Undergraduate Thesis Prospectus

Improvement of Biomechanical Function for Patients with Footfall Impairments

(technical research project in Biomedical Engineering)

Rising Drug Prices and the Strain on the American Healthcare System

(STS research project)

by

Ben Osborne

October 31, 2019

technical project collaborators:
Olivia DuCharme
Brandon Phan

On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

signed: _____ date: _____

approved: _____ date: _____
Peter Norton, Department of Engineering and Society

approved: _____ date: _____
Shawn Russel Advisor, Department of Mechanical Engineering

General Research Problem

How can the cost of American health care be reduced? The United States has one of the last remaining profit-motivated healthcare systems in the world. Americans spent $3.2 trillion on healthcare (almost $10,000 per person on average) in 2015, accounting for 17.8% of the US gross domestic product (GDP) (Branning & Vater, 2016). In a study of healthcare spending in the United States and 10 other high-income (mainly European) countries, Emanuel (2018) found that the US spends approximately twice as much on medical care and that the "prices of labor and goods, including pharmaceuticals, and administrative costs appeared to be the major drivers of the difference in overall cost."

Improvement of Biomechanical Function for Patients with Footfall Impairments

How can an algorithm inform the development of an optimized shoe midsole on a patient-by-patient basis to address overuse injuries, such as plantar fasciitis? For my BME Capstone project, I will work with Brandon Phan and Olivia DuCharme, and Professors Silvia Blemker (BME) and Shawn Russel (ME) will be our advisors.

There are many risk factors for plantar fasciitis including pes planus (flat feet), pes cavus (high-arched feet), overpronation, limited ankle dorsiflexion, weak intrinsic and plantar flexor muscles, poor biomechanics or alignment, repetitive foot contact with hard surfaces, and poor footwear (Schwartz & Su, 2014). One in ten adults will experience plantar fasciitis in their lifetime and this condition has resulted in indirect costs of $390 million per year to the United States' healthcare system (Crawford et al. 2018). Common forms of treatment for plantar heel pain include pain management via medication, injections, custom orthotic insoles, foot straps, and/or surgical intervention, however, the efficacy of these treatments vary widely across the

patient population and do not offer a convenient and affordable method for pain relief. Pain medication is commonly used to treat plantar fasciitis: 6.31% of adults with plantar fasciitis treat pain with prescription medication and 70% use over the counter drugs for general pain management (Nahin, 2018). In order to provide patients afflicted with plantar heel pain a more cost-effective and accessible method of treatment, our project aims to explore alternative methods through customized midsole design informed by patient specific biomechanical factors.

The goal of this project is to develop an algorithm that helps to inform the development of an optimized shoe midsole through considerations of anatomical and biomechanical factors on a patient-by-patient basis to address plantar fasciitis, and potentially other overuse injuries.

Foot orthoses range from ‘off-the-shelf’ heel pads and contoured prefabricated inner soles to custom-made foot orthoses of varying styles, construction materials, additions, and modifications. Custom-made foot orthoses are molded or milled from an impression of the foot, such as a plaster cast or three-dimensional laser scan, and fabricated according to practitioner-prescribed specifications (Hawke et al., 2008). These supplemental footwear accessories are used to counteract the shortcomings of shoes by providing additional cushioning and arch support as well as reducing plantar pressure by redistributing force over the contact area of the foot upon striking the ground. However, these methods can be cumbersome, time-consuming, and only provide a supplement for footwear (Kane et al., 2016). Castings can take up to multiple weeks to be completed and delivered to patients, while orthotic insoles do not provide the degree of structure, support, and everyday use offered by shoes.

The proposed algorithm will include parameters addressing body mass index (BMI), foot strike pattern, ankle angles during the gait cycle, and pressure centers of a patient's feet. A 3D scan of the patient's feet will inform the selection of size, shape, and cushioning implemented in

the customized midsoles. The midsoles will be shaped with arch support according to the positional data of the arches in a CAD model. The resulting model will be subjected to finite element analysis and material testing within the CAD software to determine which 3D printing material allows for optimized cushioning around the heel and ball of the foot to maximize comfort during movement. Finally, the fully customized midsole will be 3D printed. 3D printing the midsoles will provide a scalable manufacturing method that allows for precise material modifications, and potentially low cost. After physical material testing and iterating the 3D-printed prototype, motion analysis markers will be placed on the feet and midsole of the patient to observe changes in gait pattern, ankle angle, and stride length when walking. Barefoot walking and movement in a comparable shoe model will act as controls. To analyze forces on the foot during the gait cycle, patients in the study will walk over a force plate to determine the maximum vertical ground reaction force in all testing conditions. Finally, comfort of the shoe will be rated by the participants using a Likert scale for each of the models and compared quantitatively. These analysis methods will determine if the algorithm method of designing a midsole creates a functional prototype that addresses plantar heel pain and whether this method can be a viable option for professionals in the field of orthotics and shoe design.

By creating an algorithm that informs the design of a biomechanically optimized midsole, we expect to develop a patentable product that will directly address plantar fasciitis, and be further translatable into the treatment of many other overuse injuries. Further, 3D printing will provide a scalable, highly customizable, and potentially affordable manufacturing protocol. This patient centric approach to shoe optimization will go beyond the constraints of foot casting and orthotic inserts to meet a patient’s specific needs.

Rising Drug Prices and the Strain on the American Healthcare System

How are interest groups competing to influence drug prices in US healthcare?

High and rising drug prices in the US are a major health and health policy concern. Per capita prescription drug spending in the US exceeds that in all other countries. In 2013, per capita spending on prescription drugs in the US was $858 compared with an average of $400 for 19 other industrialized nations (Kesselheim et al., 2016). Drug manufacturers are increasing their product prices. Wineinger et al. (2019) found that of 49 top-selling brand-name drugs, 78% of those that have been on the market since 2012 have risen in insurer and out-of-pocket costs by more than 50%, and 44% have more than doubled in price. Manufacturers may set high drug prices due to market exclusivity, conferred by patents (Kesselheim et al., 2016). Pharmaceutical companies defend such protections as essential to research and development.

In a review of drug life cycles, therapeutic drug markets, and regulatory frameworks, van der Gronde et al. (2017) attributed high prices in part changes in drug life-cycle dynamics, the unintended effects of patent legislation, public policy, and orphan drug programs. However, in a risk-return analysis Popa et al. (2018) contends: “Drawing conclusions based on industry profitability only is inappropriate as such analysis does not account for risks faced by investors.” They note that from 2004 to 2016, the biopharmaceutical industry risk-adjusted return on investment did not exceed that of other industries. Johns Hopkins health policy expert Gerard Anderson argues: “The objective is getting the prices lowered so that everybody can afford the drugs, but at the same time bringing enough money onto the system – increasing the volume – so that pharmaceutical companies can continue to innovate” (Hub staff, 2017). Patent reform, reference pricing, outcome-based pricing, and incentivizing physicians and pharmacists to prescribe low-cost drugs are among the most promising short-term policy options, but their

effects on patient treatment, drug innovation, and doctor's practices are unsettled (van der Gronde et al., 2017).

Participants include pharmaceutical companies, patients, hospitals, health insurance companies, and doctors. Pharmaceutical companies must invest in R&D and manage public relations. The Pharmaceutical Research and Manufacturers of America (PhRMA) claims: "Despite what critics say, the U.S. biopharmaceutical industry spends three times more on the research and development (R&D) of new treatments and cures than on the marketing and promotion of medicines" (Campbell, 2019). Pfizer CEO Ian Read said, "We feel we appropriately price our products to the value in the marketplace, and that's essential for free market systems where you need to recover and direct resources to further innovation" (Berkot, 2017).

On the other hand, patients want affordable drugs. The advocacy Patients for Affordable Drugs commented in a press release: "Eighty six percent of Americans – majorities of Democrats, Republicans, and Independents – support allowing Medicare to negotiate for lower prescription drug prices" (PFAD, 2019). Hospitals pay for drugs when insurance and patients fail to. According to the American Hospital Association: "It is estimated that 5 percent of U.S. patients account for nearly half of the country's health care expenditures" (AHA, 2017).

Health insurance companies must balance the premiums they charge against drug costs. The President and CEO of America's Health Insurance Plans stated: "The problem is the price of drugs …drug makers must be held accountable to lower prices for consumers and patients" (Grow, 2019).

Doctors also influence prescription drug spending. Physicians may neglect price in determining a prescription. In a review, Davari et al. (2018) determined that in 33 studies of

factors that influence prescription decisions, doctors' personal attributes, cost of medicine, and pharmaceutical industries' marketing and promotion strategies were mentioned most.

Dusetzina et al. (2017) found that over time, the difference between net and list prices of drugs in the United States has widened, partly because of increases in list prices and growing rebate percentages. Gupta et al. (2016) document steep rises in drug prices of naloxone, a heroin overdose drug. They report that only Amphastar manufactures 1-mg-per-milliliter injections, which after a 95% price increase in September 2014 now cost $39.60 each. A two-dose Evzio package was priced at $690 in 2014 but is $4,500 today, a price increase of more than 500% in just over 2 years.

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