BME Design-Fall 2020 - CADE VAN HORN
Complete Notebook

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Team contact Information

CADE VAN HORN - Sep 04, 2020, 2:59 PM CDT

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Project description

CADE VAN HORN - Sep 04, 2020, 3:03 PM CDT

Course Number: BME 200/300

Project Name: Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Short Name: Global Health

Project description/problem statement:

Create a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients. Develop an app-based software to further interpret the images and thermal maps collected by the client while in India.

About the client:

Longer Description:

Initial project description from project list:

Diabetes is becoming an international epidemic with India being tagged the "Diabetic capital of the world" in recent years. It is estimated that anywhere from 50-90% of Indian diabetics are undiagnosed in rural areas of the country which allows these patients' blood sugars to go unregulated for years. This leads to costly complications of diabetes, of which the most common is the development of a diabetic foot ulcers leading to lower limb amputation. These amputations from diabetic foot ulcers account for 85% of all non-traumatic amputations world-wide. In addition, a person with diabetes in India is 10 times more likely to need an amputation in comparison to a person living in the US because of the lack of treatment and accessibility to healthcare services.

We currently have no way of identifying which patients are at greatest risk or on the brink of ulceration. In addition, patients often do not come in to the clinic until the ulcer is already developed. Thus, healthcare professionals and their resources are primarily dedicated to treating the formed ulcers rather than preventing them. Thus, healthcare costs and the incidence of amputation could greatly be reduced if we could identify and perhaps predict which patients are at greatest risk for developing an ulcer in order to initiate treatment to prevent amputation. Towards the end of the client's time in India, she hypothesized that thermal imaging could be used to reveal which diabetic patients had patches of inflammation on their feet indicating an impending ulcer.

The client spent 9 months in India on a Fulbright Grant interacting with healthcare professionals and Indian diabetic patients, and conducted a thermal imaging study of over 200 patient's feet. Primitive data analysis of the images shows that this could be a novel method of determining which patients are on the brink of ulceration, and we're currently developing machine learning algorithms to further strengthen the interpretation and predictive power of these images.

There are two parallel aspects to this design project. Please indicate your teams' strengths with respect to both aspects:
Thermal Device (Fabrication):
We would like to develop a low-cost, streamlined way of measuring temperature from the feet of diabetic patients to serve as a diagnostic tool in Indian hospitals and as a take-home device for the patients. Currently, the clients uses an IR camera and a simple tripod. We'd like to explore other ways of collecting temperature that would fit in the context of an Indian hospital (cost, portability, ease of use etc). Our main interest is in evaluating the use of thermochromatic material to visualize the temperature on a patient's foot using a simple phone camera. We're currently developing an ML algorithm using thermal images and would like to see if this could be a low-cost alternative.

AI Algorithm and Phone App (Medical Imaging, Computer Science):
We would like to develop an artificially intelligent algorithm to be able to categorize which patients are at greatest risk of ulceration based on the thermal scans and images of their feet.

This would require students interested in global health, preventative medicine, risk assessment, fabrication, machine learning, image processing (python), and app development. There is also potential for some students to travel to India next summer with the client (pandemic dependent) to try out the device and collect more data. Please speak to each team member's interest in this experience for next summer!

9/11/2020 Team Meeting 1

CADE VAN HORN - Sep 11, 2020, 12:33 PM CDT

Title: Team Meeting 1

Date: 9/11/2020

Content by: Cade Van Horn

Present: Carter, Emma, Will

Goals: The goals of this first meeting were to introduce ourselves and do a brief overview of the project.

Content:

The team spent some time doing introductions, then we all gave a brief summary of our research on the project. We had all spent some time over the past week researching the basics of diabetic foot ulceration, including causes and treatment. We also discussed the two videos that the client sent us - a talk by Dr. Paul Brand, and a talk by the client Kayle Huemer.

Conclusions/action items:

After meeting for the first time, we determined that we can begin to delve further into research on the anatomy of diabetic foot ulceration, as well as how to measure the temperature of the skin. We hope to have a more productive conversation about our research at the next team meeting.

9/17/2020 - Team Meeting 2

CADE VAN HORN - Oct 07, 2020, 10:16 AM CDT

Title: Team Meeting 2

Date: 9/17/2020

Content by: Cade Van Horn

Present: Whole Group

Goals: To talk about questions for the client and work on product design specifications

Content:

The team worked on the PDS and made a list of questions for the client.

Diabetic Foot FAQs

What work was done by the previous BME team?
The Fall 2019 team designed a foldable insulated box with image processing software that comprised of grayscaling and pixel extraction. The portable box included ankle holes, an insulated face, and a phone mount.
The Spring 2020 team designed a similar foldable insulated box and imaging system. The imaging system included a raspberry pi, temperature sensor, IR camera, ultrasonic distance sensor, and stepper motor. It recorded data using Wifi connection. The portable box also included ankle holes and a camera mount which had an adjustable distance from the box.
For this project, look at thermochromatic material and taking pictures with a regular phone camera

What makes someone at risk for developing a diabetic foot ulcer?
Bad shoes, poor hygiene, consumption of tobacco or alcohol, obesity, high blood sugar (hyperglycemia), bad blood circulation or blood clotting (blood perfusion and wound healing is affected by tobacco and other drugs), heart or kidney disease, neuropathy
Young's modulus of shoe material, how much it accommodates pressure - high modulus is bad, super low modulus is also bad - find what is the sweet spot
Overall goal is When to intervene

What causes a diabetic foot ulcer?
Hyperglycemia, bad blood circulation, nerve damage, irritated/wounded feet
Not every patient has neuropathy but still can have inflammation and warning signs for ulceration
Different stages of disease pathology
If an ulcer is already infected, amputation is probably the best option
If an ulcer is not infected, the right footwear and compliance to this is important
Cultural aspect of "prescribed shoes" not fitting with daily life
Biothesiometer

What are goals for the semester?
Further develop an imaging box?
Further develop the imaging system and circuit?
Focus on the AI software to interpret the data?
Produce a heat map, take picture, make algorithm to analyze the pictures, then upload to an app
Feed an image to an ML algorithm - supervised learning, train the computer to recognize certain things
Assign healthy and not healthy, get the computer to recognize what is at risk vs not at risky
What is the difference between HTMs and PMNs?
HTMs are High Threshold Mechano Receptors which respond to high level mechanical stress in healthy tissues - basically the normal pain response to high impact stress
PMNs are Poly-Modal Nocireceptors which respond to mechanical stresses activated in damaged tissues by chemicals released by inflammation. This is a much lower threshold pain receptor, and responds to more repeated low impact stresses, like walking several miles

What kind of temperature difference between a "hot spot" and a normal part of the foot would be considered significant?
2.2 degrees celsius (determined by professionals) - not commonly used by clinicians - not a bad metric, but shouldn't be the only metric for identifying potential ulceration

Look for an absolute temperature, such as if the foot ever reaches a certain temp, that's a red flag
Find different flags to watch for beyond the 2.2 degrees

Is there any existing data that we could use if the project goes in the direction of software building?

Are you still working with pressure sensors or is this project only focusing on temperature sensors?

What skills does each team member have with circuit design, programming, Python, app design, AI software, Solidworks, etc?

If we developed an app-based software to interpret the images and thermal maps, what kind of data would we be compiling from the images?

Is a smart phone's thermal camera accurate enough to make conclusions about the inflammation of a patient's foot? (i.e. thermal vision filter app)
Or is a separate dedicated thermal camera necessary?

How do you make a machine learning algorithm?

Has any of the ML algorithm already been created? Would we be building off of an existing program or starting from scratch?

Is there a set budget for this project?
Since most if not all of the project will be online likely, will there be anything that requires purchase (software, materials, etc)?

Who is the target audience of this device? Doctors or patients?

Conclusions/action items:

We came up with a comprehensive list of questions to ask the client.

9/23/2020 - Team Meeting 3

CADE VAN HORN - Oct 07, 2020, 11:55 AM CDT

Title: Team Meeting 3

Date: 9/23/2020

Content by: Cade Van Horn

Present: Whole Group

Goals: To work on the design matrix

Content:

https://docs.google.com/document/d/1CT7veqRPHGnuBR1WGXKVLKWWjq7ehMylm5ijFauQz28/edit?usp=sharing

Here is a link to our design matrix that we worked on.

Conclusions/action items:

We decided that the second design is the best for our project, the mixture of thermochromic powders.

9/30/2020 - Team Meeting 4

CADE VAN HORN - Oct 07, 2020, 11:57 AM CDT

Title: Team Meeting 4

Date: 9/30/2020

Content by: Cade Van Horn

Present: Whole Group

Goals: To record our preliminary presentation

Content:

https://docs.google.com/presentation/d/1uQAQmgKXyS1bg8PuwF34lNbHDc1BxOApnCICI5UQ1wg/edit?usp=sharing

Here is a link to our presentation

Conclusions/action items:

We recorded our presentation.

10/02/2020 - Team Meeting 5

CADE VAN HORN - Dec 09, 2020, 7:50 AM CST

Title: Team Meeting 5

Date: 10/01/2020

Content by: Whole Group

Present: Whole group

Goals: The team met to record the preliminary design presentation.

Content:

This week the team got together to record our video for our preliminary design presentation and work on our preliminary report.

Here is a link to our design presentation: https://drive.google.com/file/d/1SMc67SPWXYWpQXlmlItLMLKM_eaTvY_I/view?usp=sharing

We also started thinking about what materials we might need to order in order to fabricate our final design.

Conclusions/action items:

We successfully recorded our presentation in zoom and are ready to show it during class on Friday so that we can receive feedback from our peers.

10/09/2020 - Team Meeting 6

CADE VAN HORN - Dec 09, 2020, 7:55 AM CST

Title: Team Meeting 6

Date: 10/09/2020

Content by: Cade

Present: Whole Group

Goals: The goal of this meeting was to discuss the feedback we received on our preliminary design presentation and final report.

Content:

After presenting our recorded presentation to the class, we got a better idea of what was confusing to listeners and what assumptions we had been making. We learned that we can do a better job of explaining why a temperature difference in the feet is an indicator of ulceration. We also received feedback that actually programming the machine learning algorithm this semester may be too much and we might not have enough data and resources. Based on this, we decided to focus on just building the thermochromic imaging surface prototype rather than the ML algorithm.

Conclusions/action items:

The team decided to focus on building the physical prototype, so we started discussing physical materials we intend to order and potential fabrication plans.

10/30/2020 - Team Meeting 7

CADE VAN HORN - Dec 09, 2020, 7:59 AM CST

Title: Team Meeting 7

Date: 10/30/2020

Content by: Cade

Present: Whole group

Goals: To write our show and tell post on piazza so that we can receive feedback on our design before we order materials or begin fabricating.

Content:

Below is the piazza post we wrote and posted:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Diabetes is a growing problem in India that can often lead to the formation of ulcers and even amputation of the feet. Products like diabetic shoes and socks that are available in the United States are not as applicable to patients in India who might not wear socks or closed-toed shoes on a daily basis. However, the at-home monitoring of foot temperatures that these products use has been shown to effectively decrease the risk of ulceration in diabetic patients.

The thermochromic liquid crystal (TLC) imaging surface commissioned by Kayla Huemer is a low-cost, at-home device that diabetic patients in India can step on to generate a thermal map of their feet in order to provide easily understandable information about their health and whether or not they are at risk of developing an ulcer. Temperature differences in symmetric areas of the feet can be an indication of the possibility of an ulcer forming in that location. A color gradient in the thermal map will show these temperature differences. This will notify patients that they need to take action in their daily lives to significantly reduce the number of steps they take in order to prevent ulceration, which, if left untreated, could even lead to amputation. The TLC imaging surface will also be paired with a machine learning algorithm to further analyze the thermal maps, which can be photographed and uploaded to an app-based software. The software will analyze the color differences in the feet to determine if they pass a set threshold, and subsequently output a risk factor based on data that has already been collected from diabetic patients in India by our client.

The team is currently working on ordering and testing which TLC powders will generate the most vivid and long-lasting thermal map. We are testing different methods of combining and layering powders, as well as different surfaces (such as wood, plastic, or fabric). The team has about 200 thermal images of patients' feet from the client's time in India, but there is not currently enough data for an adequate machine learning algorithm, which would need hundreds more images. Below is a diagram of our design, and we would appreciate any advice on insulating surfaces and top coats, or machine learning algorithms if anyone has any knowledge of that, as well as any general comments and feedback on how we could improve upon our design. If the team completes initial fabrication and testing and submits the proper paperwork in good time, we also might be looking for people to participate in collecting data by stepping on the surface so that the team could take photos of the thermal maps for the machine learning algorithm, but that is more long term.

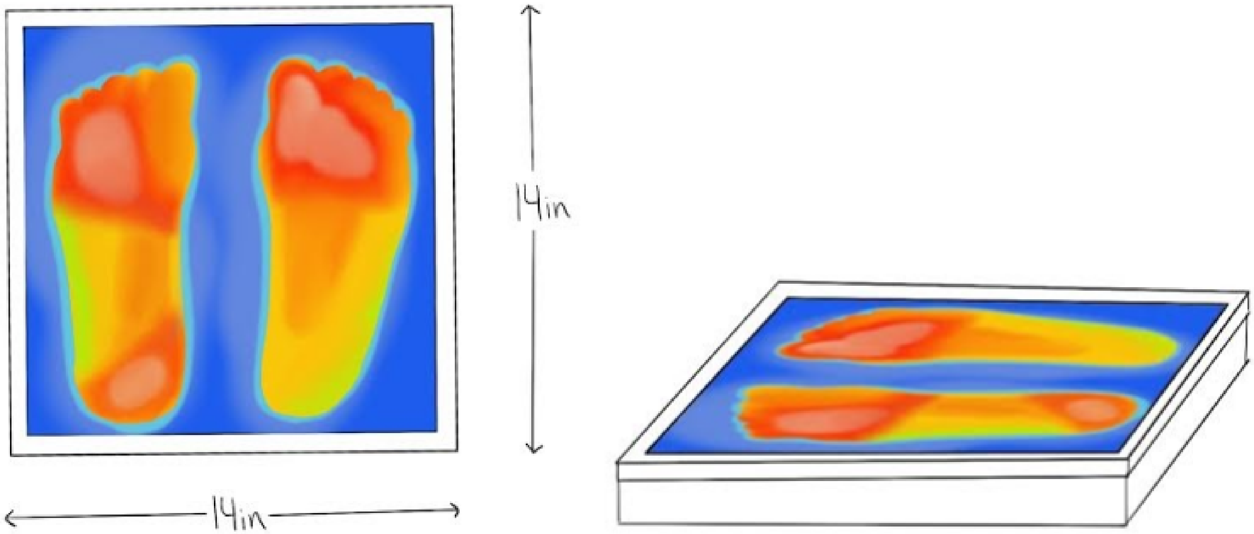

Figure 1. Top and side view of solid surface with temperature-sensitive color-changing thermochromic liquid crystal material showing a thermal image of two feet.

Link to our website for additional information: https://bmedesign.engr.wisc.edu/projects/f20/ulcer_detector

Conclusions/action items:

We posted this on piazza and are awaiting feedback from our peers.

11/06/2020 - Team Meeting 8

CADE VAN HORN - Dec 09, 2020, 8:03 AM CST

Title: Team Meeting 8

Date: 11/06/2020

Content by: Cade

Present: Whole Group

Goals: To discuss the feedback we received on our piazza post

Content:

Below is the feedback we received from the post made on piazza about our project:

"Hello!

Firstly, nice visuals it makes it very clear what the proposed design is and how it would work. I have a few questions first:

What temperature specificity is needed for determining if a region of the foot is at risk for a diabetic foot ulcer? Is there any literature backing the TLC material's ability to show different colors for this specificity needed? In other words what I am wondering is if a difference of 5 degrees is indicative of an ulcer but the TLC material only shows differences of say 7 degrees how will this impact the design.

How quickly (or maybe not quickly) do the colors of the TLC material fade out or then be subjected to errors in imaging results? How long does the patient have after they step off the mat to take an image before the data is potentially compromised.

Based on the bit of research I have done on the thermochromic powders it seems applying them to a wood or fabric surface may not be best. Typically these powders are incorporated into ink and printed onto plastic films or acrylic media. Have you also thought about the size of the stepping pad? Could this possibly be adjustable in size in order to accommodate people with small or large feet? Or would this product be custom made? I also agree with the above reply that for top coats you should be looking into clear epoxy coating and whatever you decide to use ensure that it is safe for long term use/contact with skin.

For the software side of things have you thought about how the app interface will be laid out at all? A potential design of the interface would be interesting and it would be cool if the app could store patient data to show progress (good or bad) in foot temperatures etc (all patient confidentiality accounted for obviously).

Overall good job and I am eager to follow the progression of this project throughout the semester."

"Hi,

This project is super cool and I am excited to see where it will go. Have you thought of using infrared thermometers as a way to measure the temperature of ones feet. Also will the top be like a screen that shows the temperature differences or will it be more of an imprint that fades quickly once the feet/heat are removed. I would recommend using a device that can save the feet imagine so that it can be compared to others throughout testing. Also maybe have it set up to forward an image to a doctor or database to be reviewed by a professional. Have you guys considered also making it a scale so that it can also record the patients weight? Overall great job and good luck."

"Hello,
I have taken several CS classes and might be able to provide some insight as to how to create your machine learning model. To create an effective model, it is first important to know exactly what you want your model to do, and what data is required for it. By the sound of your pitch, it sounds like a ML model capable of reading in an image and determining whether it belongs to a diabetic patient is the goal.
To create an effective model in this vein, it is important that you have access to a large amount of image data. This data would need to be for both groups: diabetic and non-diabetic. After procuring the data, it might be in the best interest of the model to rescale the images to be 1-D to normalize and make all the image data more uniform. After this, the images must be split into two separate groups, one that is used for training the model and the other for testing it. For the model you construct to have high fidelity, it is important that your datasets contain ~1000 entries. This number of entries makes it more likely that the model's accuracy of predicting disease state (or as a warning for disease state) is reasonably high.
As for constructing the model, I would recommend the usage of the KERAS Machine Learning library in Python 3 (https://keras.io/). This is a library that can be used to create various machine learning models in python based on the specifications that you are looking for. There already exist

training data sets on which you can practice making models should you want to learn more about how they work and many different tutorials for constructing simple machine learning models (https://machinelearningmastery.com/tutorial-first-neural-network-python-keras/). The usage of this library will also mean that your group does not have to get bogged down in the mathematical details of how your model works but can instead look at how changing parameters affects optimization.
I recall vaguely that in my CS 540 class, I worked on a project to create some model (not sure if it was a ML model) to classify whether or not a given image was a specific type of clothing. If it would be any help, I would be willing to share my code for that assignment, as it may provide a unique chance for your group to learn about KERAS and its quirks."

"Hi team,

Sounds like you are really on track for making a great data collection device for this clinical problem.

I expect a hurdle you will reach once you have some success with the TLC imaging surface is actual data collection and analysis. If you decide to go down the mobile camera route for image collection I would suggest adding physical markers onto the board that can aid in image recognition. Also separating the left and right foot (with a line down the middle I'm thinking) will help in image processing as you won't have to separate left and right feet and removes potential patient use error.

If you plan to use IOS for image capture something to research is VisionKit (https://developer.apple.com/documentation/visionkit) which leverages the iPhone's document scanning technology. Next once you have good images of the foot you will need to analyze and calibrate what the specific colors mean in terms of temperature. Based on your desired specificity, you will need to segment the image to focus only on the foot data. Because you are dealing with colors, I would recommend researching the K-means clustering algorithm for image segmentation (a type of machine learning!) for removing background data and even finding hotspots on the foot. Here is a link to get you started (https://www.kdnuggets.com/2019/08/introduction-image-segmentation-k-means-clustering.html). There is a lot of machine learning methods that don't require large amounts of data, especially with image recognition, so definitely do some research on this.

Another problem to think about is if the feet are rotated or not similar shapes when comparing them to each other. You can possibly mediate this by using physical positioning lines on the board. However for post processing of the image and lining up the feet, this paper (https://www.kdnuggets.com/2019/08/introduction-image-segmentation-k-means-clustering.html) has a few good algorithms and also describes the use of k-means clustering.

Good luck with the rest of the project, hope this helps a little! My email is tjlarson4@wisc.edu if you have any other questions!"

Conclusions/action items:

From this feedback, we got useful information about different clear coats we could use to seal the thermochromic materials, as well as resources if we start working on the ML algorithm.

11/16/2020 - Team Meeting 9

CADE VAN HORN - Dec 09, 202

Title: Team Meeting 9

Date: 11/16/2020

Content by: Cade

Present: Whole group

Goals: The goals of this meeting were to decide on materials and get them ordered.

Content:

Below is the list of materials we decided on and ordered for this project:

Item	Description	Manufacturer	Date	QTY	Cost Each	Total	Link
Category 1: Thermochromic Materials (powders, sheets, paints, etc)							
THERMOCHROMIC POWDER PIG	Blue to Violet Powder 22 degree	ATLANTA CHEMIC	11/6/2020	1	$9.98	$9.98	https://www.atlantache
THERMOCHROMIC POWDER PIG	Black to Green Powder 25 degre	ATLANTA CHEMIC	11/6/2020	1	$9.98	$9.98	https://www.atlantache
THERMOCHROMIC POWDER PIG	Red to Yellow Powder 28 degree	ATLANTA CHEMIC	11/6/2020	1	$9.98	$9.98	https://www.atlantache
THERMOCHROMIC POWDER PIG	Black to Pink Powder 31 degrees	ATLANTA CHEMIC	11/6/2020	1	$9.98	$9.98	https://www.atlantache
THERMOCHROMIC POWDER PIG	Black to Purple Powder 35 degre	ATLANTA CHEMIC	11/6/2020	1	$9.98	$9.98	https://www.atlantache
TLC sheets	Three Color Changing Thermoch	Amazon	11/6/2020	1	$28.40	$28.40	https://www.amazon.co
Category 2: Other Materials (for building the imaging surface, testing, etc)							
Wooden Craft Rectangles	Wooden Boards	Amazon	11/6/2020	1	$17.99	$17.99	https://www.amazon.co
1 inch thick foam	Foam to glue onto wooden boar	Amazon	11/6/2020	1	$9.99	$9.99	https://www.amazon.co
Acrylic paint base	Acrylic paint base to mix with pi	Amazon	11/6/2020	1	$11.12	$11.12	https://www.amazon.co
Epoxy Resin and Hardener	Epoxy Resin top coat to secure t	Amazon	11/6/2020	1	$13.99	$13.99	https://www.amazon.co
Black fabric	Fabric to paint the pigments ont	Amazon	11/6/2020	1	$4.99	$4.99	https://www.amazon.co
					TOTAL:	**$136.38**	
					Budget:	$500	

Link to spreadsheet: https://docs.google.com/spreadsheets/d/1fIVO4p_hwH618L1BRIEp-VXYu2-nyZhTmqeiaFfuErg/edit?usp=sharing

The thermochromic pigments were selected to be mixed with the acrylic paint base in order to make a color changing paint that could be painted onto both fabric and wood. Foam was selecte padding for the foot when the surface is stepped on, and fabric would cover this foam, allowing the entire 3D surface of the foot to show a thermal map rather than just a flat footprint. the wood serve as a solid surface beneath the foam. The epoxy resin was selected as a top coat, as suggested by one of our peers. Lastly, TLC sheets were also ordered so that comparisons between and powders could be made.

Conclusions/action items:

We decided on materials and got them all ordered.

12/02/2020 - Fabrication and Testing Meeting

CADE VAN HORN - Dec 09, 2020, 8:16 AM CST

Title: Fabrication and Testing Meeting

Date: 12/02/2020

Content by: Matt Voigt

Present: Matt Voigt, Cade Van Horn

Goals: To build and test our final product

Content:

- A fabrication process and testing protocol were created which can be found under fabrication and testing and results, respectively

Intended Fabrication Plan:

Initial Qualitative Testing of Pigments:

1. In five separate containers, add about a teaspoon of each pigment
2. In each of the containers, add the Liquitex white acrylic medium in a 2:1 acrylic to pigment ratio and mix with a stir stick to fully combine the pigment and acrylic medium
3. With a paint brush, paint a swatch (about 2 inches long, 1 inch wide) of each pigment range onto a wooden board to test the color changing abilities
    1. When the swatches dry completely, apply heat to each to test if the color changes at the desired temperature. If the color does not change as desired, apply more coats to the swatch until the desired color change is observed.
4. Repeat step 3 on the black fabric to test the color changing ability of each pigment on the fabric compared to the wood
5. Compare the swatches on the wood and the fabric and qualitatively determine if the color change is more vibrant on one or the other
6. Repeat steps 1-5 with the Craftsmart acrylic paint as a base for the pigments
    1. Compare the Liquitex and Craftsmart swatches and qualitatively determine if the color change is more vibrant with one base versus the other

Fabrication of Fabric-Foam Imaging Surface:

1. Cut a square of black fabric that is 16in x 16in.
2. Lay the square of fabric out and paint an even layer of the lowest temperature pigment. Wait for the layer to dry completely and paint another layer until the pigment is opaque.
3. Once the first layer has dried, apply a thin, even coat of the clear epoxy resin over the thermochromic layer.
4. Repeat steps 2-3 with each successive temperature pigment until all pigments have been layered in between clear coats. Apply one final clear coat.
5. Cut a 14in x 14in square of 1in thick foam and wrap the fabric around the foam, securing it with glue.
6. Glue the foam onto a wooden board for a solid base to the imaging surface

Testing of Imaging Surface - Temperature Comparison:

1. Using a container full of water heated to an unknown temperature, apply heat to the surface and let sit for five seconds.
2. Remove the heat source and use the colors to estimate and record the temperature (22 degrees Celsius = violet, 25 = green, 28 = yellow, 31 = pink, 35 = purple)
3. Measure the actual temperature of the water with a thermometer and record
4. Repeat step 2-3 eight times, recording the actual and estimated temperature
5. Calculate the mean, and standard deviation of both the estimated temperatures and the actual temperatures.
6. Perform a two sample t test to compare the means with a significance value of alpha = 0.05 to see if the actual vs estimated temperatures are significantly different

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- After going through the first steps of the fabrication plan, we realized that the TLC paints were not changing colors at all on the black fabric after numerous coats. They also had very weak color changing abilities on the wooden surface - only two of the pigments actually changed color when heat was applied to the wood
- This meant that our fabrication plan wouldn't work and we'd have to switch plans
- Luckily we had also ordered TLC sheets, which did change color as expected, unlike the pigments
- Due to the minimal amount of time left to perform testing and have it be included in our final presentation, we ended up changing our intended fabrication plan to essentially cutting up the TLC sheets and gluing them next to each other in an alternating fashion.

Description of the fabrication of the modified final prototype:

In order to fabricate the proposed final design, each pigment was added to a separate container and mixed with two different acrylic bases, a white Liquitex acrylic medium, and a Craftsmart white acrylic paint. Swatches of each pigment-paint mixture were painted onto both wood and fabric to test their color changing abilities and assess their vibrancy. Several layers of these swatches were built up, and once each pigment dried completely, heat was applied to qualitatively test the color-changing abilities. A detailed fabrication plan for the intended prototype using these pigments can be found in Appendix B.

Unfortunately, the fabrication process did not go as planned. When the pigments were mixed with the Liquitex acrylic medium and applied to wood, the color change observed when heat was applied was very weak in two of the five pigments, and no color change was observed in the other three. The same results were found with the Craftsmart acrylic base as well when applied directly to wood. Both the Liquitex and Craftsmart pigment mixtures were also applied to black fabric, but no color change was found in these swatches either when temperature was applied.

After unexpectedly finding no color change when the pigments were applied to both wood and fabric, the same process was repeated after first applying a white base coat to both materials, then painting the thermochromic mixtures. However, like the first experiment, no color change was observed when heat was applied to these swatches. This meant that fabrication of the prototype could not proceed as outlined in the fabrication plan (Appendix B).

In order to continue fabrication, the team modified plans for the final prototype to resemble the first preliminary design idea rather than the proposed final design, and ordered a set of three thermochromic sheets that change color from 20-25, 25-30, and 30-35 degrees Celsius respectively. Each sheet was cut into strips 0.5cm wide and 4in long. These dimensions were chosen because each of the three sheets were originally 4in x 4in, and they were cut into strips approximately 0.5cm wide because, when combined, the three strips of different temperature ranges had a total width of 1.5cm, which is approximately the width of the average foot ulcer [32]. These strips were glued onto a wooden board in order of increasing temperature range so that repeating groups of three strips covered the board. The strips were labeled on the board with their temperature ranges.

This design was chosen so that when heat is applied to the surface, lower temperatures cause color change in only the 20-25$_{o}$C strips, mid-range temperatures cause change in the 25-30$_{o}$C strips, and only high temperatures cause any change in the 30-35$_{o}$C strips. Different areas of the foot have different temperature ranges, the toes having an average temperature of 26.2$_o$C and the sole an average temperature of 29.3$_o$C [33]. These fall within the 25-30$_o$C temperature range, however, foot temperatures can be as much as 5$_o$C higher or lower than these averages, thus the need for the combination of thermochromic strips with different temperature ranges so that higher foot temperatures can be sensed by the device. The final surface with the thermochromic strips had dimensions 8in x 8in, which is not as large as the intended design due to lack of materials and time constraint caused by the unexpected change in design.

- After we finished fabricating the device, Matt took the materials home to perform testing:

In order to test the accuracy of the final prototype, a temperature comparison test was performed in order to compare temperatures estimated from the device and actual temperatures. A container full of water heated to an unknown temperature was used to apply heat to the thermochromic imaging surface for five seconds. After removing the heat source, the color of the different strips was used to estimate and record the temperature. Meanwhile, the actual temperature of the water was recorded with a thermometer as well. This comparison was performed eight different times, recording both the actual and estimated temperatures in table 3 below. After collecting this data, a two sample t test was performed.

Table 3. Temperature Comparison Data. This table shows the estimated temperatures and actual temperatures found during the temperature comparison test, as well as the difference between the estimated and actual values.

Trial	Estimated temperature based on color shift (Celsius)	Actual temperature from thermometer (Celsius)	Difference (Actual - Estimated)
1	36$_o$C	38.1$_o$C	2.1$_o$C
2	34$_o$C	33.2$_o$C	-0.8$_o$C
3	27.5$_o$C	28.4$_o$C	0.9$_o$C
4	24.5$_o$C	23.2$_o$C	-1.3$_o$C
5	19$_o$C	17.8$_o$C	-1.2$_o$C
6	27$_o$C	29.5$_o$C	2.5$_o$C
7	29$_o$C	28.9$_o$C	-0.1$_o$C
8	31.5$_o$C	31.3$_o$C	-0.2$_o$C
Average	28.5625	28.8	1.1375
Standard deviation	5.4145	6.1542	1.31

A second test was performed to test the amount of time an accurate thermal map lasted on the device before fading. This test was performed to quantify the approximate amount of time someone using the product would have to take an image of the thermal map while it is still sufficiently accurate. To determine this, a clear plastic bag was filled with water of known temperature and used to heat the thermochromic imaging surface for approximately thirty seconds. The heat source was then removed and the amount of time that passed until the outermost thermochromic strip lost all color change was recorded. Although the color changes were more persistent at the center of the thermal map, the disappearing time of the colors at the edges was used to quantify thermal map retention because the color differences become more ambiguous at the center of the map as time passes.

Table 4. Thermal Map Retention Data. This table shows how much time passed until all color change was lost in a strip of thermochromic material at the edge of the thermal map after removal of a heat source of known temperature.

Temperature (°C)	25-30°C Sheet Time to Color Loss (seconds)	30-35°C Sheet Time to Color Loss (seconds)
25	1	-
26	9	-
27	11	-
28	27	-
29	50	-
30	-	3
31	-	4
32	-	5
33	-	6
34	-	6.5
35	-	7
36	-	9
37	-	10
38	-	11
39	-	22
Average	19.6 seconds	8.35 seconds

Conclusions/action items:

We had to switch plans at the last minute but we were able to fabricate a final prototype and perform testing on it.

9/11/2020 Client Meeting 1

MATTHEW VOIGT - Oct 06, 2020, 2:16 PM CDT

Title: First Client Meeting

Date: 9/11/2020

Content by: Matt Voigt

Present: Whole Team

Goals: Discuss and increase are understanding of the goals of the project

Content:

- Untreated, diabetes causes neuropathy and disrupts the biofeedback loop
  - No feeling in soles of feet can lead to overuse and eventually ulcers
  - Looking to close the biofeedback loop with external monitoring of foot irritation
  - Ulcers can heal well if not infected, but the target group for the product often do not seek medical treatment until the ulcer is infected or well developed
- Footwear can greatly reduce the risk of ulcers
  - Holes punched in shoes are a simple solution
  - Not common for people in rural areas of India to consistently wear shoes, looking for an option with a higher rate of compliance
- When do we intervene? How do we anticipate the emergence of an ulcer?
  - Want a preventative measure rather than treating after the fact
  - Studies have shown 2.2C difference in temperature within a foot identifies at risk individuals
  - With only a narrow window of time available to detect risk of ulcer emergence, want to find patterns that can identify individuals with higher ulcer risk even before the 2.2C threshold is reached
  - Analyzing temperature profiles of soles of feet of patients has been shown to successfully identify the level of risk an individual has of developing an ulcer.
- Machine Learning!
  - Train AI software to determine ulcer risk with large sample of temperature profiles of feet
  - Would also like to have ability to feed multiple metrics that affect risk so ML can incorporate more than just temperature profiles in risk assessment
  - Currently using Supervisely software

More notes post-meeting from the client:

Is there any existing data that we could use if the project goes in the direction of software building?

Yes, I have about 210 patients' image data. Includes both the thermal scan of their feet + normal image

Are you still working with pressure sensors or is this project only focusing on temperature sensors?

This project completely pivoted away from pressure once we realized that temperature had much stronger predictive power than pressure

What skills does each team member have with circuit design, programming, Python, app design, AI software, Solidworks, etc?

→ I believe this was geared towards teammates?

[Check it out!]

If we developed an app-based software to interpret the images and thermal maps, what kind of data would we be compiling from the images?

Great question! Both visible and IR spectrum data seem relevant. But we could refine it a bit and work only with the pixels that pertain to the feet

Is a smart phone's thermal camera accurate enough to make conclusions about the inflammation of a patient's foot? (i.e. thermal vision filter app) Or is a separate dedicated thermal camera necessary?

→ I'm not sure that the filter on a phone app is actually reflecting temp data? From my understanding, its just a camera affect so if this assumption is wrong, lets take a look at it!

How do you make a machine learning algorithm?

→ currently we're using an online platform to annotate and interface with Python scripts we're using to train an algorithm. The online platform: Supervisely

Has any of the ML algorithm already been created? Would we be building off of an existing program or starting from scratch?

We wouldn't have to start from scratch per se - we'd want to train a similar algorithm, but using images you collect on the thermochromatic material.

Is there a set budget for this project?
Since most if not all of the project will be online likely, will there be anything that requires purchase (software, materials, etc)?

$500 is what the BME department provides (for global health projects). We can talk about this more if you need to buy anything

Who is the target audience of this device? Doctors or patients?

The target for this device is to be used in-home to help patients understand when an issue may arise. Would also be great for community health workers who would then further refer patients to a specialist if a patient is identified as having high risk.

Conclusions/action items:

Much more research will need to be done for the team to familiarize themselves with the project. We will focus primarily on research until our client meeting next Friday. It does appear as if the primary goal for the project this semester will be to develop a thermochromic material that will allow for consistent representation temperature profiles of feet.

9/18/2020 - Client Meeting 2

CADE VAN HORN - Oct 07, 2020, 10:07 AM CDT

Title: Client Meeting 2

Date: 9/18/2020

Content by: Cade Van Horn

Present: Whole group

Goals: To further discuss the goals for the semester project with the client.

Content:

- Look into how does neuropathy work
    - loss of pain is gradual
    - hyperglycemia leads to neuropathy
    - once sensation is lost, risk of ulceration skyrocks
- target audience
    - diabetic patients in india
    - people both pre and post neuropathy
- 3 different kinds of nerves
    - motor
    - parasympathetic
    - sensory
- blood sugar attacks the myelin sheath of nerves and kills them
- monofilament is a way to apply pressure and determine what force it buckles to assess pain
    - touch foot in different spots and increase force to see how much force it takes to feel it
- neuropathy
    - feel 6 or fewer out of 10 spots at 10g force with the monofilament
- biothessometer
    - apply vibrations to see at what point a patient with neuropathy can feel it
    - measured in volts
    - neuropathy causes loss of sensation of vibration
- Thermochromic materials
    - cheap
    - existing device - 2 foot pads that has thermo material to step on and show color map of feet
    - can qualitatively identify hot spots
- want to know risk timeline
    - output using AI app
    - need to make a metric

Conclusions/action items:

This meeting was helpful for getting a broad overview of the problem and how diabetes affects patients.

9/25/2020 - Client Meeting 3

CADE VAN HORN - Oct 07, 2020, 10:12 AM CDT

Title: Client Meeting 3

Date: 9/25/2020

Content by: Cade Van Horn

Present: Whole group

Goals: To discuss the project and where we should start with brainstorming

Content:

- existing algorithms
  - image j
  - cell profiler
- supervisely - a collaborative space to work on code
- charcote's foot - another thing that affects feet but not related to diabetes
- VPT zylus - vibratory perception threshold
- temperature measurement leads to much less ulceration
- siren socks - competing product
- home monitoring is very important
- could order different types of thermochromic materials and see how insulation helps the image stay
- cost comparison in design matrix
- look at temperature values and ranges
- look into custom websites
- what if we mix the different powders?
- set up tests for different thermo materials
- make sure the temp range is accurate enough for what we want

Conclusions/action items:

We talked a lot about different products and materials that are out there and how we can come up with our own design. We also talked about machine learning algorithms.

10/30/2020 - Client Meeting 4

CADE VAN HORN - Dec 09, 2020, 8:29 AM CST

Title: Client Meeting 4

Date: 10/30/2020

Content by: Cade Van Horn

Present: Whole group, Kayla Huemer

Goals: This goals of this meeting were to touch base with Kayla about the project

Content:

- We discussed our preliminary presentation and report, which Kayla had read
- She liked the idea we are going with and the plan we have for fabrication. She agrees with our group that she isn't sure if we can just mix all the powders together or if we will have to layer them similar to an article we came across
- She says to not worry to much about the machine learning algorithm side of the project
- she gave us the contact information of someone on her team who we can reach out to for more information about the data they have already collected

Conclusions/action items:

We touched base with Kayla, who seems to like the direction our project is taking.

9/11/2020 Advisor Meeting 1

CADE VAN HORN - Sep 11, 2020, 1:53 PM CDT

Title: Advisor Meeting 1

Date: 9/11/2020

Content by: Cade Van Horn

Present: Whole Group

Goals: The goals of this meeting were just to touch base at the start of the project and make sure that communication wasn't a problem.

Content:

We talked with Dr. Skala for a few minutes to make sure we all know how to communicate when needed and to confirm that we had scheduled a meeting with our client.

Conclusions/action items:

There weren't any questions at the time since we still needed to meet with our client but we decided we would come up with a list of questions and things to address after meeting with our client.

9/18/2020 - Advisor Meeting 2

CADE VAN HORN - Dec 09, 2020, 8:31 AM CST

Title: Advisor Meeting 2

Date: 9/18/2020

Content by: Cade Van Horn

Present: Whole Group

Goals: The goals of this meeting were just to touch base after we met with our client for the first time

Content:

We talked with Dr. Skala for a few minutes to make sure our first client meeting went well.

There weren't any pressing issues.

9/25/2020 - Advisor Meeting 3

CADE VAN HORN - Dec 09, 2020, 8:34 AM CST

CADE VAN HORN-Dec 09, 2020, 8:31 AM CST

Title: Advisor Meeting 2

Date: 9/25/2020

Content by: Cade Van Horn

Present: Whole Group

Goals: The goals of this meeting were just to touch base about our ideas for the project

Content:

We talked with Dr. Skala for a few minutes about our project and our potential design ideas and she said we seemed like we were on the right track.

10/30/2020 - Advisor Meeting 4

CADE VAN HORN - Dec 09, 2020, 8:34 AM CST

CADE VAN HORN-Dec 09, 2020, 8:31 AM CST

Title: Advisor Meeting 4

Date: 10/30/2020

Content by: Cade Van Horn

Present: Whole Group

Goals: The goals of this meeting were just to talk about our preliminary report and presentation

Content:

Dr. Skala thought we did well on our preliminary deliverables, and gave us a few pointers for working on our final deliverables.

9/11/2020 - Progress Report 1

MATTHEW VOIGT - Oct 06, 2020, 2:32 PM CDT

Title: Progress Report 1

Date: 9/11/2020

Content by: Whole Team

Present: Whole Team

Goals: To summarize the activities of the team over the last week.

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Progress Report #1: 9/4/2020 - 9/9/2020

Project Information

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

Matt Voigt mwvoigt@wisc.edu (Communicator)

Emma Kupitz kupitz@wisc.edu (BSAC)

Carter Rupkey rupkey@wisc.edu (Co-BWIG)

Will Nelson wjnelson4@wisc.edu (Co-BWIG)

Anvesha Mukherjee amukherjee27@wisc.edu (BPAG)

Problem Statement

Create a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients. Develop an app-based software to further interpret the images and thermal maps collected by the client while in India.

Brief Status Update

The team spent this week researching the project in order to get a better understanding of the problem. This research included finding information about diabetes and foot ulcers, as well as methods of measuring temperature and potential ways to develop an app. We look forward to learning more about the project and beginning the brainstorming process.

Summary of Team Role Accomplishments

Cade Van Horn (Leader)-This week I researched diabetic foot ulcers and amputations, both in India and on a global scale.

Matt Voigt (Communicator) - Reviewed research by other teams on the project over the last two semesters.

Emma Kupitz (BSAC)- This week I started researching diabetes in a detailed manner.

Carter Rupkey (Co-BWIG)- This week I began researching how diabetes can lead to foot ulcers and amputations.

Will Nelson (Co-BWIG)- This week I started looking at information on how diabetes is directly related to foot ulcers.

Anvesha Mukherjee (BPAG)- Initialized research on how AI algorithms can analyze heat maps through a software or an app

Team Goals for Next Week

Over the course of the next week, the team plans to continue researching to gain a more in depth understanding of the project and all of the details in order to begin brainstorming ideas.

Weekly/Ongoing Difficulties

So far there have not been any difficulties in researching the project.

Individual Goals

Cade Van Horn (Leader)- My goal for the following week is to really dive into research on measuring temperature and try to find existing patents and devices that might spark ideas.

Matt Voigt (Communicator)- Expand on the research suggested by the last team to work on the project such as researching machine learning related to analysis of heat maps and the possibility of stitching multiple images to increase resolution of an MLX camera.

Emma Kupitz (BSAC)- I plan to continue researching how ulcers and amputations happen and how to prevent them.

Carter Rupkey (Co-BWIG)- My goal for the next week is to continue researching diabetic foot ulcers and amputations as well as ways to measure temperature.

Will Nelson (Co-BWIG)- My goal for this upcoming week is to find some good research about diabetes and foot ulcers. I also want to learn more about the problem in general.

Anvesha Mukherjee (BPAG)- Delve into a body of research pertaining to methods to increase cost efficacy for underprivileged rural communities without access to healthcare, as well as to research thermochromic materials

Project Schedule

Task	September			October					November				December	
	11	18	25	2	9	16	23	30	6	13	20	27	4	11
R & D														
General Research	X													
Prototyping														
Testing														

Deliverables	
Progress Reports	X
PDS	
Design Matrix	
Preliminary Presentation	
Mid-Semester Report	
Decide on final Design	
Order Materials	
Final Presentation	
Final Report	
Meetings	
Client	
Advisor	
Team	x
Other	
Website	
Update	x

Expenses

[redacted]	
Component 1	
Component 2	
Component 3	
TOTAL:	**$0.00**

No expenses to date

Conclusions/action items:

9/18/2020 - Progress Report 2

MATTHEW VOIGT - Oct 06, 2020, 2:33 PM CDT

Title: Progress Report 2

Date: 9/18/2020

Content by: Whole Team

Present: Whole Team

Goals: To summarize the team's activities over the last week

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Progress Report #2: 9/10/2020 - 9/18/2020

Project Information

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

Matt Voigt mwvoigt@wisc.edu (Communicator)

Emma Kupitz kupitz@wisc.edu (BSAC)

Carter Rupkey rupkey@wisc.edu (Co-BWIG)

Will Nelson wjnelson4@wisc.edu (Co-BWIG)

Anvesha Mukherjee amukherjee27@wisc.edu (BPAG)

Problem Statement

Create a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients. Develop an app-based software to further interpret the images and thermal maps collected by the client while in India.

Brief Status Update

The team continued to research the project this week after getting some direction after last week's meeting. This research included finding information on neuropathy and the different kinds of nerves in the body, thermochromic material, and the basics of machine learning algorithms. We also began to work on the preliminary product design specifications, but many areas were not able to be filled out since we are still looking for a little more direction. After a second client meeting, we anticipate that we will be able to more thoroughly write out the product design specifications. We look forward to discussing the goals of the project this week and beginning to brainstorm ideas.

Summary of Team Role Accomplishments

Cade Van Horn (Leader)-This week I researched machine learning algorithms and thermochromic material. I also worked on the preliminary product design specifications.

Matt Voigt (Communicator) - Completed the human subjects training and began the linked in learning course on machine learning.

Emma Kupitz (BSAC)- This week I learned more about thermal scanning and artificial intelligence.

Carter Rupkey (Co-BWIG)- This week I researched information about neuropathy and the different kinds of nerves in the body.

Will Nelson (Co-BWIG)- This week I researched how thermal scanning is able to detect foot ulcers.

Anvesha Mukherjee (BPAG)- This week I researched information about the Xilas VPT and home monitoring of foot skin temperatures to prevent ulcerations.

Team Goals for Next Week

Over the course of the next week, the team plans to continue researching and begin to determine more specific goals for the semester, including brainstorming design ideas.

Weekly/Ongoing Difficulties

So far there have not been any difficulties in researching the project.

Individual Goals

Cade Van Horn (Leader)- My goal for the following week is to look into introductory machine learning courses available online and see what kind of programming background might be necessary to teach a computer to recognize different images.

Matt Voigt (Communicator)- I would like to complete the linked in learning learning course on machine learning.

Emma Kupitz (BSAC)- My goal is to continue researching artificial intelligence in order to start applying it to the project.

Carter Rupkey (Co-BWIG)- My goal for the following week is to continue research and begin brainstorming ideas.

Will Nelson (Co-BWIG)- My goal for this upcoming week is to continue to research thermochromic material.

Anvesha Mukherjee (BPAG)- For the upcoming week I will delve deeper into heat mapping using thermochromic materials, machine learning, and artificial intelligence

Project Schedule

Task	September			October					November				December	
	11	18	25	2	9	16	23	30	6	13	20	27	4	11
R & D														
General Research	X	X												
Prototyping														
Testing														

Deliverables		
Progress Reports	X	X
PDS		
Design Matrix		
Preliminary Presentation		
Mid-Semester Report		
Decide on final Design		
Order Materials		
Final Presentation		
Final Report		
Meetings		
Client		
Advisor		
Team	X	X
Other		
Website		
Update	X	X

Conclusions/action items:

9/25/2020 - Progress Report 3

MATTHEW VOIGT - Oct 06, 2020, 2:34 PM CDT

Title: Progress Report 3

Date: 9/25/2020

Content by: Whole Team

Present: Whole Team

Goals: To consolidate the team's progress over the last week

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Progress Report #3: 9/18/2020 - 9/25/2020

Project Information

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

Matt Voigt mwvoigt@wisc.edu (Communicator)

Emma Kupitz kupitz@wisc.edu (BSAC)

Carter Rupkey rupkey@wisc.edu (Co-BWIG)

Will Nelson wjnelson4@wisc.edu (Co-BWIG)

Anvesha Mukherjee amukherjee27@wisc.edu (BPAG)

Problem Statement

Create a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients. Develop an app-based software to further interpret the images and thermal maps collected by the client while in India.

Brief Status Update

This week the team brainstormed design ideas and compiled them all during a team meeting. We narrowed it down to three main design ideas that we thought were the most feasible given the limitations of the online-format of the semester, and compiled them into a design matrix. In the design matrix, we evaluated each of the three designs based on a set of criteria to decide which was the best design.

Summary of Team Role Accomplishments

Cade Van Horn (Leader)- This week I worked on brainstorming design ideas and continuing research on machine learning.

Matt Voigt (Communicator) - I continued machine learning research and familiarized myself with thermochromic liquid crystals.

Emma Kupitz (BSAC)- I brainstormed ideas and researched materials and artificial intelligence.

Carter Rupkey (Co-BWIG)- This week I brainstormed design ideas and continued researching about neuropathy.

Will Nelson (Co-BWIG)- This week I researched machine learning algorithms that may be useful for our project.

Anvesha Mukherjee (BPAG)- researched thermochromic materials and learned more about neuropathy and machine learning

Team Goals for Next Week

This week, the team will continue to refine our Product Design Specifications, and we will work on our preliminary design presentation which will take place next friday. We will also plan how to start working on our design and how to break up the tasks.

Weekly/Ongoing Difficulties

We will need to find a way to break up tasks for the project in a way that all of our six team members have something to do this semester since we will be doing the majority, if not all, of the project online. The team could also improve on communication and planning ahead of time.

Individual Goals

Cade Van Horn (Leader)- This week I plan to work on the preliminary presentation and figure out how to divide up tasks.

Matt Voigt (Communicator)- I will begin researching combinations of TLC formulations to be sensitive in the range required to show risk of foot ulcers.

Emma Kupitz (BSAC)- I plan to complete my portion of the presentation for next week.

Carter Rupkey (Co-BWIG)- I plan to continue brainstorming ideas and finish my portion of the preliminary presentation.

Will Nelson (Co-BWIG)- I plan to look into more a good way to get data from thermochromic material.

Anvesha Mukherjee (BPAG)- begin brainstorming ideas for preliminary presentation and affordability of thermochromatic materials

Project Schedule

Task	September			October					November				December	
	11	18	25	2	9	16	23	30	6	13	20	27	4	11
R & D														
General Research	X	X	X											
Prototyping														
Testing														
Deliverables														
Progress Reports	X	X	X											
PDS		X												

Design Matrix			X
Preliminary Presentation			
Mid-Semester Report			
Decide on final Design			
Order Materials			
Final Presentation			
Final Report			
Meetings			
Client	X	X	X
Advisor	X	X	X
Team	X	X	X
Other			
Website			
Update	X	X	X

Conclusions/action items:

10/2/2020 - Progress Report 4

MATTHEW VOIGT - Oct 06, 2020, 2:35 PM CDT

Title: Progress Report 4

Date: 10/2/2020

Content by: Whole Team

Present: Whole Team

Goals: To summarize the team's progress and activities over the last week

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Progress Report #4: 9/25/2020 - 10/02/2020

Project Information

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

Matt Voigt mwvoigt@wisc.edu (Communicator)

Emma Kupitz kupitz@wisc.edu (BSAC)

Carter Rupkey rupkey@wisc.edu (Co-BWIG)

Will Nelson wjnelson4@wisc.edu (Co-BWIG)

Anvesha Mukherjee amukherjee27@wisc.edu (BPAG)

Problem Statement

Create a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients. Develop an app-based software to further interpret the images and thermal maps collected by the client while in India.

Brief Status Update

This week we created our preliminary design presentation and recorded it so that it could be shown in class. We also worked on planning how we might be able to perform tests of our design. Below is a link for our presentation.

https://drive.google.com/file/d/1SMc67SPWXYWpQXlmlItLMLKM_eaTvY_I/view?usp=sharing

Summary of Team Role Accomplishments

Cade Van Horn (Leader)- This week I worked on the preliminary presentation slides and video, as well as some of the LinkedIn Learning course for machine learning algorithms.

Matt Voigt (Communicator) - I researched thermochromic liquid crystal suppliers and worked on the preliminary presentation.

Emma Kupitz (BSAC)- I worked on my part of the presentation.

Carter Rupkey (Co-BWIG)- This week I worked on and presented my portion of the Preliminary Design Presentation. I also submitted a PDF of the slides and the video to the website.

Will Nelson (Co-BWIG)-

Anvesha Mukherjee (BPAG)- Completed research for preliminary presentation

Team Goals for Next Week

This week we need to finalize all of our preliminary deliverables and write our mid-semester report. We will also try to find the best place to purchase thermochromic powders for our design.

Weekly/Ongoing Difficulties

We are having some difficulties finding the most accurate method to measure the temperature of a patient's feet since even the powders have a temperature range. We need to find the most accurate powders.

Individual Goals

Cade Van Horn (Leader)- This week I plan to work on the mid-semester report and find places where we could purchase thermochromic powders.

Matt Voigt (Communicator)- This week I will research more about TLC powder products and how we ought to combine them to reach the desired temperature range.

Emma Kupitz (BSAC)- Next week I plan to do research on how to execute our project.

Carter Rupkey (Co-BWIG)- Next week I plan to look even further into research based on the design we chose.

Will Nelson (Co-BWIG)-

Anvesha Mukherjee (BPAG)- Initial research on TLC powder topcoat and machine learning for the app based software algorithm

Project Schedule

Task	September			October					November				December	
	11	18	25	2	9	16	23	30	6	13	20	27	4	11
R & D														
General Research	X	X	X	X										
Prototyping														
Testing														
Deliverables														

Progress Reports	X	X	X	X
PDS		X		
Design Matrix			X	
Preliminary Presentation				X
Mid-Semester Report				
Decide on final Design				
Order Materials				
Final Presentation				
Final Report				
Meetings				
Client	X	X	X	
Advisor	X	X	X	
Team	X	X	X	X
Other				
Website				
Update	X	X	X	X

Conclusions/action items:

10/09/2020 - Progress Report 5

CADE VAN HORN - Dec 09, 2020, 8:21 AM CST

Title: Progress Report 5

Date: 10/09/2020

Content by: Cade

Present: N/A

Goals: To summarize the work we've done

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Progress Report #5: 10/02/2020 - 10/16/2020

Project Information

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

Matt Voigt mwvoigt@wisc.edu (Communicator)

Emma Kupitz kupitz@wisc.edu (BSAC)

Carter Rupkey rupkey@wisc.edu (Co-BWIG)

Will Nelson wjnelson4@wisc.edu (Co-BWIG)

Anvesha Mukherjee amukherjee27@wisc.edu (BPAG)

Problem Statement

Create a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients. Develop an app-based software to further interpret the images and thermal maps collected by the client while in India.

Brief Status Update

This week we have been working a lot on researching cost effective color changing powders from various companies with a temperature range of 25 to 36 degrees Celsius, and where to purchase them. We have also been investigating various methods of application, from spray paint to coatings to stencils, and layering configurations for the powders.

Team Goals for Next Week

The goal for next week is to decide on which products we want to purchase and get them ordered. We also want to lay our a more concrete fabrication protocol for when we receive the materials, and start working on more detailed testing plans and how we will collect data.

Weekly/Ongoing Difficulties

We are unsure if layering the powders in different patterns will impact the data that can be collected from the images via a machine learning algorithm, so we need to contact someone that knows a bit more about machine learning to answer this question.

Project Schedule

Task	September			October					November				December	
	11	18	25	2	9	16	23	30	6	13	20	27	4	11
R & D														
General Research	X	X	X	X	X									
Prototyping														
Testing														
Deliverables														
Progress Reports	X	X	X	X	X	X								
PDS		X												
Design Matrix			X											
Preliminary Presentation				X										
Mid-Semester Report					X									
Decide on final Design														
Order Materials														
Final Presentation														
Final Report														
Meetings														
Client	X	X	X			X								
Advisor	X	X	X		X	X								
Team	X	X	X	X	X	X								

Other					
Website					
Update	X	X	X	X	X

Conclusions/action items:

This week we did a lot of research on thermochromic materials we could possibly use.

10/23/2020 - Progress Report 6

CADE VAN HORN - Dec 09, 2020, 8:22 AM CST

Title: Progress Report 6

Date: 10/23/2020

Content by: Cade

Present: N/A

Goals: To summarize our progress this week

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Progress Report #5: 10/16/2020 - 10/23/2020

Project Information

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

Matt Voigt mwvoigt@wisc.edu (Communicator)

Emma Kupitz kupitz@wisc.edu (BSAC)

Carter Rupkey rupkey@wisc.edu (Co-BWIG)

Will Nelson wjnelson4@wisc.edu (Co-BWIG)

Anvesha Mukherjee amukherjee27@wisc.edu (BPAG)

Problem Statement

Create a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients. Develop an app-based software to further interpret the images and thermal maps collected by the client while in India.

Brief Status Update

This week we split up into two groups to try to narrow down what product we intend to purchase. One group focused on researching products that we would layer, so that there would be gaps in the powders on the surface similar to a research paper that Matt found. The other group researched powders that would be combined into one mixture. The team made a list of all of the products we found, and we are narrowing it down to the top one or two before we go ahead and order them.

Team Goals for Next Week

The goal for this upcoming week is to order products so that we can begin preliminary testing to see what application and fabrication process would work the best. Then we can determine more factors like how thick a top coat would need to be and what would be the best surface to layer the powders on.

Weekly/Ongoing Difficulties

We haven't run into any difficulties this week. We just need to get the materials ordered as soon as possible so that we can work on our fabrication and start collecting data. One thing we are uncertain about is how and where we will fabricate everything when we are all social distancing.

Project Schedule

Task	September			October					November				December	
	11	18	25	2	9	16	23	30	6	13	20	27	4	11
R & D														
General Research	X	X	X	X	X	X	X							
Prototyping														
Testing														
Deliverables														
Progress Reports	X	X	X	X	X	X	X							
PDS		X												
Design Matrix			X											
Preliminary Presentation				X										
Mid-Semester Report					X									
Decide on final Design						X								
Order Materials														
Final Presentation														
Final Report														
Meetings														
Client	X	X	X			X								
Advisor	X	X	X		X	X	X							

Team	X	X	X	X	X	X	X
Other							
Website							
Update	X	X	X	X	X	X	X

Conclusions/action items:

10/30/2020 - Progress Report 7

CADE VAN HORN - Dec 09, 2020, 8:24 AM CST

Title: Progress Report 7

Date: 10/30/2020

Content by: Cade

Present: N/A

Goals: To summarize our progress this week

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Progress Report #7: 10/23/2020 - 10/30/2020

Project Information

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

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Emma Kupitz kupitz@wisc.edu (BSAC)

Carter Rupkey rupkey@wisc.edu (Co-BWIG)

Will Nelson wjnelson4@wisc.edu (Co-BWIG)

Anvesha Mukherjee amukherjee27@wisc.edu (BPAG)

Problem Statement

Create a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients. Develop an app-based software to further interpret the images and thermal maps collected by the client while in India.

Brief Status Update

This week we continued to narrow down the products we intend to purchase, and we also looked into insulating surfaces and top coats that we could apply to the powders. We also worked on the show and tell post on piazza, which we included below. This will let us receive feedback from our peers on our design.

Team Goals for Next Week

The goal for this upcoming week is to order products so that we can begin preliminary testing to see what application and fabrication process would work the best. Then we can determine more factors like how thick a top coat would need to be and what would be the best surface to layer the powders on.

Weekly/Ongoing Difficulties

We haven't run into any difficulties this week. We just need to get the materials ordered as soon as possible so that we can work on our fabrication and start collecting data. One thing we are still uncertain about is how and where we will fabricate everything when we are all social distancing.

Project Schedule

Task	September			October					November				December	
	11	18	25	2	9	16	23	30	6	13	20	27	4	11
R & D														
General Research	X	X	X	X	X	X	X	X						
Prototyping														
Testing														
Deliverables														
Progress Reports	X	X	X	X	X	X	X	X						
PDS		X												
Design Matrix			X											
Preliminary Presentation				X										
Mid-Semester Report					X									
Decide on final Design						X								
Order Materials														
Final Presentation														
Final Report														
Meetings														
Client	X	X	X			X								
Advisor	X	X	X		X	X	X							
Team	X	X	X	X	X	X	X	X						

Other								
Website								
Update	X	X	X	X	X	X	X	X

Show and Tell Post:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Diabetes is a growing problem in India that can often lead to the formation of ulcers and even amputation of the feet. Products like diabetic shoes and socks that are available in the United States are not as applicable to patients in India who might not wear socks or closed-toed shoes on a daily basis. However, the at-home monitoring of foot temperatures that these products use has been shown to effectively decrease the risk of ulceration in diabetic patients.

The thermochromic liquid crystal (TLC) imaging surface commissioned by Kayla Huemer is a low-cost, at-home device that diabetic patients in India can step on to generate a thermal map of their feet in order to provide easily understandable information about their health and whether or not they are at risk of developing an ulcer. Temperature differences in symmetric areas of the feet can be an indication of the possibility of an ulcer forming in that location. A color gradient in the thermal map will show these temperature differences. This will notify patients that they need to take action in their daily lives to significantly reduce the number of steps they take in order to prevent ulceration, which, if left untreated, could even lead to amputation. The TLC imaging surface will also be paired with a machine learning algorithm to further analyze the thermal maps, which can be photographed and uploaded to an app-based software. The software will analyze the color differences in the feet to determine if they pass a set threshold, and subsequently output a risk factor based on data that has already been collected from diabetic patients in India by our client.

The team is currently working on ordering and testing which TLC powders will generate the most vivid and long-lasting thermal map. We are testing different methods of combining and layering powders, as well as different surfaces (such as wood, plastic, or fabric). The team has about 200 thermal images of patients' feet from the client's time in India, but there is not currently enough data for an adequate machine learning algorithm, which would need hundreds more images. Below is a diagram of our design, and we would appreciate any advice on insulating surfaces and top coats, or machine learning algorithms if anyone has any knowledge of that, as well as any general comments and feedback on how we could improve upon our design. If the team completes initial fabrication and testing and submits the proper paperwork in good time, we also might be looking for people to participate in collecting data by stepping on the surface so that the team could take photos of the thermal maps for the machine learning algorithm, but that is more long term.

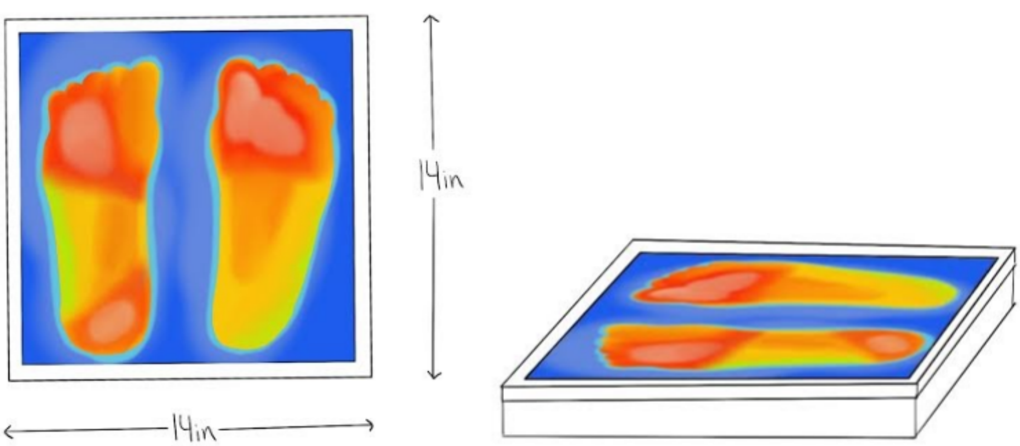

Figure 1. Top and side view of solid surface with temperature-sensitive color-changing thermochromic liquid crystal material showing a thermal image of two feet.

Link to our website for additional information: https://bmedesign.engr.wisc.edu/projects/f20/ulcer_detector

Conclusions/action items:

11/06/2020 - Progress Report 8

CADE VAN HORN - Dec 09, 2020, 8:25 AM CST

Title: Progress Report 8

Date: 11/06/2020

Content by: Cade Van Horn

Present: N/A

Goals: To summarize our progress this week.

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Progress Report #8: 10/30/2020 - 11/06/2020

Project Information

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

Matt Voigt mwvoigt@wisc.edu (Communicator)

Emma Kupitz kupitz@wisc.edu (BSAC)

Carter Rupkey rupkey@wisc.edu (Co-BWIG)

Will Nelson wjnelson4@wisc.edu (Co-BWIG)

Anvesha Mukherjee amukherjee27@wisc.edu (BPAG)

Problem Statement

Create a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients. Develop an app-based software to further interpret the images and thermal maps collected by the client while in India.

Brief Status Update

This week we posted our show and tell post on piazza so that we could receive feedback from our peers on our design. We held off on ordering materials until after posting this so that we could get advice on certain materials before committing to anything. We received a couple different comments that led our thought process, and drove us to finish deciding on materials. Pasted below are the comments we received on our design.

Comments:

“For possible top coat materials I would suggest either an epoxy resin or if you were looking into traditional paints, try a clear gesso (paint surface "primer"). Both are available as clear or white, so they would not affect the colors of the thermochromic liquid crystals. Both are able to be painted onto wood, plastic, and fabric and are tough and resistant. Since both are plastic based, they should be able to hold up to moisture, dirt, and oil pretty well. For an epoxy resin, make sure it is safe for long-term skin contact. I would recommend ArtResin, though it is on the pricier side per bottle if that's an issue. Enough epoxy could also essentially coat wood, plastic, or fabric and protect it, extending the use of the device”

“Firstly, nice visuals it makes it very clear what the proposed design is and how it would work. I have a few questions first:

What temperature specificity is needed for determining if a region of the foot is at risk for a diabetic foot ulcer? Is there any literature backing the TLC material's ability to show different colors for this specificity needed? In other words what I am wondering is if a difference of 5 degrees is indicative of an ulcer but the TLC material only shows differences of say 7 degrees how will this impact the design.

How quickly (or maybe not quickly) do the colors of the TLC material fade out or then be subjected to errors in imaging results? How long does the patient have after they step off the mat to take an image before the data is potentially compromised.

Based on the bit of research I have done on the thermochromic powders it seems applying them to a wood or fabric surface may not be best. Typically these powders are incorporated into ink and printed onto plastic films or acrylic media. Have you also thought about the size of the stepping pad? Could this possibly be adjustable in size in order to accommodate people with small or large feet? Or would this product be custom made? I also agree with the above reply that for top coats you should be looking into clear epoxy coating and whatever you decide to use ensure that it is safe for long term use/contact with skin.

For the software side of things have you thought about how the app interface will be laid out at all? A potential design of the interface would be interesting and it would be cool if the app could store patient data to show progress (good or bad) in foot temperatures etc (all patient confidentiality accounted for obviously).

Overall good job and I am eager to follow the progression of this project throughout the semester.”

“This project is super cool and I am excited to see where it will go. Have you thought of using infrared thermometers as a way to measure the temperature of ones feet. Also will the top be like a screen that shows the temperature differences or will it be more of an imprint that fades quickly once the feet/heat are removed. I would recommend using a device that can save the feet imagine so that it can be compared to others throughout testing. Also maybe have it set up to forward an image to a doctor or database to be reviewed by a professional. Have you guys considered also making it a scale so that it can also record the patients weight? Overall great job and good luck.”

Team Goals for Next Week

The goal for this week is to confirm with our advisor and client about the ordering process for materials and get all of the orders in by monday at the latest. Then as the materials begin to arrive, we can start with fabrication and testing. Until then we will try to type up a more detailed testing plan.

Weekly/Ongoing Difficulties

We had some difficulties finding products we need on sites that the BME department approves of, specifically TLC powders. None were available on the recommended sites. We are unsure if we will have any difficulties obtaining the materials we decided upon.

Cost and Materials Spreadsheet (not yet ordered):

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Category 1: Thermochromic Materials (powders, sheets, paints, etc)								
Thermochromic Color Change Cr	Nail Powder	Sophie & Toffee		11/6/2020	2	$8.37	$16.74	https://sophieandtoffee.com/th
THERMOCHROMIC POWDER PIGI	Blue to Violet 22 degrees	ATLANTA CHEMICAL ENGINEER		11/6/2020	1	$9.98	$9.98	https://www.atlantachemical.co
THERMOCHROMIC POWDER PIGI	Black to green 25 degrees	ATLANTA CHEMICAL ENGINEER		11/6/2020	1	$9.98	$9.98	https://www.atlantachemical.co
THERMOCHROMIC POWDER PIGI	Red to yellow 28 degrees	ATLANTA CHEMICAL ENGINEER		11/6/2020	1	$9.98	$9.98	https://www.atlantachemical.co
THERMOCHROMIC POWDER PIGI	Black to pink 31 degrees	ATLANTA CHEMICAL ENGINEER		11/6/2020	1	$9.98	$9.98	https://www.atlantachemical.co
THERMOCHROMIC POWDER PIGI	Black to purple 35 degrees	ATLANTA CHEMICAL ENGINEER		11/6/2020	1	$9.98	$9.98	https://www.atlantachemical.co
TLC sheets		Amazon		11/6/2020	1	$28.40	$28.40	https://www.amazon.com/Educ
Category 2: Other Materials (for building the imaging surface, testing, etc)								
Wooden Craft Rectangles	Wooden Boards	Amazon		11/6/2020	1	$17.99	$17.99	https://www.amazon.com/Unfin
1 inch thick foam	Foam to glue onto wooden boar	Amazon		11/6/2020	1	$9.99	$9.99	https://www.amazon.com/GoTo
Acrylic paint base	Acrylic paint base to mix with pi	Amazon		11/6/2020	1	$11.12	$11.12	https://www.amazon.com/dp/B
Epoxy Resin and Hardener	Epoxy Resin top coat to secure t	Amazon		11/6/2020	1	$13.99	$13.99	https://www.amazon.com/Epox
Black fabric	Fabric to paint the pigments ont	Amazon		11/6/2020	1	$4.99	$4.99	https://www.amazon.com/60in-
						TOTAL:	**$153.12**	
						Budget:	$500	

Link to actual spreadsheet with working links:

https://docs.google.com/spreadsheets/d/1fIVO4p_hwH618L1BRIEp-VXYu2-nyZhTmqeiaFfuErg/edit?usp=sharing

Project Schedule

Task	September			October					November				December	
	11	18	25	2	9	16	23	30	6	13	20	27	4	11
R & D														
General Research	X	X	X	X	X	X	X	X	X					
Prototyping														
Testing														
Deliverables														
Progress Reports	X	X	X	X	X	X	X	X	X					
PDS		X												
Design Matrix			X											
Preliminary Presentation				X										
Mid-Semester Report					X									
Decide on final Design						X								
Order Materials									X					
Final Presentation														
Final Report														
Meetings														

Client	X	X	X			X			
Advisor	X	X	X		X	X	X		
Team	X	X	X	X	X	X	X	X	X
Other									
Website									
Update	X	X	X	X	X	X	X	X	X

Conclusions/action items:

11/20/2020 - Progress Report 9

CADE VAN HORN - Dec 09, 2020, 8:26 AM CST

Title: Progress Report 9

Date: 11/20/2020

Content by: Cade

Present: N/A

Goals: To summarize our progress this week.

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Progress Report #9: 11/06/2020 - 11/20/2020

Project Information

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

Matt Voigt mwvoigt@wisc.edu (Communicator)

Emma Kupitz kupitz@wisc.edu (BSAC)

Carter Rupkey rupkey@wisc.edu (Co-BWIG)

Will Nelson wjnelson4@wisc.edu (Co-BWIG)

Anvesha Mukherjee amukherjee27@wisc.edu (BPAG)

Problem Statement

Create a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients. Develop an app-based software to further interpret the images and thermal maps collected by the client while in India.

Brief Status Update

This week we ordered our materials and began writing out a more detailed fabrication plan for when we receive the materials. We also began revising our midterm report and planning for the final report at the end of the semester.

Team Goals for Next Week

Next week is thanksgiving but the goal for the next two weeks is to receive our materials and begin fabrication and testing as soon as possible so that we can then start working on the final presentation and report.

Weekly/Ongoing Difficulties

The only thing we are worried about is time. There are only a couple weeks left in the semester, so we are hoping that we get all of our materials in time to fabricate and do testing.

Cost and Materials Spreadsheet:

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Category 1: Thermochromic Materials (powders, sheets, paints, etc)								
Thermochromic Color Change Cr	Nail Powder	Sophie & Toffee		11/6/2020	2	$8.37	$16.74	https://sophieandtoffee.com/th
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THERMOCHROMIC POWDER PIGI	Black to green 25 degrees	ATLANTA CHEMICAL ENGINEER		11/6/2020	1	$9.98	$9.98	https://www.atlantachemical.co
THERMOCHROMIC POWDER PIGI	Red to yellow 28 degrees	ATLANTA CHEMICAL ENGINEER		11/6/2020	1	$9.98	$9.98	https://www.atlantachemical.co
THERMOCHROMIC POWDER PIGI	Black to pink 31 degrees	ATLANTA CHEMICAL ENGINEER		11/6/2020	1	$9.98	$9.98	https://www.atlantachemical.co
THERMOCHROMIC POWDER PIGI	Black to purple 35 degrees	ATLANTA CHEMICAL ENGINEER		11/6/2020	1	$9.98	$9.98	https://www.atlantachemical.co
TLC sheets		Amazon		11/6/2020	1	$28.40	$28.40	https://www.amazon.com/Educ
Category 2: Other Materials (for building the imaging surface, testing, etc)								
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1 inch thick foam	Foam to glue onto wooden boar	Amazon		11/6/2020	1	$9.99	$9.99	https://www.amazon.com/GoTo
Acrylic paint base	Acrylic paint base to mix with pi	Amazon		11/6/2020	1	$11.12	$11.12	https://www.amazon.com/dp/B
Epoxy Resin and Hardener	Epoxy Resin top coat to secure t	Amazon		11/6/2020	1	$13.99	$13.99	https://www.amazon.com/Epox
Black fabric	Fabric to paint the pigments ont	Amazon		11/6/2020	1	$4.99	$4.99	https://www.amazon.com/60in-
						TOTAL:	**$153.12**	
						Budget:	$500	

Link to actual spreadsheet with working links:

https://docs.google.com/spreadsheets/d/1fIVO4p_hwH618L1BRIEp-VXYu2-nyZhTmqeiaFfuErg/edit?usp=sharing

Project Schedule

Task	September			October					November				December	
	11	18	25	2	9	16	23	30	6	13	20	27	4	11
R & D														
General Research	X	X	X	X	X	X	X	X	X	X	X			
Prototyping														
Testing														
Deliverables														
Progress Reports	X	X	X	X	X	X	X	X	X	X	X			

PDS		X									
Design Matrix			X								
Preliminary Presentation				X							
Mid-Semester Report					X						
Decide on final Design						X					
Order Materials									X		
Final Presentation											X
Final Report											
Meetings											
Client	X	X	X			X					
Advisor	X	X	X		X	X	X				X
Team	X	X	X	X	X	X	X	X	X		X
Other											
Website											
Update	X	X	X	X	X	X	X	X	X	X	X

Conclusions/action items:

9/18/2020 - Preliminary PDS

CADE VAN HORN - Oct 07, 2020, 11:29 AM CDT

Title: Preliminary PDS

Date: 9/18/2020

Content by: Whole Team

Present: Whole Team

Goals: To consolidate the requirements given to us by the client for the project

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Preliminary Product Design Specifications

Date: 09/18/2020

Team Members: Cade Van Horn Team Leader

Matt Voigt Communicator

Emma Kupitz BSAC

Carter Rupkey Co-BWIG

Will Nelson Co-BWIG

Anvesha Mukherjee BPAG

Function:

The device will be a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients using thermochromic material and an app-based software to further interpret the images and thermal maps. A machine learning algorithm will be incorporated to analyze the data collected and determine whether or not a patient is at-risk of developing a foot ulcer.

Client Requirements:

- Obtain a thermal image or map of the patients' feet
- Upload the thermal images to a software/app
- Use a machine learning algorithm that we will train to recognize whether an image is of an at-risk patient or not

Design Requirements:

1. Physical and Operational Characteristics

1. **Performance requirements:** The performance demanded or likely to be demanded should be fully defined. Examples of items to be considered include: how often the device will be used; likely loading patterns; etc.
    1. The machine learning algorithm must be accurate enough to recognize whether or not a patient is at-risk of developing an ulcer based on the thermal image of a patient's foot.
    2. The device could be used anywhere from monthly to daily. It must be able to withstand several uses in one day and still accurately display a thermal map of the patient’s feet that can be uploaded to the app.
    3. The app/software must be able to withstand the process of uploading an image several times a day, potentially by multiple different mobile devices. It cannot crash during usage.
2. **Safety:** Understand any safety aspects, safety standards, and legislation covering the product type. This includes the need for labeling, safety warnings, etc. Consider various safety aspects relating to mechanical, chemical, electrical, thermal, etc.
    1. The material used to collect temperature data and thermal maps must be safe for the patient. This includes thermal cameras and thermochromic material, neither of which can include any harmful side effects for the patient [1].
3. **Accuracy and Reliability:** Establish limits for precision (repeatability) and accuracy (how close to the "true" value) and the range over which this is true of the device.
    1. The machine learning algorithm must be very accurate and reliable, therefore it must go through a long enough “learning process” before it is used clinically.
    2. It must be accurate enough to recognize when a patient is at-risk of developing a foot ulcer.
4. **Life in Service**: Establish service requirements, including how short, how long, and against what criteria? (i.e. hours, days of operation, distance traveled, no.of revolutions, no. of cycles, etc.)
    1. Liquid crystal thermochromic material can retain its properties for several months if handled properly. Soaking the material in hot water baths can cause the material to deteriorate faster, as well as exposure to UV light [2].
5. **Operating Environment**: Establish the conditions that the device could be exposed to during operation (or at any other time, such as storage or idle time), including temperature range, pressure range, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, vibration, persons who will use or handle, any unforeseen hazards, etc.
    1. The thermochromic material will be used to obtain a thermal map of the patient’s feet when the patient steps on the material. This can be used in any indoor setting with a controlled climate.
6. **Ergonomics**: Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc..

1. The thermochromic material must be easy to use by both the doctor and the patient. All that will be required of the patient will be to step on the material to collect the thermal map, and the person looking to analyze the thermal map should be able to easily take a picture of the generated thermal map with their phone camera and upload it to the app-based software, which will generate an output. This should be an easy process for the user.

7. **Size**: Establish restrictions on the size of the product, including maximum size, portability, space available, access for maintenance, etc.
    1. The thermochromic material needs to be large enough for both of the patient's feet, but small enough so that there is not too much excess material. One sheet needs to be able to accommodate people of many different foot sizes.
    2. The size of the images must be compatible with the software/app. The app must be able to analyze images of different sizes and still generate a result.
8. **Weight**: Establish restrictions on maximum, minimum, and/or optimum weight; weight is important when it comes to handling the product by the user, by the distributor, handling on the shop floor, during installation, etc.
    1. Liquid crystal thermochromic material weighs about the same as a piece of printer paper. The weight of the paper will not be an issue for the user or distributor.
    2. The thermochromic material must be able to withstand the weight of the patient and still generate and accurate thermal map of the patient's feet.
9. **Materials**: Establish restrictions if certain materials should be used and if certain materials should NOT be used (for example ferrous materials in MRI machine).
    1. The thermochromic material will be the only physical material used in the project. This will either be thermochromic liquid crystal sheets, or leucodyes that can be printed on another material. The liquid crystal sheets are more accurate than leucodyes [3], so it is likely that will be the only material used.
10. **Aesthetics, Appearance, and Finish:** Color, shape, form, texture of finish should be specified where possible (get opinions from as many sources as possible).
    1. The user interface of the app/software must be user friendly and aesthetically appealing. It needs to be accessible to everyone eventually, so text must be readable and the image uploading process should be easy.
    2. The output generated by the app should be easy to read and non-offensive if a non-desirable (at-risk) outcome is generated.

2. Production Characteristics
    1. **Quantity**: number of units needed
        1. Only one application needs to be created.
        2. While testing the device, only a few sheets of thermochromic material need to be used to ensure the accuracy of the device and system.

3. If the product is marketed to the public, each individual using the device will require their own sheet(s) of thermochromic material.

2. **Target Product Cost**: manufacturing costs; costs as compared to existing or like products
    1. There is no set budget for this project.
    2. One 12x12in liquid crystal sheet is $25.95 [4].

3. Miscellaneous
    1. **Standards and Specifications**: international and /or national standards, etc. (e.g., Is FDA approval required?)
        1. There are several FDA regulations on temperature sensing devices, although most apply to electronic devices. The team's thermochromic imaging surface will not include any electronic components that will need to comply with FDA guidelines, but if the project progresses to the point of human subject testing and involvement, FDA guidelines and regulations will need to be followed [5]
    2. **Customer**: specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.
        1. There are no specific requests from customers since there is no one customer. The client wants the device to be applicable to all customers/patients in India.
    3. **Patient-related concerns**: If appropriate, consider issues which may be specific to patients or research subjects, such as: Will the device need to be sterilized between uses?; Is there any storage of patient data which must be safeguarded for confidentiality?
        1. The reusable thermochromic imaging surface will need to be easily usable by the patient.
        2. The imaging surface must be big enough to accommodate a variety of patients' feet.
        3. Images of the patient's thermal maps that are uploaded to the app will not include any personal data, so no personal or sensitive data will be collected or saved.
    4. **Competition**: Are there similar items which exist (perform comprehensive literature search and patents search)?
        1. There is a brand called siren that produces socks that are worn daily and monitors the temperature of the patient's foot. These socks have sensors that constantly measure temperatures of key points on the foot and send the information to the siren app. The doctor then can notify the patient when there is any sign of inflammation or something concerning. The socks then are replaced every six months to avoid misleading data from wear and tear [6].

References

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[3]C. Woodford, "Thermochromic color-changing materials", explainthatstuff.com, 2020. [Online]. Available: https://www.explainthatstuff.com/thermochromic-materials.html. [Accessed: 18- Sep- 2020].

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Conclusions/action items:

This report will likely be referenced and adjusted over the course of the semester as we continue to learn more about the project.

9/25/2020 - Preliminary Design Matrix

CADE VAN HORN - Oct 07, 2020, 11:30 AM CDT

Title: Preliminary Design Matrix

Date: 9/25/2020

Content by: Whole Team

Present: Whole Team

Goals: To compare and contrast our three preliminary design ideas based on weights of criteria the team determined were relevant.

Content:

Design Matrix

Title: Global Health: Prevention of Diabetic Foot Ulceration and Amputation

September 25, 2020

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

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Problem Statement: Design an affordable solution for at-home prevention of diabetic foot ulceration in India.

Designs:

Design Idea 1:

- Thermochromic liquid crystal sheet - patient steps on the sheet and takes a picture with their smartphone, then uploads it to the app where the algorithm (built via machine learning) will output whether or not a patient is at risk.
- Pros:
  - Reusable, a patient could test their feet daily or weekly with this method
  - When buying in bulk, the sheets are very cheap and affordable, so one patient could definitely afford one
- Cons:
  - Insulating so that the image stays long enough to take a picture

  - Temperature range/sensitivity range - 5 degree temperature range is not sensitive enough

Design Idea 2:

- Thermochromic liquid crystal changing powder - different powders change color at different temperatures, so if the powders are mixed together, it will change to different colors at different temperatures. If the right powders are mixed and then layered on a surface and secured with a top coat, the patient could step on the surface, take a picture with their smartphone, and upload it to the app so the algorithm can interpret the data.
- Pros:
  - With the right combination of temperature sensitive powders, the surface could more accurately display a range of temperatures that would fit the temperatures observed in diabetic feet
- Cons:
  - Securing the powders to a surface in a way that lets the color changing effect stay could be difficult

Design Idea 3:

- Thermal Camera smartphone attachment - purchase an IR sensing circuit component and build the necessary circuit and contraption to connect the IR sensor up to a smartphone so that a smartphone could take IR thermal images.
- Pros:
  - Potentially more accurate than various thermochromic materials
- Cons:
  - Expensive
  - May be difficult to get a still image of the patient's foot

			Design 1: Insulated color changing sheets		**Design 2: Mix of color changing powders**		**Design 3: Thermal camera smartphone attachment**	
Rank	Criteria	Weight	Score (10 max)	Weighted Score	Score (10 max)	Weighted Score	Score (10 max)	Weighted Score
1	Cost	20	10	20	10	20	4	8
2	Accessibility/Compliance	20	10	20	10	20	5	10
3	Ease of Use (for patient)	20	10	20	10	20	5	10
4	Accuracy/ Sensitivity	15	3	4.5	9	13.5	10	15

5	Durability	10	8	8	10	10	10	10
6	Ease of Fabrication	10	7	7	6	6	2	2
7	Safety	5	10	5	10	5	10	5
	Sum	**100**	**Sum**	84.5	**Sum**	94.5	**Sum**	60

Criteria Description:

1. Cost
   1. Cost is one of the most important factors for our project because our main goal is to create a solution that is affordable to the average diabetic patient in India. This needs to be an affordable device that patients can purchase either directly from their healthcare provider or from an online source.
2. Accessibility/Compliance
   1. Compliance is a big issue for at-home medical care. Other products like temperature measuring socks would not be viable in India because the majority of people do not wear socks. Finding a solution that patients would be able and willing to comply with is important. This means the device cannot interfere with daily life, and must have a minimal amount of steps to use.
3. Ease of Use (for patient)
   1. Ease of use goes hand in hand with compliance. If the device is easier to use for the patient, then compliance is less of an issue. The device should be easy to use on a daily to weekly basis, and should not take up too much time. This is an important factor because if the device is not easy to use, it is not an adequate at-home solution.
4. Accuracy/Sensitivity
   1. It is necessary for the device to be accurate in order to properly diagnose individuals who are at risk of developing foot ulcers. The most important aspect of this criterion is not necessarily the accuracy of the temperature measurement, but of the differences in temperature of the foot. If temperature differences cannot be accurately measured, the machine learning software will not be able to accurately identify at-risk individuals.
5. Durability
   1. The device must be durable enough to take daily or weekly measurements for an extended period of time. This criterion is ranked lower than most as the materials we are working with are reliable for over one year.
6. Ease of Fabrication
   1. Ease of fabrication is one of the least important factors because we only need to know if we have access to the materials and equipment required to accomplish the project. It does not matter if the product is easy to manufacture if it cannot accurately indicate the level of ulcer risk or if the patient does not comply.

7. Safety
    1. Safety is the least important factor because there aren’t any known health concerns associated with the materials being used.

Conclusions/action items:

The design we would like to pursue based on the results of the design matrix is the TLC powder design. The combination of low cost, high compliance, high accuracy, and high durability of this design set it well apart from the other two.

12/08/2020 - Final Materials and Costs Spreadsheet

CADE VAN HORN - Dec 09, 202

Title: Materials and Costs Spreadsheet

Date: 12/08/2020

Content by: Cade

Present: N/A

Goals: To summarize our materials that we purchased.

Content:

https://docs.google.com/spreadsheets/d/1fIVO4p_hwH618L1BRIEp-VXYu2-nyZhTmqeiaFfuErg/edit?usp=sharing

Item	Description	Manufacturer	Date	QTY	Cost Each	Total	Link
Category 1: Thermochromic Materials (powders, sheets, paints, etc)							
THERMOCHROMIC POWDER PIG	Blue to Violet Powder 22 degree	ATLANTA CHEMI	11/6/2020	1	$9.98	$9.98	https://www.atlantache
THERMOCHROMIC POWDER PIG	Black to Green Powder 25 degre	ATLANTA CHEMI	11/6/2020	1	$9.98	$9.98	https://www.atlantache
THERMOCHROMIC POWDER PIG	Red to Yellow Powder 28 degree	ATLANTA CHEMI	11/6/2020	1	$9.98	$9.98	https://www.atlantache
THERMOCHROMIC POWDER PIG	Black to Pink Powder 31 degrees	ATLANTA CHEMI	11/6/2020	1	$9.98	$9.98	https://www.atlantache
THERMOCHROMIC POWDER PIG	Black to Purple Powder 35 degre	ATLANTA CHEMI	11/6/2020	1	$9.98	$9.98	https://www.atlantache
TLC sheets	Three Color Changing Thermoch	Amazon	11/6/2020	1	$28.40	$28.40	https://www.amazon.co
Category 2: Other Materials (for building the imaging surface, testing, etc)							
Wooden Craft Rectangles	Wooden Boards	Amazon	11/6/2020	1	$17.99	$17.99	https://www.amazon.co
1 inch thick foam	Foam to glue onto wooden boar	Amazon	11/6/2020	1	$9.99	$9.99	https://www.amazon.co
Acrylic paint base	Acrylic paint base to mix with pi	Amazon	11/6/2020	1	$11.12	$11.12	https://www.amazon.co
Epoxy Resin and Hardener	Epoxy Resin top coat to secure t	Amazon	11/6/2020	1	$13.99	$13.99	https://www.amazon.co
Black fabric	Fabric to paint the pigments ont	Amazon	11/6/2020	1	$4.99	$4.99	https://www.amazon.co
					TOTAL:	**$136.38**	
					Budget:	$500	

Conclusions/action items:

These are the items we purchased and used in our fabrication and testing process.

12/02/2020 - Intended Fabrication Procedure

CADE VAN HORN - Dec 09, 2020, 8:35 AM CST

Title: Intended Fabrication Procedure

Date: 12/02/2020

Content by: Matt Voigt

Present: Cade Van Horn

Goals: To outline a fabrication procedure for our final product.

Content:

Intended Fabrication Plan:

Initial Qualitative Testing of Pigments:

1. In five separate containers, add about a teaspoon of each pigment
2. In each of the containers, add the Liquitex white acrylic medium in a 2:1 acrylic to pigment ratio and mix with a stir stick to fully combine the pigment and acrylic medium
3. With a paint brush, paint a swatch (about 2 inches long, 1 inch wide) of each pigment range onto a wooden board to test the color changing abilities
    1. When the swatches dry completely, apply heat to each to test if the color changes at the desired temperature. If the color does not change as desired, apply more coats to the swatch until the desired color change is observed.
4. Repeat step 3 on the black fabric to test the color changing ability of each pigment on the fabric compared to the wood
5. Compare the swatches on the wood and the fabric and qualitatively determine if the color change is more vibrant on one or the other
6. Repeat steps 1-5 with the Craftsmart acrylic paint as a base for the pigments
    1. Compare the Liquitex and Craftsmart swatches and qualitatively determine if the color change is more vibrant with one base versus the other

Fabrication of Fabric-Foam Imaging Surface:

1. Cut a square of black fabric that is 16in x 16in.
2. Lay the square of fabric out and paint an even layer of the lowest temperature pigment. Wait for the layer to dry completely and paint another layer until the pigment is opaque.
3. Once the first layer has dried, apply a thin, even coat of the clear epoxy resin over the thermochromic layer.
4. Repeat steps 2-3 with each successive temperature pigment until all pigments have been layered in between clear coats. Apply one final clear coat.
5. Cut a 14in x 14in square of 1in thick foam and wrap the fabric around the foam, securing it with glue.
6. Glue the foam onto a wooden board for a solid base to the imaging surface

Conclusions/action items:

This fabrication method was attempted by me and Cade and we determined without any official testing that this final product would not work as we intended.

12/03/2020 - Final Prototype Fabrication Process

CADE VAN HORN - Dec 09, 2020, 8:36 AM CST

Title: Final Prototype Fabrication Process

Date: 12/03/2020

Content by: Matt Voigt

Present: Matt Voigt

Goals: To outline the fabrication process that was followed to create our final prototype.

Content:

1. Cut each of the three thermochromic color changing sheets into 22 strips.
2. Apply two strips of the 20-25 Celsius TLC sheet next to each other on a wooden board using Elmer's glue.
3. Apply two strips of the 25-30 Celsius TLC sheet next to each other on the wooden board using Elmer's glue. Place them directly above the two 20-25 Celsius TLC sheet strips.
4. Apply two strips of the 30-35 Celsius TLC sheet next to each other on the wooden board using Elmer's glue. Place them directly above the two 25-30 Celsius TLC sheet strips.
5. Repeat steps 2-4 until a grid of 66x2 TLC sheet strips is glued to the board in a repeating order of 20-25 Celsius TLC strips, 25-30 Celsius TLC strips, and 30-35 Celsius TLC strips.

More detailed description of fabrication process:

In order to fabricate the proposed final design, each pigment was added to a separate container and mixed with two different acrylic bases, a white Liquitex acrylic medium, and a Craftsmart white acrylic paint. Swatches of each pigment-paint mixture were painted onto both wood and fabric to test their color changing abilities and assess their vibrancy. Several layers of these swatches were built up, and once each pigment dried completely, heat was applied to qualitatively test the color-changing abilities. A detailed fabrication plan for the intended prototype using these pigments can be found in Appendix B.

Unfortunately, the fabrication process did not go as planned. When the pigments were mixed with the Liquitex acrylic medium and applied to wood, the color change observed when heat was applied was very weak in two of the five pigments, and no color change was observed in the other three. The same results were found with the Craftsmart acrylic base as well when applied directly to wood. Both the Liquitex and Craftsmart pigment mixtures were also applied to black fabric, but no color change was found in these swatches either when temperature was applied.

After unexpectedly finding no color change when the pigments were applied to both wood and fabric, the same process was repeated after first applying a white base coat to both materials, then painting the thermochromic mixtures. However, like the first experiment, no color change was observed when heat was applied to these swatches. This meant that fabrication of the prototype could not proceed as outlined in the fabrication plan (Appendix B).

In order to continue fabrication, the team modified plans for the final prototype to resemble the first preliminary design idea rather than the proposed final design, and ordered a set of three thermochromic sheets that change color from 20-25, 25-30, and 30-35 degrees Celsius respectively. Each sheet was cut into strips 0.5cm wide and 4in long. These dimensions were chosen because each of the three sheets were originally 4in x 4in, and they were cut into strips approximately 0.5cm wide because, when combined, the three strips of different temperature ranges had a total width of 1.5cm, which is approximately the width of the average foot ulcer [32]. These strips were glued onto a wooden board in order of increasing temperature range so that repeating groups of three strips covered the board. The strips were labeled on the board with their temperature ranges.

This design was chosen so that when heat is applied to the surface, lower temperatures cause color change in only the 20-25$_{o}$C strips, mid-range temperatures cause change in the 25-30$_{o}$C strips, and only high temperatures cause any change in the 30-35$_{o}$C strips. Different areas of the foot have different temperature ranges, the toes having an average temperature of 26.2$_{o}$C and the sole an average temperature of 29.3$_{o}$C [33]. These fall within the 25-30$_{o}$C temperature range, however, foot temperatures can be as much as 5$_{o}$C higher or lower than these averages, thus the need for the combination of thermochromic strips with different temperature ranges so that higher foot temperatures can be sensed by the device. The final surface with the thermochromic strips had dimensions 8in x 8in, which is not as large as the intended design due to lack of materials and time constraint caused by the unexpected change in design.

Conclusions/action items:

After the final prototype is built by Cade, testing will need to be performed to determine the effectiveness of the prototype.

12/03/2020 - Accuracy Testing Protocol

CADE VAN HORN - Dec 09, 2020, 8:36 AM CST

Title: Accuracy Testing Protocol

Date: 12/03/2020

Content by: Matt Voigt

Present: Matt Voigt

Goals: To outline the protocol that was followed to test the accuracy of the TLC sheets used in our final prototype.

Content:

The purpose of this test is to determine if the TLC sheets change at the proper temperatures and if an accurate temperature can be estimated from the observed color changes of the various strips of TLC sheets in our prototype.

- Heat a container full of water to an unknown temperature
- Use the heated container to apply heat to the thermochromic imaging surface for about five seconds
- Remove the heat source from the prototype
- Estimate the temperature of the water in the container by observing the color changes that it induced in the thermochromic imaging surface. Record the estimate.
- Determine and record the actual temperature of the water in the container with a thermometer.
- Repeat seven more times
- Conduct a two sample t test to determine if the estimated temperatures are significantly different from the real temperatures or not

In order to test the accuracy of the final prototype, a temperature comparison test was performed in order to compare temperatures estimated from the device and actual temperatures. A container full of water heated to an unknown temperature was used to apply heat to the thermochromic imaging surface for five seconds. After removing the heat source, the color of the different strips was used to estimate and record the temperature. Meanwhile, the actual temperature of the water was recorded with a thermometer as well. This comparison was performed eight different times, recording both the actual and estimated temperatures in table 3 below. After collecting this data, a two sample t test was performed.

Table 3. Temperature Comparison Data. This table shows the estimated temperatures and actual temperatures found during the temperature comparison test, as well as the difference between the estimated and actual values.

Trial	Estimated temperature based on color shift (Celsius)	Actual temperature from thermometer (Celsius)	Difference (Actual - Estimated)
1	36°C	38.1°C	2.1°C
2	34°C	33.2°C	-0.8°C
3	27.5°C	28.4°C	0.9°C
4	24.5°C	23.2°C	-1.3°C
5	19°C	17.8°C	-1.2°C
6	27°C	29.5°C	2.5°C
7	29°C	28.9°C	-0.1°C

8	31.5$_{o}$C	31.3$_{o}$C	-0.2$_{o}$C
Average	28.5625	28.8	1.1375
Standard deviation	5.4145	6.1542	1.31

Conclusions/action items:

After this test is performed the data will need to be analyzed. Further testing is also required to determine how long the thermal map remains accurate after removal of the heat source.

12/03/2020 - Thermal Map Retention Protocol

CADE VAN HORN - Dec 09, 2020, 8:37 AM CST

Title: Thermal Map Retention Protocol

Date: 12/03/2020

Content by: Matt Voigt

Present: Matt Voigt

Goals: To outline the protocol that will be followed to determine how long the thermal map imprint left on the final prototype

Content:

A second test was performed to test the amount of time an accurate thermal map lasted on the device before fading. This test was performed to quantify the approximate amount of time someone using the product would have to take an image of the thermal map while it is still sufficiently accurate. To determine this, a clear plastic bag was filled with water of known temperature and used to heat the thermochromic imaging surface for approximately thirty seconds. The heat source was then removed and the amount of time that passed until the outermost thermochromic strip lost all color change was recorded. Although the color changes were more persistent at the center of the thermal map, the disappearing time of the colors at the edges was used to quantify thermal map retention because the color differences become more ambiguous at the center of the map as time passes.

Table 4. Thermal Map Retention Data. This table shows how much time passed until all color change was lost in a strip of thermochromic material at the edge of the thermal map after removal of a heat source of known temperature.

Temperature (°C)	25-30°C Sheet Time to Color Loss (seconds)	30-35°C Sheet Time to Color Loss (seconds)
25	1	-
26	9	-
27	11	-
28	27	-
29	50	-
30	-	3
31	-	4
32	-	5
33	-	6
34	-	6.5

35	-	7
36	-	9
37	-	10
38	-	11
39	-	22
Average	19.6 seconds	8.35 seconds

Conclusions/action items:

Data was collected on the fading time of the device

12/03/2020 - Results of Testing

CADE VAN HORN - Dec 09, 2020, 8:39 AM CST

Title: Testing Results and Analysis

Date: 12/03/2020

Content by: Cade Van Horn

Present: N/A

Goals: To analyze the raw data we collected during testing.

Content:

After collecting the temperature data, a two sample t test was performed in order to compare the means of the estimated and actual temperatures and determine if the temperatures were significantly different. A significance value of 0.05 was used, and the result of the t test was a t-value of -0.082 and a p-value of 0.94, which was not less than the significance level, indicating that the color-estimated temperature is not significantly different from the actual temperature. This means that the final prototype consisting of groups of thermochromic sheets is a successful and accurate visual depiction of the temperature of a patient's feet. Figure 10 below shows a plot of the estimated and actual temperatures and the difference between the two.

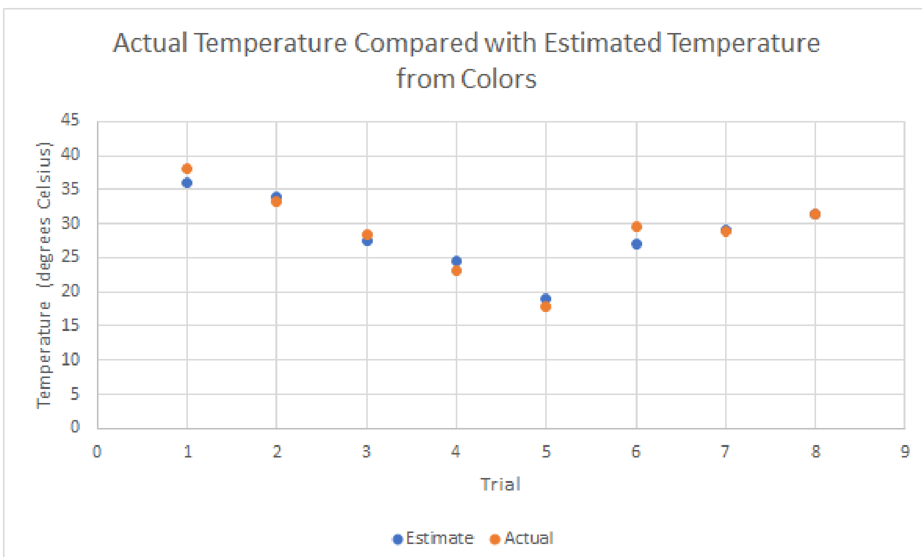

Figure 10. Graph of actual temperature (red) compared with the color-estimated temperature (blue) for each of the eight trials from the temperature testing. The average difference between these two temperatures was 1.13°C.

The results of the fading-time test found that the 25-30°C thermochromic strips fade after an average of 19.6 seconds, while the 30-35°C strips fade after an average of 8.35 seconds. No average was found for the 20-25°C strips because the test was conducted at an ambient temperature of 23.2°C, so these strips were perpetually yellow and green during the test with no fading to black. Data was not collected at temperatures above 29°C for the 25-30°C thermochromic material because the time to lose color change at the edges was longer than one minute.

Conclusions/action items:

We concluded that our device is accurate as far as measuring temperature, but has a fairly quick fading time.

10/7/2020 Product Design Specifications

CADE VAN HORN - Oct 07, 2020, 11:31 AM CDT

Title: Preliminary PDS

Date: 9/18/2020

Content by: Whole Team

Present: Whole Team

Goals: To consolidate the requirements given to us by the client for the project

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Preliminary Product Design Specifications

Date: 09/18/2020

Team Members: Cade Van Horn Team Leader

Matt Voigt Communicator

Emma Kupitz BSAC

Carter Rupkey Co-BWIG

Will Nelson Co-BWIG

Anvesha Mukherjee BPAG

Function:

The device will be a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients using thermochromic material and an app-based software to further interpret the images and thermal maps. A machine learning algorithm will be incorporated to analyze the data collected and determine whether or not a patient is at-risk of developing a foot ulcer.

Client Requirements:

- Obtain a thermal image or map of the patients' feet
- Upload the thermal images to a software/app
- Use a machine learning algorithm that we will train to recognize whether an image is of an at-risk patient or not

Design Requirements:

1. ## Physical and Operational Characteristics

    1. **Performance requirements:** The performance demanded or likely to be demanded should be fully defined. Examples of items to be considered include: how often the device will be used; likely loading patterns; etc.

        1. The machine learning algorithm must be accurate enough to recognize whether or not a patient is at-risk of developing an ulcer based on the thermal image of a patient's foot.

        2. The device could be used anywhere from monthly to daily. It must be able to withstand several uses in one day and still accurately display a thermal map of the patient’s feet that can be uploaded to the app.

        3. The app/software must be able to withstand the process of uploading an image several times a day, potentially by multiple different mobile devices. It cannot crash during usage.

    2. **Safety:** Understand any safety aspects, safety standards, and legislation covering the product type. This includes the need for labeling, safety warnings, etc. Consider various safety aspects relating to mechanical, chemical, electrical, thermal, etc.

        1. The material used to collect temperature data and thermal maps must be safe for the patient. This includes thermal cameras and thermochromic material, neither of which can include any harmful side effects for the patient [1].

    3. **Accuracy and Reliability:** Establish limits for precision (repeatability) and accuracy (how close to the "true" value) and the range over which this is true of the device.

        1. The machine learning algorithm must be very accurate and reliable, therefore it must go through a long enough “learning process” before it is used clinically.

        2. It must be accurate enough to recognize when a patient is at-risk of developing a foot ulcer.

    4. **Life in Service**: Establish service requirements, including how short, how long, and against what criteria? (i.e. hours, days of operation, distance traveled, no.of revolutions, no. of cycles, etc.)

        1. Liquid crystal thermochromic material can retain its properties for several months if handled properly. Soaking the material in hot water baths can cause the material to deteriorate faster, as well as exposure to UV light [2].

    5. **Operating Environment**: Establish the conditions that the device could be exposed to during operation (or at any other time, such as storage or idle time), including temperature range, pressure range, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, vibration, persons who will use or handle, any unforeseen hazards, etc.

        1. The thermochromic material will be used to obtain a thermal map of the patient’s feet when the patient steps on the material. This can be used in any indoor setting with a controlled climate.

    6. **Ergonomics**: Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc..

1. The thermochromic material must be easy to use by both the doctor and the patient. All that will be required of the patient will be to step on the material to collect the thermal map, and the person looking to analyze the thermal map should be able to easily take a picture of the generated thermal map with their phone camera and upload it to the app-based software, which will generate an output. This should be an easy process for the user.

7. **Size**: Establish restrictions on the size of the product, including maximum size, portability, space available, access for maintenance, etc.
    1. The thermochromic material needs to be large enough for both of the patient's feet, but small enough so that there is not too much excess material. One sheet needs to be able to accommodate people of many different foot sizes.
    2. The size of the images must be compatible with the software/app. The app must be able to analyze images of different sizes and still generate a result.
8. **Weight**: Establish restrictions on maximum, minimum, and/or optimum weight; weight is important when it comes to handling the product by the user, by the distributor, handling on the shop floor, during installation, etc.
    1. Liquid crystal thermochromic material weighs about the same as a piece of printer paper. The weight of the paper will not be an issue for the user or distributor.
    2. The thermochromic material must be able to withstand the weight of the patient and still generate and accurate thermal map of the patient's feet.
9. **Materials**: Establish restrictions if certain materials should be used and if certain materials should NOT be used (for example ferrous materials in MRI machine).
    1. The thermochromic material will be the only physical material used in the project. This will either be thermochromic liquid crystal sheets, or leucodyes that can be printed on another material. The liquid crystal sheets are more accurate than leucodyes [3], so it is likely that will be the only material used.
10. **Aesthetics, Appearance, and Finish:** Color, shape, form, texture of finish should be specified where possible (get opinions from as many sources as possible).
    1. The user interface of the app/software must be user friendly and aesthetically appealing. It needs to be accessible to everyone eventually, so text must be readable and the image uploading process should be easy.
    2. The output generated by the app should be easy to read and non-offensive if a non-desirable (at-risk) outcome is generated.

2. Production Characteristics
    1. **Quantity**: number of units needed
        1. Only one application needs to be created.
        2. While testing the device, only a few sheets of thermochromic material need to be used to ensure the accuracy of the device and system.

3. If the product is marketed to the public, each individual using the device will require their own sheet(s) of thermochromic material.

2. **Target Product Cost**: manufacturing costs; costs as compared to existing or like products

    1. There is no set budget for this project.

    2. One 12x12in liquid crystal sheet is $25.95 [4].

3. Miscellaneous

    1. **Standards and Specifications**: international and /or national standards, etc. (e.g., Is FDA approval required?)

        1. There are several FDA regulations on temperature sensing devices, although most apply to electronic devices. The team's thermochromic imaging surface will not include any electronic components that will need to comply with FDA guidelines, but if the project progresses to the point of human subject testing and involvement, FDA guidelines and regulations will need to be followed [5]

    2. **Customer**: specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.

        1. There are no specific requests from customers since there is no one customer. The client wants the device to be applicable to all customers/patients in India.

    3. **Patient-related concerns**: If appropriate, consider issues which may be specific to patients or research subjects, such as: Will the device need to be sterilized between uses?; Is there any storage of patient data which must be safeguarded for confidentiality?

        1. The reusable thermochromic imaging surface will need to be easily usable by the patient.

        2. The imaging surface must be big enough to accommodate a variety of patients' feet.

        3. Images of the patient's thermal maps that are uploaded to the app will not include any personal data, so no personal or sensitive data will be collected or saved.

    4. **Competition**: Are there similar items which exist (perform comprehensive literature search and patents search)?

        1. There is a brand called siren that produces socks that are worn daily and monitors the temperature of the patient's foot. These socks have sensors that constantly measure temperatures of key points on the foot and send the information to the siren app. The doctor then can notify the patient when there is any sign of inflammation or something concerning. The socks then are replaced every six months to avoid misleading data from wear and tear [6].

References

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[2]Hallcrest, "Thermosmart thermocolor sheets", Lcrhallcrest.com, 2020. [Online]. Available: https://www.lcrhallcrest.com/wp-content/uploads/2019/12/Labels-RE-Thermosmart-Stresssheet-SalesLit.pdf. [Accessed: 07- Oct- 2020].

[3]C. Woodford, "Thermochromic color-changing materials", explainthatstuff.com, 2020. [Online]. Available: https://www.explainthatstuff.com/thermochromic-materials.html. [Accessed: 18- Sep- 2020].

[4] [7]Educational Innovations, "Liquid Crystal Sheets (12x12 inch)", Teacher Source - Educational Innovations inc., 2020. [Online]. Available: https://www.teachersource.com/product/liquid-crystal-sheets-12x12-inch/chemistry. [Accessed: 07- Oct- 2020].

[5] FDA, "Temperature Sensors in the Regulated Industry", U.S. Food and Drug Administration, 2020. [Online]. Available: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-technical-guides/temperature-sensors-regulated-industry. [Accessed: 07- Oct- 2020].

[6]Siren, "Siren Socks & Foot Monitoring System", Siren Socks, 2020. [Online]. Available: https://siren.care/. [Accessed: 07- Oct-2020].

10/7/2020 - Design Matrix

CADE VAN HORN - Oct 07, 2020, 11:32 AM CDT

Title: Preliminary Design Matrix

Date: 9/25/2020

Content by: Whole Team

Present: Whole Team

Goals: To compare and contrast our three preliminary design ideas based on weights of criteria the team determined were relevant.

Content:

Design Matrix

Title: Global Health: Prevention of Diabetic Foot Ulceration and Amputation

September 25, 2020

Client: Kayla Huemer

Advisor: Dr. Melissa Skala

Team Members:

Cade Van Horn cavanhorn@wisc.edu (Leader)

Matt Voigt mwvoigt@wisc.edu (Communicator)

Emma Kupitz kupitz@wisc.edu (BSAC)

Carter Rupkey rupkey@wisc.edu (Co-BWIG)

Will Nelson wjnelson4@wisc.edu (Co-BWIG)

Anvesha Mukherjee amukherjee27@wisc.edu (BPAG)

Problem Statement: Design an affordable solution for at-home prevention of diabetic foot ulceration in India.

Designs:

Design Idea 1:

- Thermochromic liquid crystal sheet - patient steps on the sheet and takes a picture with their smartphone, then uploads it to the app where the algorithm (built via machine learning) will output whether or not a patient is at risk.
- Pros:
    - Reusable, a patient could test their feet daily or weekly with this method
    - When buying in bulk, the sheets are very cheap and affordable, so one patient could definitely afford one
- Cons:
    - Insulating so that the image stays long enough to take a picture

  - Temperature range/sensitivity range - 5 degree temperature range is not sensitive enough

Design Idea 2:

- Thermochromic liquid crystal changing powder - different powders change color at different temperatures, so if the powders are mixed together, it will change to different colors at different temperatures. If the right powders are mixed and then layered on a surface and secured with a top coat, the patient could step on the surface, take a picture with their smartphone, and upload it to the app so the algorithm can interpret the data.

- Pros:
  - With the right combination of temperature sensitive powders, the surface could more accurately display a range of temperatures that would fit the temperatures observed in diabetic feet
- Cons:
  - Securing the powders to a surface in a way that lets the color changing effect stay could be difficult

Design Idea 3:

- Thermal Camera smartphone attachment - purchase an IR sensing circuit component and build the necessary circuit and contraption to connect the IR sensor up to a smartphone so that a smartphone could take IR thermal images.
- Pros:
  - Potentially more accurate than various thermochromic materials
- Cons:
  - Expensive
  - May be difficult to get a still image of the patient's foot

			Design 1: Insulated color changing sheets		**Design 2: Mix of color changing powders**		**Design 3: Thermal camera smartphone attachment**	
Rank	Criteria	Weight	Score (10 max)	Weighted Score	Score (10 max)	Weighted Score	Score (10 max)	Weighted Score
1	Cost	20	10	20	10	20	4	8
2	Accessibility/Compliance	20	10	20	10	20	5	10
3	Ease of Use (for patient)	20	10	20	10	20	5	10
4	Accuracy/ Sensitivity	15	3	4.5	9	13.5	10	15

5	Durability	10	8	8	10	10	10	10
6	Ease of Fabrication	10	7	7	6	6	2	2
7	Safety	5	10	5	10	5	10	5
	Sum	**100**	**Sum**	84.5	**Sum**	94.5	**Sum**	60

Criteria Description:

1. Cost
    1. Cost is one of the most important factors for our project because our main goal is to create a solution that is affordable to the average diabetic patient in India. This needs to be an affordable device that patients can purchase either directly from their healthcare provider or from an online source.
2. Accessibility/Compliance
    1. Compliance is a big issue for at-home medical care. Other products like temperature measuring socks would not be viable in India because the majority of people do not wear socks. Finding a solution that patients would be able and willing to comply with is important. This means the device cannot interfere with daily life, and must have a minimal amount of steps to use.
3. Ease of Use (for patient)
    1. Ease of use goes hand in hand with compliance. If the device is easier to use for the patient, then compliance is less of an issue. The device should be easy to use on a daily to weekly basis, and should not take up too much time. This is an important factor because if the device is not easy to use, it is not an adequate at-home solution.
4. Accuracy/Sensitivity
    1. It is necessary for the device to be accurate in order to properly diagnose individuals who are at risk of developing foot ulcers. The most important aspect of this criterion is not necessarily the accuracy of the temperature measurement, but of the differences in temperature of the foot. If temperature differences cannot be accurately measured, the machine learning software will not be able to accurately identify at-risk individuals.
5. Durability
    1. The device must be durable enough to take daily or weekly measurements for an extended period of time. This criterion is ranked lower than most as the materials we are working with are reliable for over one year.
6. Ease of Fabrication
    1. Ease of fabrication is one of the least important factors because we only need to know if we have access to the materials and equipment required to accomplish the project. It does not matter if the product is easy to manufacture if it cannot accurately indicate the level of ulcer risk or if the patient does not comply.

7. Safety
    1. Safety is the least important factor because there aren't any known health concerns associated with the materials being used.

Conclusions/action items:

The design we would like to pursue based on the results of the design matrix is the TLC powder design. The combination of low cost, high compliance, high accuracy, and high durability of this design set it well apart from the other two.

10/07/2020 - Preliminary Design Presentation

CADE VAN HORN - Dec 09, 2020, 8:43 AM CST

Title: Preliminary Design Presentation

Date: 10/07/2020

Content by: Cade

Present: N/A

Goals: To present our initial ideas for the project

Content:

Below is a link to our preliminary design presentation:

https://drive.google.com/file/d/1SMc67SPWXYWpQXlmlItLMLKM_eaTvY_I/view

Conclusions/action items:

This is the video we presented to the class.

10/7/2020 Preliminary Design Report

CADE

Title: Mid-semester Preliminary Design Report

Date: 10/7/2020

Content by: All

Present: All

Goals: To summarize our work so far into a report.

Content:

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

BME 200/300 - Mid-semester Report, October 7th, 2020

Client: Kayla Huemer

UW Madison - College of Engineering, Department of Biomedical Engineering

Advisor: Dr. Mellisa Skala

UW Madison - College of Engineering, Department of Biomedical Engineering

UW Madison - School of Medicine and Public Health, Department of Medical Physics

Team Members: Cade Van Horn 300 Team Leader

Matthew Voigt 300 Communicator

Anvesha Mukherjee 200 BPAG

Will Nelson 200 Co-BWIG

Carter Rupkey 200 Co-BWIG

Emma Kupitz 200 BSAC

Abstract

Diabetes is a growing problem in India that can often lead to the formation of ulcers and even amputation of the feet. At-home monitoring of the temperature of the feet has been s ulceration for patients who consistently comply with the care regime specified by their health care provider. There are several devices in the United States designed to simply at-home mo use of special socks or shoes, but these devices are not as applicable to patients in India who often do not wear socks or close toed shoes. In order to create a solution to affordable at-h liquid crystal thermochromic imaging surface will be created and combined with a machine learning algorithm for analysis of the temperature data. Patients can step on the surface to ge colors on the thermal map will correspond to different temperatures, and these thermal maps can be photographed using a smartphone and uploaded to an app-based software so that a ma image. The software will output whether or not a patient is at risk of developing an ulcer based on any differences in temperature between symmetric parts of the feet. Providing a simp temperature in the feet can allow patients to take control of their own health and make lifestyle changes when necessary.

Table of Contents

Introduction

Motivation

Diabetes has recently become a prevalent problem in India. In the United States, 13.3% of the population has diabetes while India only 8.9% . However, due to its large population, this is million in the United States [1]. This increase is in part due to the number of people that lack access to healthcare. In fact, 50-90% of diabetic patients in rural areas are undiagnosed [2]. If ulcers that worsen to a point where it is too late to save the foot when people are able to receive medical treatment. The team’s role is to create a device that can predict ulcers effectively. cost solution that patients could easily use at home.

Existing Devices and Current Methods

Currently, there is a brand called siren that produces socks that are worn daily and monitors the temperature of the patient's foot. These socks have sensors that constantly measure tempera the information to the siren app. The doctor then can notify the patient when there is any sign of inflammation or something concerning. The socks then are replaced every six months to a [3].

The team that worked on this project in the previous semester created a foldable imaging box with a temperature sensor and an infrared camera. When a patient stepped onto the box, it wo sole of the foot and send that data over WiFi to a database. The data was then easily interpreted by doctors and patients if an ulcer was present and its severity [4].

In addition to these temperature reading devices, there are devices that help patients deal with diabetes. For example, diabetic shoes offer generous space for the patient's feet. These sho and stretchable material and have enough depth to ensure a loose fit that eases pressure points. Insoles can also be added that provide arch support and absorb shock. Diabetic socks are als socks are also non constricting, soft, and moisture wicking to keep the feet cool and dry[5].

Problem Statement

Diabetic patients often lose feeling in their extremities and cannot feel an ulcer which can then lead to amputation. To fight this lack of sensation, temperature monitoring is used to predict difficult in India. Many people in India don't have access to medical treatment and often don't wear socks and shoes which are the common products for diabetics. The goal of this produc for patients to monitor the state of their feet. The patients should be able to take the device home and effortlessly find out if they have an ulcer developing.

Background

Relevant Biology and Physiology

Type II diabetes affects the body's ability to use insulin to regulate glucose levels. This can either be due to the body not producing sufficient amounts of insulin or resisting the efforts o sugar level [6]. Since diabetes affects the regulation of glucose in the blood, diabetic patients develop hyperglycemia, or high blood sugar [7]. Normally, sugar obtained from food is sent i system. In response to the spike in blood sugar that follows eating, beta cells in the pancreas secrete insulin, a hormone that elicits the fat cells in the body to absorb the glucose and subseq This is a regulatory process that takes place whenever blood sugar levels increase, but when diabetes affects insulin function, this natural process cannot take place, leading to hyperglycem

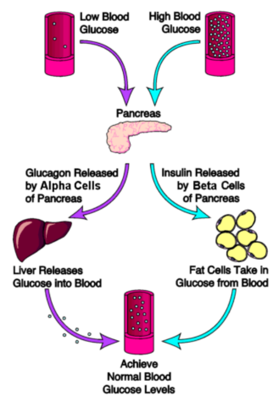


Figure 1. Insulin and glucagon regulation of blood sugar. This figure shows how insulin is released in the presence of high blood sugar to return the blood to normal

High blood sugar can damage the walls of blood vessels, particularly smaller vessels in the extremities [9]. The damage of blood vessels from hyperglycemia, combined with the harmfu hypertension, obesity, and even smoking, often leads diabetic patients to develop neuropathy, a condition where sensation in the hands and feet is lost as nerve cells are destroyed [10]. Wh cells in the peripheral nervous system are damaged, nerve terminals are no longer adequately protected by the perineurium outer layer and can be exposed to extracellular environments tha nerve cell, leading to neuropathy (see figure 2 below) [11].

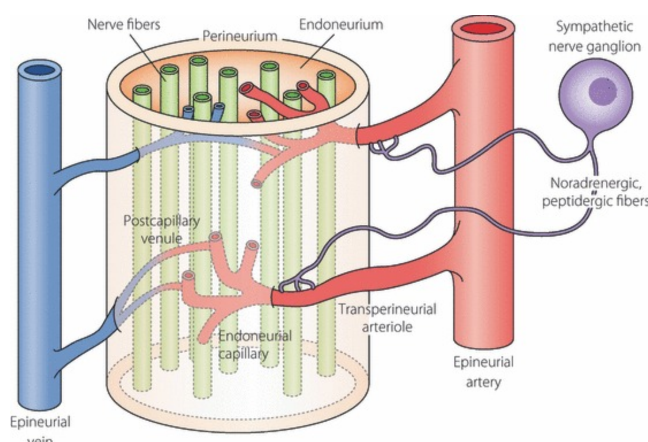


Figure 2. Diagram of nerve fiber and the blood vessels that penetrate the perineurium to supply oxygen to nerve cells. These microvessels are easily damaged, which can in turn

When diabetes progresses and is not properly managed, the layers of skin on the bottom of the foot can break down to form a foot ulcer. Diabetic foot ulcers can cause the skin to turn b severe they can expose muscles and tendons [12]. Ulcers are also prone to infection since the open wound is difficult to keep clean and free of bacteria and other substances. Infected ulcer lead to amputation [12]. Neuropathy can cause ulcers to worsen. Lack of sensation prevents diabetic patients from feeling pain in their feet, often leading them to put more pressure on the had sensation [13]. Minimal wounds can easily turn into ulcers if a patient uses their feet too much, and an improper adherence to treatment strategies often results in amputation. For all d developing ulceration is 25%, the majority of which will lead to amputation within four years of the initial diagnosis. [13]

Several diabetic patients will begin to suffer severe pain despite the absence of any high stress impact after traversing long distances on rough ground. Travelling long distances, a consequ footwear amplified by improper modes of transportation, is endured most heavily by rural or marginalized stratas in India who are often geographically dislocated because of economic, er factors. [14] Severe pain while walking is due to two distinct types of receptors, specifically nerve endings found in the skin, that are involved in the heightened pain that diabetic patients of the disease. The receptors found in healthy tissue that respond to relatively high levels of mechanical stress are referred to as High Threshold Mechano-Receptors (HTMs), or receptors upon otherwise undamaged skin [15].

Conversely, in the situation that the patient has already damaged the foot, Poly-Modal Nociceptors (PMNs) begin responding to relatively low pressure stimuli due to chemical products o patient experiences extreme pain due to PMNs in response to very minimal stimulation. A diabetic with a high risk for ulceration begins to feel severe pain despite the absence of high stre PMNs caused by the pain from constant low stress. Tenderness from a consistent hard beating results in much greater pain from a much lower threshold of pressure, and after a certain dur HTMs that report injury, inflammation induces the response of PMNs. [15]

The imminent danger that the aforementioned receptors pose to diabetic patients in India is that the foot that is neuropathic or responsive to PMNs often bears more weight than the foot th tissue that responds to HTMs, further increasing the patient’s risk of ulceration. This creates an indubitable need for a low cost and simplistic way to extrapolate a patient’s risk of ulceratic monitoring.

Development and Process Flow

Diabetic foot screening usually involves frequent measurement of infrared skin temperature, but with small, cheap and easy to use devices. This includes electrical devices such as diodes mechanical versions of temperature monitoring generally include glass thermometers with liquid. [16] Diabetic foot screening is also often achieved through devices utilizing thermal radi thermography. The use of color indicators such as pencils or paints, ultrasonic sensors, or thermochromic liquid crystals and powders are also beneficial for producing heat maps of the pat methods provide a cost effective and accessible solution to at home monitoring of skin surface temperatures. [17]

Furthermore, infrared thermography (IRT) by way of infrared cameras allows for effective determination of skin surface temperature, asserting the importance of infrared cameras and the of ulceration. Thermographic maps produced by IRT detect variations in plantar temperature, however, the plantar temperature distribution does not follow a particular pattern in diabetic p measure the changes. Thus, an interest arises in ameliorating the analysis and classification methods used in image analysis algorithms involved in artificial intelligence and machine learn structures.[18]

Producing accurate thermal images of diabetic patients' feet for analysis by machine learning algorithms involves active participation by the patient. [19] In the field of image analysis a processing algorithm is able to produce a prediction of the classification of new images based on a prior data set with known parameters. The first of two main methods of machine learnin point or “feature vector” given an image. A feature vector consists of several numbers that are measured or calculated from the image. [20] These features are then used by the second par algorithm, to classify unknown feature vectors given a large database of feature vectors whose classifications are known. [20] These images are then uploaded to an app-based software, w and frequently debugged, that outputs to the patient their risk for ulceration. The incentive for using an app based software in junction with machine image analysis Developing an image a its machine learning recognition of hot spots for potential ulcers greatly increases the chance of preventing amputation.

About the Client

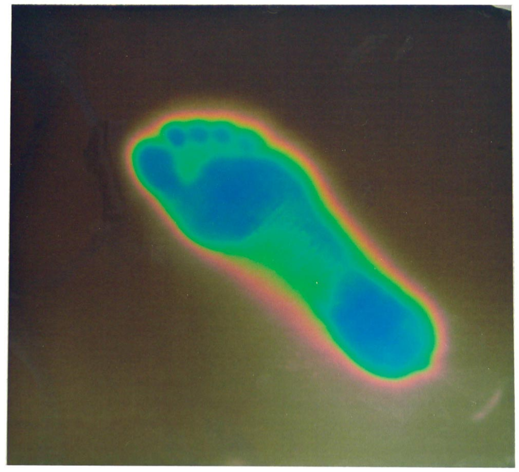
Kayla Huemer graduated from the University of Wisconsin - Madison in biomedical engineering. She is currently attending graduate school at the University of Stanford to study the inter global health. Kayla became involved with this project when she was a sophomore at the University of Wisconsin - Madison. She traveled to India in order to research the diabetes breako there she was offered the opportunity to collect data of patients at a hospital in India. She didn’t have the funds in order to continue her research so she came back in 2018 and 2019. She w Fellowship in order to continue her medical device research in India. After working a year on pressure sensing footwear she started to realize that the footwear wasn’t the best way to dete shifted her focus and started using thermal imaging of patients feet to help detect early signs of foot ulceration. Now she is trying to integrate a more cost effective way and machine learni capabilities.

Design Specifications

To summarize the product design specification the device must be a low cost at home temperature monitoring device that is easily usinable by any patient. It also must be usable by patie sandals. It also must incorporate a thermochromic material injunction with an app based software and a machine learning algorithm to intake heat map images of the thermochromic ma factor of a patient's likelihood of developing a foot ulcer. One thing to note is that the machine learning algorithm must be accurate enough to recognize multiple thermal images wheth ulceration. Also the product needs to be able to withstand multiple uses while still producing an accurate image and thermal map of the patient's feet for uploading to the app based softw design specifications.

Preliminary Designs

Design 1 - Insulated Thermochromic Color Changing Sheets



LC-2530 25-30°C Transition

Figure 3: *The temperature profile of a foot as represented by an insulated thermochromic liquid crystal sheet* [21].

The first design proposed by the team was chosen in order to minimize cost and maximize the ease of fabrication. Insulated thermochromic color changing sheets contain thermochromi molecules that can exist in a liquid state with some crystal-like order. TLCs change color due to variations in intermolecular forces at different temperatures and different molecules experi temperature ranges [22]. Insulated thermochromic sheets usually display color changes over a 5℃ range with a tolerance of ±1.5℃ and can be customized to include protection from wat properly stored at room temperature with minimal UV exposure they can be reused and maintain the expected accuracy for over one year [23]. Despite the advantages of this design, comp temperature ranges and mediocre accuracy of insulated thermochromic sheets. Due to the large variation in possible foot temperatures, consumers would need to buy multiple sheets, each ranges, to guarantee a proper temperature profile can be collected and analyzed. This could also require the machine learning software to be trained to recognize areas of high ulcer risk fo challenging and require a large amount of data to be gathered.

Design 2 - Mix of Thermochromic Color Changing Powders

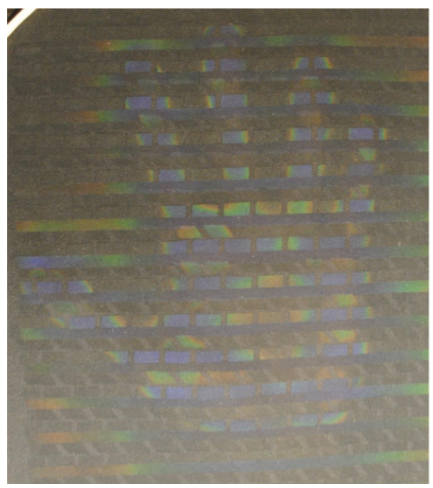


Figure 4: *The temperature profile of a hand as shown by three TLC powders each layered in a unique pattern* [24].

TLC powders can be applied to materials to create thermochromic color changing sheets. Combining powders that experience color changes at contiguous temperature ranges on one sh purchase a single sheet that would be sensitive to a wider range of temperatures. Top coats would be used to increase the durability, and therefore reusability, of the final product. It has be in unique patterns allows for significantly accurate temperature profiles to be obtained [Figure 4]. While the fabrication process of this design would be very involved, the increase in effe the first design increases accuracy and keeps the cost low. Both designs one and two require the consumer to stand on a TLC surface, take a picture of the resulting temperature profile of t app with the machine learning software trained to recognize areas of high ulcer risk. The team will need to assess whether the time required to step off the sheet and capture an image will the accuracy of the temperature profile or not.

Design 3 - IR Thermal Camera Smartphone Attachment

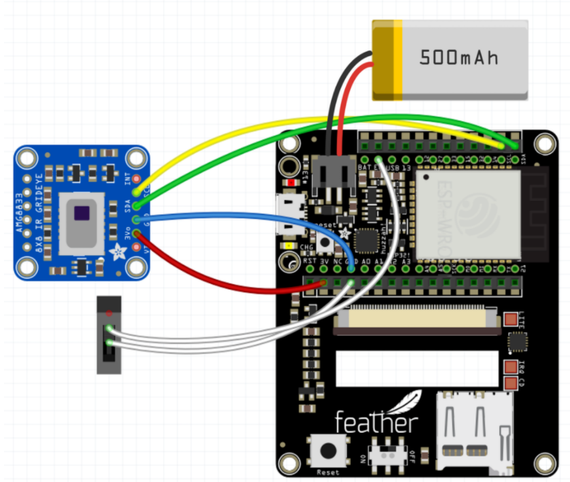


Figure 5: *Circuit with thermal camera component and display using TFT Feather* [25].

The third design the team proposed was an infrared thermal camera that could attach to a smartphone. This design would allow for digital thermal images to be taken and directly uploa processing and classification by the machine learning algorithm. Such thermal cameras have the potential to be much more accurate than the other two designs. Although the accuracy of t factor to consider, the comparatively large cost of thermal cameras to the TLC based designs outweighs the benefits of increased accuracy. It would also be difficult for a consumer to take without assistance which would likely cause a decrease in the compliance of consumers.

Preliminary Design Evaluation

Design Matrix

Table 1. Design Matrix. Evaluation of feasible design ideas amongst different criteria. Highlighted areas indicate the highest score per category. Scores ou

*Displayed as: score out of ten | weighted score

			Design 1: **Insulated color changing sheets**		**Design 2:** **Mix of color changing powders**		**Design 3:** **Thermal camera smartphone at**	
Rank	Criteria	Weight	Score (10 max)	Weighted Score	Score (10 max)	Weighted Score	Score (10 max)	Weig Sc
1	Cost	20	10	20	10	20	4	8
2	Accessibility/Compliance	20	10	20	10	20	5	1
3	Ease of Use (for patient)	20	10	20	10	20	5	1
4	Accuracy/ Sensitivity	15	3	4.5	9	13.5	10	1
5	Durability	10	8	8	10	10	10	1
6	Ease of Fabrication	10	7	7	6	6	2	2
7	Safety	5	10	5	10	5	10	5
	Sum	**100**	**Sum**	84.5	**Sum**	94.5	**Sum**	6

Summary of Design Matrix

Our design matrix included 7 different points of criteria. These points of criteria in order of importance included cost, accessibility/compliance, ease of use, accuracy/sensitivity, durability cost is one of the most important factors for our project because our main goal is to create a solution that is affordable to the average diabetic patient in India. This needs to be an affordabl either directly from their healthcare provider or from an online source.

Next, compliance is a big issue for at-home medical care. Other products like temperature measuring socks would not be viable in India because the majority of people do not wear socks. be able and willing to comply with is important. This means the device cannot interfere with daily life, and must have a minimal amount of steps to use. Ease of use goes hand in hand wit use for the patient, then compliance is less of an issue. The device should be easy to use on a daily to weekly basis, and should not take up too much time. This is an important factor becau not an adequate at-home solution.

Next, accuracy, it is necessary for the device to be accurate in order to properly diagnose individuals who are at risk of developing foot ulcers. The most important aspect of this criterion i temperature measurement, but of the differences in temperature of the foot. If temperature differences cannot be accurately measured, the machine learning software will not be able to acc Durability is important because the device must be durable enough to take daily or weekly measurements for an extended period of time. This criterion is ranked lower than most as the m for over one year. Ease of fabrication is one of the least important factors because we only need to know if we have access to the materials and equipment required to accomplish the proje easy to manufacture if it cannot accurately indicate the level of ulcer risk or if the patient does not comply. Safety is the least important factor because there aren't any known health conce used.

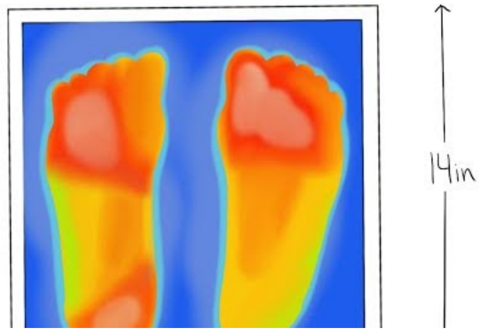
Using this criteria we ranked each of the designs. Design 1: Insulated color changing sheets and Design 2: Mix of color changing powders received maximum points for cost, accessibility designs these scores because they are cheap compared to current options, and they are both easy to use and something the patient would comply with. Design 3: Thermal camera smartpho much lower in these three categories because it is less cost effective and would be more complicated for the patient to use. After researching our three designs we came to the conclusion t accurate than design 1 which is why design 1 scored much lower than the other two in this category. All three designs scored high in the durability category. Designs 2 and 3 received a fu scored slightly lower. Designs 1 and 2 are about the same when it comes to ease of fabrication which is why they received the same score; however, design 3 would be much more difficul low. Lastly, each design received a full score in the safety category because there are no known health concerns associated with the materials that we would use of any design.

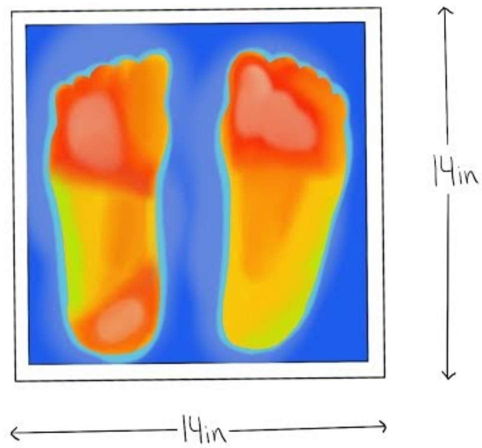
After we completed the design matrix there was a clear winner. Design 2: Mix of color changing powders scored the most points and was chosen as our proposed final design.

Proposed Final Design

The proposed final design consists of a thermochromic imaging surface which will work in conjunction with a machine learning algorithm to analyze the data. The imaging surface will powders mixed with a liquid or acrylic base so that it can be painted or spread over the solid surface. The thermochromic layer will be secured with a top coat that will prevent the lower la that it maintains its color changing properties. Preliminary testing will help the team determine the best solid material to apply the thermochromic powder mixture to (e.g. wood, plastic, fa fully assembled, the imaging device will have dimensions of 14 in. by 14 in. and will be a solid surface that the patient can stand on with their bare feet to generate a thermal map (Fig X b from the temperature sensitive color changing powder layer will last several minutes before fading, ensuring that the patient can take a picture of the imaging surface with their smartphon

Once the image is fed to the software, the machine learning algorithm will process it and analyze the colored regions. Each color will be associated with a certain temperature range, so the temperatures in different regions of both feet. It will assess whether or not there is a temperature difference of four degrees fahrenheit or greater in symmetric parts of the feet (e.g. the diff and left heel). If there are any temperature differences that meet or exceed this threshold, the software will output an 'at-risk' result, indicating that the patient is at risk of developing an ul the patient should reduce the number of steps they take daily and the amount of time they spend on their feet.





feet.

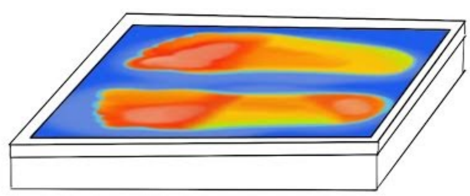


Figure 7. Side View of solid surface with thermochromic material showing a thermal image of two feet.

Development of Machine Learning Algorithm

Materials and Tools

A machine learning algorithm will be created in order to analyze the thermal maps generated when a patient takes a picture with their smartphone camera of the thermochromic material be a type of artificial intelligence program that will be trained to classify images. In order to create this algorithm, open source code will be used to train a model using Python, a coding la collection of data, which will consist of approximately 200 thermal images of diabetic patients' feet taken by the client, Kayla Huemer, in India. These images will serve as the data that th trained to recognize and classify. A model such as ImageAI [26] or TensorFlow 2.0 [27] will be used and imported into Supervisely, a collaborative workspace to compile and edit data an

Methods

In order to create the machine learning algorithm, an open source machine learning model will be used, such as ImageAI. These open source models are written in Python, and are built then classify the image type so that it can be processed. Images can either be interpreted one by one or as a dataset. For large amounts of images, like the set of thermal images provided by for organizing the data. An iterator in the Python code will allow the program to run through each photo. Processing the images will involve creating a set of parameters to classify the ima temperature scale and assign temperatures to color values. Based on these temperatures associated with colors, the code will be modified to assign temperatures to different areas of the fo is a temperature difference of four degrees Fahrenheit or more between any symmetric parts of the foot, it will classify the image as at-risk of an ulcer.

Final Prototype

The final prototype will be a functioning code that will take an input thermal image, process it by analyzing the color of each pixel and assigning a temperature value, then outputting w ulceration. 'At risk' will be defined as containing at least one area of the foot with a temperature difference of at least four degrees fahrenheit compared to the analogous section of the oth

Testing

In order to test the accuracy of the machine learning algorithm, more thermal images that the team takes will be input into the software. The output will be compared to actual data colle often or not it correctly classifies the image as at-risk or not. Inputting these images will help to further teach the algorithm to properly identify the images it is fed.

Fabrication of Thermochromic Imaging Surface

Materials

Thermochromic liquid crystal color changing powders will be used and combined to form a mixture that will change color depending on the temperature at contact with the foot. Warm temperatures, with red being the hottest, and cooler colors will indicate cooler temperatures. These powders can either be purchased pre-made from a vendor in a powder or liquid form [2 combination of cholesteryl oleyl carbonate, cholesteryl pelargonate, and cholesteryl benzoate [30]. Although they are nontoxic, appropriate eye and skin protection should be used when h combinations of these chemicals can produce mixtures that change color at varying temperatures [30].

Table 2. Temperature range of different combinations of cholesteryl oleyl carbonate, cholesteryl pelargonate, and cholesteryl benzoate from UW MRSEC Educat

	Cholesteryl oleyl carbonate	Cholesteryl pelargonate	Cholesteryl benzoate	Transition range, degrees C
Different compositions change color over different temperature ranges.	0.65g	0.25g	0.10g	17-23
	0.70g	0.10g	0.20g	20-25
	0.45g	0.45g	0.10g	26.5-30.5
	0.43g	0.47g	0.10g	29-32
	0.44g	0.46g	0.10g	30-33
	0.42g	0.48g	0.10g	31-34

Methods

To prepare the cholesteryl chemicals into a color changing liquid with the appropriate temperature range, the cholesteryl oleyl carbonate, cholesteryl pelargonate, and cholesteryl benzo in Table X) must be combined in a container. The mixture of chemicals must then be heated and melted using a hair dryer or other heat source. As the product is heated and cooled, the liq temperature. The liquid product can then be used immediately and mixed with an acrylic base, or it can be stored in a sealed container at room temperature for later use [30].

Final Prototype

The final prototype will consist of a flat solid surface with a layer of the thermochromic liquid crystal material secured with a top coat that will prevent any water or dirt from interferin This surface will be 14 in. by 14 in., which will be large enough for patients to stand on but small enough to store easily on a shelf. Preliminary testing will be performed to determine if w wooden board would serve as the best solid surface for the thermochromic powder layer.

Testing

In order to test the accuracy of the thermochromic imaging surface, the team will perform several trials where different people will step on the surface multiple times to generate a therm compared to actual temperature data of the feet taken with a thermometer. If the team is able to access a digital infrared thermal camera, the thermal maps generated by the thermochromic to real photographs taken using a thermal camera.

Results

The final prototype should be able to withstand the force of the average diabetic patient in India and accurately generate a color coded thermal image of their feet. The patient will be ab picture of thermochromic imaging surface and upload it to the software which will use the machine learning algorithm to recognize whether or not there is a significant temperature differe classify if the patient is at risk of developing an ulcer. Expected testing results include temperature data taken from the feet of multiple test subjects and several trials using the imaging sur a statistical analysis to determine if there are any statistically significant differences between the experimental temperature data and the output of the device.

Discussion

The thermochromic imaging surface and software should be accessible and easy to use for all diabetic patients in India. Each individual device should be inexpensive in order to make i despite income level. The ergonomics of the device will be simple so that each patient can simply step on the imaging surface with their bare feet in order to generate a thermal map. The g stay on the surface long enough for the patient to use their smartphone to take a picture of it.

Although there are several products on the market that are geared towards aiding diabetic patients in self-monitoring their feet to prevent injury or ulceration, many of these products inv compliance for diabetic patients in India. Siren is a growing company in the United States that uses temperature sensing technology built into a pair of socks so that patients can monitor th feet and modify their daily activities if they notice significant temperature changes. Products such as diabetic socks and shoes are not as applicable in rural communities in India, however, wear socks and close-toed shoes, but rather go about their daily lives in sandals or bare feet. The team's design of a thermochromic imaging surface that patients simply need to step on bri will not have to interfere with their daily routine to monitor the temperature of their feet.

Once the team collects data on the imaging surface, it will be compared not only to experimental data, but it will also be compared to existing products like Siren socks to determine the ef changes might be made. If the results of testing indicate that the device is accurate and effective, this will mean that the team's product will provide a much more accessible method for dia state of their feet so that they can be proactive in making decisions that will benefit their health. This will create an avenue for at-home treatment that will benefit patients who have obstac standard health care, such as money or distance.

The creation of this product will involve a mixture of chemicals, which will be ethically sourced from Sigma Aldrich, a large supplier of chemicals in the United States.

Conclusion

The thermochromic imaging surface made from liquid crystal color changing powders will be the design that the team fabricates and tests. This device will be a hard surface with a laye patients can step to generate a thermal map of their feet. This color coded thermal map can be photographed and uploaded to the software for classification by the machine learning algorit is at risk of an ulcer. Preliminary tests will be performed to determine experimentally which surface is the best for the layer of thermochromic powder (e.g. wood, plastic, fabric, etc.). Furt determine the accuracy of the powders and whether or not the prototype requires any modifications.

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Appendix

Appendix A - PDS

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Preliminary Product Design Specifications

Date: 09/18/2020

Team Members: Cade Van Horn Team Leader

Matt Voigt Communicator

Emma Kupitz BSAC

Carter Rupkey Co-BWIG

Will Nelson Co-BWIG

Anvesha Mukherjee BPAG

Function:

The device will be a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients using thermochron
to further interpret the images and thermal maps. A machine learning algorithm will be incorporated to analyze the data collected and determine whether or not a patient is at-risk of devel

Client Requirements:

- Obtain a thermal image or map of the patients' feet
- Upload the thermal images to a software/app
- Use a machine learning algorithm that we will train to recognize whether an image is of an at-risk patient or not

Design Requirements:

1. ### Physical and Operational Characteristics
   1. **Performance requirements:** The performance demanded or likely to be demanded should be fully defined. Examples of items to be considered include: will be used; likely loading patterns; etc.
      1. The machine learning algorithm must be accurate enough to recognize whether or not a patient is at-risk of developing an ulcer based on the therr a patient's foot.
      2. The device could be used anywhere from monthly to daily. It must be able to withstand several uses in one day and still accurately display a therm patient's feet that can be uploaded to the app.
      3. The app/software must be able to withstand the process of uploading an image several times a day, potentially by multiple different mobile devices crash during usage.
   2. **Safety:** Understand any safety aspects, safety standards, and legislation covering the product type. This includes the need for labeling, safety warnings, e safety aspects relating to mechanical, chemical, electrical, thermal, etc.
      1. The material used to collect temperature data and thermal maps must be safe for the patient. This includes thermal cameras and thermochromic n neither of which can include any harmful side effects for the patient [1].
   3. **Accuracy and Reliability:** Establish limits for precision (repeatability) and accuracy (how close to the "true" value) and the range over which this is true c
      1. The machine learning algorithm must be very accurate and reliable, therefore it must go through a long enough "learning process" before it is usec
      2. It must be accurate enough to recognize when a patient is at-risk of developing a foot ulcer.
   4. **Life in Service**: Establish service requirements, including how short, how long, and against what criteria? (i.e. hours, days of operation, distance traveled of cycles, etc.)
      1. Liquid crystal thermochromic material can retain its properties for several months if handled properly. Soaking the material in hot water baths can c material to deteriorate faster, as well as exposure to UV light [2].
   5. **Operating Environment**: Establish the conditions that the device could be exposed to during operation (or at any other time, such as storage or idle time temperature range, pressure range, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, vibration, persons who will use or han hazards, etc.
      1. The thermochromic material will be used to obtain a thermal map of the patient's feet when the patient steps on the material. This can be used in a setting with a controlled climate.
   6. **Ergonomics**: Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc
      1. The thermochromic material must be easy to use by both the doctor and the patient. All that will be required of the patient will be to step on the ma collect the thermal map, and the person looking to analyze the thermal map should be able to easily take a picture of the generated thermal map w phone camera and upload it to the app-based software, which will generate an output. This should be an easy process for the user.
   7. **Size**: Establish restrictions on the size of the product, including maximum size, portability, space available, access for maintenance, etc.

1. The thermochromic material needs to be large enough for both of the patient's feet, but small enough so that there is not too much excess materia needs to be able to accommodate people of many different foot sizes.
2. The size of the images must be compatible with the software/app. The app must be able to analyze images of different sizes and still generate a re

8. **Weight**: Establish restrictions on maximum, minimum, and/or optimum weight; weight is important when it comes to handling the product by the user, by t on the shop floor, during installation, etc.
   1. Liquid crystal thermochromic material weighs about the same as a piece of printer paper. The weight of the paper will not be an issue for the user
   2. The thermochromic material must be able to withstand the weight of the patient and still generate and accurate thermal map of the patient's feet.
9. **Materials**: Establish restrictions if certain materials should be used and if certain materials should NOT be used (for example ferrous materials in MRI ma
   1. The thermochromic material will be the only physical material used in the project. This will either be thermochromic liquid crystal sheets, or leucody be printed on another material. The liquid crystal sheets are more accurate than leucodyes [3], so it is likely that will be the only material used.
10. **Aesthetics, Appearance, and Finish:** Color, shape, form, texture of finish should be specified where possible (get opinions from as many sources as po
    1. The user interface of the app/software must be user friendly and aesthetically appealing. It needs to be accessible to everyone eventually, so text r readable and the image uploading process should be easy.
    2. The output generated by the app should be easy to read and non-offensive if a non-desirable (at-risk) outcome is generated.

2. Production Characteristics
   1. **Quantity**: number of units needed
      1. Only one application needs to be created.
      2. While testing the device, only a few sheets of thermochromic material need to be used to ensure the accuracy of the device and system.
      3. If the product is marketed to the public, each individual using the device will require their own sheet(s) of thermochromic material.
   2. **Target Product Cost**: manufacturing costs; costs as compared to existing or like products
      1. There is no set budget for this project.
      2. One 12x12in liquid crystal sheet is $25.95 [4].

3. Miscellaneous
   1. **Standards and Specifications**: international and /or national standards, etc. (e.g., Is FDA approval required?)
      1. There are several FDA regulations on temperature sensing devices, although most apply to electronic devices. The team's thermochromic imaging not include any electronic components that will need to comply with FDA guidelines, but if the project progresses to the point of human subject tes involvement, FDA guidelines and regulations will need to be followed [5]
   2. **Customer**: specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.
      1. There are no specific requests from customers since there is no one customer. The client wants the device to be applicable to all customers/patier
   3. **Patient-related concerns**: If appropriate, consider issues which may be specific to patients or research subjects, such as: Will the device need to be ste Is there any storage of patient data which must be safeguarded for confidentiality?
      1. The reusable thermochromic imaging surface will need to be easily usable by the patient.
      2. The imaging surface must be big enough to accommodate a variety of patients' feet.
      3. Images of the patient's thermal maps that are uploaded to the app will not include any personal data, so no personal or sensitive data will be collec saved.
   4. **Competition**: Are there similar items which exist (perform comprehensive literature search and patents search)?
      1. There is a brand called siren that produces socks that are worn daily and monitors the temperature of the patient's foot. These socks have sensors constantly measure temperatures of key points on the foot and send the information to the siren app. The doctor then can notify the patient when t sign of inflammation or something concerning. The socks then are replaced every six months to avoid misleading data from wear and tear [6].

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12/9/2020 - Final Report

CADI

Title: Final Report

Date: 12/09/2020

Content by: Whole Group

Present: N/A

Goals:

Content:

https://docs.google.com/document/d/1AOTsAoYUSw4lIH70A81E7R1t3YscRtZy8pPt8fyRYJ8/edit?usp=sharing <-- link to final report docoument.

Global Health: Thermochromic Imaging Surface For Prevention of Diabetic Foot Ulceration and Amputation

BME 200/300 - Final Report, December 9th, 2020

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Abstract

Diabetes is a growing problem in India that can often lead to the formation of ulcers and even amputation of the feet. At-home monitoring of the temperature of the feet has been s ulceration for patients who consistently comply with the care regime specified by their health care provider. There are several devices in the United States designed for at-home monitorir special socks or shoes, but these devices are not as applicable to patients in India who often do not wear socks or close toed shoes. In order to create a solution to affordable at-ho thermochromic liquid crystal (TLC) imaging surface was created and will be combined with a machine learning algorithm for analysis of the temperature data. Patients can step on the sur feet. The colors on the thermal map correspond to different temperatures, and can be analyzed directly by observing any major color differences between the right and left feet, or they c and uploaded to an app-based software to a machine learning algorithm for image processing. The software will output whether or not a patient is at risk of developing an ulcer based or symmetric parts of the feet. Although not enough data has been collected to adequately program a machine learning algorithm, a thermochromic imaging prototype was created and can feet. Providing a simple and affordable device to measure foot temperature can allow diabetic patients to take control of their own health and make lifestyle changes when necessary.

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Introduction

Motivation

Diabetes has recently become a prevalent problem in India. In the United States, 13.3% of the population has diabetes while India only 8.9% . However, due to its large population, this is million in the United States [1]. This increase is in part due to the number of people that lack access to healthcare. In fact, 50-90% of diabetic patients in rural areas are undiagnosed [2]. If ulcers that worsen to a point where it is too late to save the foot when medical treatment is finally received. Several devices, such as different types of socks and shoes, exist in the United at-home treatment plan for diabetic patients, however, since many people in rural areas of India do not wear socks or closed toed shoes, these solutions are not as applicable. Many existing therefore not accessible to low-income individuals. Thus, an inexpensive, at-home device that can effectively predict the onset of a foot ulcer before it is too late is necessary for the care a India.

The need for such a device is also motivated by client Kayla Huemer, who originally started this project in 2017 while working directly with diabetic patients. During her time in India, sh of patients' feet in order to study the relationship between foot temperature and ulceration. After finding that many patients sought out treatment only after development of an ulcer, she wa by taking into account the temperature of the foot in order to prevent ulceration in diabetic patients in India in order to prevent infection and amputation.

Existing Devices and Current Methods

Currently, there is a brand called Siren that produces socks that monitor the temperature of the patient's foot when worn daily [3]. These socks contain sensors that constantly measure tem send the information to the Siren app for the patient and even their doctor to see. A patient's healthcare provider then can notify the patient when there is any sign of inflammation or conc The socks then are replaced every six months to avoid misleading data from wear and tear [3]. Socks like these are an example of an existing device that monitors the temperature of the fo However, as the client, Kayla, observed during her time in India, many people do not wear socks on a daily basis. Thus, a device like this would clash with the daily life of many diabetic p difficult. These socks also come with a monthly cost rather than a one-time payment, making them a more expensive option. Similarly, the Orpyx SI Insole, like Siren socks, continuously findings to a smartphone app [4]. Adherence to a product like this has been found to be difficult in the United States, so a shoe insert would be even less effective for diabetic patients in ru

There are also several different brands of diabetic shoes that exist in order to take pressure off of the ball and heel of the foot, the areas that typically receive the most pressure and friction more often [5]. Often made of protective, nonbinding and stretchable material with enough depth to ensure a loose fit that eases pressure points, diabetic shoes and insoles have become a custom ordered [6]. These shoes are particularly common in the United States, with brands like Dr. Comfort [7] selling a variety of padded shoes aimed at shifting the weight and pressure the Siren socks, these shoes are not the best option for patients who are not used to wearing close-toed shoes, and they can be very costly.

Another method for at-home temperature monitoring involves sending patients home with a thermometer that they can use to directly take the temperature of their feet, without having to This method provides quicker and more direct results without having to rely on a smartphone app for feedback. Solutions like this are more appropriate for diabetic patients in India, who routine by introducing new socks or shoes to their wardrobe, but this method is also much more expensive. Thus, an inexpensive way for diabetic patients to monitor the temperature of th ulceration and even amputation.

Problem Statement

Diabetic patients often lose feeling in their extremities and cannot feel an ulcer which can then lead to amputation. To fight this lack of sensation, temperature monitoring is used to predic difficult in India. Many people in India don't have access to medical treatment and often don't wear socks and shoes which are the common products for diabetics. The goal of this produc for patients to monitor the state of their feet. The patients should be able to take the device home and effortlessly find out if they have an ulcer developing.

Background

Relevant Biology and Physiology

Type II diabetes affects the body's ability to use insulin to regulate glucose levels. This can either be due to the body not producing sufficient amounts of insulin or resisting the efforts sugar level [9]. Since diabetes affects the regulation of glucose in the blood, diabetic patients develop hyperglycemia, or high blood sugar [10]. Normally, sugar obtained from food is sent system. In response to the spike in blood sugar that follows eating, beta cells in the pancreas secrete insulin, a hormone that elicits the fat cells in the body to absorb the glucose and subse This is a regulatory process that takes place whenever blood sugar levels increase, but when diabetes affects insulin function, this natural process cannot take place, leading to hyperglycen

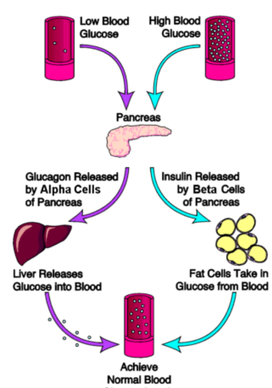


Figure 1. Insulin and glucagon regulation of blood sugar. This figure shows how insulin is released in the presence of high blood sugar to return the blood to normal

High blood sugar can damage the walls of blood vessels, particularly smaller vessels in the extremities [12]. The damage of blood vessels from hyperglycemia, combined with the harm hypertension, obesity, and even smoking, often leads diabetic patients to develop neuropathy, a condition where sensation in the hands and feet is lost as nerve cells are destroyed [13]. Wh cells in the peripheral nervous system are damaged, nerve terminals are no longer adequately protected by the perineurium outer layer and can be exposed to extracellular environments th nerve cell, leading to neuropathy (see figure 2 below) [14].

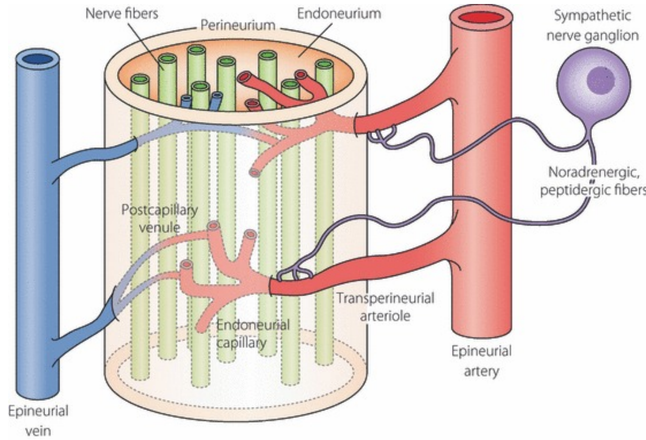


Figure 2. Diagram of nerve fiber and the blood vessels that penetrate the perineurium to supply oxygen to nerve cells. These microvessels are easily damaged, which can in turn

When diabetes progresses and is not properly managed, the layers of skin on the bottom of the foot can break down to form a foot ulcer. Diabetic foot ulcers can cause the skin to turn b severe they can expose muscles and tendons [15]. Ulcers are also prone to infection since the open wound is difficult to keep clean and free of bacteria and other substances. Infected ulce lead to amputation [15]. Neuropathy can cause ulcers to worsen. Lack of sensation prevents diabetic patients from feeling pain in their feet, often leading them to put more pressure on the had sensation [16]. Minimal wounds can easily turn into ulcers if a patient uses their feet too much, and an improper adherence to treatment strategies often results in amputation. For all d developing ulceration is 25%, the majority of which will lead to amputation within four years of the initial diagnosis. [16]

Several diabetic patients will begin to suffer severe pain despite the absence of any high stress impact after traversing long distances on rough ground. Travelling long distances, a consequ footwear amplified by improper modes of transportation, is endured most heavily by rural or marginalized stratas in India who are often geographically dislocated because of economic, e factors. [17] Severe pain while walking is due to two distinct types of receptors, specifically nerve endings found in the skin, that are involved in the heightened pain that diabetic patients of the disease. The receptors found in healthy tissue that respond to relatively high levels of mechanical stress are referred to as High Threshold Mechano-Receptors (HTMs), or receptors upon otherwise undamaged skin [18].

Conversely, in the situation that the patient has already damaged the foot, Poly-Modal Nociceptors (PMNs) begin responding to relatively low pressure stimuli due to chemical products o patient experiences extreme pain due to PMNs in response to very minimal stimulation. A diabetic with a high risk for ulceration begins to feel severe pain despite the absence of high stre PMNs caused by the pain from constant low stress. Tenderness from a consistent hard beating results in much greater pain from a much lower threshold of pressure, and after a certain dur HTMs that report injury, inflammation induces the response of PMNs [18].

The imminent danger that the aforementioned receptors pose to diabetic patients in India is that the foot that is neuropathic or responsive to PMNs often bears more weight than the foot th tissue that responds to HTMs, further increasing the patient's risk of ulceration [18]. This creates an indubitable need for a low cost and simplistic way to extrapolate a patient's risk of ulc home monitoring.

A modality such as cost-effective home thermometry provides an option to diabetic patients for early monitoring of signs of ulceration, and serves as an preventative warning system for t In a pilot study published by the American Diabetes association, it was found that patients who actively practiced at home temperature monitoring of their feet had a very low rate of foot standard therapy group [19]. Signifying the efficacy of at home temperature monitoring, the enhanced therapy group using at home temperature monitoring had shown significantly better standard group not practicing at home temperature monitoring. Furthermore, patients representing the standard therapy group were found to be 10.3 times more at risk for foot complicatio counterparts, indicating an urgency for the development of an affordable at home temperature monitoring device [19]. The aforementioned results of the pilot study create an imperative to modality that may prove effective in preventing both ulceration and the adverse risk for amputation. By interleaving affordability and convenience, home monitoring of foot skin temperat solution to diabetic foot complications and facilitates the early detection of ulceration.

Development and Process Flow

Monitoring the temperature of the feet can be an important tool in preventing diabetic foot ulceration. Studies have found that enhanced therapy involving the addition of a skin thermome temperatures in addition to therapeutic footwear and education on health care for diabetes greatly reduces the risk of ulceration [19]. Patients who consistently measured the temperature i such as taking fewer steps each day, had a much lower rate of foot complications and ulcerations compared with patients who did not measure their foot temperature. This suggests that at- serves as an effective first step in preventative care. It has also been found that a temperature difference of 2.2 degrees Celsius (4 degrees Fahrenheit) or more in analogous areas of the rig an ulcer [same as above], thus the at-home monitoring of these temperatures can be an important step in recognizing health concerns before the severity increases.

Diabetic foot screening usually involves frequent measurement of infrared skin temperature, but with small, cheap and easy to use devices. This includes electrical devices such as diodes mechanical versions of temperature monitoring generally include glass thermometers with liquid [20]. Diabetic foot screening is also often achieved through devices utilizing thermal radi thermography. The use of color indicators such as pencils or paints, ultrasonic sensors, or thermochromic liquid crystals and powders are also beneficial for producing heat maps of the pa methods provide a cost effective and accessible solution to at home monitoring of skin surface temperatures [21].

Furthermore, infrared thermography (IRT) by way of infrared cameras allows for effective determination of skin surface temperature, asserting the importance of infrared cameras and the of ulceration. Thermographic maps produced by IRT detect variations in plantar temperature, however, the plantar temperature distribution does not follow a particular pattern in diabetic measure the changes. Thus, an interest arises in ameliorating the analysis and classification methods used in image analysis algorithms involved in artificial intelligence and machine lear structures [22].

Another method of producing thermal maps of a patient's feet is by using thermochromic liquid crystals (TLCs), a material that can change from smectic phase to nematic phase, thereby e molecules in these crystals are aligned rather than facing in random directions. At low temperatures, while in the smectic phase, the molecules are arranged in layers that can slide past eac typically either translucent or completely black because they either allow all or no light to pass through them. When the material experiences a higher temperature, the molecules shift pha distance from one another, thus changing the way light interacts with the material. This causes the crystals to exhibit a color change at these higher temperatures. Depending on the materia designated color to another, or show many colors during the phase change [23].

Thermochromic liquid crystals can be manufactured in the form of pigments, leucodyes, microscopic capsules, and even embedded into polymers [same as above]. The color changing abi reversible, and can be prepared from combination of cholesteryl oleyl carbonate, cholesteryl pelargonate, and cholesteryl benzoate [24]. Different ratios of these three compounds can proc different temperature ranges. For example, combining 0.65g cholesteryl oleyl carbonate with 0.25g cholesteryl pelargonate and 0.10g cholesteryl benzoate yields a transition range of 17-2 mixture while combining the different chemicals activates the color changing ability of the material, which can last from several months to a year.

Producing accurate thermal images of diabetic patients' feet for analysis by machine learning algorithms involves active participation by the patient [25]. In the field of image analysis a processing algorithm is able to produce a prediction of the classification of new images based on a prior data set with known parameters. The first of two main methods of machine learnin point or "feature vector" given an image. A feature vector consists of several numbers that are measured or calculated from the image [26]. These features are then used by the second par algorithm, to classify unknown feature vectors given a large database of feature vectors whose classifications are known [26]. These images are then uploaded to an app-based software, w and frequently debugged, that outputs to the patient their risk for ulceration. Developing an image analysis algorithm to be more accurate in its machine learning recognition of hot spots fo chance of preventing amputation.

About the Client

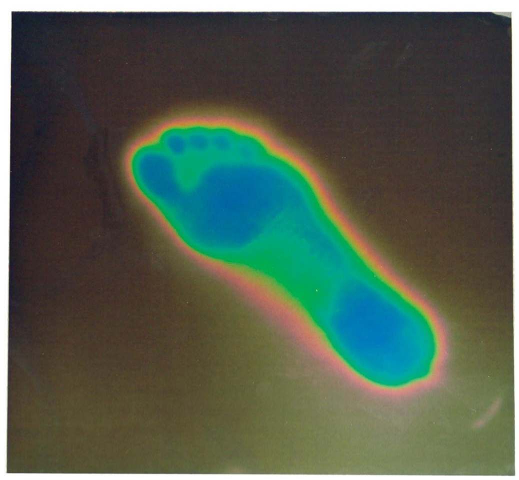
Kayla Huemer graduated from the University of Wisconsin - Madison in biomedical engineering. She is currently attending graduate school at the University of Stanford to study the inter global health. Kayla became involved with this project when she was a sophomore at the University of Wisconsin - Madison. She traveled to India in order to research the diabetes breakou there she was offered the opportunity to collect data of patients at a hospital in India. She didn't have the funds in order to continue her research so she came back in 2018 and 2019. She w Fellowship in order to continue her medical device research in India. After working a year on pressure sensing footwear she started to realize that the footwear wasn't the best way to detec shifted her focus and started using thermal imaging of patients feet to help detect early signs of foot ulceration. Now she is trying to integrate a more cost effective way and machine learni capabilities.

Design Specifications

To summarize the product design specifications, the device must be a low cost at home temperature monitoring device that is easily usinable by any patient. It also must be usable by patie sandals. It also must incorporate a thermochromic material in conjunction with an app based software and a machine learning algorithm to intake heat map images of the thermochromic m risk factor of a patient's likelihood of developing a foot ulcer. One thing to note is that the machine learning algorithm must be accurate enough to recognize multiple thermal images wheth ulceration. Also the product needs to be able to withstand multiple uses while still producing an accurate image and thermal map of the patient's feet for uploading to the app based softwa design specifications.

Preliminary Designs

Design 1 - Insulated Thermochromic Color Changing Sheets



LC-2530 25-30°C Transition

Figure 3: *The temperature profile of a foot as represented by an insulated thermochromic liquid crystal sheet* [27].

The first design proposed by the team was chosen in order to minimize cost and maximize the ease of fabrication. Insulated thermochromic color changing sheets contain thermochromi molecules that can exist in a liquid state with some crystal-like order. TLCs change color due to variations in intermolecular forces at different temperatures and different molecules experi temperature ranges [28]. Insulated thermochromic sheets usually display color changes over a 5℃ range with a tolerance of ±1.5℃ and can be customized to include protection from wat properly stored at room temperature with minimal UV exposure they can be reused and maintain the expected accuracy for over one year [29]. Despite the advantages of this design, comp temperature ranges and mediocre accuracy of insulated thermochromic sheets. Due to the large variation in possible foot temperatures, consumers would need to buy multiple sheets, each ranges, to guarantee a proper temperature profile can be collected and analyzed. This could also require the machine learning software to be trained to recognize areas of high ulcer risk fo challenging and require a large amount of data to be gathered.

Design 2 - Mix of Thermochromic Color Changing Powders

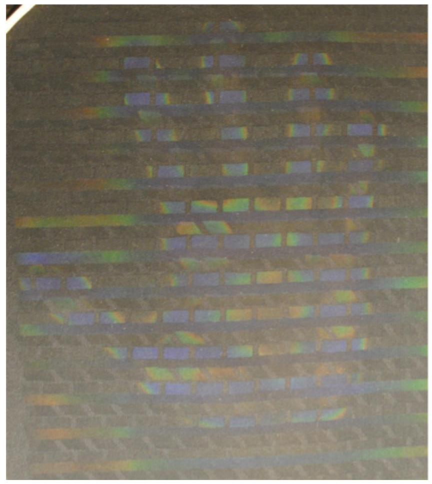


Figure 4: *The temperature profile of a hand as shown by three TLC powders each layered in a unique pattern* [30].

TLC powders can be applied to materials to create thermochromic color changing sheets. Combining powders that experience color changes at contiguous temperature ranges on one sh purchase a single sheet that would be sensitive to a wider range of temperatures. Top coats would be used to increase the durability, and therefore reusability, of the final product. It has be in unique patterns allows for significantly accurate temperature profiles to be obtained [Figure 4]. While the fabrication process of this design would be very involved, the increase in effe the first design increases accuracy and keeps the cost low. Both designs one and two require the consumer to stand on a TLC surface, take a picture of the resulting temperature profile of t app with the machine learning software trained to recognize areas of high ulcer risk. The team will need to assess whether the time required to step off the sheet and capture an image will the accuracy of the temperature profile or not.

Design 3 - IR Thermal Camera Smartphone Attachment

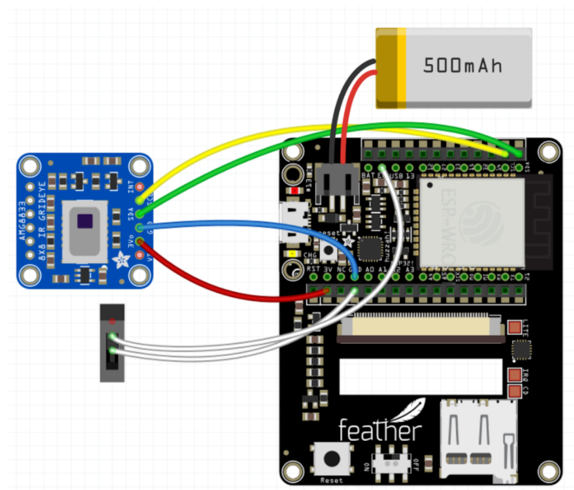


Figure 5: *Circuit with thermal camera component and display using TFT Feather* [31].

The third design the team proposed was an infrared thermal camera that could attach to a smartphone. This design would allow for digital thermal images to be taken and directly uploa processing and classification by the machine learning algorithm. Such thermal cameras have the potential to be much more accurate than the other two designs. Although the accuracy of t factor to consider, the comparatively large cost of thermal cameras to the TLC based designs outweighs the benefits of increased accuracy. It would also be difficult for a consumer to take without assistance which would likely cause a decrease in the compliance of consumers.

Preliminary Design Evaluation

Design Matrix

Table 1. Design Matrix. Evaluation of feasible design ideas amongst different criteria. Highlighted areas indicate the highest score per category. Scores ou

*Displayed as: score out of ten | weighted score

			Design 1: Insulated color changing sheets		**Design 2: Mix of color changing powders**		**Design 3: Thermal camera smartphone at**	
Rank	Criteria	Weight	Score (10 max)	Weighted Score	Score (10 max)	Weighted Score	Score (10 max)	Weig Sco
1	Cost	20	10	20	10	20	4	8
2	Accessibility/Compliance	20	10	20	10	20	5	1
3	Ease of Use (for patient)	20	10	20	10	20	5	1
4	Accuracy/ Sensitivity	15	3	4.5	9	13.5	10	1
5	Durability	10	8	8	10	10	10	1
6	Ease of Fabrication	10	7	7	6	6	2	2
7	Safety	5	10	5	10	5	10	5
	Sum	**100**	**Sum**	84.5	**Sum**	94.5	**Sum**	6

Summary of Design Matrix

Our design matrix included 7 different points of criteria. These points of criteria in order of importance included cost, accessibility/compliance, ease of use, accuracy/sensitivity, durability cost is one of the most important factors for our project because our main goal is to create a solution that is affordable to the average diabetic patient in India. This needs to be an affordabl either directly from their healthcare provider or from an online source.

Next, compliance is a big issue for at-home medical care. Other products like temperature measuring socks would not be viable in India because the majority of people do not wear socks. be able and willing to comply with is important. This means the device cannot interfere with daily life, and must have a minimal amount of steps to use. Ease of use goes hand in hand wit use for the patient, then compliance is less of an issue. The device should be easy to use on a daily to weekly basis, and should not take up too much time. This is an important factor becau not an adequate at-home solution.

Next, accuracy, it is necessary for the device to be accurate in order to properly diagnose individuals who are at risk of developing foot ulcers. The most important aspect of this criterion i temperature measurement, but of the differences in temperature of the foot. If temperature differences cannot be accurately measured, the machine learning software will not be able to acc Durability is important because the device must be durable enough to take daily or weekly measurements for an extended period of time. This criterion is ranked lower than most as the ma reliable for over one year. Ease of fabrication is one of the least important factors because the team only needs to know if they have access to the materials and equipment required to acco the product is easy to manufacture if it cannot accurately indicate the level of ulcer risk or if the patient does not comply. Safety is the least important factor because there aren't any know materials being used.

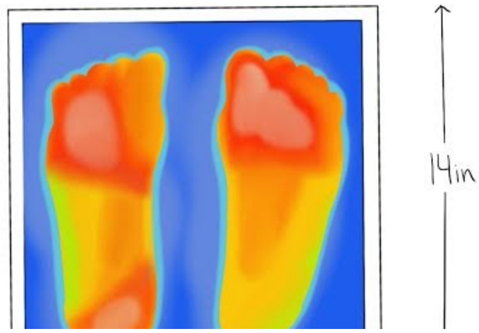
Using this criteria the team ranked each of the designs. Design 1: Insulated color changing sheets and Design 2: Mix of color changing powders received maximum points for cost, accessi these two designs these scores because they are cheap compared to current options, and they are both easy to use and something the patient would comply with. Design 3: Thermal camera hand scored much lower in these three categories because it is less cost effective and would be more complicated for the patient to use. After researching our three designs the team came t would be much more accurate than design 1 which is why design 1 scored much lower than the other two in this category. All three designs scored high in the durability category. Designs category and design 1 scored slightly lower. Designs 1 and 2 are about the same when it comes to ease of fabrication which is why they received the same score; however, design 3 would which is why it scored so low. Lastly, each design received a full score in the safety category because there are no known health concerns associated with the materials that the team would

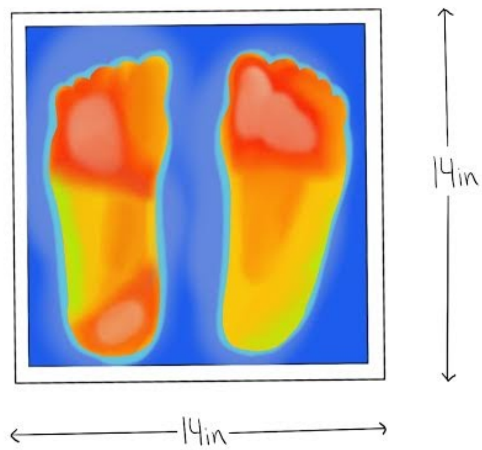
After the team completed the design matrix there was a clear winner. Design 2: Mix of color changing powders scored the most points and was chosen as our proposed final design.

Proposed Final Design

The proposed final design consists of a thermochromic imaging surface which will work in conjunction with a machine learning algorithm to analyze the data. The imaging surface will powders mixed with a liquid or acrylic base so that it can be painted or spread over the solid surface. The thermochromic layer will be secured with a top coat that will prevent the lower la that it maintains its color changing properties. Preliminary testing will help the team determine the best solid material to apply the thermochromic powder mixture to (e.g. wood, plastic, fa fully assembled, the imaging device will have dimensions of 14 in. by 14 in. and will be a solid surface that the patient can stand on with their bare feet to generate a thermal map (Fig X b from the temperature sensitive color changing powder layer will last several minutes before fading, ensuring that the patient can take a picture of the imaging surface with their smartphon

Once the image is fed to the software, the machine learning algorithm will process it and analyze the colored regions. Each color will be associated with a certain temperature range, so the temperatures in different regions of both feet. It will assess whether or not there is a temperature difference of four degrees fahrenheit or greater in symmetric parts of the feet (e.g. the diff and left heel). If there are any temperature differences that meet or exceed this threshold, the software will output an 'at-risk' result, indicating that the patient is at risk of developing an ul the patient should reduce the number of steps they take daily and the amount of time they spend on their feet.





feet.

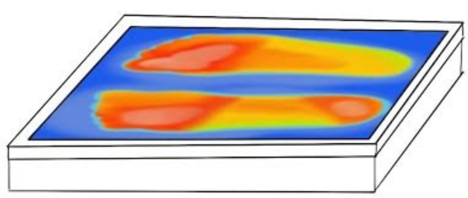


Figure 7. Side View of solid surface with thermochromic material showing a thermal image of two feet.

Development of Machine Learning Algorithm

Materials and Tools

A machine learning algorithm will be created in order to analyze the thermal maps generated after a patient steps on the thermochromic material and takes a photograph with a camera c
type of artificial intelligence program that will be trained to classify images. In order to create this algorithm, open source code will be used to train a model using Python, a coding langua
of data, of which approximately 200 thermal images of diabetic patients' feet have already been taken with an infrared camera by the client, Kayla Huemer, in India. At least 800 more pho
program the algorithm. These images will serve as the data that the machine learning model will be trained to recognize and classify. A model such as ImageAI [35] or TensorFlow 2.0 [36
Supervisely, a collaborative workspace to compile and edit data and open source software [37]. Currently, not enough thermal images have been collected to begin the machine learning pr
minimum of one thousand images in order to begin to recognize patterns in the data. Due to restrictions from Covid-19, it is unknown when Kayla's team will be able to return to India to

Methods

In order to create the machine learning algorithm after enough thermal images have been collected, an open source machine learning model will be used, such as ImageAI. These open s are built to import an RGB (color) image file, then classify the image type so that it can be processed. Images can either be interpreted one by one or as a dataset. For large amounts of ima provided by the client, a dataset is the best method for organizing the data. An iterator in the Python code will allow the program to run through each photo. Processing the images will inv classify the images [36]. The team will determine a temperature scale and assign temperatures to color values. Based on these temperatures associated with colors, the code will be modifi areas of the foot. If the algorithm recognizes that there is a temperature difference of four degrees Fahrenheit or more between any symmetric parts of the foot, it will classify the image as

Final Prototype

The final prototype will be a functioning code that will take an input thermal image, process it by analyzing the color of each pixel and assigning a temperature value, then outputting w ulceration. 'At risk' will be defined as containing at least one area of the foot with a temperature difference of at least four degrees Fahrenheit (2.2 degrees Celsius) compared to the analog

Testing

In order to test the accuracy of the machine learning algorithm, more thermal images that the team takes will be input into the software. The output will be compared to actual data colle often it correctly classifies the image as at-risk or not. Inputting these images will help to further teach the algorithm to properly identify the images it is fed. This testing cannot take place begin the machine learning process.

Fabrication of Thermochromic Imaging Surface

Materials

Table 2. Materials and Costs Spreadsheet.

Category 1: Thermochromic Materials (powders, sheets, paints, etc)				
THERMOCHROMIC POWDER PIGMENT	Blue to Violet Powder 22 degrees	ATLANTA CHEMICAL ENGINEERING®	11/6/2020	1
THERMOCHROMIC POWDER PIGMENT	Black to Green Powder 25 degrees	ATLANTA CHEMICAL ENGINEERING®	11/6/2020	1
THERMOCHROMIC POWDER PIGMENT	Red to Yellow Powder 28 degrees	ATLANTA CHEMICAL ENGINEERING®	11/6/2020	1
THERMOCHROMIC POWDER PIGMENT	Black to Pink Powder 31 degrees	ATLANTA CHEMICAL ENGINEERING®	11/6/2020	1
THERMOCHROMIC POWDER PIGMENT	Black to Purple Powder 35 degrees	ATLANTA CHEMICAL ENGINEERING®	11/6/2020	1
TLC sheets	Three Color Changing Thermochromic Sheets	Amazon	11/6/2020	1
Category 2: Other Materials (for building the imaging surface, testing, etc)				
Wooden Craft Rectangles	Wooden Boards	Amazon	11/6/2020	1
1 inch thick foam	Foam to glue onto wooden board	Amazon	11/6/2020	1
Acrylic paint base	Acrylic paint base to mix with pigments	Amazon	11/6/2020	1
Epoxy Resin and Hardener	Epoxy Resin top coat to secure the TLC material	Amazon	11/6/2020	1
Black fabric	Fabric to paint the pigments onto and secure over fabric	Amazon	11/6/2020	1

Table 2, shown above, is a compilation of all of the materials ordered for this project. Five different thermochromic liquid crystal powder pigments were ordered from Atlanta Chemical (changing from blue to violet at 22 degrees Celsius, black to green at 25 degrees Celsius, red to yellow at 28 degrees Celsius, black to pink at 31 degrees celsius, and black to purple at 35 mixed with a white acrylic base to form a paint that would change colors at their respective temperatures. Two white acrylic bases were used to mix with the thermochromic pigments, inc above) and a second that did not need to be purchased.

Four wooden boards were also purchased to use as a hard base for the imaging surface, as well as 1-inch thick foam that was intended to serve as cushioning and provide a surface that w foot, thus allowing the thermal map generated from the thermochromic paints to show the entire three dimensional surface of the foot rather than just the flat footprint. Black fabric was als the thermochromic paints. A clear coat of epoxy resin was ordered to apply in between each layer of paint on the fabric to secure the color changing abilities of the thermochromic paint. I ordered to fabricate the color-changing imaging surface, a set of thermochromic temperature sensitive sheets were also ordered with the intention of fabricating a second prototype based c comparisons could be made between the pigments and the sheets. This set came with three sheets with different temperature ranges (20-25, 25-20, and 30-35 degrees Celsius). Additional glue, staples, paint brushes, and plastic cups, which did not need to be purchased.

Methods

In order to fabricate the proposed final design, each pigment was added to a separate container and mixed with two different acrylic bases, a white Liquitex acrylic medium, and a Crafts each pigment-paint mixture were painted onto both wood and fabric to test their color changing abilities and assess their vibrancy. Several layers of these swatches were built up, and once was applied to qualitatively test the color-changing abilities. A detailed fabrication plan for the intended prototype using these pigments can be found in Appendix B.

Unfortunately, the fabrication process did not go as planned. When the pigments were mixed with the Liquitex acrylic medium and applied to wood, the color change observed when he the five pigments, and no color change was observed in the other three. The same results were found with the Craftsmart acrylic base as well when applied directly to wood. Both the Liqu were also applied to black fabric, but no color change was found in these swatches either when temperature was applied.

After unexpectedly finding no color change when the pigments were applied to both wood and fabric, the same process was repeated after first applying a white base coat to both materi mixtures. However, like the first experiment, no color change was observed when heat was applied to these swatches. This meant that fabrication of the prototype could not proceed as out B).

In order to continue fabrication, the team modified plans for the final prototype to resemble the first preliminary design idea rather than the proposed final design, and ordered a set of th color from 20-25, 25-30, and 30-35 degrees Celsius respectively. Each sheet was cut into strips 0.5cm wide and 4in long. These dimensions were chosen because each of the three sheets v cut into strips approximately 0.5cm wide because, when combined, the three strips of different temperature ranges had a total width of 1.5cm, which is approximately the width of the aver glued onto a wooden board in order of increasing temperature range so that repeating groups of three strips covered the board. The strips were labeled on the board with their temperature r

This design was chosen so that when heat is applied to the surface, lower temperatures cause color change in only the 20-25$_o$C strips, mid-range temperatures cause change in the 25-30$_o$C any change in the 30-35$_o$C strips. Different areas of the foot have different temperature ranges, the toes having an average temperature of 26.2$_o$C and the sole an average temperature of 29 temperature range, however, foot temperatures can be as much as 5$_o$C higher or lower than these averages, thus the need for the combination of thermochromic strips with different temper temperatures can be sensed by the device. The final surface with the thermochromic strips had dimensions 8in x 8in, which is not as large as the intended design due to lack of materials an unexpected change in design.

Final Prototype

The final prototype consists of a flat wooden surface with thermochromic liquid crystal sheets of different temperature ranges arranged in repeating groups of three strips, with the lowe at the top of each group of three, the mid-range (25-30$_o$C) in the middle, and the highest temperature range (30-35$_o$C) at the bottom of each group (figures 8 and 9 below). Each group of th board with their corresponding temperatures so that each strip's temperature range is easily legible. Unlike many infrared cameras, the warmer colors (red, orange, and yellow) in this prot in each range, and the cooler colors (blue and green) correspond to higher temperatures in each range. Thus, the blue areas on each strip coincide with the high end of the corresponding te

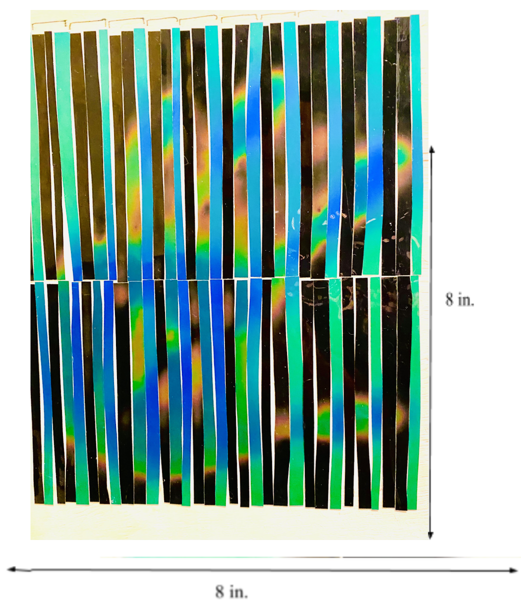


Figure 8 - Final Prototype. Image of layered thermochromic liquid crystal (TLC) strips layered in order from 20-25$_o$C, 25-30$_o$C, and 30-35$_o$C. Brackets on the side show repeating gr temperature range starting at the top of each group of three and the highest temperature range at the bottom of each group. Pictured is a thermochromic heat map left from pressing a han removing. The surface has dimensions 8in x 8in.

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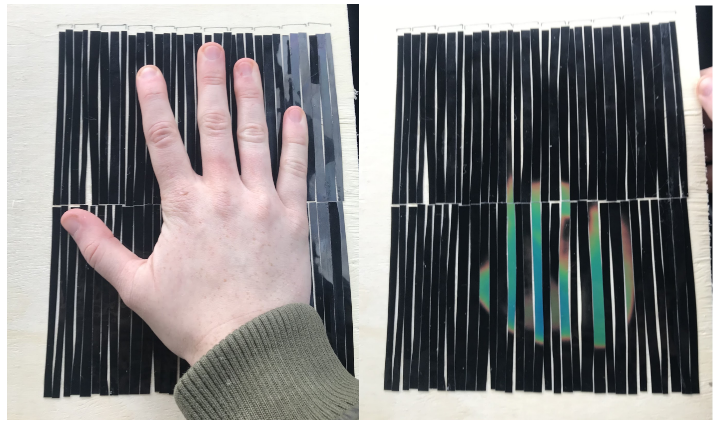

Figure 9. Image of hand pressed onto thermochromic imaging surface and subsequent heat map produced.

In order to use the prototype, a patient must stand on the surface, allowing their foot to press against the temperature sensitive strips for at least five seconds. After stepping on the surfa patient can take a photograph with a camera or smartphone for further analysis after the image fades. After using the device, the patient can take the time to observe which strips experienc foot temperature ranges from 26.2$_{o}$C at the toes and 29.3$_{o}$C at the toes, any color change in the 30-35$_{o}$C strips indicates a slightly above-average foot temperature, and may be reason to co since a 2.2$_{o}$C temperature difference in symmetric areas of the feet (for example, between the heel on the right and left feet) can serve as an indicator of potential ulceration [34], a noticea temperature maps of the two feet can also be cause for concern, potentially leading a patient to take fewer steps each day and get in touch with a doctor about preventative health care.

Testing

In order to test the accuracy of the final prototype, a temperature comparison test was performed in order to compare temperatures estimated from the device and actual temperatures. A unknown temperature was used to apply heat to the thermochromic imaging surface for five seconds. After removing the heat source, the color of the different strips was used to estimate the actual temperature of the water was recorded with a thermometer as well. This comparison was performed eight different times, recording both the actual and estimated temperatures i data, a two sample t test was performed.

Table 3. Temperature Comparison Data. This table shows the estimated temperatures and actual temperatures found during the temperature comparison test, as well as the difference be

Trial	Estimated temperature based on color shift (Celsius)	Actual temperature from thermometer (Celsius)	Difference (Actual - Estimated)
1	36$_{o}$C	38.1$_{o}$C	2.1$_{o}$C
2	34$_{o}$C	33.2$_{o}$C	-0.8$_{o}$C
3	27.5$_{o}$C	28.4$_{o}$C	0.9$_{o}$C
4	24.5$_{o}$C	23.2$_{o}$C	-1.3$_{o}$C
5	19$_{o}$C	17.8$_{o}$C	-1.2$_{o}$C
6	27$_{o}$C	29.5$_{o}$C	2.5$_{o}$C
7	29$_{o}$C	28.9$_{o}$C	-0.1$_{o}$C
8	31.5$_{o}$C	31.3$_{o}$C	-0.2$_{o}$C
Average	28.5625	28.8	1.1375
Standard deviation	5.4145	6.1542	1.31

A second test was performed to test the amount of time an accurate thermal map lasted on the device before fading. This test was performed to quantify the approximate amount of time to take an image of the thermal map while it is still sufficiently accurate. To determine this, a clear plastic bag was filled with water of known temperature and used to heat the thermochro thirty seconds. The heat source was then removed and the amount of time that passed until the outermost thermochromic strip lost all color change was recorded. Although the color chang the thermal map, the disappearing time of the colors at the edges was used to quantify thermal map retention because the color differences become more ambiguous at the center of the ma

Table 4. Thermal Map Retention Data. This table shows how much time passed until all color change was lost in a strip of thermochromic material at the edge of the thermal map afte temperature.

Temperature (°C)	25-30°C Sheet Time to Color Loss (seconds)	30-35°C Sheet Time to Color Loss (seconds)
25	1	-
26	9	-
27	11	-
28	27	-
29	50	-
30	-	3
31	-	4
32	-	5
33	-	6
34	-	6.5
35	-	7
36	-	9
37	-	10
38	-	11
39	-	22
Average	19.6 seconds	8.35 seconds

Results

After collecting the temperature data, a two sample t test was performed in order to compare the means of the estimated and actual temperatures and determine if the temperatures were value of 0.05 was used, and the result of the t test was a t-value of -0.082 and a p-value of 0.94, which was not less than the significance level, indicating that the color-estimated temperatu actual temperature. This means that the final prototype consisting of groups of thermochromic sheets is a successful and accurate visual depiction of the temperature of a patient's feet. Fig estimated and actual temperatures and the difference between the two.

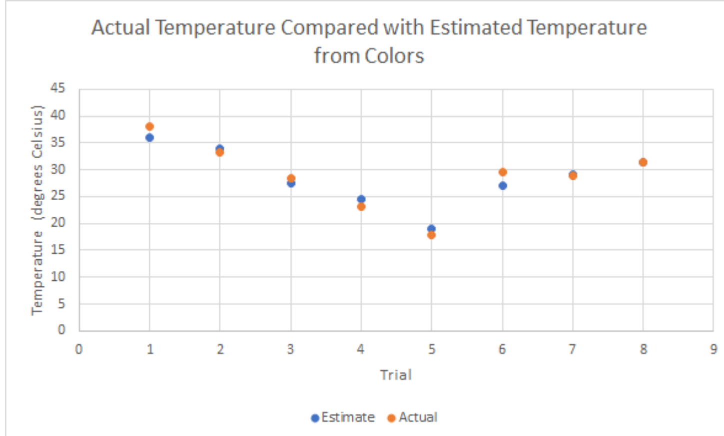

Figure 10. Graph of actual temperature (red) compared with the color-estimated temperature (blue) for each of the eight trials from the temperature testing. The average difference betwe

The results of the fading-time test found that the 25-30$_o$C thermochromic strips fade after an average of 19.6 seconds, while the 30-35$_o$C strips fade after an average of 8.35 seconds. No strips because the test was conducted at an ambient temperature of 23.2$_o$C, so these strips were perpetually yellow and green during the test with no fading to black. Data was not collected 30$_o$C thermochromic material because the time to lose color change at the edges was longer than one minute.

Discussion

A thermochromic imaging surface was created from TLC sheets. Temperature testing found that the temperature estimated from the device was not significantly different from actual te accurate and successful, despite the change in designs that followed the failed tests of the thermochromic pigments. The surface is easy to use, and simply needs to be stepped on with bare The brackets on the side of the thermochromic strips provide information about the temperature range of each strip so that the colors on the surface can be easily interpreted. Although the thermochromic pigments mixed with an acrylic base resulted in no color change with applied heat, the thermochromic sheets showed vibrant colors that changed at the correct temperature step off of the surface and take a photograph for later interpretation.

Although there are several products on the market that are geared towards aiding diabetic patients in self-monitoring their feet to prevent injury or ulceration, many of these products inv compliance for diabetic patients in India. Siren is a growing company in the United States that uses temperature sensing technology built into a pair of socks so that patients can monitor th feet and modify their daily activities if they notice significant temperature changes. Products such as diabetic socks and shoes are not as applicable in rural communities in India, however, wear socks and close-toed shoes, but rather go about their daily lives in sandals or bare feet. The team's design of a thermochromic imaging surface that patients simply need to step on bri will not have to interfere with their daily routine to monitor the temperature of their feet. Instead, patients simply need to stand on the surface once a day to see a visual representation of th removes the need for an extra piece of clothing or a costly infrared skin thermometer. The total cost of this final prototype was about $36.40, but the individual cost of this device would be purchased in bulk. The overall expenses of this project were much higher at $136.38 including all of the materials for the failed thermochromic pigment design.

Overall, the results from the testing of the prototype show that it is successful in indicating when there are significant differences in the temperature of the feet, and thus when there is pote means that the product will provide a much more accessible method for diabetic patients in India to monitor the state of their feet so that they can be proactive in making decisions that wil any major color differences in the right and left foot, a patient can take steps to limit the number of steps each day and, when possible, meet with a health care provider about further treatm avenue for at-home treatment that will benefit patients who have obstacles that keep them from accessing standard and consistent health care, such as money or distance.

In the future, the team would like to modify the imaging surface so that it is more precise when extracting data and see if the colors fade quicker at different ambient temperatures. The tea machine learning algorithm that will analyze a picture of the imaging surface and definitively tell the patient whether there is cause for concern for ulceration. In order to do this, the team the machine learning algorithm. This data would consist of thermal maps of both healthy feet and ulcerated feet. The algorithm will then learn to identify the difference. This algorithm is a Huemer has begun, but has not been able to collect enough data to move forward due to the current situation with the Covid-19 pandemic. The device will also be tested under different co The data taken from the imaging surface will also be compared to existing products such as Siren socks to learn the efficiency and effectiveness of the device and where improvements car

Conclusion

The final prototype uses thermochromic liquid crystal sheets of different temperature ranges. These sheets are arranged into repeating groups of three strips with varying temperature range surface. The team came about with this final prototype based off of tests that were done in order to decide the most accurate way to generate the thermal map of a patient's feet. This final p the surface and generate a thermal map of their feet, which successfully and accurately displays the temperature of the feet. In the future, the color-coded thermal map that is generated wo software for classification by a machine learning algorithm. This software would output whether or not the patient is at risk of an ulcer.

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Appendix

Appendix A - PDS

Global Health: Prevention of Diabetic Foot Ulceration and Amputation

Preliminary Product Design Specifications

Date: 09/18/2020

Team Members: Cade Van Horn Team Leader

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Will Nelson Co-BWIG

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Function:

The device will be a preventative solution to India's diabetic foot ulcer problem by developing a low-cost way to measure temperature from the feet of diabetic patients using thermochrom
to further interpret the images and thermal maps. A machine learning algorithm will be incorporated to analyze the data collected and determine whether or not a patient is at-risk of devel

Client Requirements:

- Obtain a thermal image or map of the patients' feet
- Upload the thermal images to a software/app
- Use a machine learning algorithm that we will train to recognize whether an image is of an at-risk patient or not

Design Requirements:

1. ## Physical and Operational Characteristics
    1. **Performance requirements:** The performance demanded or likely to be demanded should be fully defined. Examples of items to be considered include:
    will be used; likely loading patterns; etc.
        1. The machine learning algorithm must be accurate enough to recognize whether or not a patient is at-risk of developing an ulcer based on the therr
        a patient's foot.
        2. The device could be used anywhere from monthly to daily. It must be able to withstand several uses in one day and still accurately display a therm
        patient's feet that can be uploaded to the app.
        3. The app/software must be able to withstand the process of uploading an image several times a day, potentially by multiple different mobile devices
        crash during usage.
    2. **Safety:** Understand any safety aspects, safety standards, and legislation covering the product type. This includes the need for labeling, safety warnings, e
    safety aspects relating to mechanical, chemical, electrical, thermal, etc.
        1. The material used to collect temperature data and thermal maps must be safe for the patient. This includes thermal cameras and thermochromic n
        neither of which can include any harmful side effects for the patient [1].
    3. **Accuracy and Reliability:** Establish limits for precision (repeatability) and accuracy (how close to the "true" value) and the range over which this is true c
        1. The machine learning algorithm must be very accurate and reliable, therefore it must go through a long enough "learning process" before it is usec
        2. It must be accurate enough to recognize when a patient is at-risk of developing a foot ulcer.
    4. **Life in Service**: Establish service requirements, including how short, how long, and against what criteria? (i.e. hours, days of operation, distance traveled
    of cycles, etc.)

1. Liquid crystal thermochromic material can retain its properties for several months if handled properly. Soaking the material in hot water baths can c material to deteriorate faster, as well as exposure to UV light [2].

5. **Operating Environment**: Establish the conditions that the device could be exposed to during operation (or at any other time, such as storage or idle time temperature range, pressure range, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, vibration, persons who will use or han hazards, etc.
    1. The thermochromic material will be used to obtain a thermal map of the patient's feet when the patient steps on the material. This can be used in a setting with a controlled climate.
6. **Ergonomics**: Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc
    1. The thermochromic material must be easy to use by both the doctor and the patient. All that will be required of the patient will be to step on the ma collect the thermal map, and the person looking to analyze the thermal map should be able to easily take a picture of the generated thermal map w phone camera and upload it to the app-based software, which will generate an output. This should be an easy process for the user.
7. **Size**: Establish restrictions on the size of the product, including maximum size, portability, space available, access for maintenance, etc.
    1. The thermochromic material needs to be large enough for both of the patient's feet, but small enough so that there is not too much excess materia needs to be able to accommodate people of many different foot sizes.
    2. The size of the images must be compatible with the software/app. The app must be able to analyze images of different sizes and still generate a re
8. **Weight**: Establish restrictions on maximum, minimum, and/or optimum weight; weight is important when it comes to handling the product by the user, by tl on the shop floor, during installation, etc.
    1. Liquid crystal thermochromic material weighs about the same as a piece of printer paper. The weight of the paper will not be an issue for the user
    2. The thermochromic material must be able to withstand the weight of the patient and still generate and accurate thermal map of the patient's feet.
9. **Materials**: Establish restrictions if certain materials should be used and if certain materials should NOT be used (for example ferrous materials in MRI ma
    1. The thermochromic material will be the only physical material used in the project. This will either be thermochromic liquid crystal sheets, or leucody be printed on another material. The liquid crystal sheets are more accurate than leucodyes [3], so it is likely that will be the only material used.
10. **Aesthetics, Appearance, and Finish:** Color, shape, form, texture of finish should be specified where possible (get opinions from as many sources as po
    1. The user interface of the app/software must be user friendly and aesthetically appealing. It needs to be accessible to everyone eventually, so text r readable and the image uploading process should be easy.
    2. The output generated by the app should be easy to read and non-offensive if a non-desirable (at-risk) outcome is generated.

2. Production Characteristics
    1. **Quantity**: number of units needed
        1. Only one application needs to be created.
        2. While testing the device, only a few sheets of thermochromic material need to be used to ensure the accuracy of the device and system.
        3. If the product is marketed to the public, each individual using the device will require their own sheet(s) of thermochromic material.
    2. **Target Product Cost**: manufacturing costs; costs as compared to existing or like products
        1. There is no set budget for this project.
        2. One 12x12in liquid crystal sheet is $25.95 [4].

3. Miscellaneous
    1. **Standards and Specifications**: international and /or national standards, etc. (e.g., Is FDA approval required?)
        1. There are several FDA regulations on temperature sensing devices, although most apply to electronic devices. The team's thermochromic imaging not include any electronic components that will need to comply with FDA guidelines, but if the project progresses to the point of human subject tes involvement, FDA guidelines and regulations will need to be followed [5]
    2. **Customer**: specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.
        1. There are no specific requests from customers since there is no one customer. The client wants the device to be applicable to all customers/patier
    3. **Patient-related concerns**: If appropriate, consider issues which may be specific to patients or research subjects, such as: Will the device need to be ster Is there any storage of patient data which must be safeguarded for confidentiality?
        1. The reusable thermochromic imaging surface will need to be easily usable by the patient.
        2. The imaging surface must be big enough to accommodate a variety of patients' feet.

3. Images of the patient’s thermal maps that are uploaded to the app will not include any personal data, so no personal or sensitive data will be collec saved.

4. **Competition**: Are there similar items which exist (perform comprehensive literature search and patents search)?
    1. There is a brand called siren that produces socks that are worn daily and monitors the temperature of the patient's foot. These socks have sensors constantly measure temperatures of key points on the foot and send the information to the siren app. The doctor then can notify the patient when t sign of inflammation or something concerning. The socks then are replaced every six months to avoid misleading data from wear and tear [6].

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[6]Siren, "Siren Socks & Foot Monitoring System", Siren Socks, 2020. [Online]. Available: https://siren.care/. [Accessed: 07- Oct- 2020].

Appendix B - Fabrication and Testing Plans

Intended Fabrication Plan:

Initial Qualitative Testing of Pigments:

1. In five separate containers, add about a teaspoon of each pigment
2. In each of the containers, add the Liquitex white acrylic medium in a 2:1 acrylic to pigment ratio and mix with a stir stick to fully combine the pigment and acrylic m
3. With a paint brush, paint a swatch (about 2 inches long, 1 inch wide) of each pigment range onto a wooden board to test the color changing abilities
    1. When the swatches dry completely, apply heat to each to test if the color changes at the desired temperature. If the color does not change as desired, app swatch until the desired color change is observed.
4. Repeat step 3 on the black fabric to test the color changing ability of each pigment on the fabric compared to the wood
5. Compare the swatches on the wood and the fabric and qualitatively determine if the color change is more vibrant on one or the other
6. Repeat steps 1-5 with the Craftsmart acrylic paint as a base for the pigments
    1. Compare the Liquitex and Craftsmart swatches and qualitatively determine if the color change is more vibrant with one base versus the other

Fabrication of Fabric-Foam Imaging Surface:

1. Cut a square of black fabric that is 16in x 16in.
2. Lay the square of fabric out and paint an even layer of the lowest temperature pigment. Wait for the layer to dry completely and paint another layer until the pigme
3. Once the first layer has dried, apply a thin, even coat of the clear epoxy resin over the thermochromic layer.
4. Repeat steps 2-3 with each successive temperature pigment until all pigments have been layered in between clear coats. Apply one final clear coat.
5. Cut a 14in x 14in square of 1in thick foam and wrap the fabric around the foam, securing it with glue.
6. Glue the foam onto a wooden board for a solid base to the imaging surface.

Testing of Imaging Surface - Temperature Comparison:

1. Using a container full of water heated to an unknown temperature, apply heat to the surface and let sit for five seconds.
2. Remove the heat source and use the colors to estimate and record the temperature (22 degrees Celsius = violet, 25 = green, 28 = yellow, 31 = pink, 35 = purple)
3. Measure the actual temperature of the water with a thermometer and record
4. Repeat step 2-3 eight times, recording the actual and estimated temperature

5. Calculate the mean, and standard deviation of both the estimated temperatures and the actual temperatures.
6. Perform a two sample t test to compare the means with a significance value of alpha = 0.05 to see if the actual vs estimated temperatures are significantly differer

Conclusions/action items:

12/08/2020 - Final Poster

CADE VAN HORN - Dec 09, 2020, 8:47 AM CST

Title: Final Poster

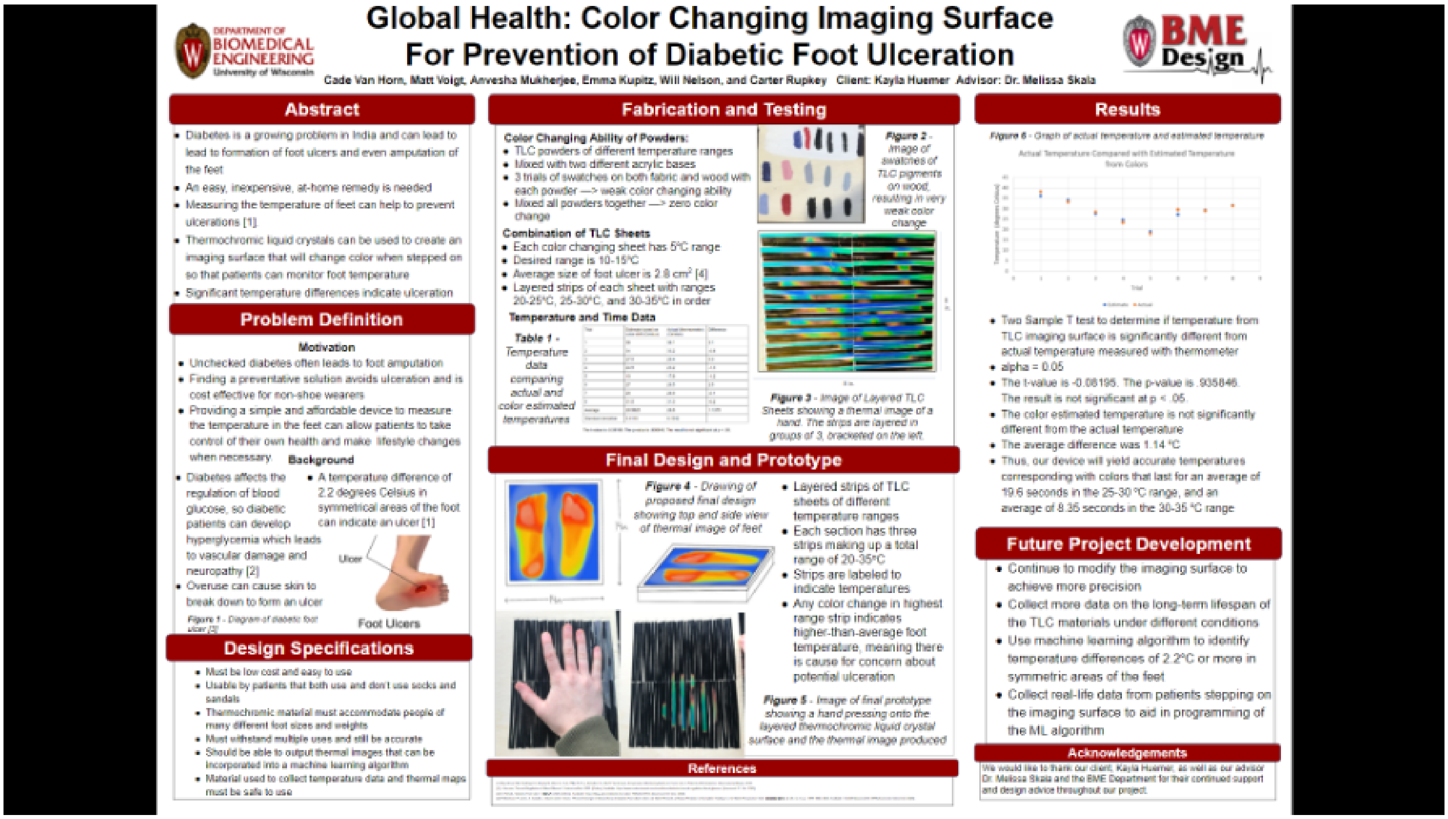
Date: 12/08/2020

Content by: Whole Group

Present: Whole Group

Goals: To present our final design in a poster format

Content:



Link: https://docs.google.com/presentation/d/1p2-uXS0iH09Yf1sFXKLoKisXuEbCNLY4N91VOCRtHwQ/edit?usp=sharing

Conclusions/action items:

This is our final poster.

12/08/2020 - Final Presentation

CADE VAN HORN - Dec 09, 2020, 8:45 AM CST

Title: Final Design Presentation

Date: 12/08/2020

Content by: Cade

Present: N/A

Goals: To present our final prototype to the class

Content:

Below is a link to our final design presentation video:

https://drive.google.com/file/d/1AlhkE5-gdsquAZegQklkbXmemTwaGo-e/view

Conclusions/action items:

We presented our final design to the class.

9/8/2020 Diabetic Foot Ulcer Research

CADE VAN HORN - Sep 11, 2020, 9:16 AM CDT

Title: Research on Diabetic Foot Ulcers

Date: 9/8/2020

Content by: Cade Van Horn

Present: N/A

Goals: The goal of this research is to better understand the causes and symptoms of diabetic foot ulcers and how they are treated.

Content:

[1]S. Kim, "Diabetic Foot Pain and Ulcers: Causes and Treatments", Healthline, 2020. [Online]. Available: https://www.healthline.com/health/diabetic-foot-pain-and-ulcers-causes-treatments. [Accessed: 11- Sep- 2020]. https://www.healthline.com/health/diabetic-foot-pain-and-ulcers-causes-treatments#when-to-see-your-doctor

Skin tissue on the foot breaks down to form ulcers as a result of uncontrolled diabetes. These are easily preventable with proper treatment of diabetes, but when patients go without seeing professional help, these ulcers can result in amputation.

Signs of an ulcer:

- drainage from foot
- swelling and irriration
- redness
- black tissue (eschar) surrounding the ulcer - due to lack of healthy blood flow
- Gangrene around the ulcer - tissue death from infection
- pain
- numbness

Causes of an ulcer:

- bad blood circulation
- hyperglycemia (high blood sugar)
  - high glucose levels slow the healing of ulcers
  - people with type 2 diabetes have a difficult time fighting off infections from ulcers
- nerve damage
- irritated/wounded feet

Risk factors for people with diabetes that could lead to ulcers:

- bad shoes - can be particularly a problem in low income patients/areas
- poor hygiene
- improper toenail trimming
- consumption of alcohol
- eye disease from diabetes
- heart or kidney disease
- obesity
- tobacco use

Treatment:

Not using the feet - called offloading - is important in preventing pain and minimizing risk because pressure from walking can make ulcers expand and can worsen infections. Doctors recommend various things to protect the feet, like diabetic shoes, casts, braces, compression wraps, or shoe inserts. Doctors can remove a foot ulcer with a debridement where they remove any dead skin or infections that may have caused the ulcer. Infections are very serious and need to be treated as quickly as possible. Infections can be prevented by disinfecting the skin around an ulcer, taking foot baths, dressing the ulcer frequently and keeping the skin clean and dry, or using enzyme treatments or other medications. In some cases, surgery is necessary to help the ulcer by shaving down the bone or removing bunions or hammertoes. Overall, when caught early ulcers are treatable.

[2] S. Wu, V. Driver, J. Wrobel, D. Armstrong, "Foot ulcers in the diabetic patient, prevention and treatment", *Vascular health and risk management*, *3*(1), 65–76, 2007. Available: PMC1994045.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1994045/

Foot complications in people with diabetes can begin with neuropathy - numbness and pain from nerve damage in the extremeties - and can lead to foot wounds, infection, and even amputation. Diabetic foot ulcers can be prevented with adequate health care, including a screening of health history and a simple test for loss of sensation in the lower limbs (can use the Semmes-Weinstein monofilament to do this). The status of the nerves in the foot can also be assessed with the Doppler ultrasound and ankle-brachial blood pressure indices. Taking measurements is important, but so is patient education and managing blood sugar levels and stressing the importance of proper foot care. There are a few fundamental basics to keep in mind when healing diabetic foot ulcers: adequate perfusion, debridement, infection control, and pressure mitigation.

Foot ulceration is one of the most common complications of diabetes mellitus - it occurs in anywhere from 4-10% of diabetic patients (as of 2005). Foot ulcers frequently become infected and require hospitalization. The treatment of these complications are also very costly, with costs conservatively estimated as high as $45000 per patient (estimate from 2004). Foot ulcers and amputation also leads to deleterious psychosocial effects on the patient’s quality of life due to mobility impairments and loss of productivity.

Ulcerations create an avenue for infections and can cause progressive tissue necrosis (death of cells through disease or injurty) and poor wound healing in the presence of critical ischemia (a condition where part of the body is not getting enough blood or oxygen, usually because of artery blockages). Approximately 56% of diabetic foot ulcerations become infected and 20% of these patients with infected foot wounds end up with some type of lower extremity amputation (as of 2005).

Annual foot examinations are recommended for all individuals with diabetes to identify high-risk foot conditions including peripheral vascular insufficiency, structural foot deformities, and loss of protective sensation for which specific interventions have been shown to be effective in reducing amputation risk.

Conclusions/action items:

Ulcers are both preventable and treatable when patients have access to the right healthcare options, but when left untreated, ulcers can lead to amputation.

9/11/2020 Prof. Paul W. Brand Video Notes

CADE VAN HORN - Sep 11, 2020, 10:45 AM CDT

Title: Notes on Prof. Paul W. Brand On Leprosy, Diabetes, Wounds, and a Life of Service Video

Date: 9/11/2020

Content by: Cade Van Horn

Present: N/A

Goals: To take notes on Prof Brand's talk on the diabetic foot.

Content:

The neuropathic foot:

- turtle contact cast and molded insole and rigid soles for shoes, all very helpful for the diabetic foot, were initially developed for leprosy neuropathy
- many people outside hospital in india with diseases and deformities of the limbs - lepers - who couldn't come into the hospital
- Prof Brand wanted to find a way to treat the "non healing flesh" of the lepers because the wounds were so similar to diabetic ulcers
- He knew the patients had neuropathy because leprosy destroyed the nerves
- They tracked wounds and how the wounds were acquired to find the cause of the wound
- After the patients learned how to protect and take care of themselves, the frequency of new wounds decreased
- Wounds still appeared while they were sleeping so they watched the sleeping and found that a rat was biting the boys while they were sleeping so they bred cats to drive away the rats
- They began to recognize that the patients could not feel anything in their limbs which was allowing them to get wounds and not know where they came from - they had significant nerve damage
- Then they got interested in temperature - when only one foot is insensitive, the insensitive foot is hotter than the sensitive foot
- When you cut all the nerves in a limb, the limb is supposed to become cooler, so they wanted to know why the neuropathic limbs felt hotter
- They did tests and found the insensitive feet of outpatients were hotter and the insensitive feet of inpatients were cooler (compared to the other sensitive foot)
- The outpatient people walked barefoot on the rough ground and the bad foot took more weight on the road while the good foot came down gently, so because of neuropathy, the limping of patients spared the sensitive foot and put the burden on the insensitive foot
- They found that the relationship between temperature and damage included a phase while walking long distances where the foot is inflamed before it breaks down
- There are two distinct types of nerve endings, both of which produce the sensation of pain (research pioneered by Sherrington)
- The first is called "High Threshold Mechano-Receptors". Impulses from these HTMs are carried by A-Delta nerve fibers and they give pain sensation in response to relatively high levels of mechanical stress that impinge on healthy tissues
- If a patient has already damaged the foot, even if the foot tissues are inflamed, moving toward damage, a new set of pain nerve endings come into effect, called:
- Poly-Modal Nociceptors, of PMNs - these respond to mechanical stresses by severe pain, at much lower thresholds of force, and only if they have already been activated by chemical products of inflammation or of actual damage to living tissue - very severe pain in response to very small stimulation
- After walking several miles on rough ground, you begin to feel pain despite no high stress impacts - this is because of the PMNs, the pain from constant low stress
- Tenderness is a good way to explain this
- A hard sudden beating hurts, but after being beaten several times, you become tender, so a much smaller blow will create a much greater pain - after a while of normal tissue responding to HTMs, then it becomes inflamed tissue responding to PMNs
- The foot becomes tenderized after constant stress
- Measuring temperature of a persons foot as they ran several miles let them guage how the foot was doing under repetitive stress. The further we walk, the more we adjust the way we put our weight down to spare the inflamed areas
- The hot spot is the inflamed spot
- Pain tells you when your foot is hurting but these people with neuropathy dont feel pain so they don't adjust to spare the hot spot, one spot becomes more and more inflamed until it becomes an ulcer
- most podiatrists who treat insensitive feet in diabetics are very concerned about the amount of stress per step, but they don't tell the patient how many steps they can take per day
- the number of steps per day is more important than the stress of each step
- temperature is the best remaining index that a foot is about to break down
- every patient got a thermograph to find the hot spot, then take its temperature and give the patient a take home thermometer so they can take the temperature of the hot spot and compare it to a standard cool spot of the same foot. If the temperature differential persists in getting higher, they are walking too many steps. This is a way each patient could regulate their own lifestyle to take

preventative steps

Conclusions/action items:

Prof Brand discovered in his time in India that temperature is very important in monitoring diabetic feet because it allows you to see a hot spot where an ulcer has formed or is most likely to form and allows patients to take more preventative steps.

9/11/2020 - Kayla Huemer Conference Video Notes

CADE VAN HORN - Sep 11, 2020, 11:45 AM CDT

Title: Video Notes: Fulbright in India E17: Kayla Huemer's talk at Fulbright Midway Conference

Date: 9/11/2020

Content by: Cade Van Horn

Present: N/A

Goals: To take notes on our client's conference in India

Content:

- India is becoming known as the diabetic capital of the world because so many people lack access to healthcare
- Diabetic foot ulcers develop and progress beyond help before patients make it to a clinic
- Neuropathy develops in the feet of diabetics after 10-15 years after diabetes diagnosis, involves gradual loss of sensation in feet
- Neuropathy leads to ulcers which become infected and might require amputation
- 3/4 diabetics live in a low income country so affordable healthcare is important
- Nurses monitor loss of sensation in feet using a monofilament to gauge how far progressed loss of sensation is, they also prescribe good footwear or confirm access to good footwear. They also try to educate patients.
- When ulcers do form, they do their best to prevent infection by removing dead skin and offloading areas with proper footwear or confining patient to bed or a wheelchair
- pressure is the problem
- She developed a pressure sensor in a sandal and a circuit to bluetooth the readings to a phone app
- she hypothesized that a threshold of pressure could be found and identify high risk patients
- the problem was patients show up to the hospital when its too late
- the pressure sensing device was futile to help ulcers that are already developed
- she studied the works of Dr Paul Brand
- without the sense of pain, patients inflict very bad injuries on themselves, sometimes without knowing
- 2 kinds of pain receptors
    - High Threshold Mechano Receptors (HTMs)
        - response to high level of mechanical stress
        - healthy tissue
    - Poly-Modal Nocireceptors (PMNs)
        - respond to mechanical stresses
        - activated only in damaged tissue by chemical products inflammation
        - much lower threshold
- Home monitoring of temperature
    - standard education group (n = 58)
    - temperature measurement group (n = 59)
        - told to contact a nurse if there was a temp dif of over 4 degrees)
    - The temperature measurement group had a much smaller percentage of ulceration by the end of the study compared to the standard education group
- Studying pressure and temperature readings
- They got a portable thermal camera
- they want a take-home solution for patients
- maybe a low-cost thermal probe or something else

Conclusions/action items:

The client is working on a project to develop an easy low-cost way to measure temperature in patients feet so that preventative measures can be taken.

9/17/2020 - Thermochromic Materials Research

CADE VAN HORN - Sep 18, 2020, 10:03 AM CDT

Title: Thermochromic Materials Research

Date: 9/17/2020

Content by: Cade Van Horn

Present: N/A

Goals: To gain a better understanding of thermochromic materials and how we can use them in our project.

Content:

[1]C. Woodford, "Thermochromic color-changing materials", explainthatstuff.com, 2020. [Online]. Available: https://www.explainthatstuff.com/thermochromic-materials.html. [Accessed: 18- Sep- 2020].

https://www.explainthatstuff.com/thermochromic-materials.html

- Thermochromic material changes color with temperature changes
- when heated, metals change color due to incandescence, where heat energy is converted to light energy
    - atoms become excited and unstable, and their electrons absorb energy then release it as light particles (photons)
- Thermochromic materials change color at lower temperatures than metals, and not because of incandescence
    - some use liquid crystals
    - others use organic dyes called leucodyes

Thermochromic Liquid Crystals:

Liqiuid crystals, in nematic and smectic phases, have molecules arranged in layers roughly all facing the same way. Shining light on nematic liquid crystals causes irridescence.

- incoming light waves reflect off nearby crystals and add together by a process called interference, which produces the reflection
- The color of the reflected light depends (in a very precise way) on how closely the crystals are together
- Heat up or cool down your liquid crystals and you'll change the spacing between them, or push them into a different phase, altering the amount of interference and changing the color of the reflected light
- the liquid crystals look a different color depending on what temperature they are because changes in temperature make them move closer together or further apart (depending on the material)
- the molecules in liquid crystals can form themselves into a number of different phases, and because they're not pointing randomly in all directions, they're generally anisotropic (they do different things to light when it hits them from different directions)
- In some thermochromic devices, the crystals start off, at low temperatures, in what's called the smectic phase, which means the molecules are organized in layers that slide easily past one another. In this form, they happen to be completely transparent (they reflect little or no light, allowing virtually all light to pass through them)
    - At higher temperatures, they shift to a different phase (known as chiral/cholesteric), and start to show shifting colors (sometimes called "color play") as they get hotter
    - At a certain higher temperature, known as the clearing point, the molecules stop behaving like liquid crystals altogether and shift to an entirely different form, known as an isotropic state, which means they have the same optical properties in every direction. In this form, they're transparent once again
- Thermochromic liquid crystals (TLCs, as they're known) give a relatively accurate measurement of temperature within certain bands, so they're widely used in such things as strip thermometers
- Typically they're manufactured in the form of microscopic spheres (capsules) embedded in a plastic (polymer).

Leucodyes: special temperature-sensitive dyes (or inks) called leucodyes, which start off transparent (or have a particular color) and become visible (or change to a different color) as the temperature rises or falls

- Leucodyes are organic (carbon-based) chemicals that change color when heat energy makes their molecules shift back and forth between two subtly differently structures—known as the leuco (colorless) and non-leuco (colored) forms
- The leuco and non-leuco forms absorb and reflect light differently, so appear very different colors when printed on a material such as paper or cotton
- Unlike TLCs, which shift color up and down the red-violet spectrum as they get hotter or colder, leucodyes can be mixed in various ways to produce all kinds of color-changing effects at a wide range of everyday temperatures
- Leucodyes are much cruder indicators of temperature than TLCs, generally just indicating "cold" versus "hot" with one simple color change
    - because all can they do is switch back and forth between their two different forms (leuco and non-leuco)
- Like TLCs, leucodyes can be printed on the surface of other materials in the form of microscopic capsules, but they can be produced more easily with traditional printing methods such as screenprinting
- That's why leucodyes are more widely used in mass-produced, everyday, novelty items than TLCs, which tend to require special printing equipment

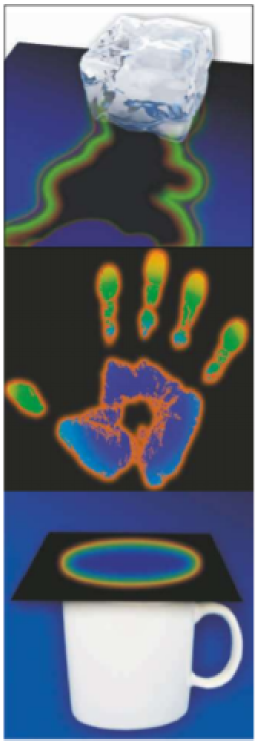
ThermoSmart - Thermocolor sheets

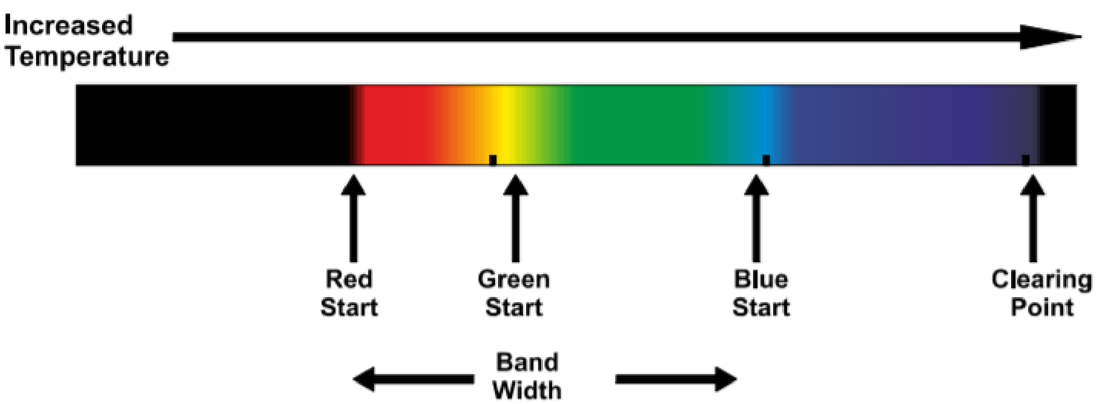
https://www.lcrhallcrest.com/liquid-crystal-thermal-mapping/#toggle-id-1

20-25°C

25-30°C
(Hand Touch)

30-35°C





Part No.	°C	Size	Backing
SH1LCRR20C05WA05	20°C TO 25°C	150MM X 300MM	Adhesive
SH1LCRR25C05WA06	25°C TO 30°C	150MM X 300MM	Adhesive
SH1LCRR30C05WA03	30°C TO 35°C	150MM X 300MM	Adhesive
SH1LCRR35C05WA03	35°C TO 40°C	150MM X 300MM	Adhesive
SH1LCRR40C05WA02	40°C TO 45°C	150MM X 300MM	Adhesive
SH1LCRR29C04WA01	STRESS 29°C	450MM X 300MM	Adhesive

USAGE INSTRUCTIONS

1. Clean surface thoroughly to remove all dirt, grease, etc. Acetone, petroleum ether and similar organic solvents may be used. Ensure that the surface is completely dry before proceeding.
2. Remove protective backing from adhesive and place sheet lightly in position on surface. Press down firmly with fingers in centre of sheet and smooth outward, in each direction in turn, to ensure that no air bubbles are trapped between the sheet and the surface.
3. The sheet is now ready for use as a temperature indicating film.

REMOVAL

After use, the sheet may be removed from the surface by pulling it off, although it may be destroyed in the process. Residual adhesive can be removed by washing with a suitable solvent. The choice of solvent will depend on the nature of the surface to which the sheet was attached.

STORAGE

Unused sheets should be stored out of direct sunlight at room temperature (20-25°C), in a solvent-free environment. Sheets in position on test surfaces should also be protected from UV light and organic solvents wherever possible. The colour play properties of the sheets should be checked at regular intervals. If stored correctly, the sheets should have shelf lives of up to a year or more.

LIFETIMES

TLC coated sheets should retain their colour play characteristics for many months under normal handling conditions. Continued submersion and temperature cycling in hot (40ºC+) water baths will accelerate degradation, as will continued temperature cycling at elevated temperatures in general, and exposure to UV light.

No pricing available

Conclusions/action items:

It seems like the liquid crystal thermochromic material would be more accurate and better suited for our intentions than the leucodye material.

10/01/2020 - Diabetes background research

CADE VAN HORN - Oct 06, 2020, 5:06 PM CDT

Title: Research on Diabetes and Hyperglycemia

Date: 10/01/2020

Content by: Cade Van Horn

Present: N/A

Goals: To understand the mechanisms of diabetes and how it leads to high blood pressure.

Content:

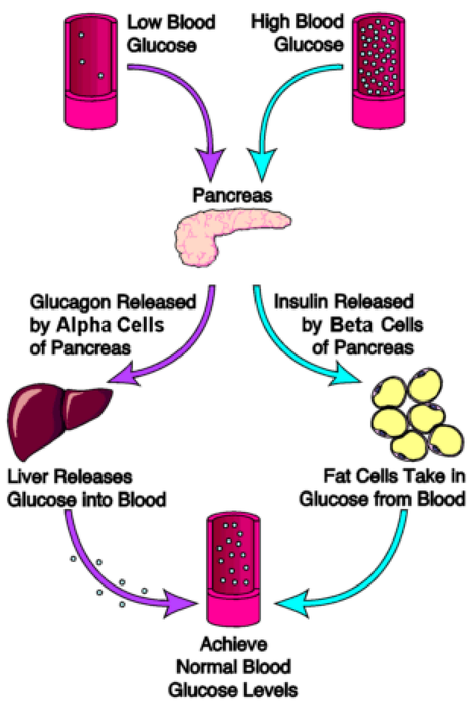
[1]Mayo Clinic, "Type 2 diabetes - Symptoms and causes", *Mayo Foundation for Medical Education and Research (MFMER)*, 2020. [Online]. Available: https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193. [Accessed: 01- Oct- 2020].

- Type 2 diabetes is a chronic condition that affects the way your body metabolizes sugar
- The body either resists the effects of insulin — a hormone that regulates the movement of sugar into your cells — or doesn't produce enough insulin to maintain normal glucose levels
- Develops when the body becomes resistant to insulin or when the pancreas is unable to produce enough insulin

[2]American Diabetes Association, "Blood Sugar and Insulin at Work | ADA", *Diabetes.org*, 2020. [Online]. Available: https://www.diabetes.org/diabetes-risk/prevention/high-blood-sugar. [Accessed: 01- Oct- 2020].

- body breaks food down into sugar and sends it into the blood
- Insulin then helps move the sugar from the blood into your cells
- insulin resistance - body does not use insulin properly
- over time your pancreas can't make enough insulin to keep your blood sugar at normal levels

[3]J. Norman, "Normal Regulation of Blood Glucose", EndocrineWeb, 2020. [Online]. Available: https://www.endocrineweb.com/conditions/diabetes/normal-regulation-blood-glucose. [Accessed: 01- Oct- 2020].

- 

- the stimulus for insulin secretion is a high blood glucose
- insulin has an effect on a number of cells, including muscle, red blood cells, and fat cells
- in response to insulin, these cells absorb glucose out of the blood, having the net effect of lowering the high blood glucose levels into the normal range

Conclusions/action items:

This research helped understand how insulin helps regulate blood sugar levels, and since diabetes affects insulin production, diabetic patients often have high blood sugar.

10/01/2020 - Siren Socks - Diabetic temperature sensing socks

CADE VAN HORN - Oct 07, 2020, 9:50 AM CDT

Title: Siren diabetic temperature sensing socks

Date: 10/01/2020

Content by: Cade Van Horn

Present: N/A

Goals: To gain a better understanding of some competing products

Content:

https://siren.care/

- Siren's Socks and Foot Monitoring System continuously track foot temperature
- The NIH recommends that people with neuropathy check their feet daily for signs of injury that can lead to foot ulcers, infection, and more
- Temperature monitoring, in contrast to visual checks alone, has been shown to improve outcomes related to ulcers by 87%
- six key points on the foot
- includes a mobile app to monitor temperature

Conclusions/action items:

This is a great product for people that wear socks but it probably wouldnt work in India where a lot of people don't wear socks.

9/24/2020 - Design 1 - Thermochromic sheet insulated with styrofoam

CADE VAN HORN - Oct 07, 2020, 9:53 AM CDT

Title: Design idea 1 - thermochromic sheet

Date: 9/24/2020

Content by: Cade Van Horn

Present: N/A

Goals: To think of several design ideas

Content:

Design Idea 1:
Thermochromic liquid crystal sheet - patient steps on the sheet and takes a picture with their smartphone, then uploads it to the app where the algorithm (built via machine learning) will output whether or not a patient is at risk.
Pros:
Reusable, a patient could test their feet daily or weekly with this method
When buying in bulk, the sheets are very cheap and affordable, so one patient could definitely afford one
Cons:
Insulating so that the image stays long enough to take a picture
Temperature range/sensitivity range - 5 degree temperature range is not sensitive enough

Conclusions/action items:

9/24/2020 - Design 2 - thermochromic powder mixture

CADE VAN HORN - Oct 07, 2020, 9:55 AM CDT

Title: Design idea 2 - mixture of thermochromic powders

Date: 9/24/2020

Content by: Cade Van Horn

Present: N/A

Goals: To think of more design ideas

Content:

Design Idea 2:
Thermochromic liquid crystal changing powder - different powders change color at different temperatures, so if the powders are mixed together, it will change to different colors at different temperatures. If the right powders are mixed and then layered on a surface and secured with a top coat, the patient could step on the surface, take a picture with their smartphone, and upload it to the app so the algorithm can interpret the data.

Pros:
With the right combination of temperature sensitive powders, the surface could more accurately display a range of temperatures that would fit the temperatures observed in diabetic feet
Cons:
Securing the powders to a surface in a way that lets the color changing effect stay could be difficult

Conclusions/action items:

this design might be more accurate than the first design since there would be a mix of temperature ranges.

9/24/2020 - Design 3 - thermal camera phone attachment

CADE VAN HORN - Oct 07, 2020, 9:57 AM CDT

Title: Design idea 3 - IR thermal camera smartphone attachment

Date: 9/24/2020

Content by: Cade Van Horn

Present: N/A

Goals: to come up with more design ideas to present to the group

Content:

Design Idea 3:
Thermal Camera smartphone attachment - purchase an IR sensing circuit component and build the necessary circuit and contraption to connect the IR sensor up to a smartphone so that a smartphone could take IR thermal images.
Pros:
Potentially more accurate than various thermochromic materials
Cons:
Expensive
May be difficult to get a still image of the patient's foot

Conclusions/action items:

This design idea would be much harder to actually make but it would be more accurate.

10/7/2020 - Great Permit Documentation

CADE VAN HORN - Oct 07, 2020, 9:59 AM CDT

Title: Green Permit Training Documentation

Date: 10/07/2020

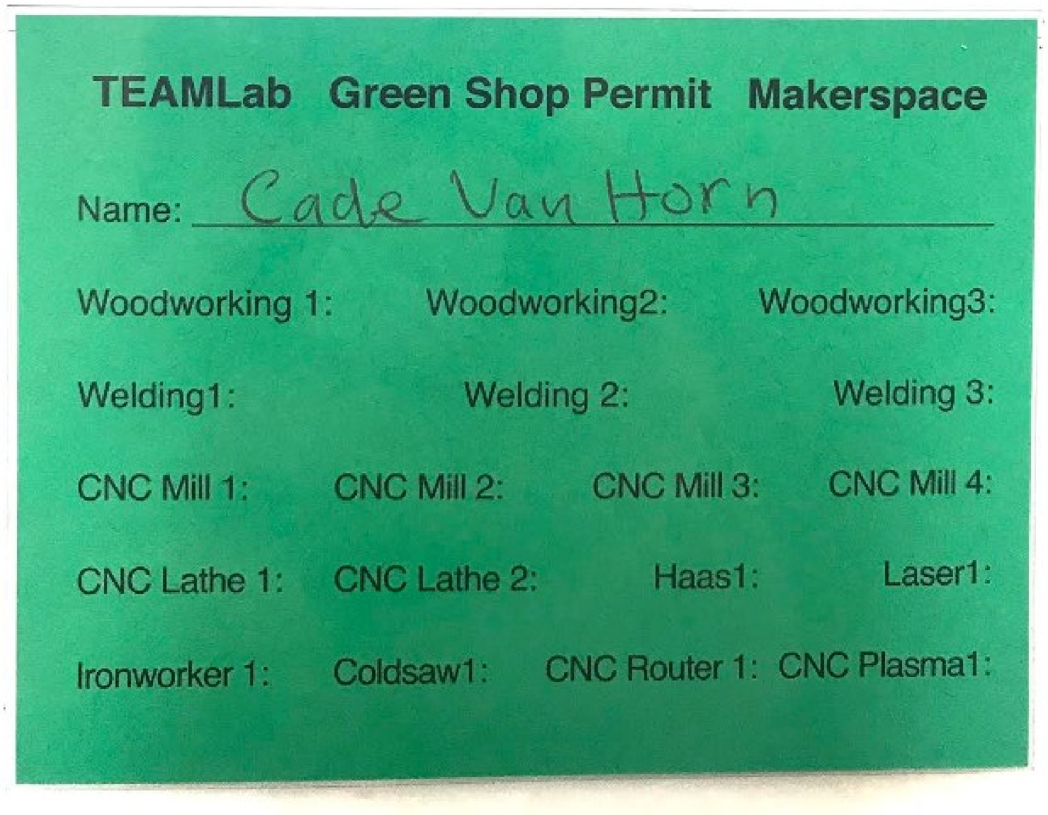
Content by: Cade Van Horn

Present: N/A

Goals: The goal of this page is to document my green permit.

Content:

I took all of the quizzes and training last year and received my green permit on 11/25/2019.



Conclusions/action items: I received my green pass and now I can work in the team lab.

10/07/2020 - Biosafety training documentation

CADE VAN HORN - Oct 07, 2020, 10:00 AM CDT

Title: Biosafety Training Documentation

Date: 10/07/2020

Content by: Cade Van Horn

Present: N/A

Goals: To document my completed Biosafety training

Content:

University of Wisconsin-Madison

This certifies that CADE VAN HORN has completed training for the following course(s):

Course Name	Curriculum or Quiz Name	Completion Date	Expiration Date
BIOSAFETY REQUIRED TRAINING	BIOSAFETY REQUIRED TRAINING QUIZ	4/12/2020	

Data Effective: Sun Apr 12 23:41:39 2020
Report Generated: Tue Apr 21 11:36:31 2020

Conclusions/action items: None

9/9/2020 - Research by Previous Teams

MATTHEW VOIGT - Oct 06, 2020, 5:19 PM CDT

Title: Research by Previous Teams

Date: 9/9/2020

Content by: Matt Voigt

Present: Matt Voigt

Goals: To gain an understanding of what the previous BME team working on this project accomplished before our first client meeting

Content:

The previous team developed a home monitoring system consisting of a box equipped with a thermal camera. An individual performing home monitoring would simply have to place their feet in the box and press a button to capture a temperature profile of their feet. They faced multiple obstacles, the worst of which appeared to be that the thermal camera they chose malfunctioned and stopped outputting data through the SDA pin. It also appears they spent very little time developing software to analyze the thermal images for ulcer risk.

Conclusions/action items:

Based on the project description and the proposed future directions of the team working on this project last year, machine learning software will be a large focus of the project this semester. Also, considering the last team was not able to complete testing on their thermal imaging prototype, we will likely be asked to develop a thermal imaging prototype of our own. After the client meeting on Friday I expect we will have a much better understanding of what the client would like us to improve upon or develop from scratch.

9/20/2020 - Machine Learning Research

MATTHEW VOIGT - Oct 06, 2020, 6:11 PM CDT

Title: Machine Learning Research

Date: 9/20/2020

Content by: Matt Voigt

Present: Matt Voigt

Goals: To record what I learn from LinkedIn learning course suggested by Kayla along with any other relevant notes I find concerning machine learning.

Content:

- perceptron - a decision function that can accept binary inputs and outputs
  - weights multiplied by criteria fed into perceptron, but output isn't binary then
- sigmoid neurons - scale numbers to be in a range from 0-1
  - use activation levels between 0 and 1 instead of binary inputs of 0 OR 1 and multiply by weights still.
  - use sigmoid function to scale result to value between 0 and 1
- Bias - spend a lot of time fine tuning
  - add value before output is scaled by sigmoid function
- Neural network has input layer, several hidden layers, and an output layer
  - hidden layers are for processing the input
- Images are broken into pixels, each one having a number associated with it
  - neurons in hidden layers have levels of activation
  - each neuron in a layer connects to each neuron in the next and previous layer
- different neurons have different weights between each other, so they are fine tuned to recognize certain parts of an image (like faces)
  - sigmoid activation function squeezes the activation levels of neurons down to scale
- neurons given a bias before being squeezed down by reLU
- A network is initialized by assigning random numbers to activation levels and biases between neurons
  - training set is used to perform supervised machine learning
  - cost function used to let network know how well it's classifying data (low = good)
  - gradient descent strategy is used to find lowest cost function
  - cost function only tells if network is performing well
- back propagation - how network tweaks weights to decrease the cost function
  - starts with neurons with greatest weights and slightly tweaks them and sees how cost function changes
  - prioritizes making correct answers more correct, then making wrong answers less wrong
- stochastic gradient descent
  - break images into smaller categories, optimize network for one batch then move to next
  - more efficient, but gives up some accuracy for one right answer to increase accuracy over all data
- Chain rule
  - change activation of neuron at beginning has large effect on output
- Supervised machine learning = classifying data
  - data is labeled previously to giving to network
  - classify into predefined categories
- Unsupervised ML = cluster data
  - group data that doesn't have labels, let's network break data into it's own groups/categories
  - easier to find unlabeled data too
  - human checks for value in customers
- Challenges
  - need lots of data - networks aren't great at learning at first
    - capsule networks being developed to improve learning efficiency
  - need to know how to use data
    - need to carefully choose training data to be similar to test data
  - need to collect insights
    - need to continuously improve the networks

Conclusions/action items:

I ought to spend some time looking into the program Kayla is currently using to create and train the AI for this project. Although this course provided a decent background of machine learning, I'd like to learn more specifics about what type of learning she is planning to implement and how we could sort and label the training data or add biases based on external factors inputted by the user such as age and weight.

9/23/2020 - Thermochromic Materials Research

MATTHEW VOIGT - Oct 06, 2020, 6:49 PM CDT

Title: Thermochromic Materials Research

Date: 9/23/2020

Content by: Matt Voigt

Present: Matt Voigt

Goals: To learn how thermochromic materials work, where they can be purchased, and how they can be used to accurately represent temperature profiles of feet.

Content:

http://materiability.com/portfolio/thermochromics/

- Can be one time use or reusable
- Liquid Crystals
    - material structure changes based on temperature
    - viewing from different angles changes perceived color
    - provided as microencapsulated slurry which is mixed with other items to achieve desired surface effects
    - Phase from red-yellow-green-blue with increasing temp.
- Leuco systems
    - change from colored to colorless
    - versatile
    - can be applied in various ways
- Single color liquid crystal systems
    - show one color above or below a temperature
    - can be developed to be very precise within a range of temperatures
- Scattering liquid crystal systems
    - under development, change from white to a color or vice versa
- Irreversible systems
    - used to signal if critical temp has been reaches
- All thermochromics sensitive to UV light and other elements

https://www.researchgate.net/publication/223049188_Accurate_heat_transfer_measurements_using_thermochromic_liquid_crystal_Part_1_Calibration_and_characteristics_of_crystals

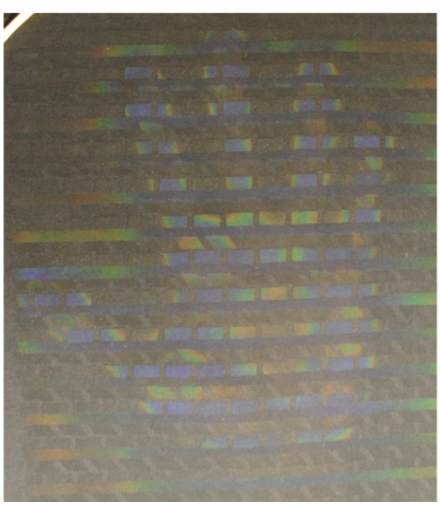
- Encapsulated thermochromic liquid crystal (TLC)
    - Narrow-band - color change over about 1C with 0.1C uncertainty
    - Wide-band - color change over 5-20C, good for mapping surface temp distributions

https://www.materialsampleshop.com/products/thermochromic-sheet

- Small (15cmx35cm) TLC Sheets can be obtained from this website for 15 Euros or $17.60 per sheet
    - each sheet has approximately 5C effective temp range
    - options from 20-25 up to 35-40C

https://etd.ohiolink.edu/!etd.send_file?accession=kent1478957374245124&disposition=inline

- Dissertation by a Kent State University student
- layered three different nematic LC sprayable coatings from LCR Hallcrest LLC onto a black fabric in different patterns
    - solid, horizontal bars
    - rhomboids
    - rectangles
- The combination of coatings was chosen because they have contiguous effective temperature ranges
- The final product had a total temperature range of 24-35C



- image of final product being used to show temperature of a hand

https://www.hallcrest.com/DesktopModules/Bring2mind/DMX/Download.aspx?EntryId=159&Command=Core_Download&language=en-US&PortalId=0&TabId=163

- List of TLC products for research and testing applications that can be obtained from LCR Hallcrest
  - Products listed involve microencapsulated TLC slurries, sprayable TLC coatings, and TLC coated polyester sheets.
  - prices not available
  - provides applications and specifications for available products

Conclusions/action items:

It appears multiple sprayable TLC materials should be obtained to achieve a larger temperature range. I am not sure if these materials can be layered on top of each other and still be effective. The AI being developed by Kayla may have a difficult time recognizing common patterns for people at a high risk of developing an ulcer in the model developed by the Kent State student due to the non-continuous color play. I would also like to find the cost of the materials that can be obtained through LCR Hallcrest to determine the most efficient and cost effective way to develop an accurate TLC sheet.

9/25/2020 - TLC Powder Combination Design

MATTHEW VOIGT - Oct 06, 2020, 7:19 PM CDT

Title: TLC Powder Combination Design

Date: 10/6/2020

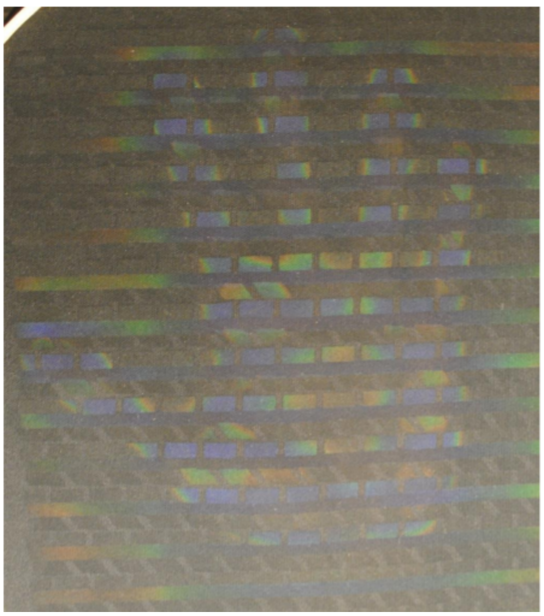
Content by: Matt Voigt

Present: Matt Voigt

Goals: To describe a preliminary design idea involving TLC powders

Content:

From previous research on TLC materials, I believe a combination of TLC materials should be combined and layered in some way on a plastic sheet. At least two different TLC materials should be used together to give a useful effective temperature range. A top coat will likely be required for this design to be competitive in terms of durability, so more research will be required to determine the exact effects this may have on the total cost of development. These materials tend to have bandwidths of 5C and minimal error. These materials are also accurate within about 1C and have been proven to be consistent with data gathered by thermal cameras in this sort of application.



^An example of this type of design from previous research

How the TLC materials are layered will need to be carefully considered in order to be sure they can be effectively analyzed by the AI software that has been developed by Kayla

Conclusions/action items:

Although there is much more work to be done before this idea can be finalized and built, I believe this is a step in the right direction. It should be lower in cost in comparison to what was designed by last years team and just as accurate at representing the temperature profile of the sole of a foot.

10/6/2020 - Human Subjects Training Certification

MATTHEW VOIGT - Oct 06, 2020, 3:42 PM CDT

Title: Human Subjects Training Certification

Date: 10/6/2020

Content by: Matt Voigt

Present: Matt Voigt

Goals: To provide proof of completion of the human subjects training course Kayla asked us to do.

Content:

University of Wisconsin-Madison

This certifies that MATTHEW VOIGT has completed training for the following course(s):

Course Name	Curriculum or Quiz Name	Completion Date	Expiration Date
BIOSAFETY REQUIRED TRAINING	BIOSAFETY REQUIRED TRAINING QUIZ	4/12/2020	
UW BIOMEDICAL COURSE	BASIC/REFRESHER COURSE - HUMAN SUBJECTS RESEARCH	9/9/2020	9/9/2023

Data Effective: Wed Sep 9 18:57:49 2020
Report Generated: Tue Oct 6 15:29:04 2020

Conclusions/action items:

I am now prepared to continue working on the project if the IRB Kayla has been planning for this fall moves forward.

9/18/2020 Temp Monitoring/Ulcer Prevention

ANVESHA MUKHERJEE - Sep 18, 2020, 3:32 AM CDT

Title: Temperature Monitoring and Ulceration Prevention

Date: 9/18/2020

Content by: Anvesha Mukherjee

Present: N/A

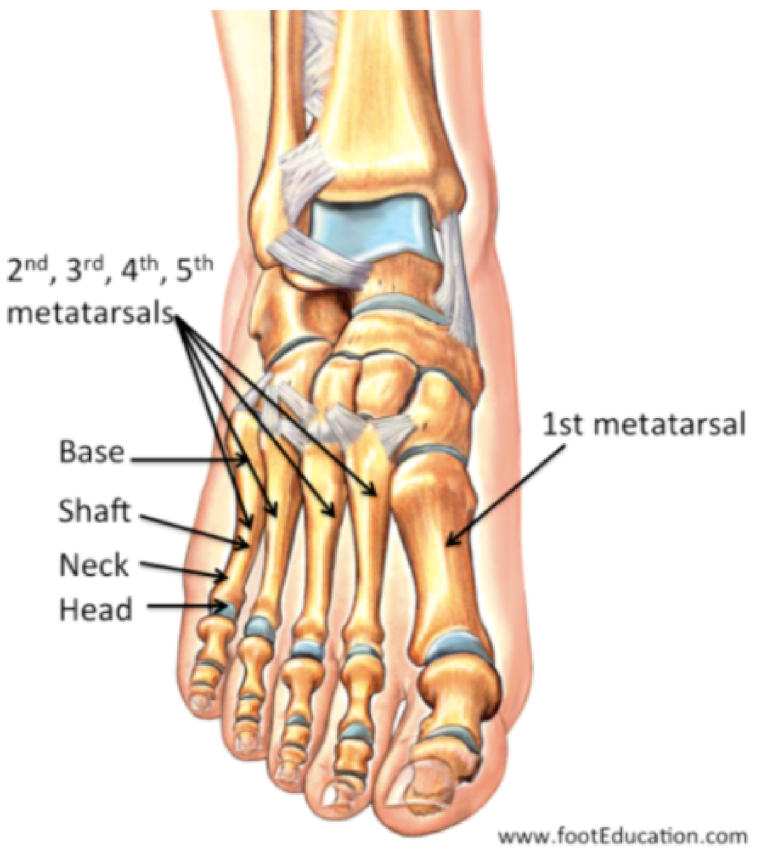
Goals: A synopsis of answers to inquiries about preventative methods for diabetic foot ulceration and home monitoring of foot skin temperatures.

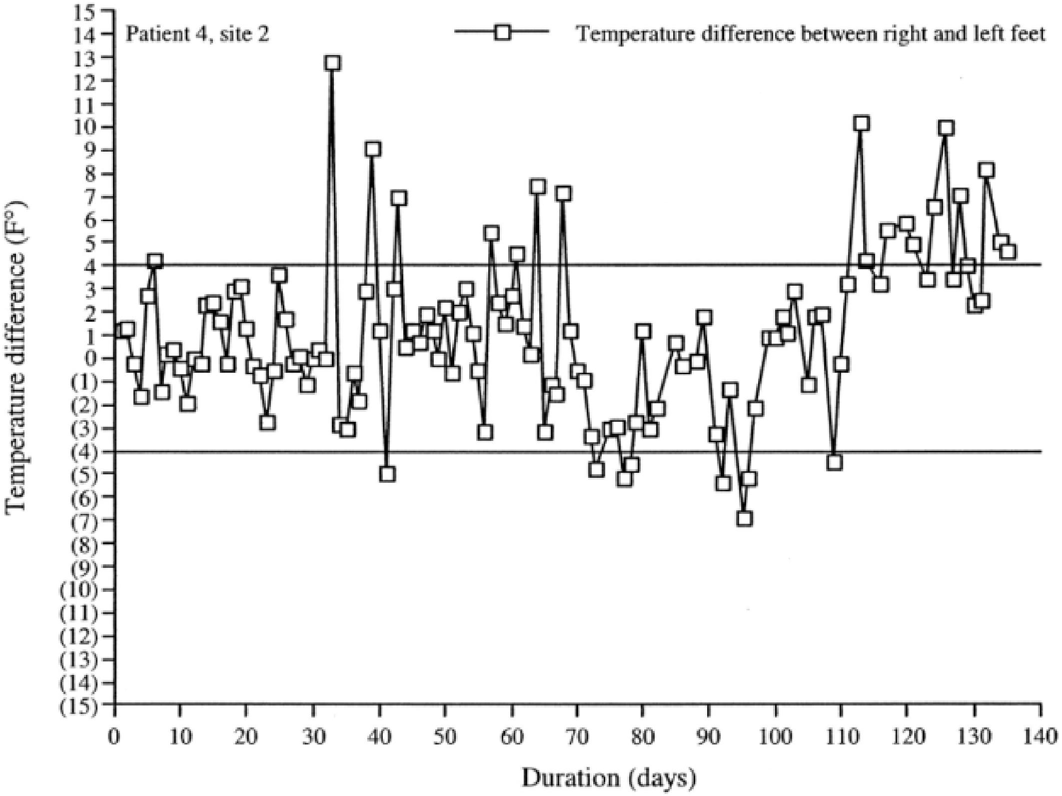
Content:

[1] Lavery, Lawrence A., et al. "Home Monitoring of Foot Skin Temperatures to Prevent Ulceration." Diabetes Care, American Diabetes Association, 1 Nov. 2004, care.diabetesjournals.org/content/27/11/2642.

For a diabetic foot study of 85 patients:

- Neurologic assessment was completed using the Xilas VPT meter (Xilas Medical, San Antonio, TX).
- VPT = vibratory perception threshold
- The presence of sensory neuropathy was defined as VPT >25 V.
- if a temperature difference between the right and left foot >4°F (4.0°F ~ 2.2°C) between the left and right corresponding sites, advice to drastically reduce number of steps taken until the temperature differences fell <4°.
- The clinical outcomes that were evaluated were incident foot ulcers, infections, Charcot fractures* (condition causing weakening of the bones in the foot that can occur in people who have significant nerve damage (neuropathy)), and amputations.
- In this study, temperatures are generally taken under the first, third, and fifth metatarsal of the foot, shown in the diagram below:





2 of 2

This graph shows the difference in temperature of patient 4's left and right feet as daily temperature measurements were taken over a span of 140 days under their first metatarsal.

The highest temperature difference recorded was marked as 13 degrees Fahrenheit between the right and left foot of patients whose temperatures were taken at home using a home monitoring technique (a skin temperature sensor).The graph shows daily temperature measurements taken under the first metatarsal head of a study patient who developed a wound at this site.

Conclusions/action items:

Ulcers often lead to amputation of the lower extremities, preventative methods include avoiding walking on already inflamed tissue, home monitoring of foot skin temperature, and drastically reducing number of steps until temperature differences falls below 4 degrees Fahrenheit.

9/18/2020 Prof. Paul W. Brand Video and Kayla Heumer Talk Notes

ANVESHA MUKHERJEE - Sep 18, 2020, 3:20 AM CDT

Title: Prof. Paul W. Brand Video and Kayla Huemer Talk notes

Date: 9/18/2020

Content by: Anvesha Mukherjee

Present: N/A

Goals: Concise notes on introductory videos by Professor Paul Brand and client Kayla Huemer.

Content:

First video - Dr. Paul Brand: https://www.youtube.com/watch?v=30piDE5iIVw
Second video - Kayla Huemer conference: https://www.youtube.com/watch?v=C-EA2DJcuhc&list=PLD95pGtO4j5zz7ERyHLHamfiq-2eQcNJ_&index=17

Important facts:

- High Threshold Mechano-Receptors (HTMs) - respond to high levels of mechanical stress that impacts unaffected/healthy tissue
  - healthy tissue, requires repetitive high level mechanical stress
  - A-Delta nerve fibers
- Poly-Modal Nociceptors (PMNs)- response with severe pain even if low force applied - aka when patient has an already damaged foot, PMNs respond to much less force due to chemical releases from inflamed sites
  - extreme pain from minimal stimulation/tenderness
  - think of walking for a while even though there is no direct high stress impact
-

Conclusions/action items:

10/8/2020 Home Monitoring of Foot Skin Temperatures

ANVESHA MUKHERJEE - Dec 09, 2020, 12:20 AM CST

Title: Home Monitoring of Foot Skin Temperatures to Prevent Ulceration

Date: 10/8/2020

Content by: Anvesha Mukherjee

Present: N/A

Goals: Study results of this pilot study to prove why home monitoring of foot skin may prove as an effective preventative solution for diabetic foot patients.

Content:

[1] Lavery, Lawrence A., et al. "Home Monitoring of Foot Skin Temperatures to Prevent Ulceration." Diabetes Care, American Diabetes Association, 1 Nov. 2004, care.diabetesjournals.org/content/27/11/2642.

Pilot study conclusions section notes:

"She had several episodes of temperatures above the 4°F range. She failed to call the study nurse as instructed when her temperatures spiked throughout the study. On day 138, she was seen in clinic, and a superficial wound under the first metatarsal head was identified. The patient failed to contact the health care provider upon recording a series of >4°F temperature differences on 21 consecutive days just before ulceration. This patient was the only subject in the enhanced therapy group who developed a wound."

"Even among educated, well-informed, and highly motivated patients, there is a high rate of recidivism of diabetic foot complications. These patients almost uniformly have severe sensory loss. Often they are obese, have limited mobility of the hip and knee, or are visually impaired. These factors make self-inspection and identification of early signs of foot disease difficult. For instance, in an earlier study (3), we identified that 15% of diabetic patients with foot ulceration were legally blind, and 54% of these patients did not have adequate visually acuity and the ability to position their extremity to view the foot for self-care. In addition, visual cues probably occur late in the disease process. They are often subtle, and because pain is usually our primary trigger to provide self-care or seek professional care, a patient's ability to take action to avoid neuropathic foot ulceration is poor. As part of patient education, both treatment groups were instructed to inspect their feet on a daily basis. Most likely by the time there were visual signs of a foot problem, implementing prevention was too late. The simple home monitoring device used in this study allowed high-risk patients a self-assessment tool they could easily use and from which to obtain actionable information."

Notes:

- Failure to alert a medical professional in the days following an increase greater than 4 degrees Fahrenheit caused one patient in the enhanced group therapy to develop foot complications

-The results of this pilot study suggest that home monitoring with daily foot temperatures could be an effective adjunctive modality to prevent foot complications.

-Indicates that maybe the user based app that the heat foot map image is uploaded to needs a warning functionality to alert the patient when to see a doctor or nurse

-Using at home monitoring device aided high risk patients in self assessing their risk for ulceration and helped them attain actionable information about their status

Draft for intro/background section:

Several diabetic patients will begin to suffer severe pain despite the absence of any high stress impact after traversing long distances on rough ground. Travelling long distances, a consequence of restrained access to proper footwear amplified by improper modes of transportation, is endured most heavily by rural or marginalized stratas in India who are often geographically dislocated because of economic, environmental, or migrational push or pull factors. Severe pain while walking is due to two distinct types of receptors, specifically nerve endings found in the skin, that are involved in the heightened pain that diabetic patients are subjected to throughout the course of the disease. The receptors found in healthy tissue that respond to relatively high levels of mechanical stress are referred to as High Threshold Mechano-Receptors (HTMs), or receptors that respond to high pressure impinging upon otherwise undamaged skin.

Conversely, in the situation that the patient has already damaged the foot, Poly-Modal Nociceptors (PMNs) begin responding to relatively low pressure stimuli due to chemical products of inflammation.This means that the patient experiences extreme pain due to PMNs in response to very minimal stimulation. A diabetic with a high risk for ulceration begins to feel severe pain despite the absence of high stress impacts, activating the response from PMNs caused by the pain from constant low stress. Tenderness from a consistent hard beating results in much greater pain from a much lower threshold of pressure, and after a certain duration of normal tissue responses to HTMs that report injury, inflammation induces the response of PMNs.

Conclusions/action items:

A modality such as cost-effective home thermometry provides an option to diabetic patients for early monitoring of signs of ulceration, and serves as an preventative warning system for the development of diabetic foot wounds. In a pilot study published by the American Diabetes association, it was found that patients who actively practiced at home temperature monitoring of their feet had a very low rate of foot complications in comparison to the standard therapy group. Signifying the efficacy of at home temperature monitoring, the enhanced therapy group using at home temperature monitoring had shown significantly better clinical outcomes in comparison to the standard group not practicing at home temperature monitoring. Furthermore, patients representing the standard therapy group were found to be 10.3 times more at risk for foot complications than their enhanced therapy group counterparts, indicating an urgency for the development of an affordable at home temperature monitoring device. The aforementioned results of the pilot study create an imperative to provide diabetic foot patients with a modality that may prove effective in preventing both ulceration and the adverse risk for amputation. By interleaving affordability and convenience, home monitoring of foot skin temperature serves as a potential preventative solution to diabetic foot complications and facilitates the early detection of ulceration.

10/09/2020 - Siren Socks

ANVESHA MUKHERJEE - Dec 09, 2020, 12:28 AM CST

Title: Siren diabetic temperature sensing socks

Date: 10/09/2020

Content by: Anvesha Mukherjee

Present: N/A

Goals: To familiarize with any competing designs for at home temperature monitoring devices

Content:

https://siren.care/

- Siren's Socks and Foot Monitoring System continuously track foot temperature, sending information to your doctor to help them track issues related to inflammation.

-Temperature monitoring, in contrast to visual checks alone, has been shown to improve outcomes related to ulcers by 87%2.

- A user claims that "The app let me see a rise in temperature that I couldn't feel due to my neuropathy. Siren Socks helped me get to the doctor early."

indicating that neuropathy makes it more difficult to self assess risk for ulceration

- Continuously updates the wearers medical professional to update them regularly on temperatures differences, creating little to no effort on the user's part

- Also includes a user based software/app to track temperatures

Conclusions/action items:

Ranging more on the unaffordable side for non shoe wearers in India, the siren socks may not be the best solution for all patients of all social stratas, but is efficient for sock wearers.

9/10/2020 - Basic Diabetes Research

EMMA KUPITZ - Sep 10, 2020, 5:45 PM CDT

Title: Basic Diabetes Research

Date: 9/10/20

Content by: Emma Kupitz

Present: N/A

Goals: Find information about diabetes to further understand the problem

Content:

Diabetes is where blood glucose is too high. This is caused when the body doesn't make insulin (Type 1) or the body doesn't make enough or efficiently use insulin (Type 2). High blood sugar can cause damage to the eyes, kidneys, and nerves.

https://medlineplus.gov/diabetes.html#cat_93

"More than 80 percent of amputations begin with foot ulcers." Amputation occurs when there is a "severe loss of tissue" or there is a life-threatening infection from an ulcer. Signs that may lead to amputation include swelling, redness, warmth in one area, and discolored skin.

https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/amputation-and-diabetes/art-20048262#:~:text=Good%20diabetes%20management%20and%20regular,ulcers)%20that%20can%20worsen%20quickly.

When there is high blood sugar, nerves can be damaged and can't send messages to the rest of the body. These damaged nerves cause uncomfortable feelings in arms in legs called peripheral neuropathy. When the nerves are damaged, muscles can start to lose their shape as well. The muscles then can't hold the bones together causing them to become deformed. The damaged nerves also mean that people can't feel if something is wrong with their feet.

https://wa.kaiserpermanente.org/healthAndWellness/index.jhtml?item=%2Fcommon%2FhealthAndWellness%2Fconditions%2Fdiabetes%2FnerveDamage.html

PAD is when "fatty deposits build up in the inner linings of the artery walls of the legs" which causes less or no blood flow. If the case becomes severe enough, amputation is used. People with diabetes have a high risk of PAD.

https://www.heart.org/en/health-topics/diabetes/why-diabetes-matters/peripheral-artery-disease--diabetes

Conclusions/action items: Research current devices that are used to prevent diabetic amputation and how they work

9/18/2020 - Kayla Huemer

EMMA KUPITZ - Oct 06, 2020, 9:38 PM CDT

Title: Kayla Huemer Videos

Date: 9/18/2020

Content by: Emma Kupitz

Present: N/A

Goals: To learn more about the problem with videos the client recommended

Content:

- India is becoming the diabetic capital of the world
- This is due to the large population and lack of access to healthcare
- 50-90% of diabetic patients in rural communities are undiagnosed
- Ulcers will progress past the point where health professionals can help
- Neuropathy will develop 10-20 years after initial diagnosis
- Don’t feel when high-pressure points develop into a foot ulcer, which then gets infected which leads to amputation
- Nurses will measure the amount of neuropathy
- Nurses will also educate their patients and prescribe footwear to relieve pressure
- Ulcers will only heal with offload the areas and clear it of infection
- Build a shoe that monitored the pressure and Bluetooth them to a cellphone, this would not work
- Told to look into Dr. Paul Brand- lepers will also lose feeling
- Without pain, one doesn’t know when to stop hurting themselves
- 2 pain receptors
    - High Threshold Mechano-receptors: respond to a high level of stress and are in healthy tissue
    - Poly-Modal Nociceptors: only present in damaged tissue, much lower threshold,
- Diabetic patients will not shift their weight, the pressure will remain on the same part of the foot until the body can’t keep up with the damage
- 4-degree temperature change is a cause for concern
- A study found that at home temperature monitoring reduced the chance of ulceration

https://www.youtube.com/watch?v=C-EA2DJcuhc&list=PLD95pGtO4j5zz7ERyHLHamfiq-2eQcNJ_&index=17&ab_channel=KaylaHuemer

Conclusions/action items: Diabetic patients need an at-home device to measure the temperature of their feet in order to prevent ulcers.

9/18/2020 - Ulcer Prevention

EMMA KUPITZ - Oct 06, 2020, 9:57 PM CDT

Title: Ulcer Prevention using foot skin temperature monitoring

Date: 9/18/2020

Content by: Emma Kupitz

Present: N/A

Goals: Find out if skin temperature monitoring would be an effective way to prevent foot ulcers

Content:

The enhanced therapy group in this study was given a handheld infrared skin thermometer to measure temperatures on the sole of the foot. If they had elevated temperatures of >4 degrees Fahrenheit, they were considered at risk and reduced their activity or contact the nurse. The enhanced therapy group had fewer diabetic foot complications.

- Repetitive trauma at pressure points causes ulcerations\
- Prevention so far is padded insoles, protective shoes, eductation, and regular foot inspection
- Inflammation is one of the earliest signs of an ulcer
- Temperature can provide quantitative information and be preventative in ulcers
- Both groups received standard care for a diabetic foot
- Six predetermined sites were measured and recorded
- The neurologic assessment included vibratory perception threshold(VPT)
- Sensory neuropathy: VPT>25V
- The standard therapy group were 10.3 times more likely to develop a foot complication compared to the enhanced therapy group
- If there were visual signs of a problem, prevention was too late
- This should be studied further with cost-effective devices

https://care.diabetesjournals.org/content/27/11/2642

Conclusions/action items: Temperature monitoring may be a way diabetic patients can prevent foot ulcerations.

10/5/2020 - Diabetic Shoes

EMMA KUPITZ - Oct 06, 2020, 9:38 PM CDT

Title: Diabetic Shoes

Date: 10/5/2020

Content by: Emma Kupitz

Present: N/A

Goals: Research what diabetic shoes offer for diabetic patients

Content:

- Have a protective interior made of soft material
- The inside of the shoe in non-binding and stretchable to ease pressure points
- Provide arch support and conforms to the foot to reduce pressure
- There is extra room for the toes
- Ensures a loose fit to avoid extra pressure or possibly insoles
- Shoes are often wider than normal
- “Accommodates swelling and maintains proper blood circulation”
- Diabetic socks are also worn
    - Seamless, nonconstricting, and soft
    - Moisture-wicking system to keep feet cool and dry
- Insoles can provide protective cushioning and shock absorption

orthofeet.com/blogs/news/what-is-special-about-diabetic-shoes

Conclusions/action items: Diabetic shoes might be helpful for patients in the United States, compliance will be difficult in India

10/6/2020 - Siren Socks

EMMA KUPITZ - Oct 06, 2020, 5:36 PM CDT

Title: Siren Socks Research

Date: 10/5/2020

Content by: Emma Kupitz

Present: N/A

Goals: To research siren socks to understand how they work

Content:

https://siren.care/

- socks with sensors on the sole that continuously monitor the temperature
- data is stored on the app so patients can easily check the status of their foot
- patients get a notification when there is inflammation
- prevent ulcers from forming
- gets replaced every 6 months
- more effective and easier than visual checking

Conclusions/action items: Siren socks work well in the United States however will likely not worn in India.

10/6/2020 - Human Subjects Research Training

EMMA KUPITZ - Oct 06, 2020, 4:49 PM CDT

Title: Human Subjects Research Training Certification

Date: 10/6/2020

Content by: Emma Kupitz

Present: N/A

Goals: To verify that I completed the human subjects research training for our client

Content:

CITI PROGRAM

Completion Date 18-Sep-2020
Expiration Date 18-Sep-2023
Record ID 38369405

This is to certify that:

EMMA KUPITZ

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

Basic/Refresher Course - Human Subjects Research (Curriculum Group)
UW Biomedical Course (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

University of Wisconsin - Madison

CITI
Collaborative Institutional Training Initiative

Conclusions/action items: Now I am ready to research with humans if needed.

9/13 Diabetes Background

WILL NELSON - Oct 07, 2020, 11:19 AM CDT

Diabetes Epidemic in India

- India is facing a twin burden of under-nutrition and overnutrition: it figures prominently both in the hunger map of the world as well as being the diabetes capital of the world.1 A country experiencing rapid socioeconomic progress and urbanization, India carries the highest burden of diabetes with escalating prevalence in both urban and rural populations.
- India is facing an epidemic of diabetes, with high prevalence in urban areas. Over the past 30 years, the prevalence of diabetes has increased to 12-18% in urban India and 3-6% in rural India with significant regional variations.These rates in India are 50-80% higher than China (10%).
- Another 14% having prediabetes —a harbinger of future diabetes— is as high as diabetes in Indians.
- The difference in prevalence of diabetes across India could be due to dissimilar levels of urbanization and lifestyle factors such as different diets and varying obesity levels.
- Significant determinants of diabetes are age, body-mass index (BMI), waist-hip ratio, low physical activity, and family history of diabetes. The driving forces behind the epidemic are urbanization (30%) and economic development with resultant increase in GDP, sedentary lifestyle, western diet, and fast food diet on a background of genetic susceptibility.
- The prevalence of both diabetes and prediabetes increases by age with 60% of Indians having diabetes or prediabetes by age 60
- While some genes confer increased susceptibility to diabetes among Indians, other genes that are protective in Europeans do not appear to protect Indians. 10-12
- Indians develop diabetes at a younger age and those younger than 45 years account for 36% of all diabetics in India.13 Longer duration of diabetes leads to greater complications and this could threaten the national economy.
- Given that 80% of diabetics will die from cardiovascular disease (CVD), the medical and socioeconomic costs will be insurmountable unless urgent steps are taken to prevent or ameliorate the CVD complications which are higher among Indians than other populations
- CVD risk is primarily due to elevated lipids and blood pressure (much more than elevated blood sugar). Unfortunately, management of blood pressure and cholesterol remains dismally poor among diabetics in India
- The latest data (2012) shows a prevalence of diabetes in excess of 25% in most states
- The major challenge is to translate current knowledge into prevention programs throughout the community and the country.15

Background_on_Diabetes_in_India.pdf(38.5 KB) - download

9/20 Preventing Foot Ulcers

WILL NELSON - Oct 07, 2020, 11:30 AM CDT

Ways to prevent foot ulcers:

- *Daily Foot Inspection*
  - People should inspect both feet for blisters, cuts, scratches and ingrown toenails
  - Doctors also recommend monitoring your feet for signs of infection, including redness, swelling, and warmth
  - If you notice these changes, seek treatment immediately
- *Proper Footwear*
  - Where shoes that don't fit well increase the chance of forming blisters
  - A well-fitting shoe has half an inch of space between the toes and the tip of the shoe and provides ample arch support
  - Podiatrists recommend wearing clean, dry socks that don't have tight elastic bands, which may restrict blood flow to the foot
  - You should also avoid high-heeled shoes because they put excess stress on the front of the foot
- *Blood Sugar*
  - You must monitor blood sugar levels and ensure that they are in a healthy range.
  - High blood sugar may lead to foot complications and difficulty healing
- *Weight Loss*
  - Being overweight or obese places increased stress on the feet, which can create friction when wearing shoes and lead to blisters and cuts
- *Tobacco Cessation*
  - Cigarettes and other tobacco products contain chemicals that slow healing, which may prevent a full recovery from a foot ulcer
  - Tobacco products are also linked to circulatory problems and may significantly increase the risk of lower extremity arterial disease, which reduces blood flow in the legs and feet

Preventing_Foot_Ulcers.pdf(48.7 KB) - download

9/27 Machine Learning

WILL NELSON - Oct 07, 2020, 11:32 AM CDT

Machine Learning Basics:

- **Traditional Programming**: Data and program is run on the computer to produce the output.
- **Machine Learning**: Data and output is run on the computer to create a program. This program can be used in traditional programming.

Applications of Machine Learning

Sample applications of machine learning:

- **Web search**: ranking page based on what you are most likely to click on.
- **Computational** biology: rational design drugs in the computer based on past experiments.
- **Finance**: decide who to send what credit card offers to. Evaluation of risk on credit offers. How to decide where to invest money.
- **E-commerce**: Predicting customer churn. Whether or not a transaction is fraudulent.
- **Space exploration**: space probes and radio astronomy.
- **Robotics**: how to handle uncertainty in new environments. Autonomous. Self-driving car.
- **Information extraction**: Ask questions over databases across the web.
- **Social networks**: Data on relationships and preferences. Machine learning to extract value from data.
- **Debugging**: Use in computer science problems like debugging. Labor intensive process. Could suggest where the bug could be.

Key Elements of Machine Learning

There are tens of thousands of machine learning algorithms and hundreds of new algorithms are developed every year.

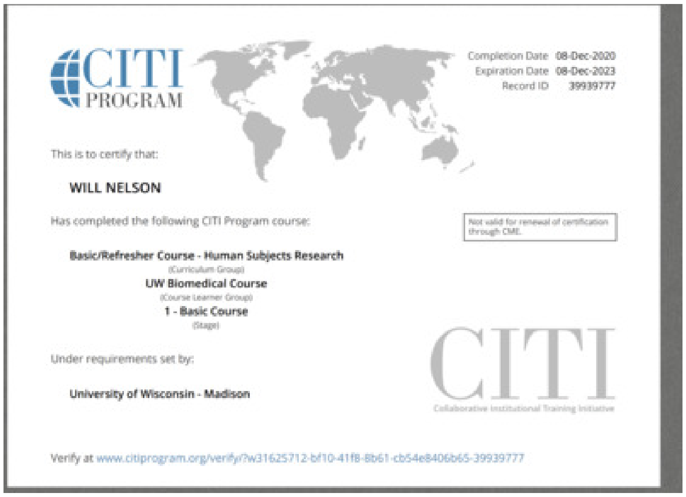
Every machine learning algorithm has three components:

- **Representation**: how to represent knowledge. Examples include decision trees, sets of rules, instances, graphical models, neural networks, support vector machines, model ensembles and others.
- **Evaluation**: the way to evaluate candidate programs (hypotheses). Examples include accuracy, prediction and recall, squared error, likelihood, posterior probability, cost, margin, entropy k-L divergence and others.

Machine_Learning.pdf(55.6 KB) - download

10/6/2020 - Human Subjects Training Certification

WILL NELSON - Dec 08, 2020, 1:06 PM CST


CITI PROGRAM

Completion Date 08-Dec-2020
Expiration Date 08-Dec-2023
Record ID 39939777

This is to certify that:

WILL NELSON

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
UW Biomedical Course
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

University of Wisconsin - Madison

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w31625712-bf10-41f8-8b61-cb54e8406b65-39939777

Screen_Shot_2020-12-08_at_12.05.13_PM.png(677.7 KB) - download

WILL NELSON - Dec 08, 2020, 1:08 PM CST

Title: Human Subjects Research Training Certification

Date: 11/8/2020

Content by: Will Nelson

Present: N/A

Goals: To verify that I completed the human subjects research training for our client

Content:

Screen_Shot_2020-12-08_at_12.05.13_PM.png

Background Research

CARTER RUPKEY - Sep 09, 2020, 11:29 PM CDT

Title: Background Research

Date: 9/9/20

Content by: Carter Rupkey

Present: N/A

Goals: Begin research

Content:

Cause of Diabetic Foot Ulcers:

Diabetic foot ulcers affect 15% of people with diabetes, and 15-20% of these people go on to needing an amputation. These foot ulcers are caused by peripheral neuropathy and ischemia from peripheral vascular disease.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2878694/

Diabetic Foot Ulcers in India:

With approximately 42 million cases, India is ranked as the nation most affected with diabetes.

https://jdfc.org/spotlight/prevalence-of-diabetic-foot-ulcer-and-associated-risk-factors-in-diabetic-patients-from-north-india/#:~:text=India%20with%20approximately%2042%20million,patients%20during%20their%20lifetime2.

Measuring Temperature from Foot

Infared imaging systems can be used to measure the temperature of the skin on the foot.

https://pubmed.ncbi.nlm.nih.gov/16221458/

Conclusions/action items: Continue researching.

Neuropathy Research

CARTER RUPKEY - Oct 07, 2020, 12:31 PM CDT

Title: Neuropathy Research

Date: 9/17/20

Content by: Carter Rupkey

Present: N/A

Goals: Research Neuropathy and the different kinds of nerves in the body.

Content:

Peripheral neuropathy is a result of damage to the nerves outside the brain and spinal cord. This often causes numbness and pain that usually persists in your hands and feet. Diabetes is one of the most common causes of peripheral neuropathy however, it can be caused by traumatic injuries, infections, and more.

The signs of peripheral neuropathy include, numbness which can spread further than just your hands and feet, sharp pains, lack of coordination, muscle weakness, and feeling like you are wearing socks or gloves when you are not.

One complication with peripheral neuropathy is infection. This happens because your feet and other areas lack sensation and may become injured without you knowing. These areas should be checked regularly and when injuries are noticed they should be treated immediately. People with diabetes especially need to treat these injuries early on because if infected areas may need amputation.

Prevention of peripheral neuropathy includes eating a diet rich in fruits, vegetables, whole grains and lean protein in order to keep nerves healthy, exercise regularly, and avoid things that may cause nerve damage.

https://www.mayoclinic.org/diseases-conditions/peripheral-neuropathy/symptoms-causes/syc-20352061

Conclusions/action items: N/A

Siren Socks

CARTER RUPKEY - Oct 07, 2020, 2:17 PM CDT

Title: Siren Socks

Date: 10/7/20

Content by: Carter Rupkey

Present: N/A

Goals: Research existing solutions to diabetic foot ulceration.

Content:

Information about Siren Socks

- There is a brand called siren that created socks to monitor the temperature of a patient's foot.
- The socks contain sensors that constantly measure the temperatures at key points on the foot.
- The information about the temperatures of the patient's foot gained by the socks is sent to the siren app.
- Using this information, doctors can notify the patient if there is any sign of anything that is concerning.
- These socks are replaced every six months in order to make sure data does not go bad due to wear and tear on the sock from wearing them for awhile.

This would not be viable in India because many people do not wear socks due to the hot temperatures.

Conclusions/action items: There are solutions that exist, but for example this solution would not work in India because socks are not worn by everybody there due to the hot temperatures.

Thermochromic Color Changing Powders

CARTER RUPKEY - Oct 07, 2020, 12:19 PM CDT

Title: Thermochromic Color Changing Powders

Date: 9/26/20

Content by: Carter Rupkey

Present: N/A

Goals: Brainstorm design ideas for our project.

Content: The thermochromic color changing powders would be put under a sheet of material such as plastic. The patient would step on the plastic sheet and the powders would return a thermal image of the patients foot. The patient would then be able to take a picture of the image they received. With that image, they will upload it to an app that will be able to recognize areas of high risk for foot ulceration.

Conclusions/action items: Keep brainstorming ideas.

2014/11/03-Entry guidelines

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity, subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03-Template

John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: