Educating Tomorrow's Engineering Entrepreneur through Participating NSF I-Corps Program

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Abstract

A foot orthotics team at Mississippi State University (MSU) participated a 7-week NSF I-Corps program to gain a deep understanding of customers, partners, and markets. Based on intensive interviews with potential customers and partners, the team has formed a business canvas model to translate research results into viable products, which are metal-based additively manufactured foot orthotics. Important lessons learned from customer discovery activities are detailed in this paper. The student, who is also the entrepreneur lead (EL) of this team, has gained substantial entrepreneurship skills through the I-Corps training program.

Keywords

Engineering entrepreneurship, NSF I-Corps program, customer discovery, foot orthotics, additive manufacturing

1. Introduction

Currently used foot orthoses are made of nonmetallic materials such as ethylene-vinyl acetate (EVA), polyethylene (PE), polyvinyl chloride (PVC), and polyurethane (PU) [1]. Those materials offer good shock absorption capacity and cushioning properties. However during usage these capacity and properties deteriorate fast, indicating a functional fatigue in the material. In addition, some of the cushioning materials such as PUs are highly susceptible to environmental conditions (temperature, humidity, etc.). For instance, their functional properties vanish in a wet environment.

There are many patents registered that focus on artificial limbs that incorporate superelastic supports made of a shape memory alloy (SMA), nitinol [2-5]. Compared with the plastics, nitinol offers high superelasticity, strength, resistance to corrosion, biocompatibility, and is more capable of being deflected to human body-support interaction forces. Its superelastic supporting nature can further be utilized for reinforcing and stabilizing other body parts.

In the past, the true potential of nitinol supports was not fully realized due to the difficulty in its machining/fabrication. However, additive manufacturing (AM) techniques provide the opportunity to fabricate complex, customized parts for a variety of applications even in logistically weak (remote) locations from only CAD models [6, 7]. By combining the superelasticity of nitinol with the capabilities of additive manufacturing, highly durable and comfortable orthotic equipment can be fabricated on a patient-by-patient base. Moreover, by controlling the manufacturing and design parameters and selecting appropriate post-build treatments, cellular nitinol orthoses per requirements provided by patients can be fabricated to achieve target foot elasticity for specified patient rehabilitation or mission constraints.

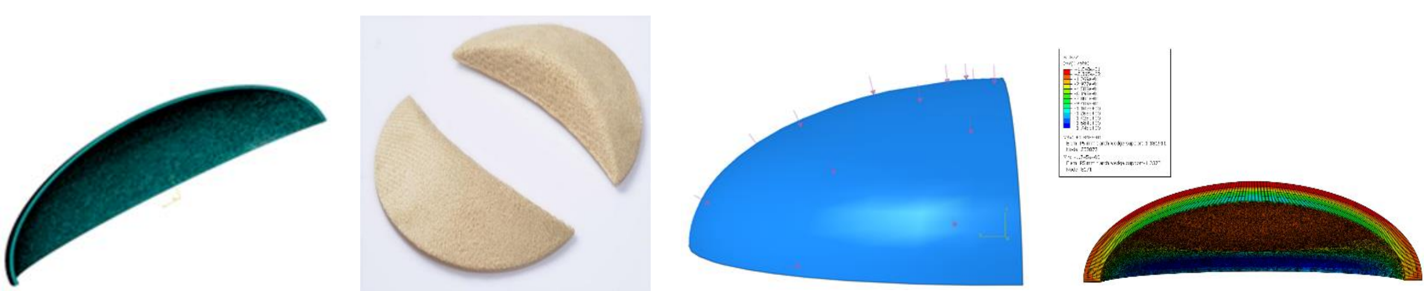
A team was formed to verify the commercial viability of the proposed technology of applying AM techniques to build custom metal-based foot orthotics. A mechanical engineering graduate student at MSU became the entrepreneur lead (EL) of that team and conducted extensive customer discovery during MSU's I-Corps Site summer 2017 cohort and NSF I-Corps 2018 spring cohort.

2. Metal-Based AM Foot Orthoses

Foot orthoses support and align the foot to prevent or correct foot deformities, provide an even distribution of the body weight, or to improve the functions of the foot. A computational study has been completed to evaluate the force bearing and deflection performance of arch wedge support (AWS) made of nitinol [8, 9]. Finite element analysis (FEA) models for the AWS with different thickness and material properties were created at first. Shape and size of those FEA models were extracted from an over-the-counter (OTC) AWS (Fig. 1b). Five representative human movements, standing, self-selected walking pace, brisk walking pace, running, and standing vertical jump were selected to define loading conditions for the FEA models. The amount of forces generated during the selected actions were measured from 24 healthy male adults aged 26 ± 8 years old using a synced 10-infrared camera 3D motion analysis system, dual force plates, an 8-channel electromyography system, and a 2D video capture system in the Human Performance Laboratory at MSU. Simulation results showed that for all the FEA models, the highest stress (20.98 MPa, caused by running motion when the model was fully constrained, whose thickness is 1 mm) yielded from the simulations was clearly lower than the yield strength of nitinol (200 ~ 266 MPa). Thus, it is confirmed that a 1 mm thick nitinol AWS would be strong enough to resist various forces and motions and can restore to its original shape after the loading is removed. Table 1 displays the stress and deflection results of the AWS models that were fully constrained. Fig. 1a shows an FEA AWS model, Fig. 1c shows the distributed force applied on the surface area of that model, and Fig. 1d displays one example of the calculated stress distribution.

Table 1. Stress and deflection results of fully constrained nitinol AWS models

Actions	1 mm thick		2.5 mm thick		5 mm thick	
Standing	13.75 MPa	16 µm	4.12 MPa	5 µm	1.75 MPa	1 µm
Self-selected walking	16.58 MPa	19 µm	4.97 Mpa	6 µm	2.10 Mpa	2 µm
Brisk walking	18.60 MPa	21 µm	5.58 MPa	6 µm	2.36 MPa	2 µm
Jumping	32.32 MPa	37 µm	9.69 MPa	11 µm	4.10 MPa	3 µm
Running	37.99 MPa	44 µm	11.39 MPa	13 µm	4.82 MPa	4 µm



(a) (b) (c) (d)

Figure 1. Computational study of arch wedge support. (a) An FEA model; (b) OTC arch wedge supports; (c) loading condition; (d) an example of stress plot

3. I-Corps Program

The National Science Foundation (NSF) Innovation Corps (I-Corps) program was designed to provide NSF-funded researchers with additional support in the form of entrepreneurial education, mentoring and funding to accelerate innovation that can attract subsequent third-party funding. With the support of the NSF I-Corps Site award, we interviewed 15 active military service members and veterans from different branches. All of the interviewees mentioned about the repeated wear and tear of normally used polymer orthoses due to the extensive workload they experienced in the military and suggested a huge need for more durable foot orthotics in the military. From those interviews we also learned the need of the service members with flat feet and undergoing heaving training for a durable and affordable foot orthotic device to prevent the symptoms form growing. With that finding, we participated a 7-week I-Corps program in spring of 2018. Our I-Corps team includes the EL, a PhD student of MSU; the PI and the co-PI, who are faculty member from the Department of Mechanical Engineering and Department of Kinesiology at MSU, respectively; and the I-Corps mentor (IM), an experience entrepreneur with 25 years' experience in medical device industry. In our team, the EL (PhD student) works on design, development, and commercialization of the metal-based AM foot orthotics under the direction of the PI and the co-PI. The role of the IM is to continuously mentor the EL, and the PI and co-PI, and provide feedback on interpreting the outcomes of the customer interviews.

The entire I-Corps program includes a 3-day kickoff meeting, 6 online classes, a 2-day closing workshop, and extensive customer discovery interviews. The kickoff meeting aims at setting the standards and expectation from the teams. In the weekly online class, we learned how to build a startup and met with the teaching team to present our findings and received feedback. Discovery interviews are at the core of this program. During the 7-week I-Corps program, we conducted 102 interviews with nurses, therapists, podiatrists, and military procurement officers. Those interviewees were selected because they are either have more direct contact with patients who need foot care or they are considered as potential influencers of the proposed AM foot orthotics. A deep understanding of the customers, partners, and markets for the proposed AM foot orthotics were developed from those interviews. The I-Corps program concluded with a closing workshop where each team reported their findings and present their business model canvas if they decide to move forward. From the results of the interviews, the team was convinced that the designed metal-based AM foot orthotics addressed the need of the service members undergoing heavy training for foot orthotics with the same comfort, but higher durability and longer service life. We are in the process of refining the design and pushing the foot orthotics project from an exciting academic find to a commercially successful enterprise.

4. Results

From the customer discovery process, the typical customers of the metal-based AM foot orthotics were identified as (1) active military service members, (2) athletes, (3) other professionals suffering from foot or ankle injuries due to work or exercise, and (4) those who belong to the footwear industry (orthopedic shoemakers, orthotists, physical therapists, etc.). Two customer needs that will be met by the proposed metal-based AM foot orthotics are: (1) Its cellular structure developed via AM processes provides greater comfort by helping to absorb more shock energy from every step a customer takes. Therefore, the designed foot orthoses can improve balance/gait performance of the customers and prevent injuries. (2) The proposed nitinol foot orthoses have a longer lifetime and are more durable when subjected to fatigue loading or in corrosive environment. Thus, it is expected that the application of the metal-based AM foot orthotics can shorten the leave time of customers (patients) due to lower extremity injuries and ankle sprains and reduce the number of doctor visits.

Currently customers purchase OTC foot orthoses at about $40 per pair. Those orthoses are made of foam, plastic, fiberglass, graphite and may have gel filings for better cushioning effect. Some customers have their podiatrists prescribe custom orthoses for them, which are made of the same materials but more suited for their medical situation. The custom orthoses cost about $400 to $600 for each pair. Compared with the current foot orthoses, the proposed metal-based foot orthoses offer competitive advantages of longer life span, higher durability, and greater shock absorption. The average cost of nitinol powder is about $500 per kilogram, and if the weight of a pair of thin-walled nitinol foot orthoses can be maintained around 50 g, the unit price of the nitinol foot orthoses can be set at $67 (for a 65% gross margin) but their service life should be an order of magnitude higher compared to that of the current foot orthoses. Fig. 2 shows a comparison of fatigue lives between AM-produced nitinol and several plastics. From that figure it can be seen that the AM-produced nitinol has significantly higher fatigue strength than the plastics. Due to the demonstrated advantages of the designed AM foot orthotics and considering the fact that the current foot orthotic insoles market is estimated at $ ~ 2.6 billion with an anticipated growth to $ ~ 3.7 billion by 2021, the team believes that the presented product and technology of applying AM techniques in design and development of medical devices have vast potential for commercialization.

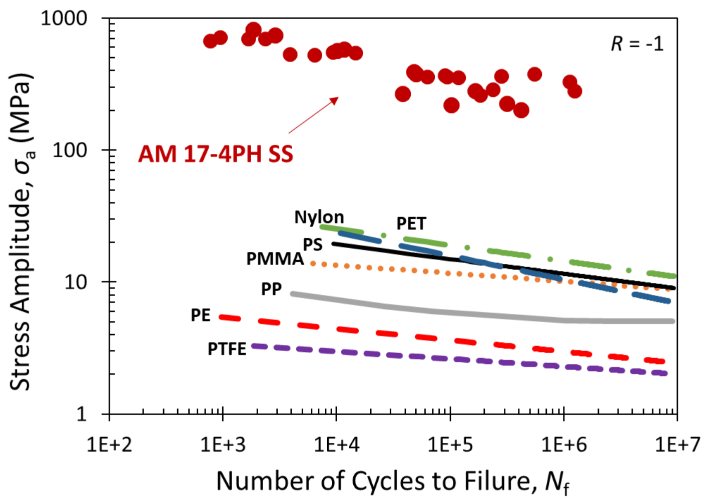


Figure 2. Fatigue-life comparison between nitinol [10] and PET, nylon, PS, PMMA, PP, PE, and PTFE [11]

A business model canvas introduced by Osterwalder [12] was developed by the end of the I-Corps program (Fig. 3), which includes nine sections including value propositions, customer segments, key resources, cost structure and revenue streams.

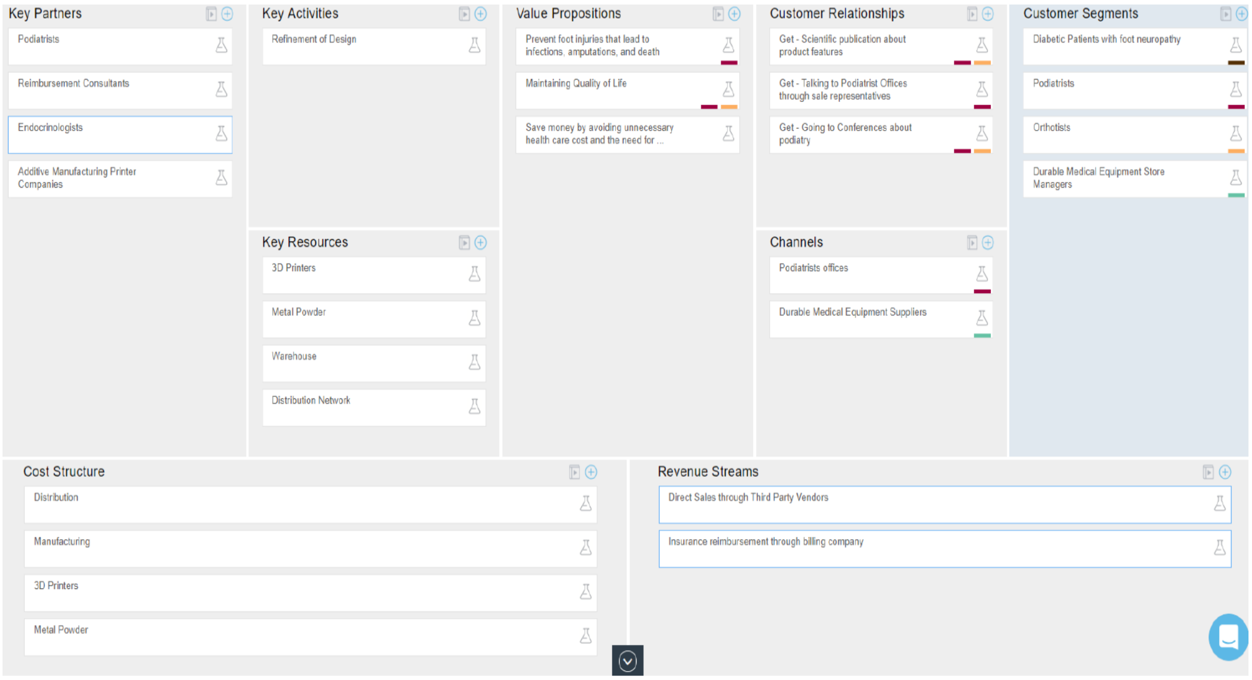


Figure 3. Business model canvas developed from the NSF I-Corps program

5. Conclusions

In this paper, a thin-walled nitinol AWS is presented, whose capacity to resist various forces and motions are evaluated through FEA. The FEA results show that the proposed AWS design is strong enough to resist various forces and motions and can restore to its original shape after unloading. Fifteen active military service members and veterans were interviewed during the I-Corps Site Program and 102 interviews were conducted over the 7-week I-Corps Teams Program. The need of the service members with flat feet and undergoing heavy training for more durable and affordable foot orthotic devices was identified during those interview sessions. A business model canvas was developed based on the results of those interviews to enable us to fulfill customer needs at a competitive price and sustainable cost.

In the next phase, prototypes of thin-walled nitinol AWS will be developed using AM techniques and used for human factors testing and material testing to fully realize its potential of replacing the plastic, traditionally-manufactured foot orthotics available in the market. Commercial viability of the metal-based AM-produced foot orthotics will also be assessed to guide further development for achievement of product-market fit.

Through this project, the PhD student conducted most of the interviews and received training in the process of translating and commercializing fundamental research fundamental research results to marketable products. He also participated the Entrepreneurship Program at MSU. That program was designed for engineering students who eager to launch their own business. In the future, the PI plans to involve more entrepreneurially-minded students into future customer-driven research and prepare them to be founders and leaders of tomorrow’s high-tech ventures through this unique program.

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