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Cover Page Footnote

We are grateful to our community partners, HR and Dr. Nicole Scheiman; our advisers, Asem Aboelzahab and Hyowon Lee; the Service-Learning Grant for its financial support; the Weldon School of Biomedical Engineering; and the students who brought these ideas to reality: Carl Russell, Anjollie M. Ramakrishna, Christopher H. Johns III, Alana V. van Wijnen, and Adaugo D. Ufomba.

Authors

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GETTING OFF ON THE RIGHT FOOT

Addressing Severe Lymphedema through a Novel Shoe Design

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STUDENT AUTHOR BIO SKETCHES

Carl R. Russell III is a senior in biomedical engineering at Purdue University. He has participated in EPICS since his freshman year and been a project manager of the Biomedical Engineering EPICS team for five semesters. Throughout his time in EPICS, he has worked on projects ranging from a young boy's prosthetic to an automated CPR machine. Carl is active on the leadership teams of the Caduceus Club, the Undergraduate Research Society of Purdue, and Alpha Eta Mu Beta. After graduation, he will attend the Indiana University and Purdue University Medical Scientist Training Program (MD/PhD).

Anjollie M. Ramakrishna is a sophomore in biomedical engineering. She has been a part of the EPICS program since her freshman year and on the EPICS Biomedical Engineering team for the past three semesters. Anjollie is involved in the Woman in Engineering program and is a member of the Caduceus Club. She plans to attend medical school postgraduation.

Christopher H. Johns III is a first-year engineering student transitioning into computer engineering at Purdue University. He is involved in Greek life and actively participates in community service. This is Christopher's first EPICS project. Christopher plans to work for a software engineering company postgraduation.

Alana V. van Wijnen is a freshman currently studying the first-year engineering curriculum at Purdue University. Next year she will transition into biomedical engineering. Alana is involved with the Purdue Society of Women Engineers and the Women in Engineering Program. She is also a team leader for Boiler Gold Rush. Alana will continue for a second semester with the EPICS Biomedical Engineering team. After graduation, she plans to pursue a master's degree in engineering.

ABSTRACT

Engineering Projects in Community Service (EPICS) is a service-learning design program run by the College of Engineering at Purdue University. EPICS teaches students design skills by providing solutions for individuals, communities, and organizations in the surrounding area while mirroring engineering industry standards. Biomedical Engineering is a team within EPICS that strives to serve community partners through biomedical applications. HR is a patient who suffers from severe lymphedema. This condition results in her foot swelling three times its original size and requires her to utilize weekly leg compression therapy. Prescription shoes are slightly adequate. However, they lead to sores and pain due to fitting improperly and the expansion of her legs before her next compression treatment. HR reached out to the Weldon School of Biomedical

Engineering to seek a solution. This project entails the design and fabrication of a prototype shoe that addresses the patient's need to walk with shoes while effectively accommodating her symptoms. The user needs include condition accommodation, aesthetics, comfort, ease of use, cost, utility, and standardized documentation language. The design uses a novel break-sole passive expansion system that exceeds the normal passive expandable properties of other shoes, in addition to several expandable points that aid in functionality and comfort. The goal is that with this product, HR can get back to the things that she loves, including photography and hiking.

INTRODUCTION

The Biomedical Engineering (BME) team at Purdue University is part of a service-learning program administered through Engineering Projects in Community Service (EPICS). The BME EPICS team was established in the spring of 2017 and is one of the many EPICS teams at Purdue University (Teams, n.d.). The EPICS program as a whole consists of about 600 students and is run by the Purdue University College of Engineering. Students of all majors and disciplines at Purdue have the opportunity to participate in EPICS (EPICS at Purdue, n.d.).

Within the EPICS BME program, students are given the opportunity to collaborate and utilize engineering principles in order to address medical problems that arise within the community. Currently, there are 24 students on the BME team (Welcome to the EPICS BME Team, n.d.). The team includes students of various educational levels, experience, and academic disciplines. The BME team has four different subteams that are each working on various medical projects.

A new subteam (Sole-Spand) was recently formed to develop custom shoes for a middle-aged female patient with severe lymphedema (Figure 1). Lymphedema affects about 250 million people worldwide (Schulze et al., 2018). This condition results in extreme swelling of the extremities. In this case, it was the most prominent in the leg and foot area. The project partner, HR, reached out to the team for a solution. The shoes that she currently wears are uncomfortable and cause chaffing in the ankle area. Therefore, the goal is to develop a shoe that looks aesthetically pleasing while addressing her condition. All designs are developed with the intention of allowing the patient to return to the hobbies she loves, such as hiking and photography, while using a shoe that addresses her needs.

Figure 1. Patient HR, Following Compression Therapy

Figure 2. Dr. Nicole Scheiman, Huntington University (Huntington University, 2022)

The project team has worked closely with HR and is currently consulting with clinicians, including Dr. Nicole Scheiman, to allow for a personalized shoe while gaining feedback from an expert in this field (Figure 2).

The Sole-Spand team is developing a hybrid mechanical and elastic footwear expansion system inspired by

designs that people wear every day. Since the fall of 2022, the team has developed multiple iterations of a design that optimizes components while simultaneously validating and testing expansion properties.

In addition to the Sole-Spand team, there are four other projects on the EPICS BME team. One team is developing an interchangeable cable management system for use on vitals machines to assist medical personnel in providing timely, quality care to their patients and prevent cords from getting damaged or interfering in their work. Another team is developing a way to detect proper placement of a feeding tube. A third team is working on building a versatile seat timer to encourage people to stand after sitting for long periods of time. Finally, a team is developing a mechanical prosthetic hand demonstration to be shown to prospective students touring the Martin Jischke Hall of Biomedical Engineering. Each week it is expected that a team member commits to a two-hour lab with two hours in outside lab work. Team members document details related to their personal contributions to the project. Interested students should contact the EPICS office at epics@purdue.edu.

DESCRIPTION

A lymphedema shoe typically includes footwear with adjustable straps and elastic materials, with expansion restricted at the top and sides of the foot. While this provides outward expansion, it does not account for swelling around the ankle, which is our patient's primary concern. Hence, we seek to create a better solution. Our goal is to create a shoe that expands for the back of the foot to account for ankle swelling. Additionally, we are looking to create a product that serves more than mere functionality. Our patient has expressed frustration in current styles of lymphedema shoes because they look like a medical device rather than normal footwear. Therefore, our goal is to create a product that is functional and stylish.

Workflow for the project is reliant on the EPICS design process, which ensures that all components of design are considered (Figure 3). The project teams are formed during the beginning of the semester, with interests and skill sets being considered in regard to placement. The overall teams are managed by project managers, who oversee three to four projects headed by design leads.

During the initial design and planning stages of the project, the team sought inspiration from current shoe designs. A Fila sneaker, the shoe that HR was currently wearing, was considered, as was another, a Sperry boat shoe (Sperry, n.d.). Each current design has advantages and disadvantages, so the team decided to base the decision making around the design requirements (Table 1).

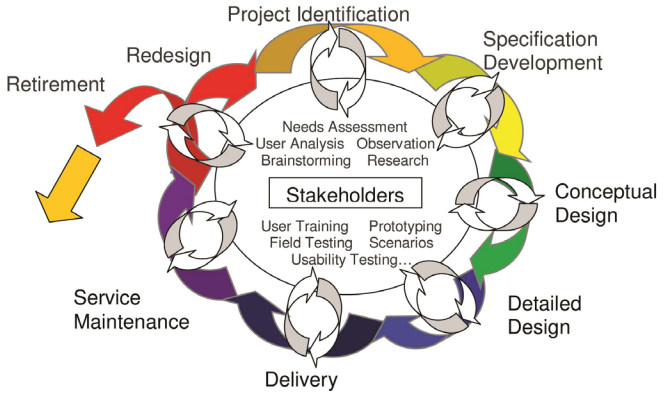

Figure 3. The EPICS Design Process Flowchart (Image from EPICS, Purdue)

Table 1. Design Requirements

Users	Requirement
Patient	Solution must fit patient in nonswelled state
	Solution must fit patient in swelled state
	Solution should not share similar appearance to that of a medical device
	Solution should share similar appearance to that of a common shoe brand
	Fits patient's preference and style
	Patient should experience pain lower than a 2 while wearing the solution
	Patient should experience pain lower than a 2 while wearing the solution for prolonged durations (>3 hours)
	The solution will passively expand or be adjustable in <10 secs
	The solution should be able to be worn in <30 secs
	Shoe materials do not exceed $150
Clinician	Design should be able to accommodate various shoe sizes
	Design should be able to accommodate different degrees of swelling
Shoe companies	Solutions should use industry standard language

Input is required from three groups: the patient, the clinician, and the shoemaker. With the patient, the team wanted to ensure that interactions with the patient would be easy and convenient. HR helped shed light on issues for consideration during brainstorming. She previously

Figure 4. Sperry Boat Shoe (Image from Sperry)

considered wearing therapeutic lymphedema-specific shoes; however, she was dissatisfied with the clinical appearance of the current selection of footwear. Additionally, she mentioned that when she wears the Fila sneakers, the primary issue is the front of her ankle. Therefore, when the user needs and design input requirements were written as shown in Table 1, the top three requirements included were that the solution was patient-specific, aesthetically pleasing, and not causing pain. After considering the design requirements listed in Table 1, the team chose a passive, mechanical expansion shoe inspired by the open concept of the Sperry Boat Shoe (Figure 4). This would accommodate the user's various degrees of swelling and limit shoe contact in problem areas and the need for shoe adjustments while looking aesthetically pleasing.

The team developed a break-in-the-sole modification of a Sperry Boat Shoe. A cut spans the width of the shoe just forward of the sole arch. This cut provides an expansion system for the shoe to stretch in length. The expansion system of the shoe has a flexible and durable 3D printed guide secured with rivets that align the guide with the direction of expansion. In addition, the rivets also secure an elastic polyester strap to assist in the compression of the shoe when the system is in its expanded state. Tests determined that elastic straps that run parallel to the length of the shoe performed best. Beyond the expansion system, the shoe consists of several cuts with sewn-in fabric that aids with expansion in locations that commonly swell, particularly within the dorsal surface of the shoe. Lycra, neoprene, and spandex were the candidate fabrics that the team tested. Ultimately, spandex came out on top and was installed into the prototype (Figures 5–8).

The team spent the duration of the fall 2022 and spring 2023 semesters iterating on many initial prototype

Figure 5. Prototype Side View (Image from Carl Russell)

Figure 6. Prototype Top View (Image from Carl Russell)

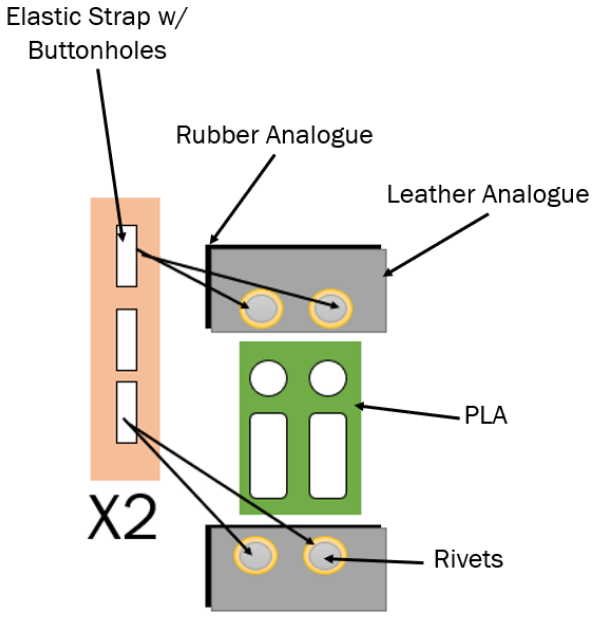

Figure 7. Expansion System Schematic (Image from Carl Russell)

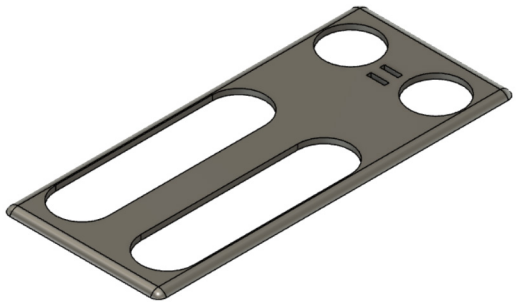

Figure 8. Expansion System Guide (Image from Carl Russell)

fabrications and executing characterization tests for features in the shoe, such as the expansion system and the interactions between the elastic material and the leather. Additional prototypes are in development using the outcomes from these characterization studies and lessons learned from previous prototypes. The team plans to use the duration of the 2023–2024 school year to finalize the minimum viable prototype that includes all necessary features for the solution concept. Delivery of the final project will be made to the user and the clinician specialist.

This project was presented at the 2022 Service-Learning and Engagement Summit and at the senior design expo at the end of the spring of 2023.

COMMUNITY IMPACT

Until the prototype is complete, the team is not able to begin validation trials with the stakeholder. In the lab, the team was able to identify failure points for some of the current shoe prototype and immediately redesigned and reprinted our 3D printed tracks to be more stable. The current prototype allows for the shoe to expand and retract. The measure of success for our shoe is its ability to expand and contract with the user's foot while protecting the foot from the outside environment and being aesthetically pleasing.

It is hoped that this project has a positive impact on patients who suffer with lymphedema and will adapt to multiple forms of therapy, such as compression therapy, and allow them to walk more easily.

Currently, the team is focusing on implementation of devices in the shoe. After implementation and details are completed, the team will begin strength-testing and also begin working on the aesthetics of the shoe. The team plans to deliver a finalized shoe prototype to HR by the end of the spring 2024 semester.

The prototype will allow for a variety of different patient applications. Not only can patients with lymphedema benefit from the shoe, but those with other conditions, such as bunions and swollen feet, might also find the shoe to be beneficial.

STUDENT-AUTHOR IMPACT

Carl: I am fortunate to have this project as my senior design project. It allowed me to apply the skills that I have gained throughout my undergraduate career to a project that has the potential to positively impact a patient in need. We were fortunate, as the project partner was clear with her wants and needs. This allowed us to purposefully focus our efforts on developing a solution. As a teammate, I spent countless hours talking through shoe modification and potential design considerations. It was a treat to be able to bounce ideas off passionate students who were motivated in assisting this patient.

I was able to hone my leatherworking and mechanical testing skills as we sought to produce a thorough and well-tested solution. I learned about writing detail documentation to allow others to reference our work more easily. While contributing to that documentation, I applied my experience in testing and documentation that I gained during my engineering internship. We spent over four months testing various components. This was the longest time that I had spent on this phase, but it is paying off, as the project is proceeding smoothly as we implement the design solution born because of those reports.

As I felt more comfortable with my contributions to the project, I shared my knowledge with my teammates. I introduced them to medical device regulation, needs finding, and documentation fundamentals. When the project was in a state where we could present it, I helped mentor my teammates in presenting at the Service-Learning and Engagement Summit and at the senior design expo later in the spring of 2023. When design review came around, I made sure that my teammates knew what to expect and gave them tips on technical presenting.

Overall, working on this project has been a very rewarding experience. It allowed me to design and develop a prototype, potentially leaving a lasting impact on a patient, and work with bright minds who are passionate about the work they are doing. Working with this subteam as project manager has shown me different scenarios and has given me the opportunity to advise students on skills that they can use to achieve objectives. Reflecting on the past, I find that this experience is

dependent on the efforts of the students who engage with projects. Projects such as these build skills sets and form close professional bonds with peers. I encourage those who wish to participate in EPICS to put in considerable effort. That effort is likely to be met with equally considerable outcomes. I look forward to seeing this project through to completion.

Christopher: In this project, I have gained both teamwork skills and technical skills. I have learned about the importance of teamwork and having a planned schedule that keeps the team working. I have valued being a part of the Sole-Spand team, as it has allowed me to work in a collaborative environment where everyone is contributing to the final design of the project.

When I first joined EPICS I did not have much experience working with an actual community partner, because at my previous schools our projects were merely for a grade and never for an actual purpose. Working with my team in EPICS, I have had the opportunity to make something that will actually be used to help someone in need, which is incredible. It is harder working with a community partner because communication is not always easy, but it gives the project a lot more meaning and allows me to be more invested in the success of our project.

I would like to thank the EPICS program and my team for their assistance throughout this whole project and for being amazing team members. Being a part of the Sole-Spand BME EPICS team has provided me with more opportunities than I can count, and the guidance from upper-level students alone has been well worth the commitment that I have given to this team. This team has done a lot in these past two semesters, but I know that we have a lot of work left to do. Everyone is ready and willing to get going. I look forward to seeing what we can accomplish.

Alana: Joining EPICS has been one of my most rewarding experiences at Purdue. EPICS has taught me how to collaborate with a team on a long-term project and provided an opportunity to work with an engineering team on real-world projects. What I appreciate so much about our project is that it is directly benefiting our community; it has been incredibly gratifying to see our efforts leave a tangible impact.

When I first joined the team, I never expected it to have such an impact on my education. However, it has truly taught me valuable work experience that cannot be gained from a typical lecture setting, including how to work on a team to improve a design. By completing testing and research, we have expanded our project and tackled hurdles as they came. I love the ability to do hands-on work, as we have seen our ideas emerge from a drawing on a whiteboard to implementation of a prototype.

All in all, EPICS has been a unique and enriching opportunity. As my team and I have continued to work together, we have formed an incredible team dynamic. I could not have asked for a better group, as we all act as part of a unified front toward a common goal. Working alongside them has allowed me to grow as an engineering student by learning from my peers and the feedback of upper-level students. I am very excited about the future of our project and the direction in which it takes us.

Anjollie: Being a part of the EPICS program has been one of the most enriching experiences I've had at Purdue. I've been able to apply engineering concepts I've learned as well as my own experiences to create designs that help benefit the community around me. The EPICS program is centered around hands-on design, allowing students to collaborate with one another and learn how to manage team-based projects. In this program, I have not only learned new engineering concepts but also gained knowledge on design process, communication, and the ethics of engineering.

Coming into EPICS, I had never delivered viable products to a community partner. I had never been through the design process that EPICS is centered around. Through my time here, I've learned about the importance of a simple brainstorm; collaborating with my partners and being able to bounce ideas off of one another is possibly one of the most important steps of the design process. I've also learned the importance of patience in engineering. Whether it be the brainstorming/developing phase taking some time, communication being rocky with a project partner, or hitting bumps in the road while testing, I've learned that the design process is never a quick process or a smooth one. But you must learn to work as a team, embrace these obstacles, and move forward. In the end, you grow to appreciate your team's success even more knowing the work you put in to get there.

I could not be more satisfied with my time here at EPICS. I am thankful for the knowledge I gained in the program, and I am very appreciative of the people I've met and the friendships I've made. In this team, we've grown to learn how to communicate and collaborate with one another in order to create a very efficient and positive environment. Overall, I am very proud of what

my team has achieved thus far and cannot wait to see what we achieve moving forward.

CONCLUSION

Lymphedema continues to be a condition that negatively affects the quality of life for patients around the world. Current solutions are not aesthetically pleasing and can lead to chaffing and other forms of injury for the user. This team is designing a way to alleviate those issues through a novel concept for a break-in-the-sole expandable shoe system.

There is the strong potential for this project to leave a lasting impact on one individual. However, there is the potential for the project to reach a wider range of users. It is the hope that a novel design system such as this performs well under validation testing. Likewise, this project has impacted the engineering, leadership, and interpersonal skills of the project members. These skills will be valuable as the project progresses and in carrying on to more impactful ventures.

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