Preliminary ReportEGR 555: Mechatronics Device Innovation February 3, 2023

3 Smart Sole Inserts





Team Name

SoulTech

Team members

Sai Srinivas Tatwik Meesala Danis Nugroho Sriram Rama Prakash Sabareesh Karthick Senthilkumar Vishnu Bhargav Muthyala (Leader)

Client(s) name(s)

Kyle Sandoval, Physical Therapist: kyle.sandoval@commonspirit.org
Joelly Lobato de Faria, Occupational Therapist (NRU): joelly.lobatodefaria@commonspirit.org

Team Slogan

A little balance makes life a little better

About Project

Smart sole shoe insert that fits in patient's shoe to detect pressure such as time to shift weight, stance phase time and swing phase time; step length, initial contact, and gait distance/speed.

• The sole should have real-time on a phone app or tablet data/feedback to provide real-time therapy input to the patient.

Team Mission Statement

The team aims to expand and apply the knowledge of the real engineering industry to develop an embedded sole system for gait analysis and real-time therapy feedback to doctors and improve gait balance for patients at the Barrow Institute.

Q&A

During the first meeting with the client, the team discussed the following questions.

1. **Vishnu:** What is the background of the problem? How does the problem exist? What would you hope the patients gain from this?

Kyle: A lot of the people that we see in our setting, have various neurological conditions that affect the way they walk. You and I, when we walk, our feet are very symmetrical and we're putting pretty even weight on both feet or we're stepping pretty evenly with both feet. But if you had a stroke, you might be taking a big step with one foot, then kind of dragging the other foot along

Joelly: What we will do is gather a couple of YouTube videos and try to find some stereotypical abnormal walking for, say, a spinal cord injury versus a stereotypical stroke patient or maybe someone, if I can find it with extensor tone, just so you get an idea of what an abnormal gait pattern is and why we're trying to address it.

2. **Danis:** How serious is the problem? What is the impact on patients?

Kyle: They might be dragging their feet or they might be landing on their toes first. That's sometimes something that's kind of hard to see when we're trying to have these patients walk.

3. **Vishnu:** What are the kinds of patients we are targeting (demographics are we targeting both male/female? Their age?)? Do they have any deformities in their legs?

Joelly: You know, in our setting, we really get all adult ages. 16 plus, I would say the orthopedic population is probably a little bit older. People that, you know, people that have weight-bearing restrictions like they're only supposed to put 25% of their weight on their leg. Those people tend to be older. But in terms of the neurological population, we see so many people that had brain injuries from car accidents, and those people can be of any age. So it's all ages overall, maybe skewing a little bit older, but it's really all ages above 16, all genders

4. **Tatwik:** Will the product only be used in a hospital environment or does it include outside as well?

Kyle: It would be more in use in a treatment environment, so it wouldn't be something they have to do all the time or take home. So it would be a device they would most likely be using with a therapist in a hospital or inpatient rehab setting may be outpatient, but as you said, if they get to the point where they're they're walking safely, they're going to be going home and they then they might not need this device anymore.

5. **Sabareesh:** Are there any materials that we should avoid using that can potentially hurt the patient's feet? Any sole material recommendation?

Joelly: Oh, it can't be like a hard piece of metal.

Kyle: skin integrity would be an issue with people, like, say, they have very limited or even no sensation on their leg. Well, one that's really going to affect the way you walk if you can't feel your leg at all. But it also leads you to be at risk for things like developing pressure ulcers or pressure sores or a small cut or abrasion on your foot that could get really, really bad. So we wouldn't want to potentially add to that with something that's really hard or uncomfortable that fits in the shoe.

6. **Danis:** How would you rate your patient's comfort with the use of technology such as applications and smartphones? Are they pretty up to date?

Kyle: I suppose the feedback and the data would have to be simple and user-friendly enough that a patient could also easily learn how to read it themselves, understand it themselves in case they take it home, or if it's somebody that is just going to use it. One for patients, one for. One for the doctors. Doctors. One obviously would give you more, more features and more data, more accurate data on other stuff. But for patients, it's more or less how to replace the therapy that happens in the hospitals, and more or less, regardless of whoever uses it, they can guide the patients. Like, as I said, taking you I

mean, holding you're holding their feet from one place to another place and kind of act like a guide for them.

7. **Danis:** Out of all the products available, which one is the most successful in solving the problem? There's a product called Feetme insoles that already meets all the requirements. What would you like to do differently?

Joelly: There are other gait assistance or measurement devices such as a Q pad, and that one measures weight distribution. So even if we were to get just weight distribution, how many pounds of pressure are you putting on your foot? 50% of weight bearing, 25% weight bearing. Those are terms commonly coined by medical professionals, especially doctors, and surgeons like you can only put 50% of your weight on your foot. The Q pad can measure this, however, it is a pad. They're not walking with the pad and it presents a problem when you're trying to get them to walk long distances. And if they put on more weight than they're supposed to, they can make their fracture or their injury worse. So those are just some ideas as far as measurement goes.

Kyle: So my idea was to have some sort of smart sole device, something that can fit inside of a shoe, that gives the therapist and the patient some sort of feedback. With that, it could give us information on how they're doing when they're walking. Something that can measure the amount of weight that's going through your foot with each step. So we can see if people are leaning more to the right or left side. Also, like the stance time or the amount of time that you're just standing on that foot from when your heel first touches the ground from when you take your foot off like how much time that is. The other thing we might be interested in is information on what part of the foot is hitting the ground first, and in a normal walking pattern, your heel should hit the ground first, and then your foot kind of goes flat.

8. **Danis:** You mentioned the C-MILL in the project description. Could you explain more about what it is and why is it not enough to solve the problem?

Joelly: to be honest, especially for our orthopedic patients who they're in car accidents. They also have neurological injuries, but they can only put 25% or a quote, toe touch weight bearing on their leg. And it's impossible to measure because we can't with the C-MILL which has more advanced features. It is a very sophisticated technology and device or I guess I should say, a treadmill that is very neat. It has a harness system and everything. If that kind of thing could be thrown into a shoe for measurement for people, we cannot get onto this email. They have internal precautions. The vest will pull on their chest and they'll hurt them. We can't do that. They have spinal precautions. It'll twist their back maybe, and it can possibly harm them. There are a couple of devices out on the market that does a lot of this type of gait analysis. One of them that he referred to is called the C-MILL. We do have this device. It runs about, I want to say, over \$200,000. And we have one of the few in North America. So if you guys did want to come and see how it works and those kinds of things, you guys are welcome to come into our facility. I've already gotten permission from my supervisor. C-Mills are pretty expensive. We will inform you guys later why we prefer other products after asking our other

physiotherapists. The reason why we chose to give this project is that it could be very portable and fit inside the shoe.

9. **Tatwik:** How accurately do you want to know the time to shift weight, stance phase, and swing phase? (Milliseconds or just seconds)

Kyle: We probably don't need the millisecond mark. Most likely it should be in the 10th of a second.

10. **Sabareesh:** What are the standards that we have to use? Safety standards, hospital standards?

Joelly & Kyle: This product is pretty safe. The only thing we would like is to clean it before each use. If we can't clean it we can use the product for more than one patient.

11. **Sabareesh:** Is there any, like, common data set among common injuries? Kind of like that. You look for, like, say, a person with an accident. Like, do all those people with accidents have the same gait pattern, or do you see the same type of data and certain injuries?

Joelly: It's difficult to describe, but there are stereotypical patterns for spinal cord incompletes versus ambulating, not complete pairs versus, oh, there's someone on someone who's had a stroke versus, Oh, yeah, look at that guy's got right there. Thank you. Versus someone who has had a brain injury like a craniotomy. So part of their skull has been removed. For example, there are some stereotypical gait patterns for those.

Kyle: Something that we see across a lot of different conditions is just what we would call foot drop, which is caused by brain injuries or also orthopedic issues like you broke your leg badly and it's just you have your foot and your ankle. Normally you can pick up your toes like this with a foot drop. It just kind of hangs down your whole foot. It just kind of hangs down. Maybe you can use the muscles to point it down, but you can't bring it back up. So when you're stepping with this. This foot you're not landing on or you're kind of landing on your toes first like that each time you step. So it's that people have that to varying degrees. And sometimes it's easy to see. Sometimes they're not easy to see. And something like this could kind of help us. See it and quantify it a little bit. So foot drop, something that's common that we deal with.

12. **Tatwik**: How much would your patients buy this sold for? What's their limit like?

Joelly: It depends on the person. We do have some, but I want to say if someone really needs something, they'll be willing to spend up to it. I want to say 5,000 to 1000, maybe 2000 at the most. At the very most. But it has, like I said, we'll have to create a better blurb. This one runs up to, I want to say 16,000. I saw.

13. **Sriram**: Do you have any research papers that are good and that have good info on this stuff that you would want us to go through? Like any particular source of data that we can use.

Joelly: We can send you guys just some videos of some of the common like gait deviations. As we're saying there is a good amount of information just. The mechanics of walking have been studied very well, and there's a lot of information out there. I have a textbook that's right in front that's right here, right now that I was just looking through. So. But I wouldn't try to get too nitty gritty with it.

14. **Vishnu:** What's the success rate of your treatments? Do most people, do they get treated well or what is the success rate?

Joelly: We have a very good success rate. So basically our hospital is scored on what's called a QI. So it's a quality indicator if someone comes in and needs three persons to get them to walk by the time they leave. Maybe they'll need one person, although, or they'll be called what, supervised, or modified independently. They can do it themselves. Or I'm there just in case. So we're judged and reimbursed based on how well we can get people functional again. We have a success rate of more than 90%.

15. **Vishnu:** Can we do it with an app that teaches the patient what to do and how to walk?

Kyle: Well. If it's simplified enough, it would have to be for a person that would at least be safe enough that they can. Your average person is not going to understand what the device data outputs mean and what to do about it.

Joelly: Professionals, but it would have to be for if it's going to be for use for somebody without a physical therapist there, it would have to be somebody that's at least safely walking on their own. We wouldn't want to like, try to give this product to a person that's. Going to use it and then they're going to fall and hurt themselves.

Interview Best practices

Before the interview, the team had prepared questions to ask the client. It is very crucial to prepare questions before the interview as this shows that you are prepared and show great interest in the project. At the start of the interview, the team had also asked for permission to record. In the interview, the team decided that it was best not to ask questions out of the blue. It is best to be casual just like a normal conversation and when the client speaks, listen carefully and take notes.

Engineering Design Processes

Need: Design a portable and light device to perform gait analysis for patients.

Problem: Design a portable and light device (not necessarily a shoe sole) to perform gait analysis for patients. The device must perform gait analysis by measuring the pressure applied on the patient's foot, walking pattern, stance phase time, initial contact, and time shift. The device should also be cleanable after each use

The team intends to research current gait disorders by searching for related scholarly articles, evaluating existing products, what they aim to solve, and talking to clients. If time allows, the team will also take the time to observe the client on how they perform the treatment.

Scheduling

Every Saturday: 1 PM to 3 PM team meeting as well as a client meeting

Sunday 1:30 PM to 2:30 PM team meeting

Contributions

Danis: Q&A, Team slogan, Mission Statement, Interview Best Practices

Tatwik: Q&A, About Project, Mission Statement, Interview Best Practices, and Format of paper

Sriram: Engineering Design Process Sabareesh: Engineering Design Process Vishnu: Engineering Design Process

Everyone attended the team meeting outside the class. Everyone interacted during the first client

meeting.