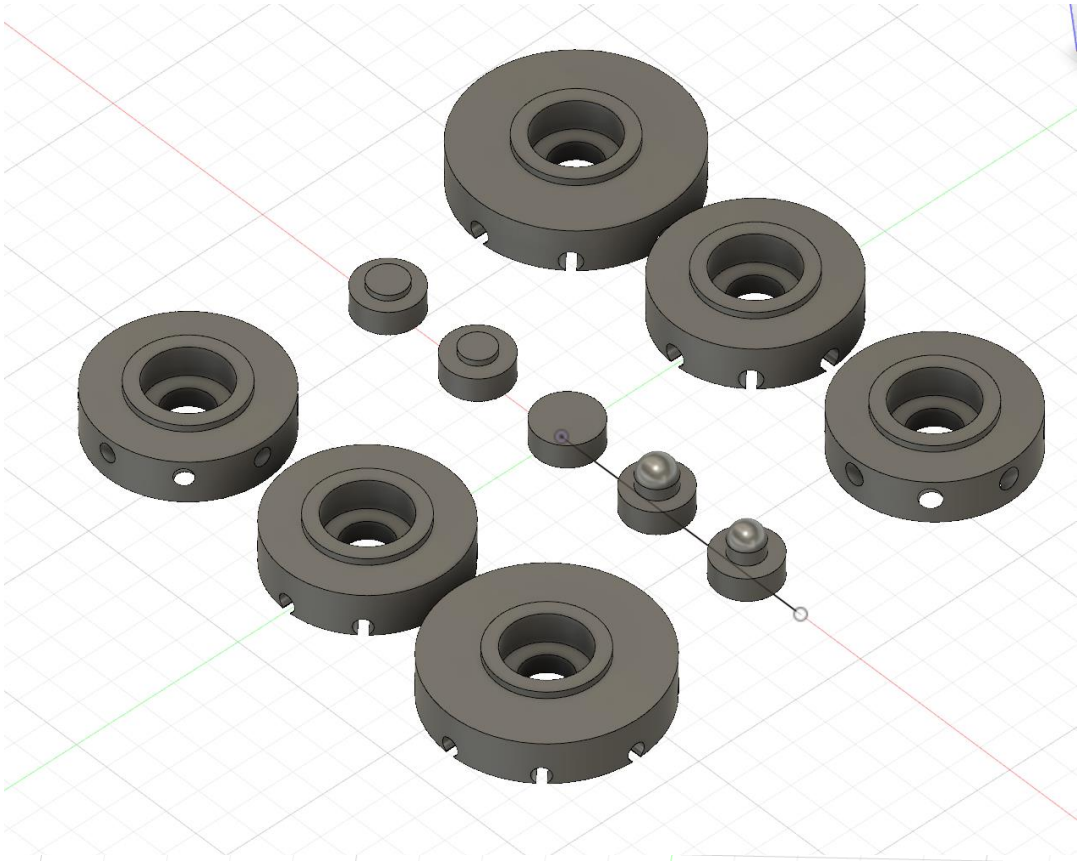
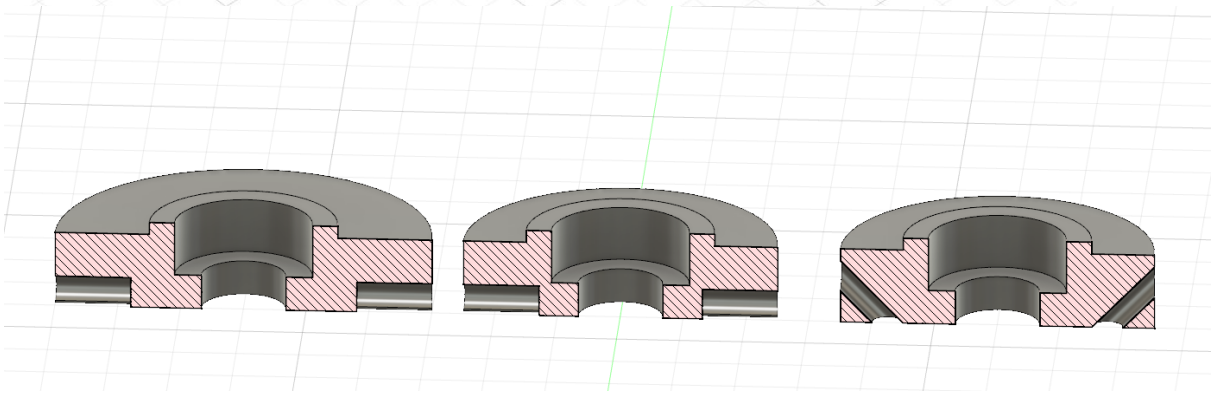
- Early schematic of integrated sensing array circuit
    - mux stacking not depicted for simplicity, though this is a plan

        - wheatstone bridge circuit not depicted for simplicity, though we plan to use them
            - Question: we understand wheatstone bridges are valuable for getting precise measurements for modulus sensors AND thermistors. However, the hardware cost, footprint cost, and layout restrictions make us uncertain whether we should have wheatstone bridges for every single thermistor and modulus sensor. Do you have any input here? We also understand there are ways to optimize/minimize hardware layout and use in cases in which we use many sensors.
        - 

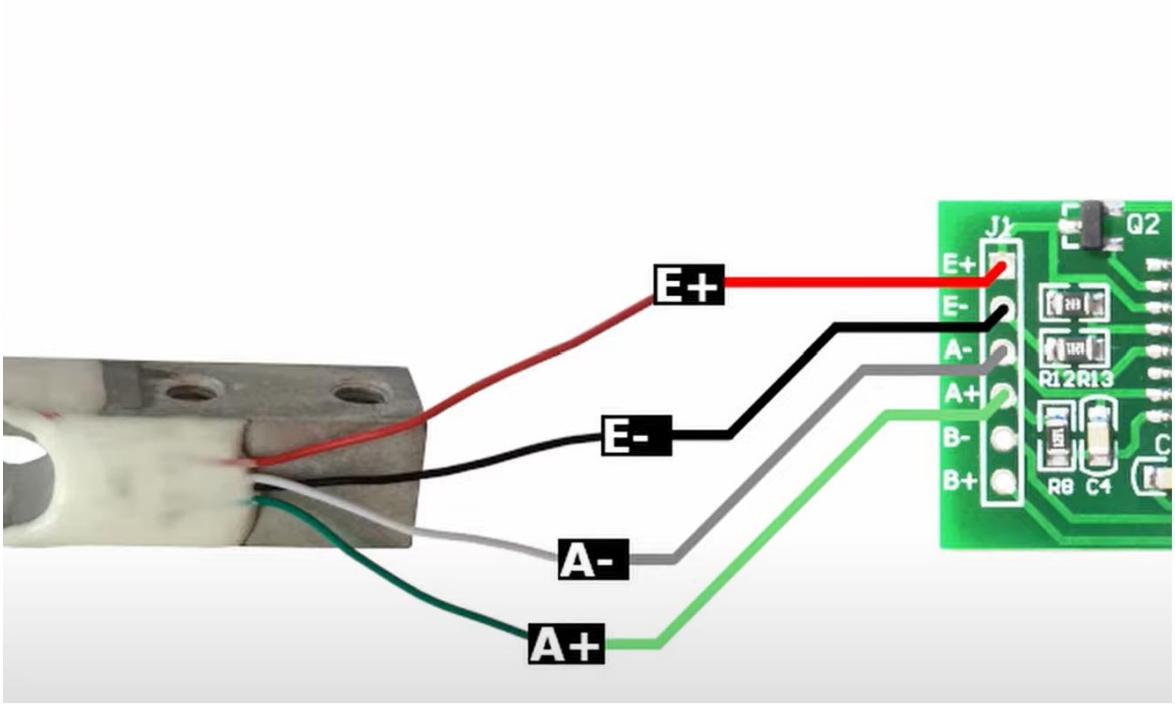
    - Sensing unit (i.e., sensors connected to a single top-layer mux)
        - 

- Second iteration of FSR-based sensor hardware design
    - integrates thermistors into indenter
    - various tolerances and designs tested
    - larger frame diameter (indenter probe same diameter)
        - hoping this accentuates inflection points (testing tomorrow morning)

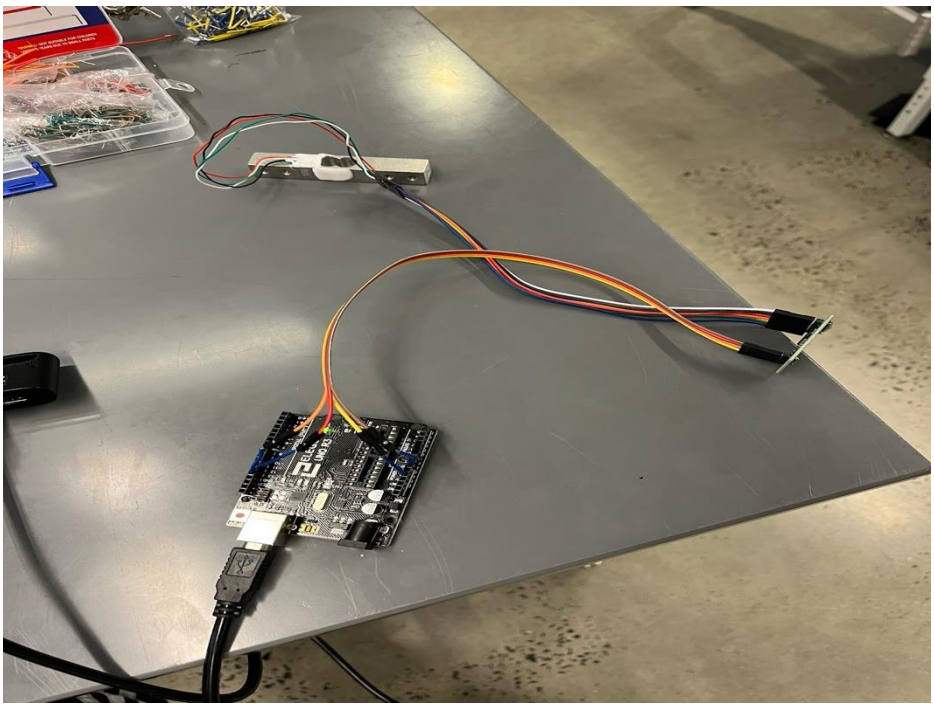
- Question: we want to hear your thoughts on using thermally conductive epoxy to 1) embed thermistors into the thermistor holes in the indenter frames (pictured below) AND 2) cast a spherical indenter with a thermistor embedded in the tip
- 
    - thermistors will be placed into each of the 8 holes in the frames (we will explore increasing thermistor density)

- 
- 

- Performed testing with FSR-based indentation device
  - implemented python script to automate data collection from serial communications between arduino and computer OS
- Used a HX711 with a Four Wire Load Cell and Arduino
  - There are two pairs of wires - black and red as well as red and green. One of the pairs connects to the E+ and E- power outputs of the HX711 module while the other pair is for measurement and goes to the A+ and A- inputs of the amplifier module.
  - On the Arduino side, the Vcc pin is connected to the Arduino 5V pin and the GND to the Arduino ground. The amplifier's data pin is connected to a digital pin (D4 in this case) and the clock is connected to another digital pin (D5 in this case).



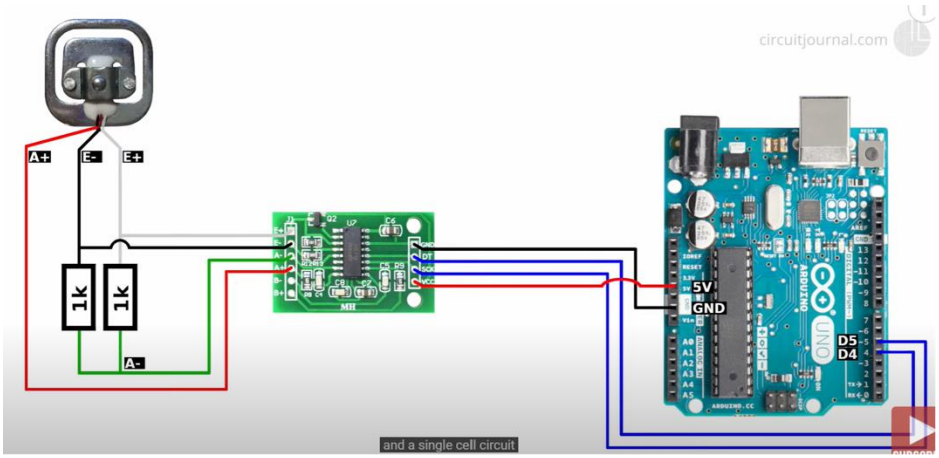
- With the help of Lokesh, we crimped DuPont connectors to the end of the four wires to make it much easier to do experiments.
- The final circuit setup is shown below:

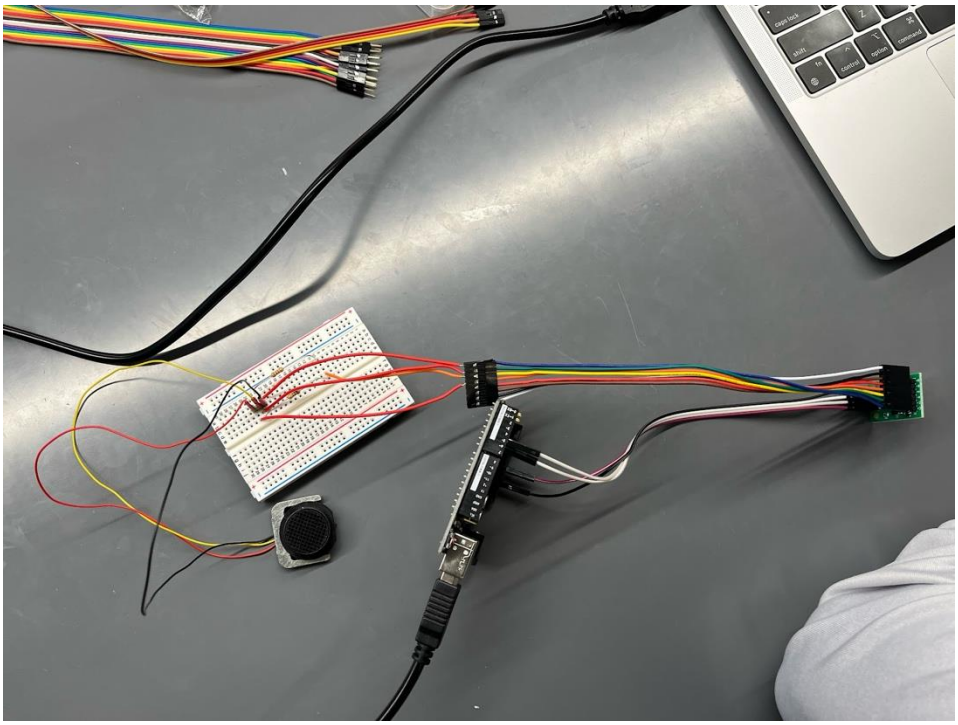


- Since this load cell is a straight metal block, additional setup is required to obtain force measurements. We need to build a frame around it so that the force coming from the top will deform the middle part. One option is to screw it between two wooden planks with some spacers between the load cell and the board. Another option is to 3D print a top plate and a base frame and screw them in.

- Due to the “simpler” setup, we also set up the Three Wire load cell according to the diagram below. This load cell has the same operating principle, with a Wheatsone bridge. When no pressure is applied, all the resistor resistance values are equal and the voltage

measurement is zero. This three wire load cell has half bridges that can be combined to form a full bridge. The circuit (with two external 1kOhm resistors) is shown below.



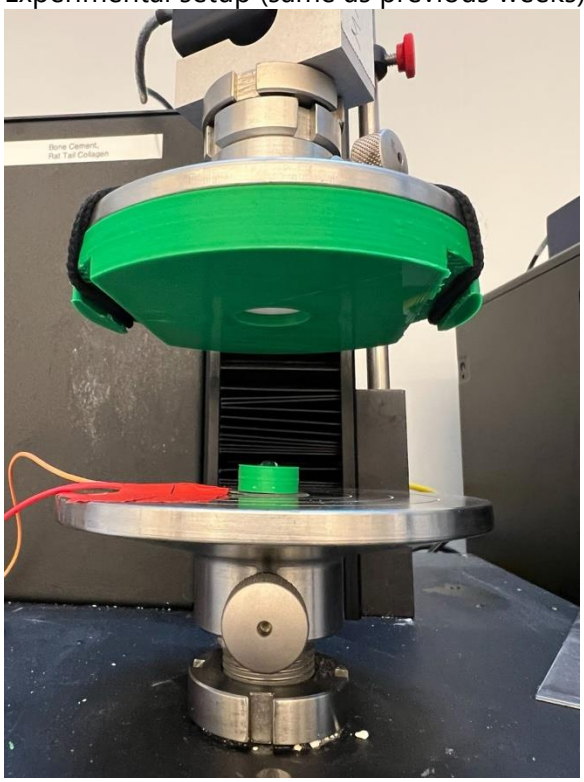


- Communicating with the Balance Module requires a driver for the HX711 sensor. The simplest way to install the driver is to download the HX711 library. We attempted multiple times on multiple devices to download the library, extract to our Arduino Uno library folder, and use sample code in Arduino IDE. However, this step has given us trouble and we still have been able to successfully calibrate and tare down the load cell (the first step prior to obtaining accurate weight measurements).
- Although this has been an obstacle recently, we are optimistic that the load cell may be a more effective approach to extracting reliable quantitative force measurements for our device.

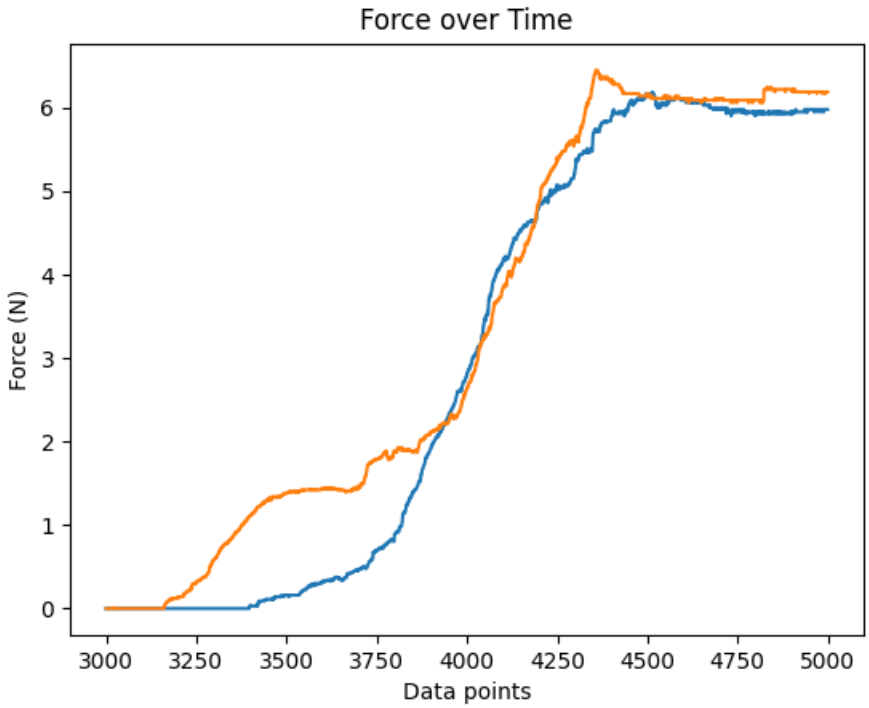
DATA:

Charts, figures, tables w/ stat analysis

- Continued testing with old experimental setup (ball bearing, 3D printed platform, FSR) to determine whether the FSR could be calibrated to be accurate relative to the gold standard load cell in the Test Resources machine.
    - Experimental setup (same as previous weeks)

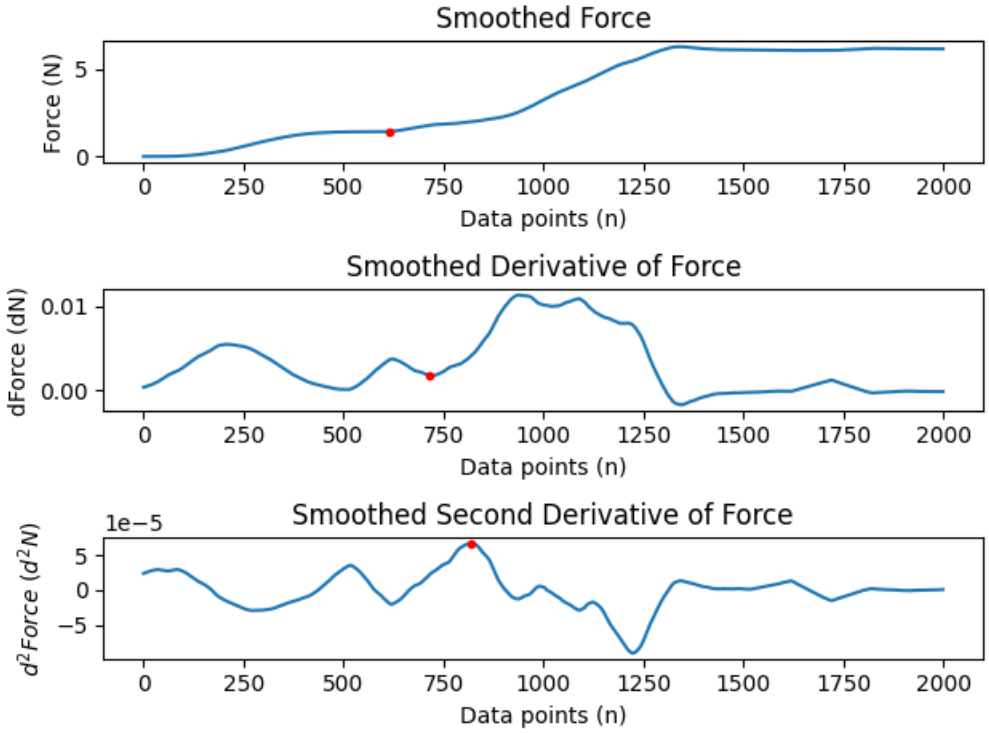


- Raw force data from the gold standard:

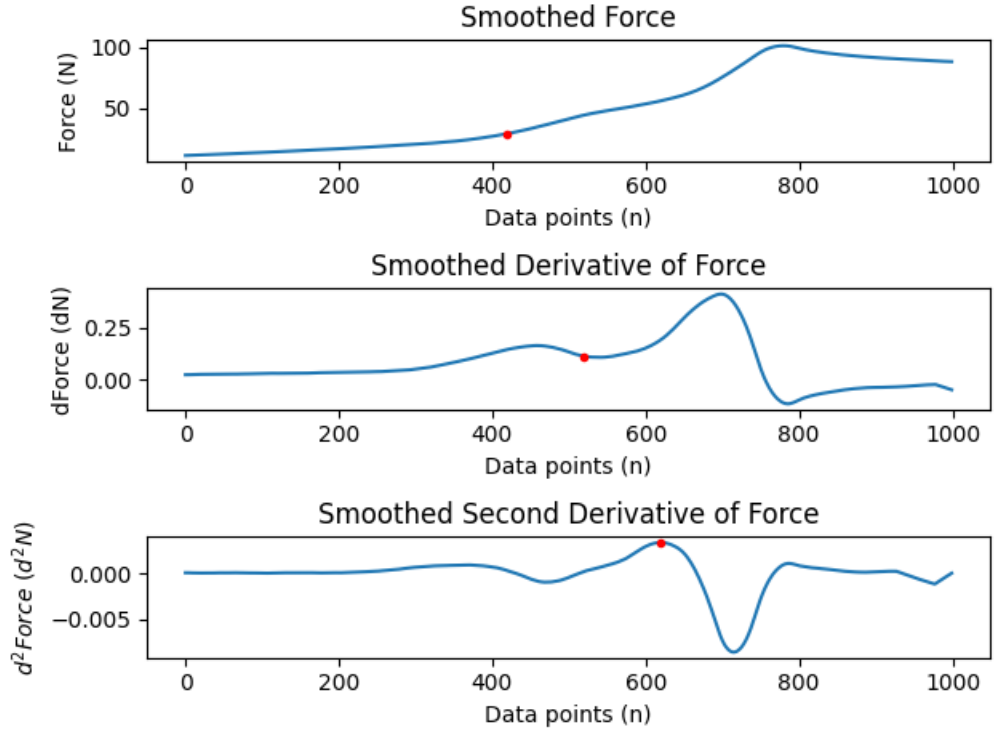


- Wrote a Python script for reading the FSR/gold standard force data in from a csv, smoothing the data via a moving average, and calculating the first and second derivatives of the force. Then, the code finds the point of maximum positive concavity, which is where an inflection point would be present. Future iterations of this code will be able to pinpoint several local maxima to find more than one inflection point.

- Plot of the smoothed force and derivative curves for the FSR data, with a red dot where the inflection point is calculated to be:



- Plot of the smoothed force and derivative curves for the gold standard data, with a red dot where the inflection point is calculated to be:



    - Plot from FSR with larger casing, 6.35 mm ball bearing

- Results:
    - The FSR showed much lower forces than the gold standard (scaled down to a ratio of ~6 N to 100 N), but showed the same general shape. The FSR data was much noisier than the gold standard data and sampled at a higher frequency, so it required more smoothing (100 point moving average vs 50 point moving average).
    - The force curves did not always have 2 apparent inflection points.
    - With the sample that worked, the modulus was calculated to be 1.72 MPa from the FSR and 1.46 MPa with the gold standard, which is a 17.8% error. When using the moving average values, the FSR measured a modulus of 2.03 MPa and the gold standard measured a modulus of 2.14 MPa, which shows a much improved 5.4% error. Given that the material being probed was an old sample of the 40% w/v alginate, the actual modulus of the sample was expected to be >2.3 MPa, so the measured values were lower than expected.

NEXT STEPS

From Team:

Short-term goals:

- Iterate circuit schematic based on instructor thoughts regarding 1) chaining muxes AND 2) using wheatstone bridges
    - implement physical circuit with high number of muxes and sensors using arduino mega
- Prototype casting thermistors in epoxy
- Continue to iterate FSR-based indenter mechanical hardware (if necessary)
    - continue to test accuracy of modulus measurement and inflection point detection capabilities
- Explore the possibility of using moisture sensors to detect contact with indenter frame
    - if it works, look into examining moisture as another DFU biomarker
- Begin prototyping mat components to integrate our circuit into
- Begin prototyping display (LED?)
- Put everything together to make an early prototype of our integrated system

Milestones:

- Early to mid-February: Deciding which avenue to pursue for the indentation component (FSR vs locking strain sensor)
-

Kanban board: https://trello.com/b/wjGsrVLe/team-6-josh-will-sarah-kishen

From Instructors:

-

BREAKDOWN OF WORK:
Who did what
There are three main "arms" involved to address the top FR

- flexible sensors and thermistors - Josh, Will, and Sarah
    - circuit schematic - Will
    - integrated indenter/thermistor hardware CAD - Will
- Fabricating a strain sensor - Kishen, Will, and Josh
    - N/A (no progress)
- Developing a FSR-based system - Sarah and Kishen
    - FSR testing - Sarah (lead), Will
- Validating a load cell based approach - Kishen and Josh

Meeting Notes:

- Temperature sensors as opposed to thermistor
    - Still analog, internal sensing circuitry, would not require a bunch of wheatstone bridges
    - Accuracy is not as good as thermistor, 0.5 degree in range, 1.5 degree outside of range
    - Are we multiplexing from multiple bridges?
    - Why can't we add a wheatstone bridge to the multiplexed output?
        - Highly unlikely that a single bridge would be balanced for several thermistors due to different calibration and different temperatures
    - A bridge might only be necessary for very high precision – 0.1 degrees, but not for 1 degree differences
- What is the resolution we need to measure the 2.2 degree threshold difference
    - Resolution could be 2.2 degrees
    - Ideally it would be less – look at IR standard resolution value
    - 0.3 degrees for peripheral temperature on foot
- Temperature plan:
    - We could use thermistors and voltage dividers with multiplexor after
    - Do more PoP-type testing will someone's foot against the module for a while to allow temperature to equilibrate
    - Heat up the phantom and do both tests at once? One at room temp and one heated up at increments until we can detect the difference
        - Reach out to DVT group about heating up phantoms
- Stiffness:
    - Make comparative plot of FSR vs gold standard

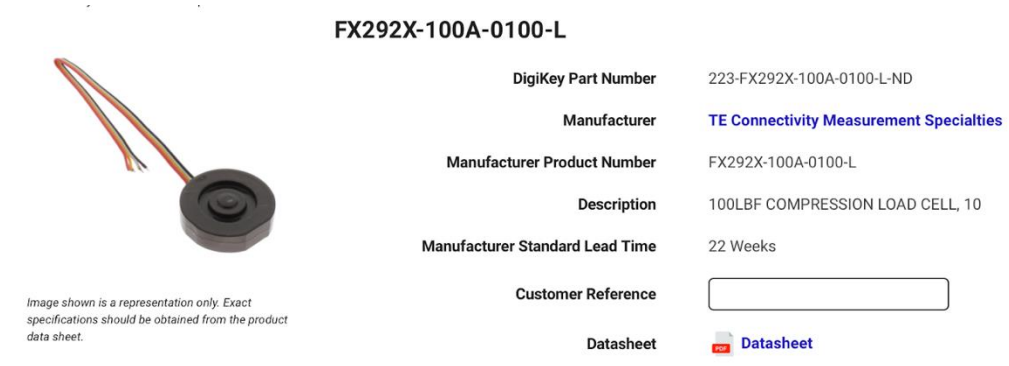
    - Comparative plot of modulus for gold standard vs Hertz method
    - Get load cell Arduino code working
- Strain gauge
    - Meet with Chenhang and Dr. Ni about lab relationship
- Signal processing
    - Teager Energy operator
    - Parseval's theorem
    - Move forward with another sensor
- Presentation
    - Talk about the process: make contact, use force to take modulus value, hold foot on mat to equilibrate temperature sensor

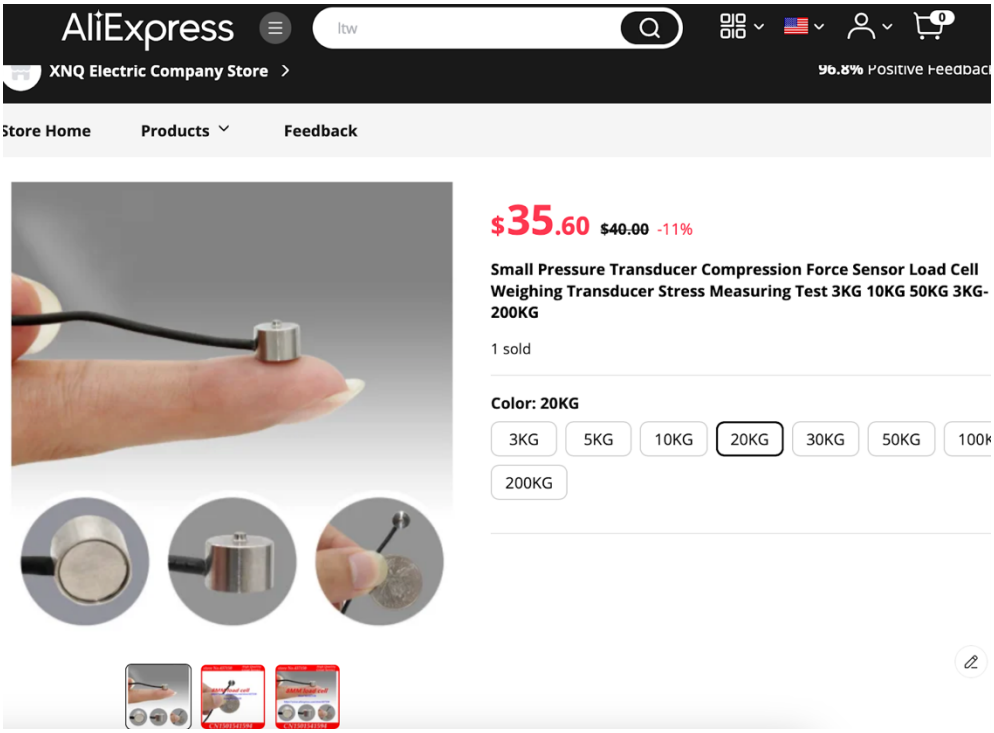
Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 3/21/2024

Meeting Lead: Will Temme
Meeting Scribe: Josh Tennyson

RECAP:
Charge from previous meeting (Team's & Instructors')
Action items

- Discuss feedback on midterm presentation "prototype and testing" section and delve into feedback
    - stiffness
        - "How do you isolate the stiffness of the callus vs the deeper tissues of the foot (e.g., subcut fat)?"
    - temperature
        - "For temp sensing, did you measure across a range of temperature?"
        - "Surprised the thermistor wires were that confounding an aspect of your system"
    - Any other issues with our prototype and testing? Seemed to be one of our weaknesses, as far as instructor evaluation
- Discuss recent purchases and updated plan for indentation testing
    - stiffness
        - Purchased new compressive load cells. Have either of our instructors had experience with such sensors?





  - temperature
    - ordered more TMP117s, but we're approaching our budget cap. For constructing an array, what are expectations regarding the number of sensors we implement? Using more sensors will cost more money.
- Get input regarding constructing overarching project timeline
  - When is the latest we should shoot to have both components of our sensor (temperature and modulus) validated and producing accurate results? (other than ASAP, obviously)
    - 2 wks at end of semester to do last testing
  - When should we begin working on overall, higher-fidelity code flow that guides how a user interacts with our device?
  - Can we discard the functional requirement that indicates our device must interface with clinical systems?
    -
  - At what specific date should we expect a design freeze to occur?

- Discuss expectations about what a final product looks like
    - Can it use an Arduino?
    - What are expectations regarding manufacturing? Is it just expected to have a written plan? Or do we have to modify aspects of our prototype to make it more manufacturable?

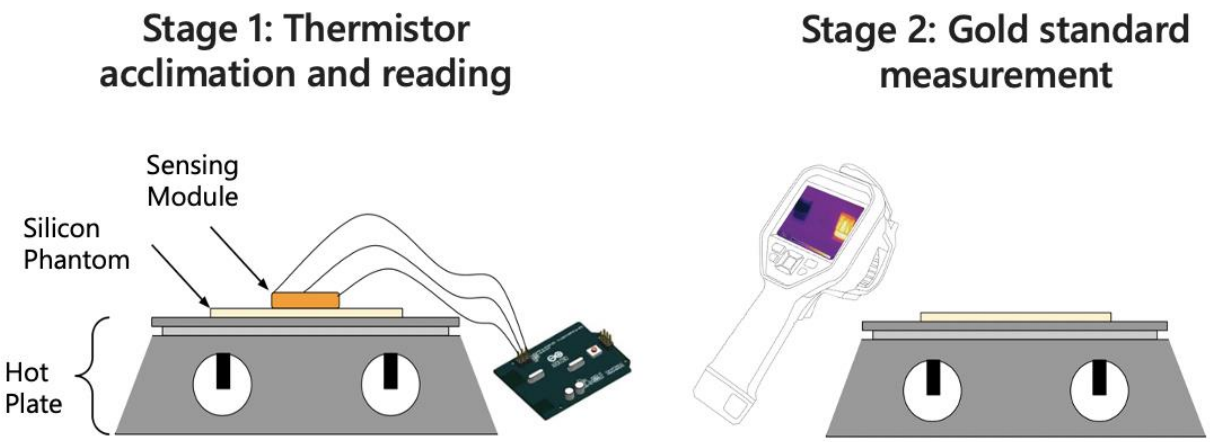
WEEK'S ACTIVITIES:
What's been done and why

Between our last DRM and our midterm presentation, we conducted several experiments with temperature, modulus, load cells, and combined testing. We've already discussed some of these experiments after the presentation, but we are hoping to discuss them in more detail in the DRM to further identify our best steps going forward.

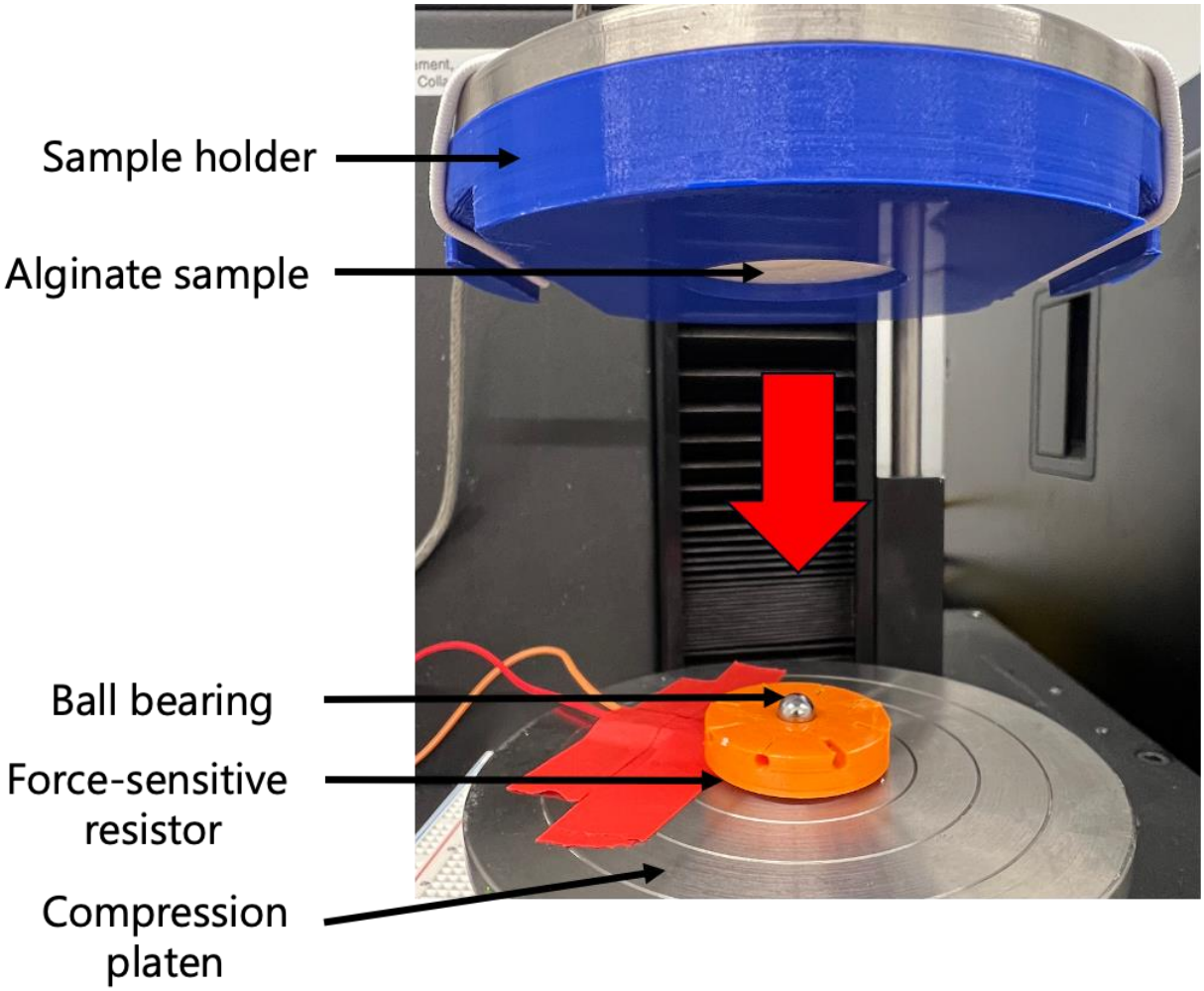
- We repeated temperature testing with a set up involving our silicon skin phantom on a hot plate. The new set up was used so that we could verify that our combined sensor could accurately detect temperature, specifically at the physiological plantar surface temperature, given that our previous testing had confirmed that we could measure a range of temperatures. The temperature was measured with our sensing circuit as well as with the gold standard IR camera.
- Compression tests were conducted and the Hertz contact model was applied.
    - An integrated 3D-printed holder was developed in order to build a chassis to combine the force and temperature sensors. We wanted to check if the increased surface area of the chassis would change the inflection points in our output curves when conducting force testing.
- We attempted to conduct integrated testing, but it was too difficult to maintain the heat of the gels for the duration of testing. Furthermore, the thermistor outputs were unreliable (perhaps due to unstable electrical connections) and the abundance of wires connected to the thermistors sometimes interfered with our mechanical testing
    - We established with instructors that this test was not necessary

Experiments, prototypes (photos, videos, live demos)

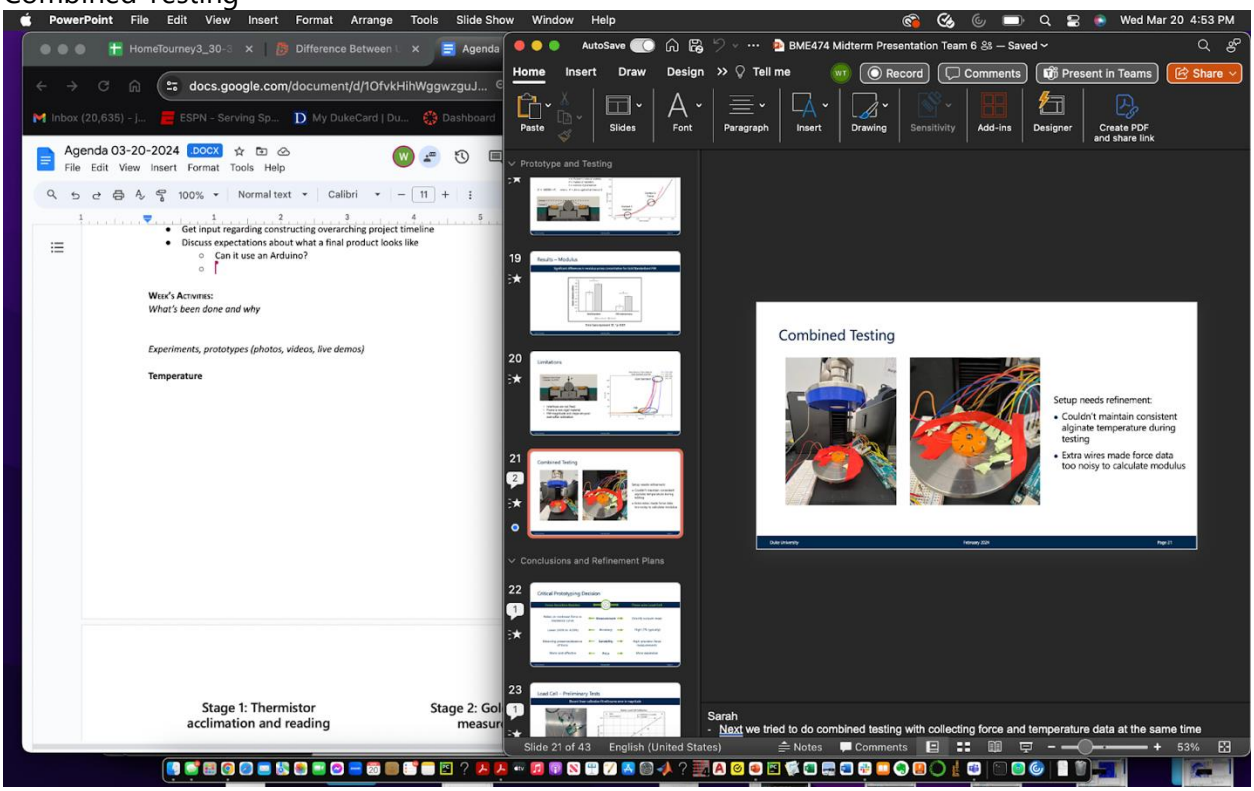
Temperature


Stage 1: Thermistor acclimation and reading
Stage 2: Gold standard measurement
Sensing Module
Silicon Phantom
Hot Plate

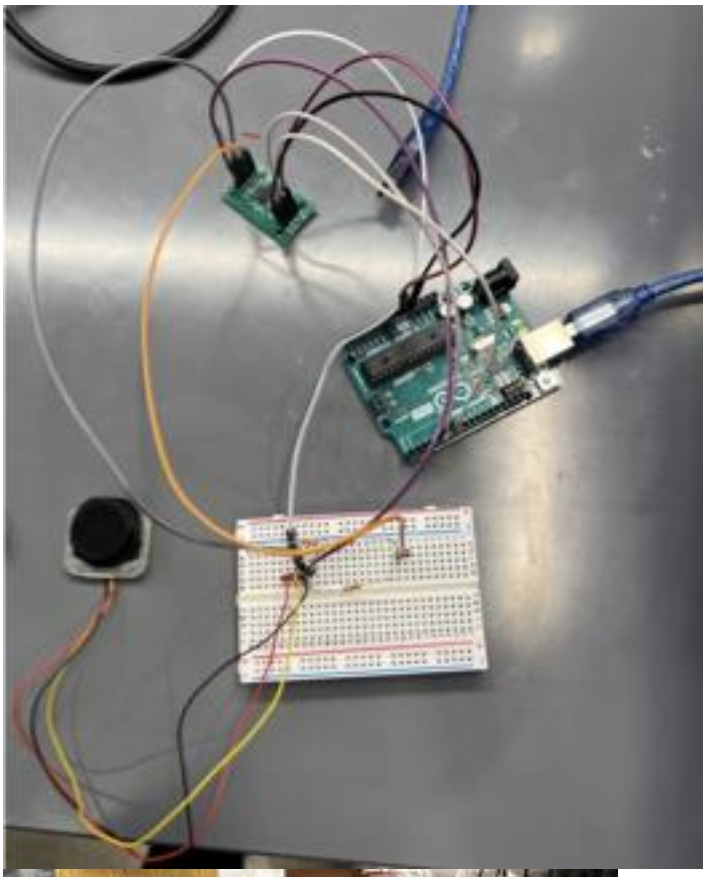
Modulus

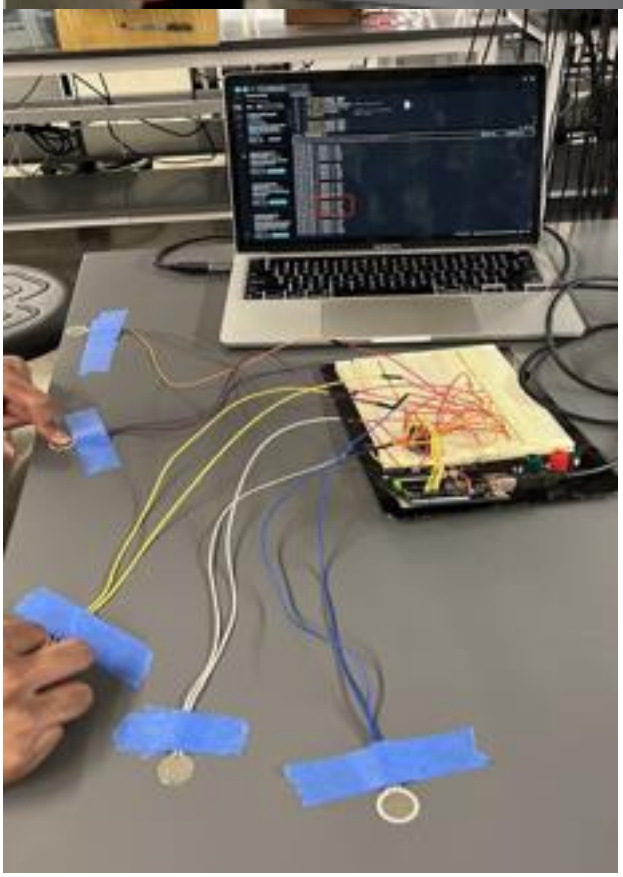

Sample holder
Alginate sample
Ball bearing
Force-sensitive resistor
Compression platen

Combined Testing



Load Cell

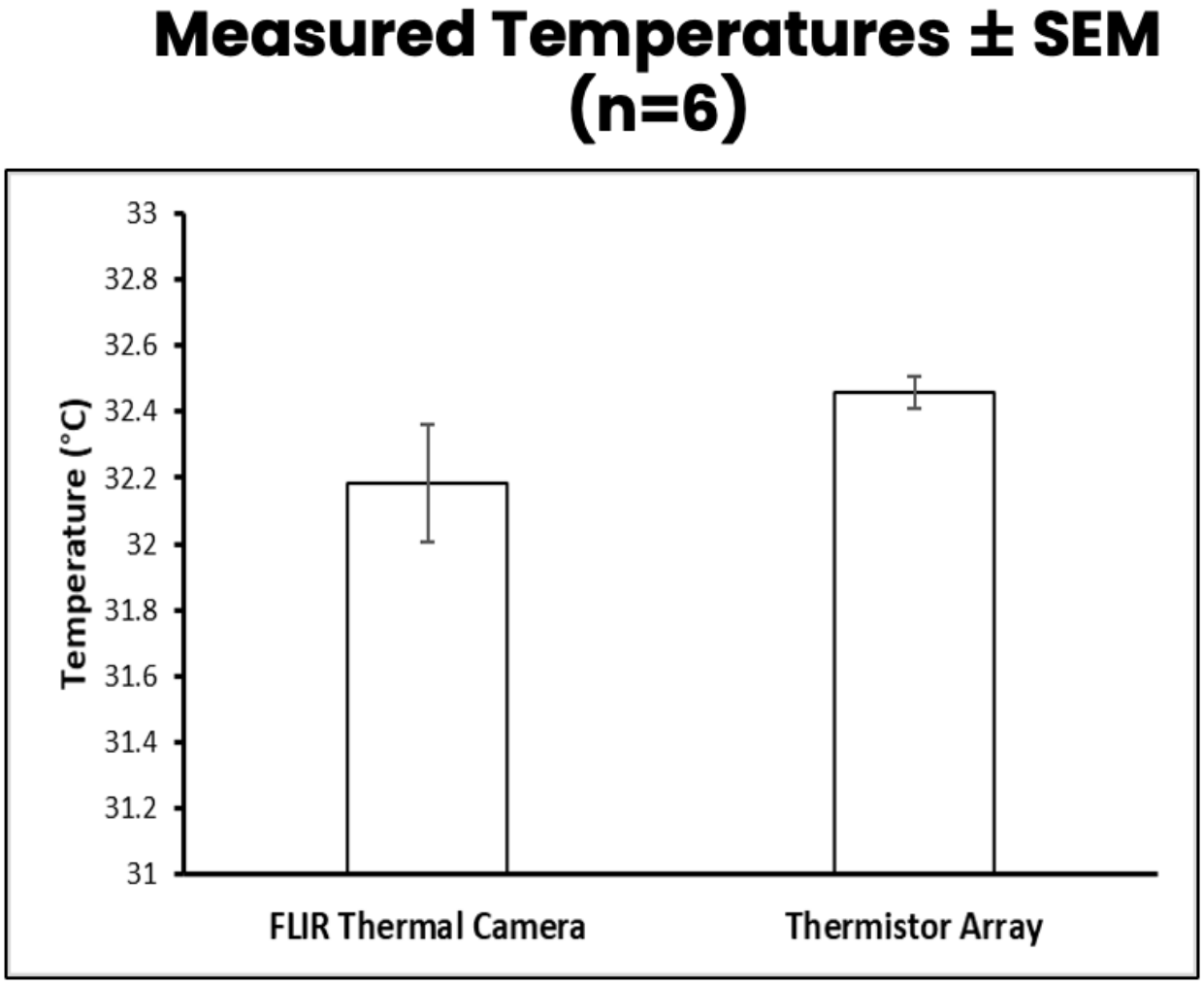


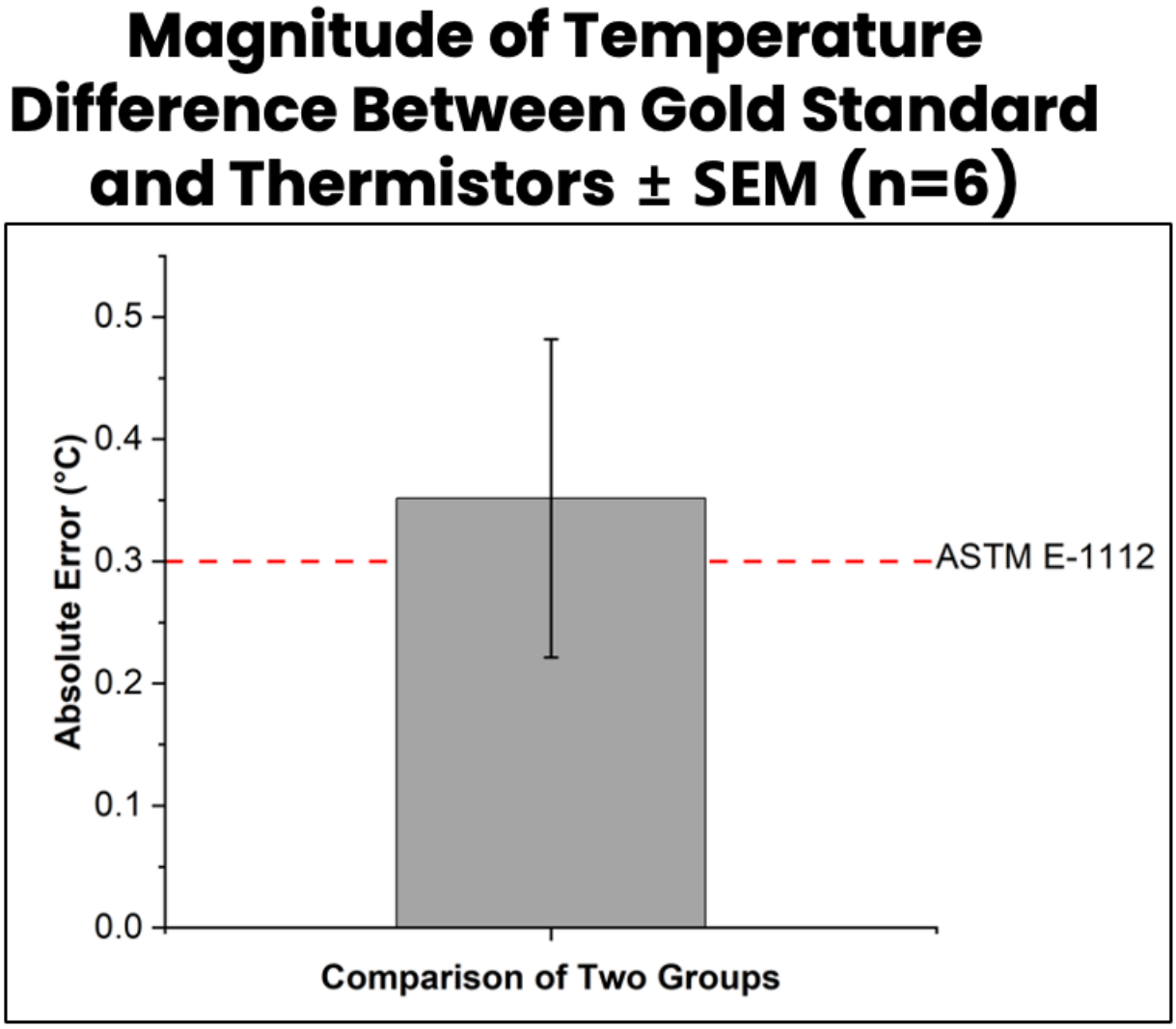


DATA:
Charts, figures, tables w/ stat analysis

Temperature

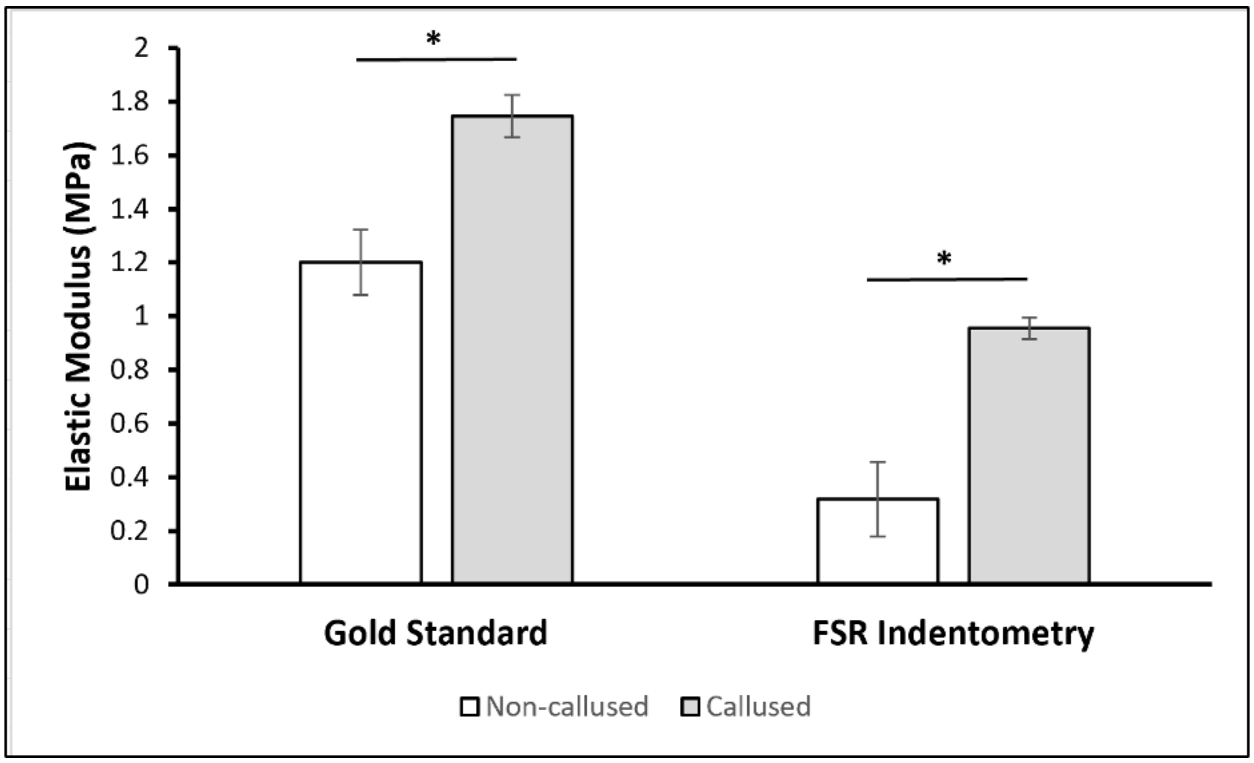
- As can be seen in the plots below, the temperatures measured by our circuit, when compared to the IR camera gold standard, was more precise than the gold standard but toed the line of the ASTM E-1112 standard for accuracy (within 0.3 degrees).

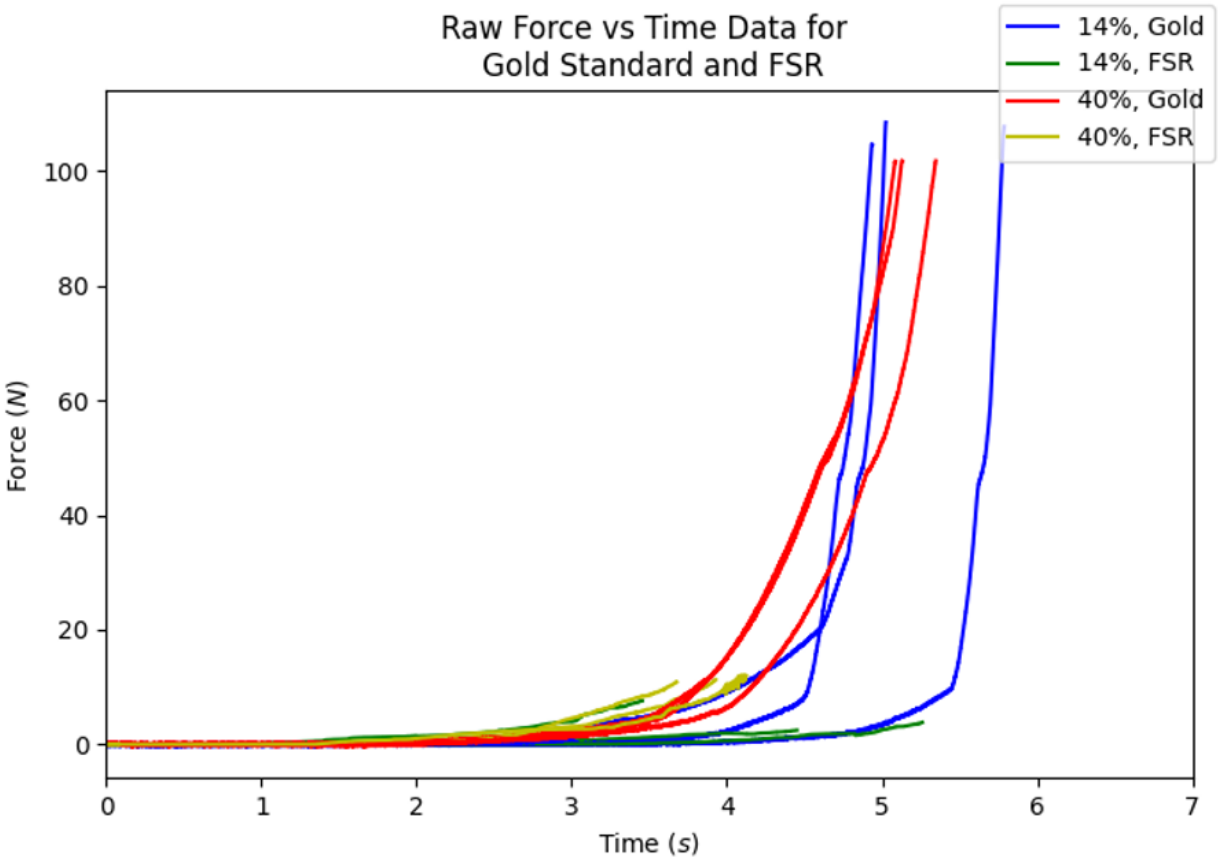




Modulus

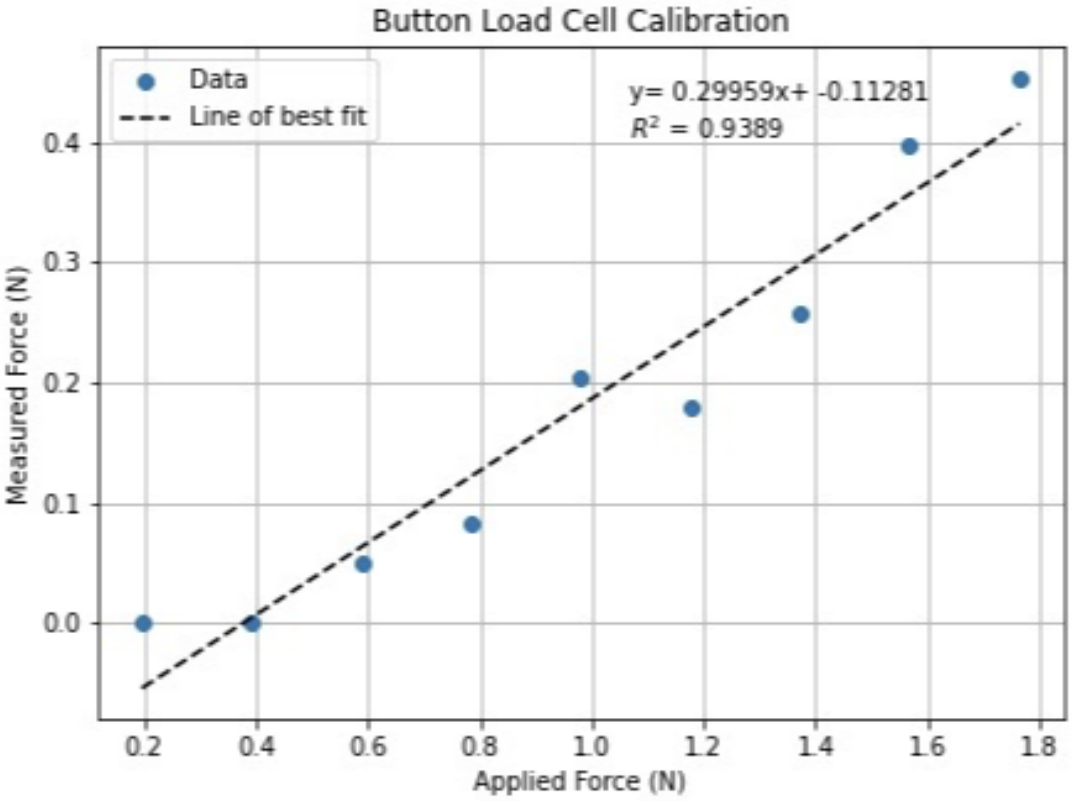
- The below plots show that:
    - The device detected significant differences between non-callused and callused gel representations, but the magnitude and shape of the device curves and the resulting output calculated moduli magnitudes were less. This implies loss or dispersion


Elastic Modulus (MPa)
2
1.8
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
*
*
Gold Standard
FSR Indentometry
Non-callused
Callused


Raw Force vs Time Data for
Gold Standard and FSR
14%, Gold
14%, FSR
40%, Gold
40%, FSR
Force (N)
100
80
60
40
20
0
0
1
2
3
4
5
6
7
Time (s)

Load Cell

- The load cell was calibrated, but it only detected force on select parts of the button.



NEXT STEPS

From Team:

- Test accuracy of compressive load cells once they arrive
    - Refine integrated sensor based on new load cell OR begin fabricating alternative approach for thermistor array
- Continue testing of thermistors to determine if we can get readings compliant with ASTM E1112-00(2018) 4.2

-

TABLE 1 Maximum Error Temperature Ranges

Temperature	Maximum Error
Celsius Scale:	
Less than 35.8°C	±0.3°C
35.8°C to less than 37°C	±0.2°C
37.0°C to 39.0°C	±0.1°C
Greater than 39.0°C to 41.0°C	±0.2°C
Greater than 41.0°C	±0.3°C
Fahrenheit Scale:	
Less than 96.4°F	±0.5°F
96.4°F to less than 98.0°F	±0.3°F
98.0°F to 102.0°F	±0.2°F
Greater than 102.0°F to 106.0°F	±0.3°F
Greater than 106.0°F	±0.5°F

- Begin consolidating and constructing code such that all data processing and user interaction steps can be run on a single arduino
- Begin constructing user interface (LED display)
- After validation of sensors for both biomarkers, create higher fidelity, integrated prototype

Milestones:

- Tested integrated sensor
  - Tested thermography component of integrated sensor
  - Tested integrated sensor's modulus measurement capabilities
- Tested load cell force output to determine if reliable numbers could be derived
- Examined inflection point magnitude for > SA indenter frame

Kanban board: https://trello.com/b/wjGsrVLe/team-6-josh-will-sarah-kishen

From Instructors:

- Test load cells
- Test temperature with skin phantom
- Integrate force and temperature components

BREAKDOWN OF WORK:

Who did what

- Temperature
  - Will took the lead
- Load Cells
  - Josh and Kishen took the lead
- Mechanical testing and combined testing
  - everyone

- Mechanical testing analysis
    - Sarah

Meeting Notes:

- Do research into how consistent the placement of the toes is for both big toe and small toes
    - Consider data about high risk areas of the foot/toes as defined by the literature
- Consider customizability/manufacturability of device
    - Don't need to have this implemented into final prototype
    - Need a well-formed written idea about how to produce large scale and how customer interacts with the device
    - Touch base next week
- How will we encourage repeatability of measurements for one patient?
    - Consider having a divot that allows the foot to settle at the bottom (different sizes of shoe)
- Is it worth improving the resolution of the thermistor even more?
    - Do a t-test to see whether mean and stdev are significantly different from the standard
    - Less of a worry than integration, modulus testing
- Final prototype should show temperature/modulus map to prove that we are able to accurately measure
    - Should show more than what a final patient would see (ie. red, yellow, green)
    - Live demo with foot-like object to place on mat with different stiffnesses
- Interfacing with clinical systems
    - Don't get rid of it entirely
    - Can still have a very successful prototype if we don't address this at all
    - Ideal solution would be a USB flash drive
- Code timeline
    - If we have an idea of what the person-machine interface will look like, we should start coding this now

Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 3/28/2024

Meeting Lead: Kishen Mitra
Meeting Scribe: Josh Tennyson

RECAP:
Action items

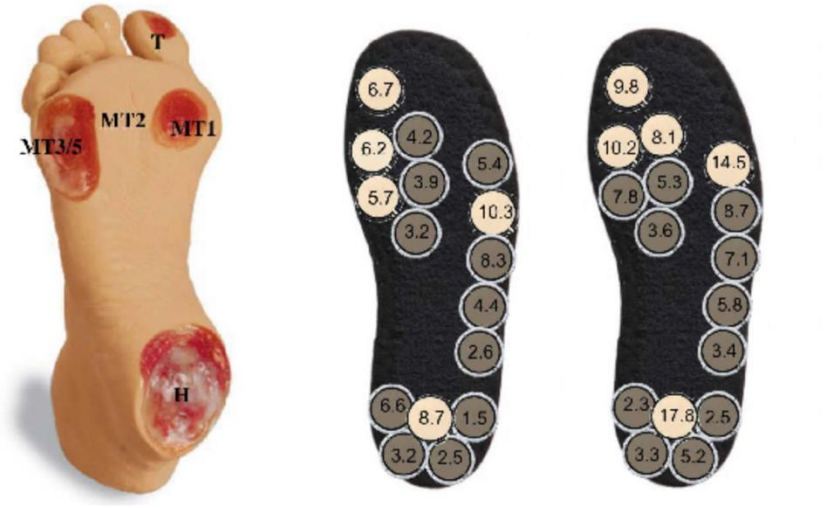
- We established a plan to ensure repeatability of modulus measurements. We hope to get instructor feedback about this
- We gathered evidence of key areas to monitor for DFU incidence. We hope to confirm whether our plan to use these data to inform our sensor layout is appropriate

- We want to discuss expectations regarding when we must establish a plan for manufacturing/reproducibility.
- We are combining our sensing and analysis code files to create a singular code pipeline to collect and process data with our Arduino microcontroller to incorporate into the final device

WEEK'S ACTIVITIES:

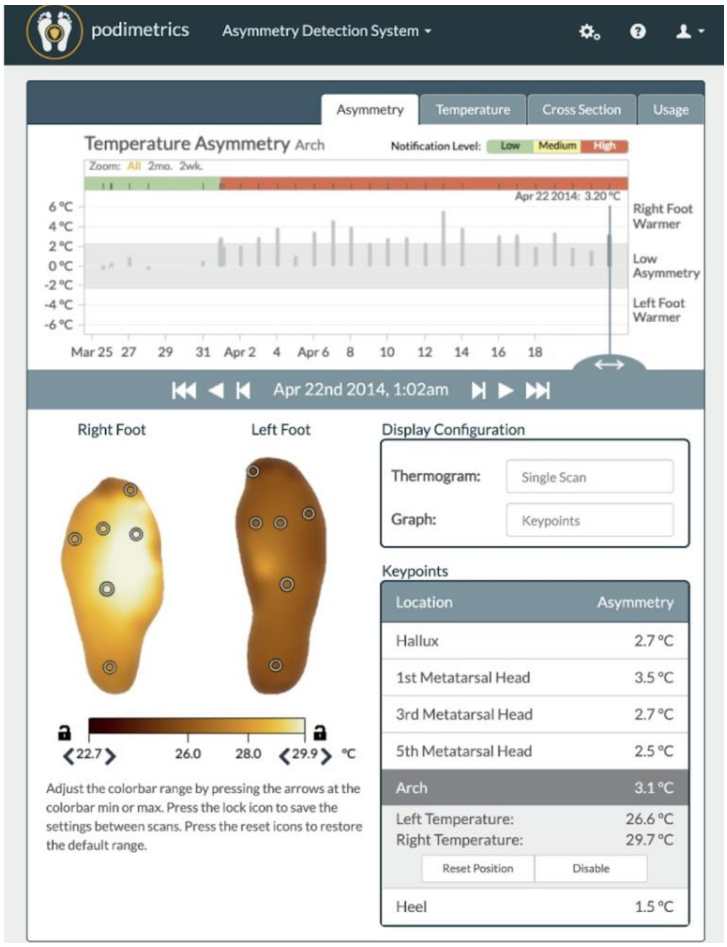
What's been done and why

- We established key areas on plantar surface (i.e., areas with high DFU risk) for surveillance, which informs sensor density in different locations of the device. A literature review was conducted to determine optimal sensor placement. Here are key findings:
    - We learned that numerous existing solutions increase sensor density on metatarsal heads, the hallux, the heel, and the lateral midfoot.



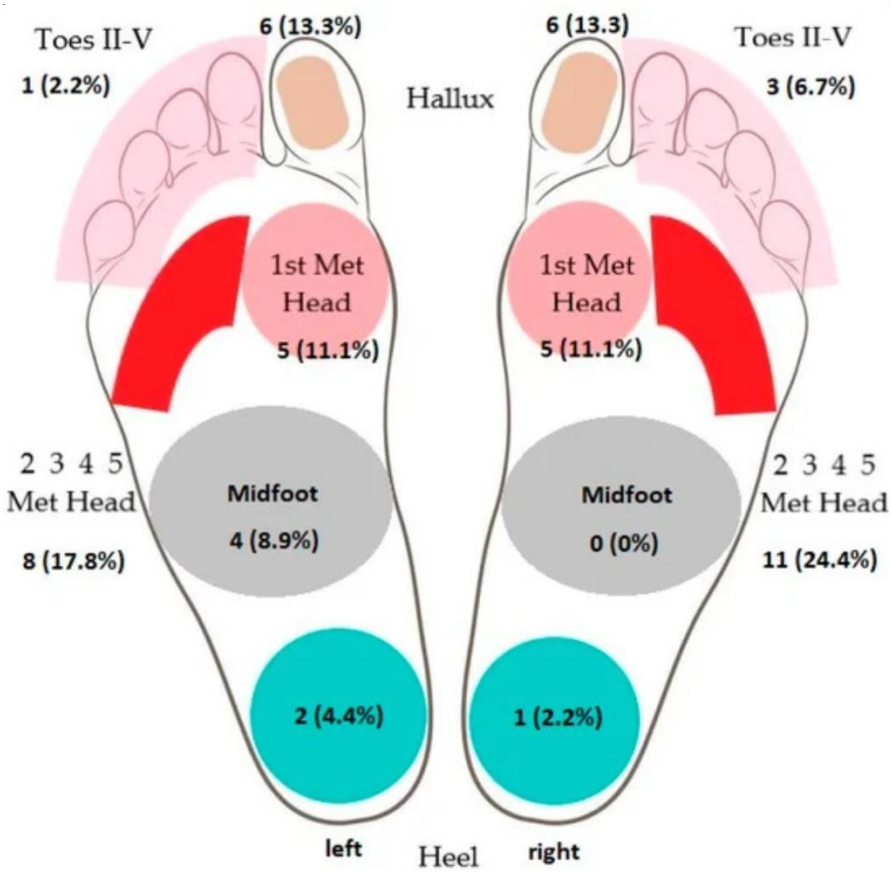
(a) High risk regions (b) Force readings (lbs) from two different subjects

- (https://pubmed.ncbi.nlm.nih.gov/23367463/)

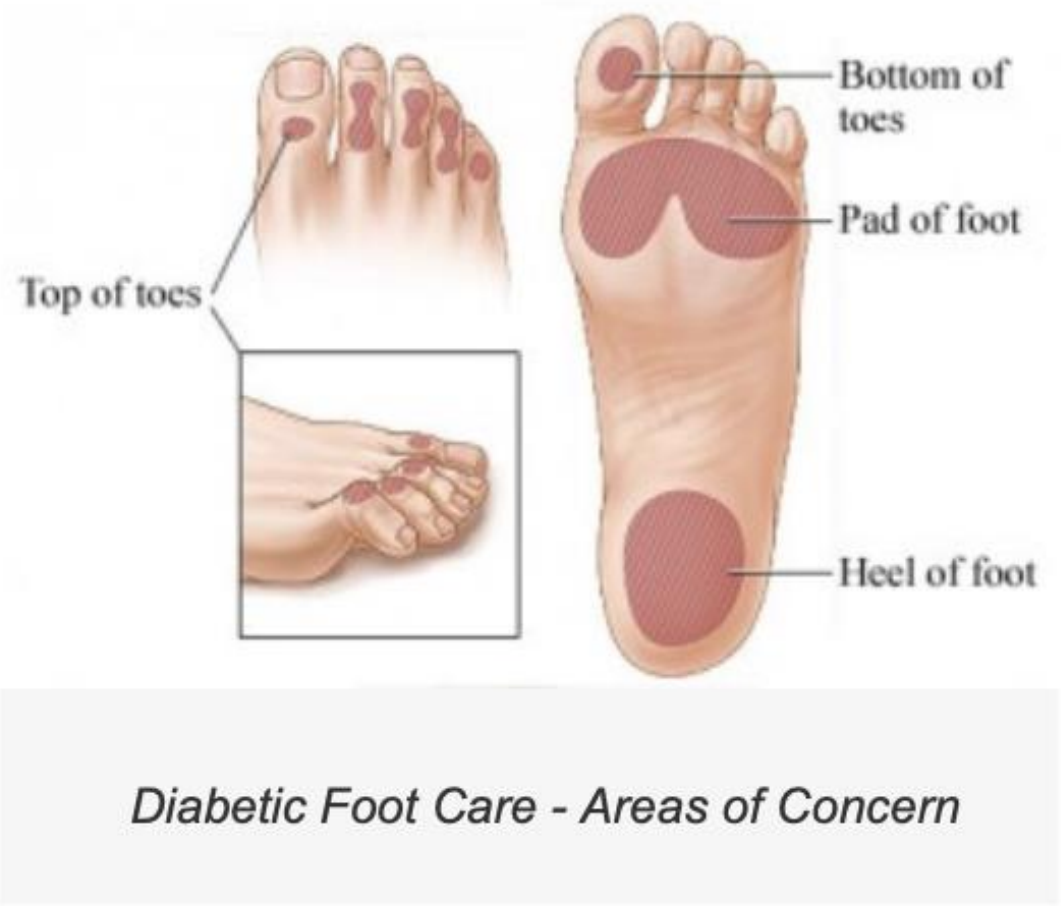


- Podimetrics mat (industry leading DFU monitoring device) has elevated sensor density at the circled locations above

- Finally, we learned that DFU occurrence (and peripheral neuropathy symptoms) are most common on the hallux, metatarsal heads, and lateral midfoot



- (https://www.mdpi.com/2077-0383/12/20/6516)
- "Ulceration sites correlate with the highest plantar pressure points." (https://www.tandfonline.com/doi/full/10.2147/vhrm.s12187345)



  - (https://ronaldsmithmd.com/diabetic-foot-care-avoiding-amputation/)
- Select and obtain a Display
  - The most common display types that suit our project needs are OLEDs, graphical LCDs, and TFT LCD displays. Realistically, any of these could be used. However, we hope to begin experimenting with graphical LCDs. They tend to be much less expensive, have relatively low power consumption, are arduino compatible, and are widely used for similar purposes to our own. Their wide use ensures that we will have adequate resources to assist in prototyping.
  - Particularly, the display driver ILI9488 is robustly used. As such, we plan to purchase:

3.5 Inches TFT LCD Touch Screen Shield Display Module 480x320 SPI Serial ILI9488 with Touch Pen Compatible with Arduino R3/Mega2560 Development Board

Visit the Hosyond Store

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Size: 3.5" SPI

2.4" SPI $12.99 | 2.8" SPI $13.99 | 3.2" SPI $15.99 | 3.5" SPI $16.99 | 4.0" SPI $18.99

- 3.5-inch color screen, supports 16BIT RGB 65K color display, rich in color display.

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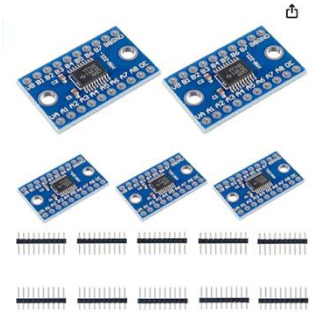
Quantity: 1

- Despite indicating that it is Arduino compatible, the ILI9488 requires a GPIO logic level of 3.3 V. As such, we also plan to purchased logic level converters, which are SPI compatible



TXS0108E High Speed Full Duplex Logic Level Converter 8 Channel SPI 8 Way 3.3V 5V IIC 8-Bit Bi-Directional Converter Module Apply to Raspberry Pi and Arduino (Pack of 5 Set)

Brand: EPLZON

4.1 ★★★★☆ 26 ratings | Search this page

$7.99 ($1.60 / Item)

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- ✅Provide two-way communication capabilities,OE active high enable IO recommended by a low voltage side of the IO port.
- ✅ Supply voltage VA:1.2V to 3.6V - VB: 1.65V to 5.5V.
- ✅ Allows the use of 5V modules on 3.3V microcontrollers, or 3.3V modules on 5V microcontrollers.
- ✅ Supports SCM, I²C, SPI.
- ✅Widely used in the MCU and SD card, MCU and serial devices,MCU and 5V/3V module communiction.

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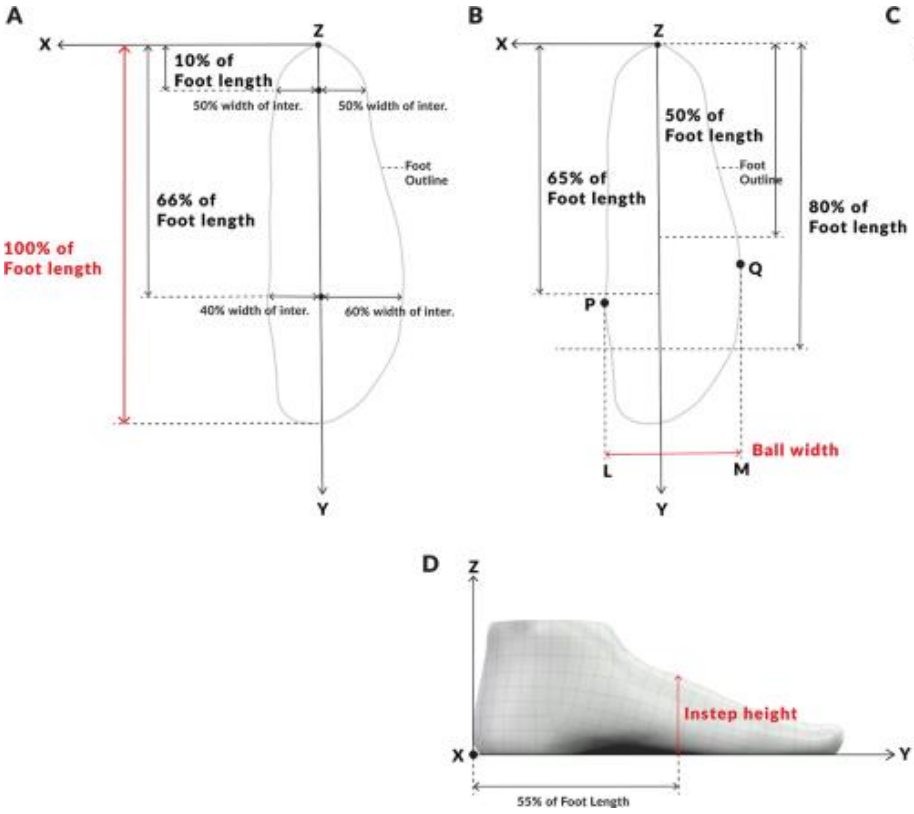
- To save money, we also began exploring existing displays in Teer, though they tend to be a bit less convenient to work with

- Created an Arduino file to process force readings using Hertz spherical indentation method without external data processing in python
  - The original Arduino file output force readings. Data was processed in an external python script to analyze and process it to create plots.
    - This external python script had the conversion that used the Hertz method that enabled us to get modulus
  - In order to make it so that the entire sensing-to-alerting pipeline could be incorporated into our final device, we have been combining code files so that we can have a singular Arduino file that can collect data from sensors, process it, analyze it, send out necessary alerts, and then loop
  - Modulus data will be collected for some time period, then temperature data will be collected, then processing will occur, then alerting will occur if needed, and then it will loop
- Researched and designed user workflow. Begin working on arduino code to implement such a workflow
  - When no weight is placed on the mat, the strain gauge of the load cell(s) remains in their original shape, and the circuit experiences minimal change in resistance. To conserve battery life, the mat will enter a “low-power mode.” In this mode, the display will be off, and the internal processing might be limited.
  - When the user steps on the mat, the strain gauge bends, causing a significant shift in its electrical resistance. This change is instantly detected by the circuit,

which triggers the mat to turn on completely. The circuit then processes the signal from the strain gauge, converts it to a force (and then to an elastic modulus in our case), and displays data on the screen.
    - Once user steps off the scale, the strain gauge will return to its original shape. The circuit detects a return to normal resistance, and the mat understands there's no foot to be measured. After a pre-determined time (usually a few seconds), the mat will go back into the low-power mode.
    - We may also be able to leverage the contact pressure sensors to trigger the "on-off" functionality of the device. Would this be a more realistic/feasible strategy?
    - Is this automated workflow necessary? Or can part of the device instructions for use be to press a button?
- Began designing physical components to stabilize foot and ensure controlled placement onto indenters
    -
    - Outlined the patient workflow from start to finish
        - Since the display is small/far away and we are working with a generally elderly population, one instruction step at a time will be displayed on the screen.
        - How will we know if the patient has completed the alignment steps? Is it worth embedding sensors/code to automate this, or can we have a button/timer to move on?
- Manufacturability/generalizability
    - Eliminating the extra toes significantly reduces the degrees of freedom for variability between patients, which makes generalizability more accomplishable
    - Foot shape/size research: https://www.nature.com/articles/s41598-019-55432-z



- Remaining degrees of freedom include:
  - Foot length (by shoe size or S/M/L, like socks)
  - Foot width (narrow, normal, wide)
  - Heel width (narrow, normal, wide)
  - Instep height (flat, normal, arched)
- Assumptions:
  - Foot proportions remain relatively constant in the heel/ball/hallux region
  - Patients do not have a flat foot
  - Patients do not have hammer toes

NEXT STEPS

From Team:

- Test accuracy of compressive load cells once they arrive
  - Refine integrated sensor based on new load cell OR begin fabricating alternative approach for thermistor array
- Establish the final form of our thermistor setup (i.e., what layers will be between our sensors and the user's tissue) and continue testing of thermistors to determine if we can get readings compliant with ASTM E1112-00(2018) 4.2 using such a setup

-

TABLE 1 Maximum Error Temperature Ranges

Temperature	Maximum Error
Celsius Scale:	
Less than 35.8°C	±0.3°C
35.8°C to less than 37°C	±0.2°C
37.0°C to 39.0°C	±0.1°C
Greater than 39.0°C to 41.0°C	±0.2°C
Greater than 41.0°C	±0.3°C
Fahrenheit Scale:	
Less than 96.4°F	±0.5°F
96.4°F to less than 98.0°F	±0.3°F
98.0°F to 102.0°F	±0.2°F
Greater than 102.0°F to 106.0°F	±0.3°F
Greater than 106.0°F	±0.5°F

- Continue consolidating and constructing code such that all data processing and user interaction steps can be run on a single arduino
- Prototype selected user interface (OLED or TFT LCD display)
- After validation of sensors for both biomarkers, create higher fidelity, integrated prototype
- Continue creating code to implement user workflow
    - Integrate LCD display into this process. Create graphic to display temperature and elasticity data
- Establish and implement data output mechanism (for "interfacing with clinical systems") using one of the below
    - output to other machine using Wi-Fi/Bluetooth compatible Arduino or microcontroller (e.g., ESP32)
    - load data into an SD card or USB stick
    - transmit from microcontroller to other machine using wired connection
- Implement multiplexer chaining

Milestones:

- Most of the sensors (except for one of our compressive load cells) arrived on Wednesday (the day before our DRM)
- Selected display
- Established user workflow
- Refined analytical capabilities of Arduino script, allowing it to interpret data independently

Kanban board: https://trello.com/b/wjGsrVLe/team-6-josh-will-sarah-kishen

From Instructors:

-

BREAKDOWN OF WORK:
Who did what

- Sensor/DFU localization research
  - Will, Sarah
- Display research
  - Will
- User workflow planning
  - Sarah, Kishen
- Converting python data analysis script to Arduino
  - Josh

Meeting Notes:

- Save customization stuff for future steps; can do it for most common shoe or foot size for now
- focus on core functionalities for now; leave customization out
- automation (although industry standard) is a lower priority at the moment
- Final prototype testing
  - liquid bandage to create pockets on the phantom and then infuse hot water
  - need to combine tests
  - have person place foot on hot pad or restrict blood flow, then place feet on mat to pick up temperature differences
- durometer in room Wilk 127 from richardson
- An alternative to reporting sensitivity and specificity of device could be to compare our indentometry/thermography readings to durometer and IR camera readings. Show what the delta is to these benchmarks
- Need to focus on automating the process of taking force measurement at the time of contact

Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 4/4/2024

Meeting Lead: Kishen Mitra
Meeting Scribe: Sarah Glomski

RECAP:
Action items

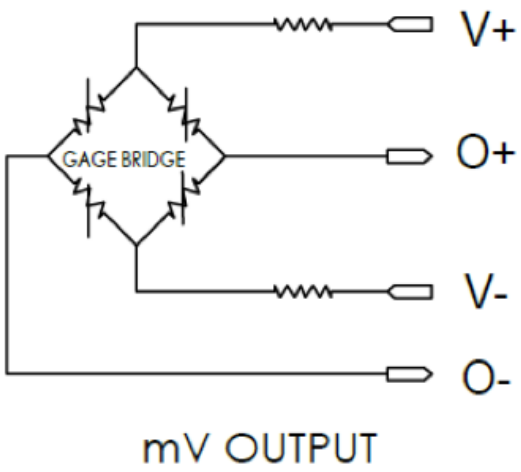
- We hope to discuss what a good user-perceivable output would be. This is partially hypothetical, given that we currently hope to display an output that would be valuable to someone evaluating our technology (i.e., a heatmap)
- We want to review our proposed testing setup

- Reevaluate how we can improve our progress a group to align with expectations

WEEK'S ACTIVITIES:
What's been done and why/Experiments, prototypes (photos, videos, live demos)

https://youtube.com/shorts/qop9WFbjGEI

- Successfully implemented the FX29 analog compressive load cell in a signal processing circuit (see video above)



  -
  - The problem: Load cell has an internal wheatstone bridge. The component was designed such that forces applied (at our scale) produced raw signals that were not detectable by an arduino. In other words, the component had too low of a sensitivity to get a meaningful reading, given the arduino's ADC resolution. Furthermore, the "zero offset," or the differential reading (between O+ and O-) in the state in which no load was applied, was approximately 20x as large as the detectable change in raw output when applying forces by hand. Finally, the signal was somewhat noisy – it had periodic oscillations due to room noise.
  - The solution: simply applying a gain to the raw sensor output would be insufficient. In this case, noise and the zero offset would be amplified in such a way that the signal would no longer be readable by an arduino. Thanks to the help of Dr. Kyle, we crafted a signal processing circuit to circumnavigate these issues. The circuit included a pre-amp (AD623), passive low pass filter, and gain stage (implemented with MCP6002). The output of the pre-amp was the difference of the two outputs from the wheatstone bridge. The low pass filter then (partially) eliminated room noise. This step needs optimization. At this point, the output of the circuit was a de-noised, shifted difference. Finally, this signal was fed into a gain stage with a reference voltage as close as possible to the vertical shift in the signal output by the last step. Note that the reference voltage was not exactly V+/2, but rather a value that was obtained experimentally based

on the measured offset of the signal being fed into the op amp. Also note that this reference voltage could be further optimized.
        - The final output of this signal processing circuit was a signal that was adequately sensitive (a perturbation of ~30% of the full scale voltage range could be created with my hand) and did not have an awful 0-offset. Again, this can be optimized further.
    - See the video above for demo of implementation. Note that the sensor was being powered with 10V and the oscilloscope was set to have a scale of 2V
- Built on integration code from last week by implementing an analysis to user interface output pipeline. This code still needs to be validated in a sensor setup - as of now, it essentially outlines the logic for our final workflow.
    - Stores moduli and temperatures from over the past month, collecting data once every 6 or 12 hours
    - Compares newly collected moduli and temperatures to the distributions of past moduli and temperatures from the past month to determine whether it should be flagged as high or moderate risk
        - High temperature alone is moderate risk
        - High temperature and higher modulus is high risk
    - If there are 3 flagged time points, then it is output to the user and PCPs
        - Current output is a ternary signal of risk - high (red), medium (yellow), low (green)
        - Ultimate goal would be to output a heat map using an array of modulus and temperature collections. Each point in the heatmap would be one ternary output outlined above
- Brainstormed foot phantom for testing
    - Silicone has been selected as the skin-like material that will surround our foot phantom.
    - To simulate a rise in local temperature, a miniature hot plate will be incorporated into the phantom so that it is mobile. A CAD structure would hold the hot plate in place so that it can heat up the silicone sheet. Styrofoam will be added as necessary to create a realistic heat distribution on the silicone surface.
        - There will be six “pockets” where the hot plate can be inserted to to simulate the six high-risk areas that will be monitored by our device
    - To simulate a rise in local modulus, fast-drying two-part epoxy will be used. The epoxy will be applied to one of the six high-risk regions on the foot to simulate the presence of a callus.
        - This is a quick and effective way to create a difference in elastic modulus in a concentrated region of the plantar surface of the foot

- Orders placed:
    - For testing phantom:
        - Silicone sheets
        - Fast drying epoxy

- Mini hot plate
- Foot warmer packs

NEXT STEPS

From Team:

- Compression load cell
  - Optimize signal processing circuit described at the start of the document
  - Develop Arduino script for this load cell (current work has involved an oscilloscope for debugging purposes)
- Establish the final form of our thermistor setup (i.e., what layers will be between our sensors and the user's tissue) and continue testing of thermistors to determine if we can get readings compliant with ASTM E1112-00(2018) 4.2 using such a setup
  -

TABLE 1 Maximum Error Temperature Ranges

Temperature	Maximum Error
Celsius Scale:	
Less than 35.8°C	±0.3°C
35.8°C to less than 37°C	±0.2°C
37.0°C to 39.0°C	±0.1°C
Greater than 39.0°C to 41.0°C	±0.2°C
Greater than 41.0°C	±0.3°C
Fahrenheit Scale:	
Less than 96.4°F	±0.5°F
96.4°F to less than 98.0°F	±0.3°F
98.0°F to 102.0°F	±0.2°F
Greater than 102.0°F to 106.0°F	±0.3°F
Greater than 106.0°F	±0.5°F

- Continue creating code to implement user workflow by adding more sophisticated user interface outputs
  - Integrate LCD display into this process. Create graphic to display temperature and elasticity data
- After validation of sensors for both biomarkers, create higher fidelity, integrated prototype
- Design and 3D print a frame/construct that can be placed around the load cell to adapt the spherical indenter to the force sensor, while also integrating thermistors and a touch sensor for contact sensing
- Establish and implement data output mechanism (for "interfacing with clinical systems") using one of the below
  - output to other machine using Wi-Fi/Bluetooth compatible Arduino or microcontroller (e.g., ESP32)
  - load data into an SD card or USB stick
  - transmit from microcontroller to other machine using wired connection
- Implement multiplexer chaining

Milestones:

- The signal processing circuit for the compressive load cell was developed and validated
- Selected display (TFT LCD display)
- Established user workflow
- Refined analytical capabilities of Arduino script, allowing it to interpret data independently and output a rudimentary output signal for the users. Implemented modular design (one load cell, 3 contact sensors, and 4 thermistors in one module to be placed in one region of the foot) with muxes into our code workflow
- Began CAD of foot phantom structure

Kanban board: https://trello.com/b/wjGsrVLe/team-6-josh-will-sarah-kishen

From Instructors:

- Focus on integrating subsystems into one complete unit, i.e, a mat or platform with the ability to interrogate stiffness and temperature
- Determining testing apparatus, i.e., mannequin foot with stiff pads in target regions or local warming
- Order backup load cells (at least 10% more than needed for a single device)

BREAKDOWN OF WORK:

Who did what

- Load sensor circuit design
    - Will
- Prototype testing protocol
    - Kishen and Sarah
- Integration, analysis, and user interface code
    - Josh

Meeting Notes:

- Look into heated hunting socks on Amazon
    - If this doesn't work, need to design a setup that intersects the 2.2 degree range, measures temperature in chunks and alerts when this passes 2.2 degrees
- Get durometer, variable 2-part silicone, create silicone molds of different hardnesses
    - Measure shore hardness with durometer
    - Shore A (soft) to modulus conversion
    - Determine which concentrations are within physiological range
    - Normal shore durometer is around A40

Shore A	Modulus (MPa)
31.3	1.1
40	1.35
60	2.16

62.7	2.3

- Testing should focus on asymmetry analysis rather than historical comparisons

Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 4/11/2024

Meeting Lead: Kishen Mitra
Meeting Scribe: Sarah Glomski

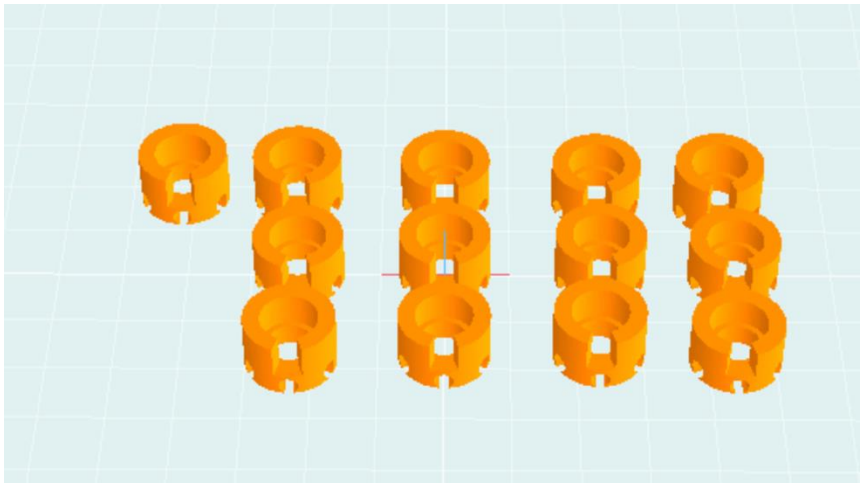
RECAP:
Action items

- We want to discuss:
    - Mat implementation approaches and ideas
        - Backing, elevation, wiring, etc
    - Testing expectations
        - what needs to be tested and to what degree. What statistical analyses need to be performed
    - Display expectations

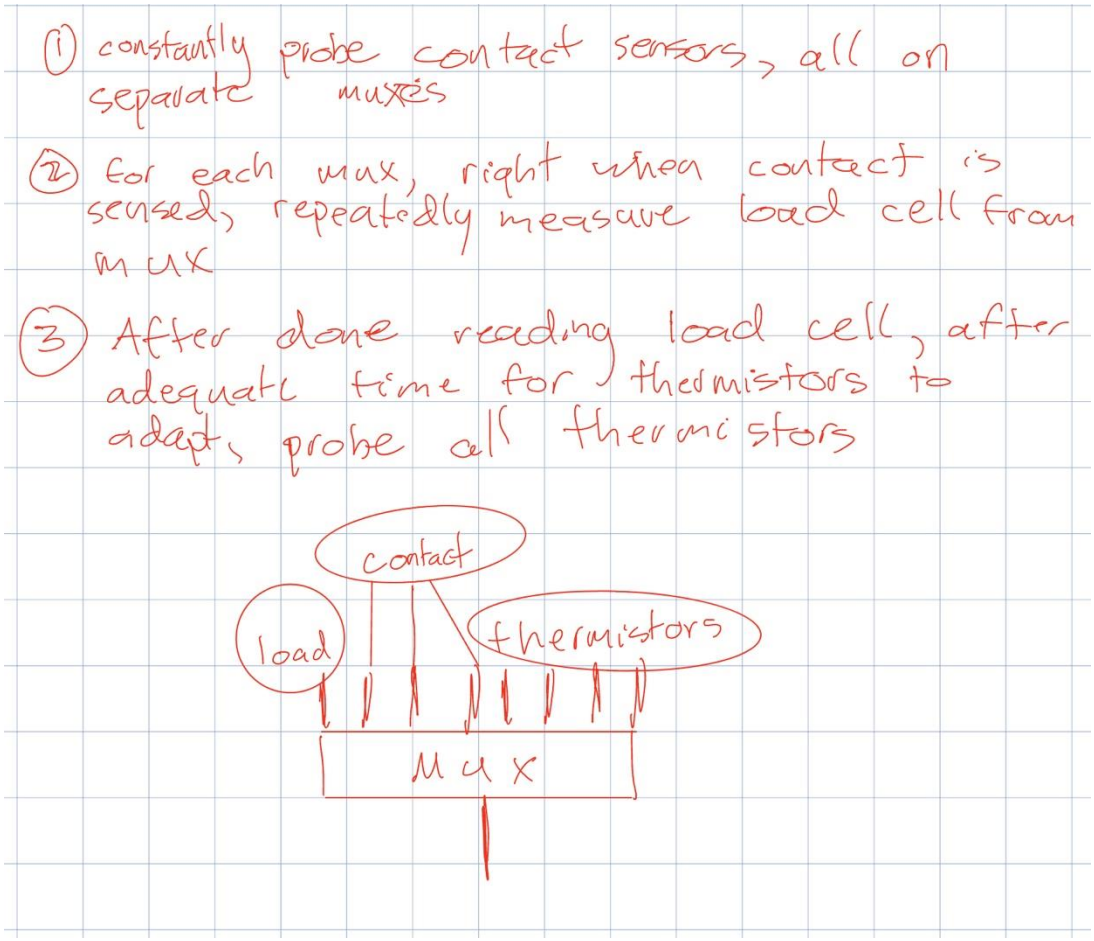
WEEK'S ACTIVITIES:
What's been done and why/Experiments, prototypes (photos, videos, live demos)

- Load cell
    - Circuit
        - https://youtu.be/3-fgPKqFyXw
        - Created signal processing circuit for DYHW-108 load cell
            Pre amp (with maximized gain)
            Low pass filter
                - Particularly necessary when powering with an arduino

            Gain stage
                - tuned to map voltage output to desired force range
        - Circuit is now optimized such that the 0-70N range of expected forces is mapped to an output of 0 to ~5 V
            pre amp and gain stage reference voltage close to 5V. Zero load signal is approximately 5V; applying load decreases voltage output
    - Mechanical Hardware (3 iterations, each with many different tolerance options)
        - Designed and 3D printed a frame/construct that can be placed around the load cell to adapt the spherical indenter to the force sensor, while also integrating thermistors and a touch sensor for contact sensing
        - Final iteration:



- Code (pseudocode for script included at end of document)
    - Developed Arduino script for this load cell (moved from oscilloscope to Arduino script similar to that of FSRs)
    - Script implements modular multiplexing design for data collection, implementing three full modules
        - Collects after FSRs detect contact (tuned contact threshold with experimentation)
    - Script outputs 2D array that will be turned into a heatmap for temp/modulus
- Modular Design (and implementation): Multiplexing Basis
    - Idea:

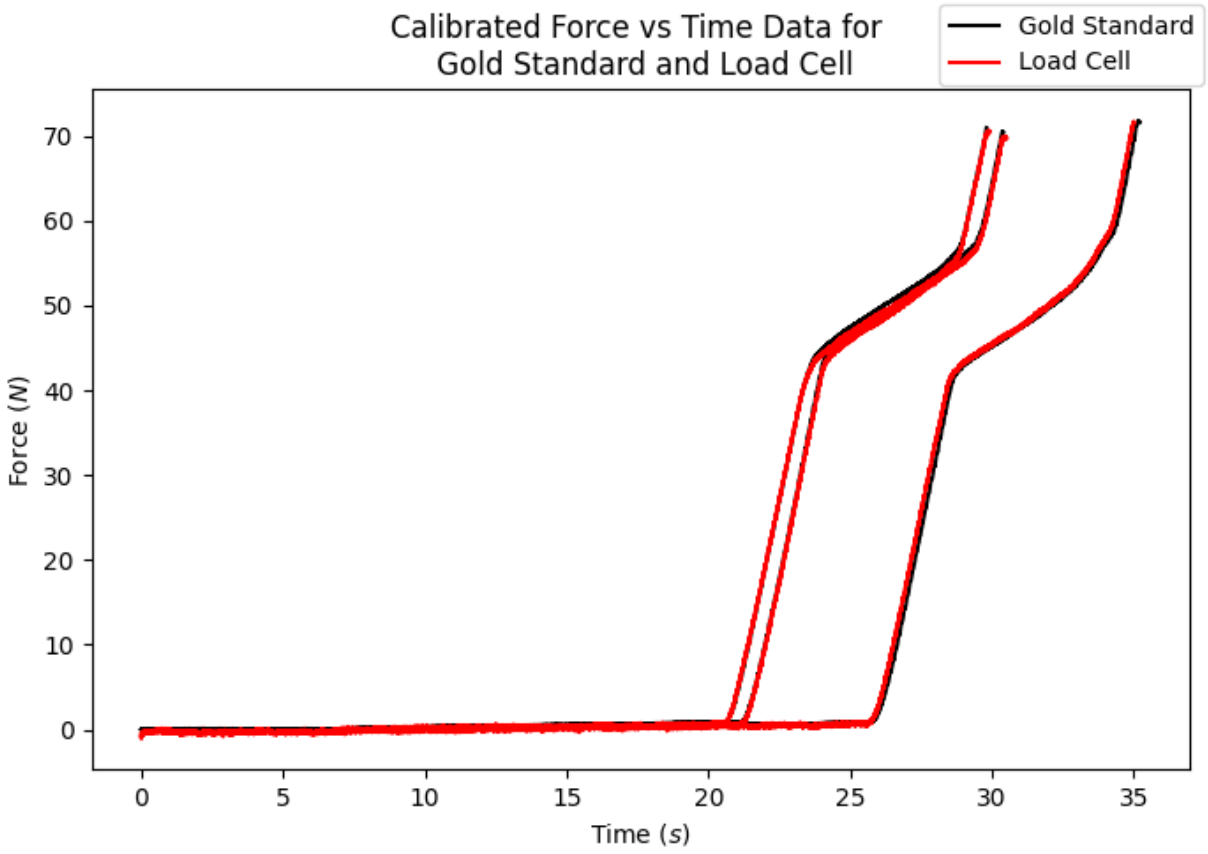


    - Implementation for a single module
        - Mux input 0: load cell
        - Mux inputs 1-3: FSRs
        - Mux inputs 4-11: thermistors
    - This modular design was implemented into the code and a single module was designed in circuitry for testing purposes
- Load cell calibration
    - Designed a test setup to calibrate the load cell based on the load cell within the gold standard Test Resources machine.
        - https://youtube.com/shorts/hjbJnY6EydU
    - After tuning the gain of the load cell circuit to yield the appropriate range of force values, 3 trials were performed where the compression platen applied 70 N of force to the ball bearing on top of the load cell.
    - The traces from the gold standard and the load cell were lined up and interpolated to have matching timestamps. Then, a 2-parameter least-squares optimization was performed to generate scale factors to transform the load cell data to match the gold standard data. After averaging across the 3 trials, the 2 parameters were found to be:

        Calibration Factor 1 (slope): 16.4 ± 0.19

        Calibration Factor 2 (intercept): -1.55 ± 0.24

- The scaled data from the load cell as well as the unscaled gold standard data is shown in the plot below:



- Modulus validation testing
  - Designed a test setup in which a container holds silicone of different durometers. The case can be lowered onto the sensing module by hand to simulate the lowering of the foot onto the device.
  - The sensing module was tested using A-60 durometer silicone (which corresponds to a modulus of 1.07 MPa) and A-30 durometer silicone (which corresponds to a modulus of 2.16 MPa). The mapping between durometer values and modulus values was outlined by the following equation:

    Shore-A to Young's Modulus (in MPa):
    =EXP((Shore-A Durometer)*0.0235-0.6403)

    Source: https://www.cati.com/blog/convert-durometer-to-youngs-modulus/

- 
- Contact Detection Testing
    - Implemented 3.5 mm diameter sensing area FSR and tuned circuit to ensure adequate sensitivity
- Data display design and TFT implementation
    - We outlined a rough idea of what the screen design would look like for demo purposes of the product. This view is not intended for a patient to see for the final product.

- We are considering adding a second heat map with the same visual layout as below to illustrate both the temperature and modulus on different parts of the foot.
-

NEXT STEPS

From Team:

- Establish the final form of our thermistor setup (i.e., what layers will be between our sensors and the user's tissue) and continue testing of thermistors to determine if we can get readings compliant with ASTM E1112-00(2018) 4.2 using such a setup

TABLE 1 Maximum Error Temperature Ranges

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37.0°C to 39.0°C	±0.1°C
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Greater than 41.0°C	±0.3°C
Fahrenheit Scale:	
Less than 96.4°F	±0.5°F
96.4°F to less than 98.0°F	±0.3°F
98.0°F to 102.0°F	±0.2°F
Greater than 102.0°F to 106.0°F	±0.3°F
Greater than 106.0°F	±0.5°F

- Optimize code workflow
  - Integrate LCD display into this process. Create two heat maps from the 2D array that is currently output - one for temperature and one for modulus data
- After validation of sensors for both biomarkers, create higher fidelity, integrated prototype
- Establish and implement data output mechanism (for "interfacing with clinical systems") using one of the below
  - output to other machine using Wi-Fi/Bluetooth compatible Arduino or microcontroller (e.g., ESP32)
  - load data into an SD card or USB stick
  - transmit from microcontroller to other machine using wired connection

Milestones:

- Found and implemented adequately sensitive load cell
  - Created working signal processing circuit
- Created mechanical hardware for integrated sensor

- Implemented hardware and code for multiplexing setup/policy
- Created much of the user workflow code for device
    - Prepped data output in 2D tabular form for display
- Created (integrated) testing setup using modular design in code and circuitry
- Began validating/calibrating load cell force output
- Implemented a form of contact detection

Kanban board: https://trello.com/b/wjGsrVLe/team-6-josh-will-sarah-kishen

From Instructors:

- Begin integrating sensing modules into mat for system testing, i.e., measuring temp and stiffness in full device

Breakdown of work: Who did what

- Created working signal processing circuit
    - Will
- Implemented hardware and code for multiplexing setup/policy
    - Kishen and Josh
- Created user workflow code with multiplexed modular design for device and prepped data output in 2D tabular form for display
    - Josh
- Designed initial layout for TFT screen visuals
    - Sarah
- Created mechanical hardware for integrated sensor
    - Will
- Created (integrated) testing setup
    - Sarah and Kishen
- Validated/calibrated load cell force output
    - Sarah
- Implemented a form of contact detection
    - Will

Meeting Notes:

- test with fixed weights?
- load cells april 20?
- Redesign indenter frame to have 4 thermistors, FSR further away, maybe smaller displacement
- Create PLA frames for thermistors only for other parts of the foot
- Create acrylic rigid “mat” with locations of modules mapped out
- Create one functional unit and prepare for everything else that’s still on the way
- Switch to full time testing after first module is functional
- Create flip-flop type thing to go under socks
- Consider foam layer on top of rigid backing instead of heel guide
    - Ask Liz about the foam ring things in Wilk basement

Meeting Title: Design Review Meeting Team 6 (Sarah, Kishen, Will, Josh)
Date: 4/18/2024

Meeting Lead: Sarah Glomski
Meeting Scribe: Josh Tennyson

RECAP:
Action items

- We hope to talk about logistics and expectations heading into finals. Want to get advice for making a strong poster, pitch, DHF, etc.
- We want to explain our most recent specific thoughts for testing protocols and make sure that instructors don't see any major flaws

WEEK'S ACTIVITIES:
What's been done and why/Experiments, prototypes (photos, videos, live demos)

Since the last DRM, we have:

- Designed and laser cut a "mat" or board to integrate sensors into

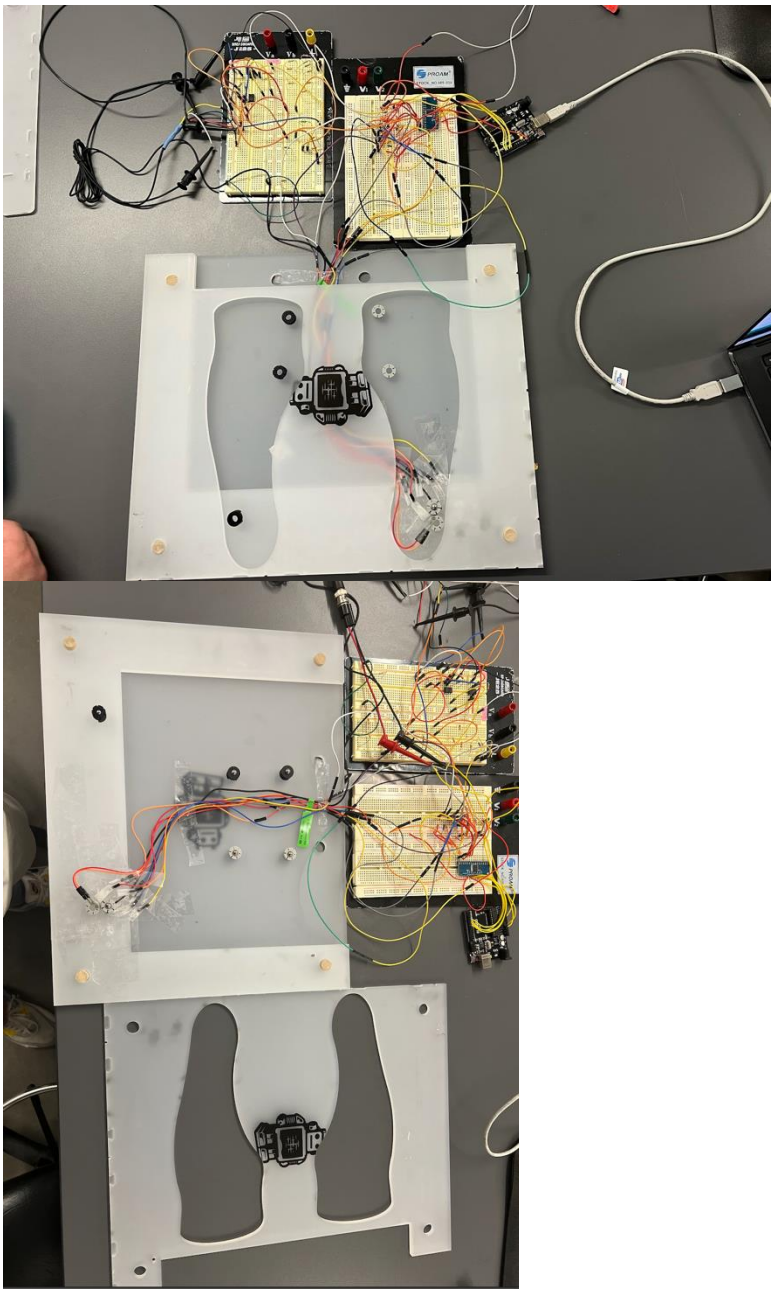

Figure 1. Integrated prototype setup, including circuit and laser cut rigid acrylic mat.

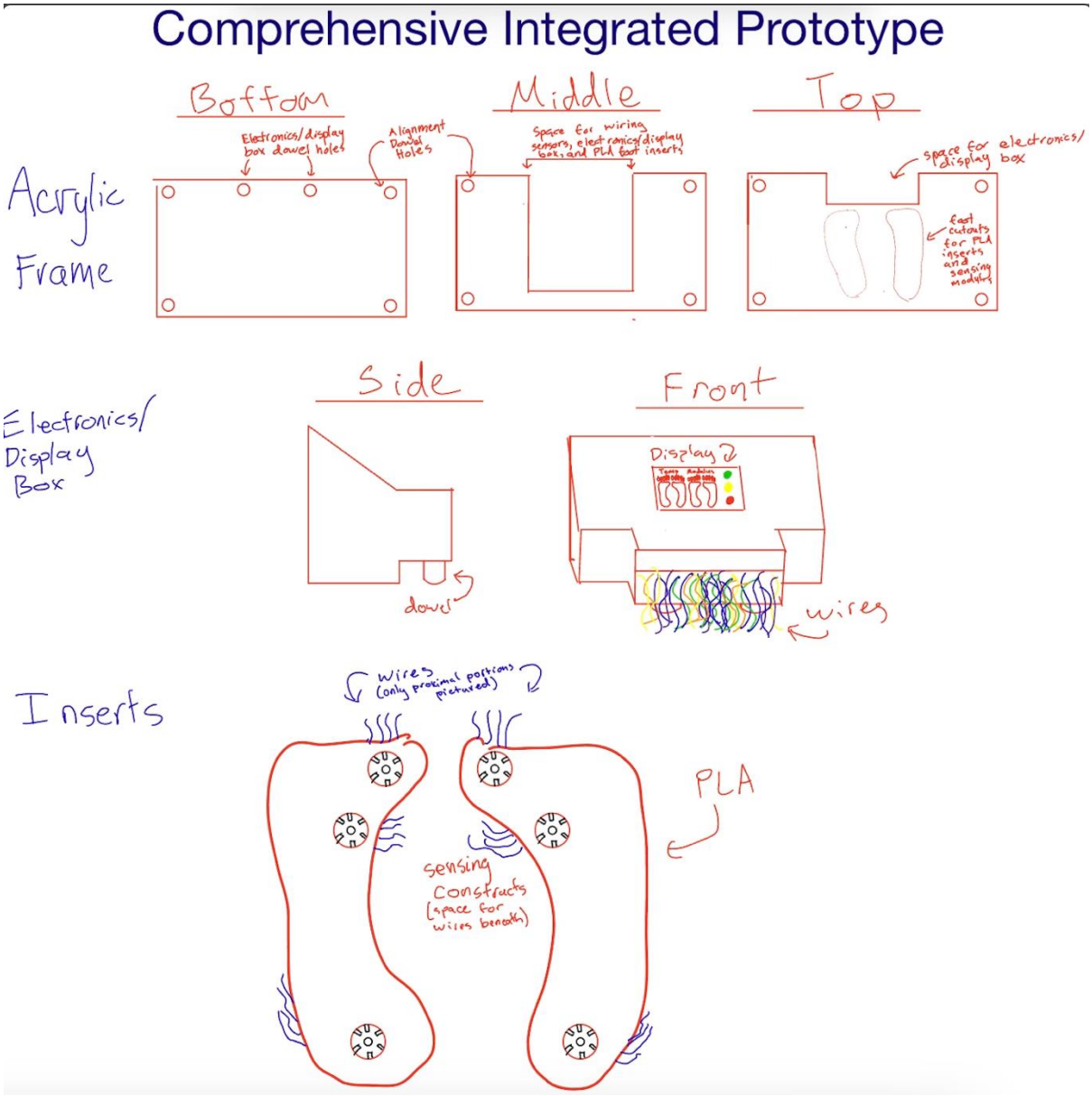

Figure 2. Integrated prototype theoretical design

- Completed simple/straightforward assessment of our sensing ability using our integrated sensors within the laser cut board
    - Confirmed we can measure temperature while obtaining accurate/precise modulus readings
- Created testing apparatus components
    - We plan to test with a foot shaped cutout that a user may lower onto the sensing plane of the mat (depiction of system below). In the depiction, note that the sock will be attached to the rest of the construct.

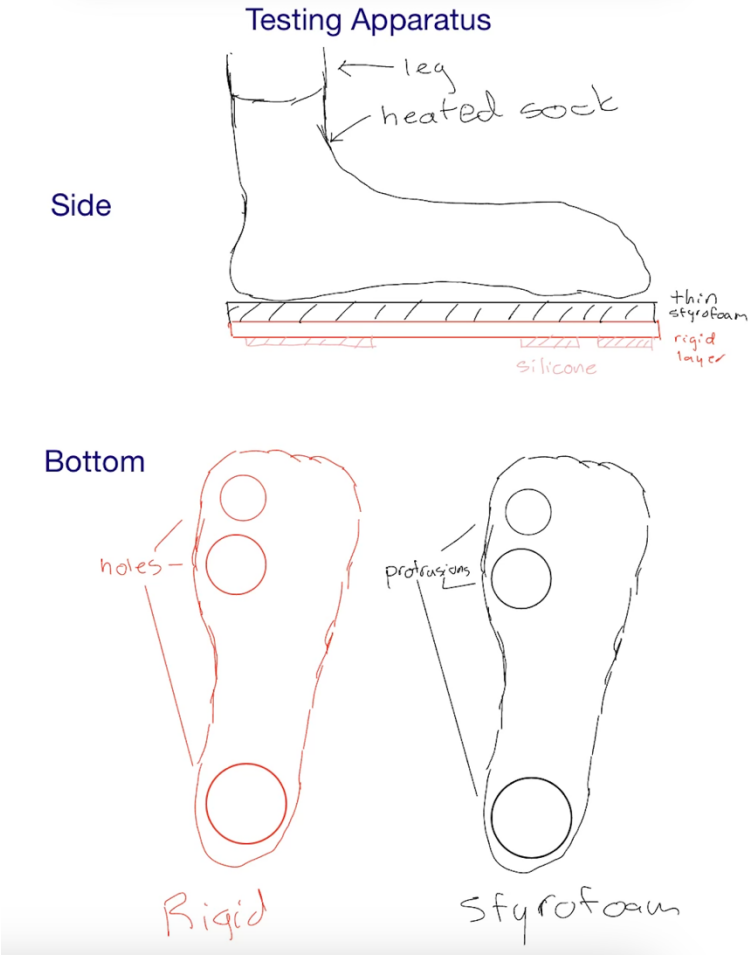

Figure 3: Testing plan

- We have created out rigid, laser cut backings

Figure 4. Laser Cut Acrylic/Wood Foot Cutouts

- Made a new set of designs to test out for our integrated sensing frame

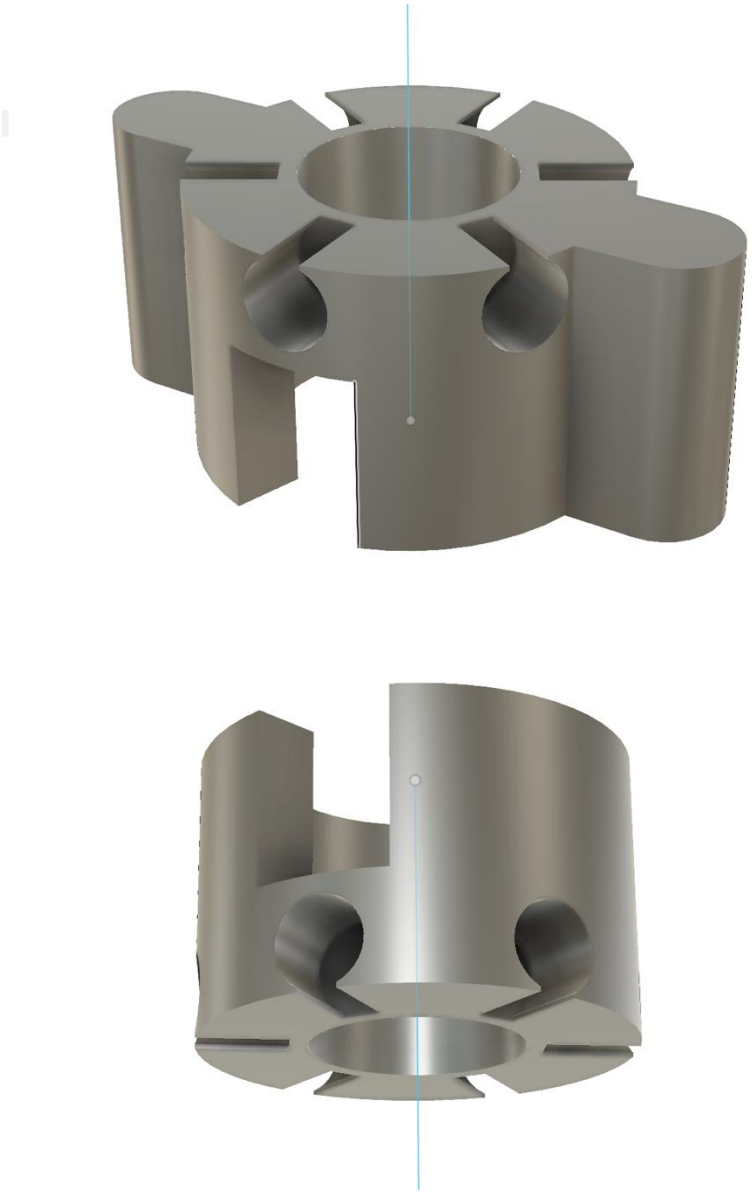

Figure 5. New Revision of Integrated Sensing Frames

- We have begun characterizing the temperature profile of our thermistors to calibrate their readings, given that this may be affected by their setup in the integrated sensing constructs.
    - We will likely have data to share for this by the time of our DRM meeting
- We intend to make small tweaks to the CAD for our PLA "inserts" in Figure 2. These may be done by the time of our DRM meeting

NEXT STEPS

From Team:

- Possibly will be done before DRM

    - characterize and recalibrate temperature readings of thermistors within new indenter setup
    - Create CAD for "insert" component of device (Figure 2)
- Code TFT LCD display
    - implement data display and final components of user workflow
- Enable data output functionality
- Assemble device
- Execute final testing of fully functional, integrated prototype

Milestones:

- Created single functional module
- Began testing aspects of our sensing abilities within this single module

Kanban board: https://trello.com/b/wjGsrVLe/team-6-josh-will-sarah-kishen

From Instructors:

- Create a detection system with a single fully functioning module (due to only having one cell). Populate the other regions with all the components currently available so that when parts arrive (load cells, FSRs) they can be placed and testing can commence.
- Test stiffness and temp detection on system (not individual units or modules); i.e., foot being placed on plate with sensing modules

Breakdown of work: Who did what

- Integrated system design (acrylic board laser cutting, refining sensing modules, integrating sensors and circuit)
    - Josh, Kishen, Sarah, Will
- Integrated system testing (verification that temperature/modulus readings could be obtained within existing components of integrated system, design of final testing apparatus)
    - Josh, Kishen, Sarah, Will

Meeting Notes:

- metal sheet rather than styrofoam
- for testing, focus on repeatability: laying bricks on the device as opposed to a person with sandals stepping on the device
- demo: person stepping on with sandals (callused sandals with soft and hard areas and then normal sandals)
    - one hard sandal and one soft sandal proposed by Dr. Kyle
- make a future works spiel as well in the dhf and poster?
    - thermistor array spread throughout may be down the road the road
- PLA guides for repeatability
- testing for the poster with one module embedded in the final system

XVI. References

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XVIII. Appendix

Integrated Arduino *Code*

```
#include <SPI.h>
#include <Wire.h>
#include <math.h>
#include <Time.h>
#include <SD.h>
#include <Statistic.h>
#include <LCDWIKI_GUI.h>
#include <LCDWIKI_SPI.h>

#define MODEL ST7796S
#define CS   A10
#define CD   A8
#define RST  A9
#define MOSI 51
#define MISO 50
#define SCK  52
#define LED  A7

LCDWIKI_SPI mylcd(MODEL,CS,CD,MISO,MOSI,RST,SCK,LED);

#define BLACK   0x0000
#define BLUE    0x001F
#define RED     0xF800
#define GREEN   0x07E0
#define CYAN    0x07FF
#define MAGENTA 0xF81F
#define YELLOW  0xFFE0
#define WHITE   0xFFFF

// for each module, true if no data has yet been recorded
bool firstMods[6] = {true, true, true, true, true, true};
bool firstMod_tot = true;

// mux signal pins - one for each module
const int muxSIG1 = A0;
const int muxSIG2 = A1;
const int muxSIG3 = A2;
const int muxSIG4 = A3;
const int muxSIG5 = A4;
const int muxSIG6 = A5;
int sigPins[6] = {muxSIG1, muxSIG2, muxSIG3, muxSIG4, muxSIG5, muxSIG6};
unsigned long tripTimes[6] = {-1,-1,-1,-1,-1,-1};

// mux channel control pins
const int muxS0 = 8;
```

```
const int muxS1 = 9;
const int muxS2 = 10;
const int muxS3 = 11;

// initialize some functions
void firstAddData(float data[], float newData);
void addData(float data[], float newData);
float readForce(float adc);
float readTemp(float adc);
float readLoad(float adc);
float calc_modulus(float force);
int SetMuxChannel(byte channel);

// for fsr reading readForce()
float fsrScale = 0.65;
// for temp reading readTemp()
float Rref = 3300;
float Vref = 5;

// times
unsigned long startTime;
unsigned long currentTime;

// holds data for three modules (mod 1 temp, mod 1 modulus, mod 2 temp, ...)
// assuming collection once a day, holds data from last 28 days
float data[12][28];

// THRESH (can be changed) for FSR contact
// threshold for contact for FSRs
float contactThresh = 1000;

// for stats
Statistic myStats;

// see if contact sensed
bool triggered = false;

int moduleFSRs[6] = {0,0,0,0,0,0};
bool pressed[6] = {false, false, false, false, false, false};
bool firstCollect[6];
bool cutTemp[6] = {false, false, false, false, false, false};
bool finishTemp = false;
float allMyTemps[6] = {0,0,0,0,0,0};
float allMyLoads[6] = {0,0,0,0,0,0};


void setup() {
  // put your setup code here, to run once:
```

```
  Serial.begin(115200);
  startTime = millis();

  // clear stats
  myStats.clear();

  // initialize pins
  pinMode(muxSIG1, INPUT);
  pinMode(muxSIG2, INPUT);
  pinMode(muxSIG3, INPUT);
  pinMode(muxSIG4, INPUT);
  pinMode(muxSIG5, INPUT);
  pinMode(muxSIG6, INPUT);
  pinMode(muxS0, OUTPUT);
  pinMode(muxS1, OUTPUT);
  pinMode(muxS2, OUTPUT);
  pinMode(muxS3, OUTPUT);

  // initialize mux channel to nonsense channel
  digitalWrite(muxS0, HIGH);
  digitalWrite(muxS1, HIGH);
  digitalWrite(muxS2, HIGH);
  digitalWrite(muxS3, HIGH);

  // initialize LCD
  mylcd.Init_LCD();
  mylcd.Fill_Screen(CYAN);
}

void loop() {
  // put your main code here, to run repeatedly:

  // probe all six FSRs
  digitalWrite(muxS0, LOW);
  digitalWrite(muxS1, HIGH);
  digitalWrite(muxS2, LOW);
  digitalWrite(muxS3, HIGH);
  for (int i = 0; i<6; i++) {
    moduleFSRs[i] = analogRead(sigPins[i]);
    if (moduleFSRs[i] < contactThresh) {
      pressed[i] = true;
      triggered = true;
    }
    firstCollect[i] = (pressed[i] && firstMods[i]);
  }

  float getLoads[6] = {0,0,0,0,0,0};
  float getTemps[6] = {0,0,0,0,0,0};
```

```
while (triggered) {
  for (int i=0; i<6; i++) {
    if (firstCollect[i]) {
      if (firstMods[i]) {
        tripTimes[i] = millis();
      }
      firstMods[i] = false;
    }
  }

  // loop over modules to get load cell readings
  digitalWrite(muxS0, LOW);
  digitalWrite(muxS1, LOW);
  digitalWrite(muxS2, LOW);
  digitalWrite(muxS3, LOW);


  if (firstMod_tot) {
    for (int i=0; i<3; i++) {
      for (int j=0; j<6; j++) {
        if (firstCollect[j]) {
          getLoads[j] = getLoads[j] + calc_modulus(readLoad(analogRead(sigPins[j])));
          if (i==2) {
            getLoads[j] = getLoads[j] / 3.0;
            //firstAddData(data[2*j+1], getLoads[j]);
            data[2*j+1][-1] = getLoads[j];
            allMyLoads[j] = getLoads[j];
            cutTemp[j] = true;
            Serial.println("ADDING LOAD DATA");
            Serial.println(j);
            Serial.println(getLoads[j]);
          }
        }
      }
    }
  }

  // get temp measurements
  if (firstMod_tot) {
    for (int j=0; j<6; j++) {
      for (int i=0; i<30; i++) {
        if (pressed[j] && cutTemp[j]) {
          digitalWrite(muxS0, HIGH);
          digitalWrite(muxS1, HIGH);
          digitalWrite(muxS2, HIGH);
          digitalWrite(muxS3, HIGH);
          float currTemp1 = readTemp(sigPins[j]);
```

```
          digitalWrite(muxS0, LOW);
          digitalWrite(muxS1, HIGH);
          digitalWrite(muxS2, HIGH);
          digitalWrite(muxS3, HIGH);
          float currTemp2 = readTemp(sigPins[j]);
          digitalWrite(muxS0, HIGH);
          digitalWrite(muxS1, LOW);
          digitalWrite(muxS2, HIGH);
          digitalWrite(muxS3, HIGH);
          float currTemp3 = readTemp(sigPins[j]);
          digitalWrite(muxS0, LOW);
          digitalWrite(muxS1, LOW);
          digitalWrite(muxS2, HIGH);
          digitalWrite(muxS3, HIGH);
          float currTemp4 = readTemp(sigPins[j]);
          currentTime = millis();

          unsigned long elapsed = (currentTime - tripTimes[j]);
          if ((elapsed > 5000) && (i==29)) {
            getTemps[j] = getTemps[j] + (currTemp1+currTemp2+currTemp3+currTemp4);
            Serial.println("ADDING TEMP DATA");
            getTemps[j] = getTemps[j] / 4.0;
            //firstAddData(data[2*j], getTemps[j]);
            data[2*j][-1] = getTemps[j];
            allMyTemps[j] = getTemps[j];
            Serial.println(getTemps[j]);
            cutTemp[j] = false;
            firstCollect[j] = false;
          }
        }
      }
      finishTemp = (!cutTemp[0] && !cutTemp[1] && !cutTemp[2] && !cutTemp[3] && !cutTemp[4] && !cutTemp[5]);
      if (finishTemp && pressed[0] && pressed[1] && pressed[2] && pressed[3] && pressed[4] && pressed[5] &&
!firstCollect[0] && !firstCollect[1] && !firstCollect[2] && !firstCollect[3] && !firstCollect[4] && !firstCollect[5]) {
        Serial.println("Exiting triggered");
        firstMod_tot = false;
        // done with iteration so set triggered to false
        triggered = false;
      }
    }

  if (!triggered) {
    Serial.println("Finding booleans");

    // threshes evaluated in booleans
    bool mod1_modulus;
    bool mod2_modulus;
    bool mod3_modulus;
```

```
bool mod1_temp;
bool mod2_temp;
bool mod3_temp;

// foot identifier if any of above are true
bool mod1_modulus_left;
bool mod2_modulus_left;
bool mod3_modulus_left;
bool mod1_temp_left;
bool mod2_temp_left;
bool mod3_temp_left;

// CURRENT THRESH FOR MODULUS IS 3; ASSUMING modules 1-3 on left foot
for (int i=0; i<3; i++) {
 if (getLoads[i] > getLoads[i+3]) {
  if (i==0) {
   mod1_modulus = (getLoads[i] > 1.5*getLoads[i+3]);
   mod1_modulus_left = true;
  }
  else if (i==1) {
   mod2_modulus = (getLoads[i] > 1.5*getLoads[i+3]);
   mod2_modulus_left = true;
  }
  else if (i==2) {
   mod3_modulus = (getLoads[i] > 1.5*getLoads[i+3]);
   mod3_modulus_left = true;
  }
 }
 else {
  if (i==0) {
   mod1_modulus = (getLoads[i] > 1.5*getLoads[i+3]);
   mod1_modulus_left = false;
  }
  else if (i==1) {
   mod2_modulus = (getLoads[i] > 1.5*getLoads[i+3]);
   mod2_modulus_left = false;
  }
  else if (i==2) {
   mod3_modulus = (getLoads[i] > 1.5*getLoads[i+3]);
   mod3_modulus_left = false;
  }
 }
 if (getTemps[i] > getTemps[i+3]) {
  if (i==0) {
   mod1_temp = ((getTemps[i] - getTemps[i+3])>2.2);
   mod1_temp_left = true;
  }
  else if (i==1) {
```

```
      mod2_temp = ((getTemps[i] - getTemps[i+3])>2.2);
      mod2_temp_left = true;
    }
    else if (i==2) {
      mod3_temp = ((getTemps[i] - getTemps[i+3])>2.2);
      mod3_temp_left = true;
    }
  }
  else {
    if (i==0) {
      mod1_temp = ((getTemps[i] - getTemps[i+3])>2.2);
      mod1_temp_left = false;
    }
    else if (i==1) {
      mod2_temp = ((getTemps[i] - getTemps[i+3])>2.2);
      mod2_temp_left = false;
    }
    else if (i==2) {
      mod3_temp = ((getTemps[i] - getTemps[i+3])>2.2);
      mod3_temp_left = false;
    }
  }

}

// get results
int allRes[6];

if (mod1_modulus && mod1_modulus_left) {
  allRes[0] = 1;
  allRes[3] = 0;
}
else if (mod1_modulus && !mod1_modulus_left) {
  allRes[0] = 0;
  allRes[3] = 1;
}
else {
  allRes[0] = 0;
  allRes[3] = 0;
}

if (mod1_temp && mod1_temp_left) {
  allRes[0] = 2;
}
else if (mod1_temp && !mod1_temp_left) {
  allRes[3] = 2;
}
```

```
if (mod2_modulus && mod2_modulus_left) {
  allRes[1] = 1;
  allRes[4] = 0;
}
else if (mod2_modulus && !mod2_modulus_left) {
  allRes[1] = 0;
  allRes[4] = 1;
}
else {
  allRes[1] = 0;
  allRes[4] = 0;
}

if (mod2_temp && mod2_temp_left) {
  allRes[1] = 2;
}
else if (mod2_temp && !mod2_temp_left) {
  allRes[4] = 2;
}

if (mod3_modulus && mod3_modulus_left) {
  allRes[2] = 1;
  allRes[5] = 0;
}
else if (mod3_modulus && !mod3_modulus_left) {
  allRes[2] = 0;
  allRes[5] = 1;
}
else {
  allRes[2] = 0;
  allRes[5] = 0;
}

if (mod3_temp && mod3_temp_left) {
  allRes[2] = 2;
}
else if (mod3_temp && !mod3_temp_left) {
  allRes[5                                                    ] = 2;
}

Serial.println("Results below");
Serial.println(allRes[0]);
Serial.println(allRes[1]);
Serial.println(allRes[2]);
Serial.println(allRes[3]);
Serial.println(allRes[4]);
Serial.println(allRes[5]);
```

```
// key locations
int locs[6][2] = {{210,224}, {190,224}, {115,200}, {210,256}, {190,256}, {115,280}};

// make loads into MPa for easier numbers
for (int i=0; i<6; i++) {
  getLoads[i] = round(getLoads[i]/1000.0)/1000.0;
}

float vals[6][2] = {{0,0},{0,0},{0,0},{0,0},{0,0},{0,0}};
for (int i=0; i<6; i++) {
  vals[i][0] = getTemps[i];
  vals[i][1] = getLoads[i];
  Serial.println(vals[i][0]);
  Serial.println(vals[i][1]);
}

Serial.println("DONE");

int r =5;
bool seePod = false;
bool cautionPod = false;
int ji;

for (ji=0; ji < 6; ji++) {
  if (allRes[ji] == 2) {
    seePod = true;
    break;
  }
  else if (allRes[ji] == 1) {
    cautionPod = true;
  }
}

mylcd.Init_LCD();

// put your setup code here, to run once:
mylcd.Fill_Screen(WHITE);

// draw mat
mylcd.Set_Draw_color(CYAN);
mylcd.Fill_Rectangle(80, 120, 240, 360);

// draw feet
// left foot
mylcd.Set_Draw_color(BLACK);
mylcd.Fill_Rectangle(100, 170, 200, 230);
mylcd.Fill_Rectangle(200, 170, 208, 180);
mylcd.Fill_Rectangle(200, 182, 212, 192);
```

```
mylcd.Fill_Rectangle(200, 194, 216, 204);
mylcd.Fill_Rectangle(200, 206, 218, 216);
mylcd.Fill_Rectangle(200, 218, 220, 230);
// right foot
mylcd.Fill_Rectangle(100, 250, 200, 310);
mylcd.Fill_Rectangle(200, 250, 220, 262);
mylcd.Fill_Rectangle(200, 264, 218, 274);
mylcd.Fill_Rectangle(200, 276, 216, 286);
mylcd.Fill_Rectangle(200, 288, 212, 298);
mylcd.Fill_Rectangle(200, 300, 208, 310);

// print val labels
mylcd.Set_Text_Mode(0);
mylcd.Set_Text_Back_colour(WHITE);
mylcd.Set_Text_colour(BLACK);
mylcd.Set_Text_Size(1);
mylcd.Set_Rotation(45);
mylcd.Print_String("Temp",20,80);
mylcd.Print_String("Modulus",60,80);
mylcd.Print_String("Temp",380,80);
mylcd.Print_String("Modulus",420,80);
mylcd.Set_Rotation(0);

// populate circles and print vals
for (int i = 0; i < 6; i++) {
  int result = allRes[i];
  int resLocX = locs[i][0];
  int resLocY = locs[i][1];
  if (result == 0) {
    mylcd.Set_Draw_color(GREEN);
    mylcd.Fill_Circle(resLocX, resLocY, r);
  }
  else if (result == 1) {
    mylcd.Set_Draw_color(YELLOW);
    mylcd.Fill_Circle(resLocX, resLocY, r);
  }
  else if (result == 2) {
    mylcd.Set_Draw_color(RED);
    mylcd.Fill_Circle(resLocX, resLocY, r);
  }

  // print moduli and temps

  mylcd.Set_Text_Mode(0);
  mylcd.Set_Text_Back_colour(WHITE);
  mylcd.Set_Text_colour(BLACK);
  mylcd.Set_Text_Size(1);
```

```
  mylcd.Set_Rotation(45);
  if (i<3) {
    mylcd.Print_Number_Float(vals[i][0],2,20,80+20*(i+1),'.',0,' ');
    mylcd.Print_Number_Float(vals[i][1],2,60,80+20*(i+1),'.', 0,' ');
  }
  else {
    mylcd.Print_Number_Float(vals[i][0],2,380,80+20*(i-2),'.',0,' ');
    mylcd.Print_Number_Float(vals[i][1],2,420,80+20*(i-2),'.', 0,' ');
  }
  mylcd.Set_Rotation(0);
}

if (seePod) {
  mylcd.Set_Text_colour(RED);
  mylcd.Set_Text_Size(4);
  mylcd.Set_Rotation(45);
  mylcd.Print_String("NOT NORMAL",120,40);
  mylcd.Print_String("SEE PODIATRIST",80,260);
  mylcd.Set_Rotation(0);
}
else if (cautionPod) {
  mylcd.Set_Text_colour(YELLOW);
  mylcd.Set_Text_Size(4);
  mylcd.Set_Rotation(45);
  mylcd.Print_String("CAUTION",180,40);
  mylcd.Print_String("SEE PODIATRIST",80,260);
  mylcd.Set_Rotation(0);
}
else {
  mylcd.Set_Text_colour(GREEN);
  mylcd.Set_Text_Size(4);
  mylcd.Set_Rotation(45);
  mylcd.Print_String("NORMAL",180,40);
  mylcd.Set_Rotation(0);
}
triggered = false;
delay(600000);
}

// probe all six FSRs
digitalWrite(muxS0, LOW);
digitalWrite(muxS1, HIGH);
digitalWrite(muxS2, LOW);
digitalWrite(muxS3, HIGH);
for (int i = 0; i<6; i++) {
  moduleFSRs[i] = analogRead(sigPins[i]);
  if (moduleFSRs[i] < contactThresh) {
    pressed[i] = true;
```

```
      }
      firstCollect[i] = (pressed[i] && firstMods[i]);
    }
  }
  delay(10);
}

// read thermistors
float readTemp(float adc){
  // parameters from curvefit based on datasheet
  float Rref = 3000;
  float Vref = 5;
  float u = 75.81962652363053;
  float v = -0.008138072537797122;
  float w = 4.3891764357697204e-07;
  float x = -1.1922894916418047e-11;
  float y = 7.468047328620244e-21;
  float z = -1.1931342726996567e-25;

  float volt = (1023-adc)*Vref/1023.0;
  float R = Rref*(Vref/volt - 1);
  float Fahrenheit = u + v*R + w*pow(R,2) + x*pow(R,3) + y*pow(R,5) + z*pow(R,6);
  float Celsius = (Fahrenheit - 32) * 5/9;
  return Celsius;
}

// update compression load cell read
float readLoad(float adc) {
  // analog voltage reading ranges from 0 to 1023 which maps to 0V to 5V (= 5000mV)
  float fsrVoltage = map(adc, 0, 1023, 0, 5000);
  int Vin = 5;
  fsrVoltage = fsrVoltage / 1000.0;                    // change fsrvoltage to volts
  float fsrResistance = (Vin - fsrVoltage);  // fsrVoltage is in volts

  // convert value to force using FSR datasheet
  // unit conversion to get force output in N from R input in ohms
  // Adjust calibration here
  float Force = (16.4 * fsrResistance) - 1.55;
  return Force;
}

// calc modulus from force reading
float calc_modulus(float force) {
  // parameters from curvefit
  float R = 0.00278;
  float d = 0.00278;
  float v = 0.45;
  float modulus = 3 * force * (1 - pow(v,2)) / (4*pow(R,0.5)*pow(d,1.5));
```

```
  return modulus;
}

// add data when data has not yet been initialized
void firstAddData(float data[], float newData){
  for (int ind=0; ind < 28; ind++){
    data[ind] = newData;
  }
}

// add data post-initialization
void addData(float data[], float newData){
  for (int ind=0; ind < 27; ind++){
    data[ind] = data[ind+1];
  }
  data[27] = newData;
}
```