Practical Exosuit Design for Patients with Amyotrophic Lateral Sclerosis
(Technical project)

Duty Ethics Within Insulin Manufacturing
(STS project)

A Thesis Prospectus
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By
Willis Williams

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Technical Team Members:

Nicholas Yantiss
Ellianna Bailey
Patrick Evans
Lilly Xu
Priti Patel

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.

ADVISORS

Professor MC Forelle, Department of Engineering and Society

Professor Sarah Sun, Department of Mechanical Engineering

Introduction

Some medical conditions require those afflicted to become dependent on either a drug or a piece of technology in an attempt to maintain their standard quality of living. Research labs and companies are hard at work trying to be the first ones to find the next revolutionary drug or solution that will lead to treatments that are more effective than anything seen so far and can be life changing for people with a condition that affects their everyday life. With these solutions and treatments that are found comes the question of how accessible will it be for those that need treatment in terms of distribution and pricing. Some corporate bodies may be more focused on having a higher profit margin and will increase the price arbitrarily, while research institutes may be more inclined to leave the price low so more people can access it.

For my technical portion, I will be working with my capstone team to establish a prototype soft/textile exoskeleton for an arm that produces one degrees of freedom, as well as produce convincing research into methods for improving construction of soft exoskeletons. Amyotrophic Lateral Sclerosis (ALS) is a debilitating disease that causes the body to slowly lose all functions over time until it is impossible to even drink water by yourself and eventually leads to death (ALS Association, 2022). The primary user demographic would be ALS patients that are losing arm functionality, to extend their range of motion in their arms. With this exoskeleton, we are hoping to improve the quality of life of the person with ALS in their remaining years by helping them maintain arm functionality and through that, a more autonomous lifestyle where they do not need to rely on a caregiver.

For the STS portion of my paper, I will be focusing on insulin as the life-changing medical treatment for diabetes. This monetization of medical technology can be seen with diabetes and insulin. 95% of the US's insulin is produced by just three primary manufacturers, Eli Lilly, Novo Nordisk, and Sanofi (Quinn, 2018). Resulting from this, there is essentially a monopoly on insulin manufacturing that lets these three companies have much more influence on where the pricing should be based on their own whims. In America, there are around 1.9 million Americans diagnosed with type 1 diabetes (American Diabetes Association, 2022). Type 1 diabetics need to take insulin everyday just to survive, with the average annual medical costs being about $9600 in 2017 (American Diabetes Association, 2018), with about $700 of that being spent on out-of-pocket insulin charges alone (Cefalu et al., 2018). This puts a high financial burden on these individuals that rely on insulin to have a healthy, functioning life, and while this is true for the US, globally it is also challenging with one in two people that need insulin lacking the proper access (Ewen et. al, 2019). I am hoping that my STS research will help guide future implementations of medical technology. Without understanding how insulin pricing and policies got to where they are today, it is there is no guarantee that future technologies, such as soft exoskeletons, will not undergo similar paths.

Technical Topic

Many current exoskeletons employ the use of rigid bodies to accomplish additional mobility and strength. Some of these are stationary arms that assist in moving things (Gandolla, Gasperia, Longatelli, & Manti, In Progress) while others are used to rehabilitate use of a limb (González-Mendoza et al., 2022). These rigid body designs are very bulky and hard for the user to carry around, if at all. Additionally, the degrees of freedom that they support are usually limited to one or two. Degrees of freedom are the different ways that a limb is able to move naturally. Arms have a total of seven degrees of freedom, with three in the shoulder, two in the elbow, and two in the wrist. Each degree has its own range of motion, which is the angle the limb can move to, usually stated in how many degrees it can move from its resting position.

Figure 1

Table of Arm Degrees of Freedom and Range of Motion in Each Direction in Degrees

Joint	**Physiological ROM of β_i**
Base	Zero
Shoulder	Internal rotation (-90^0), external rotation ($+90^0$)
Shoulder	Abduction (-180^0), adduction ($+50^0$)
Shoulder	Flexion (-180^0), extension ($+80^0$)
Elbow	Extension (-10^0), flexion ($+145^0$)
Elbow	Pronation (-90^0), supination ($+90^0$)
Wrist	Flexion (-90^0), extension ($+70^0$)
Wrist	Abduction (-15^0), adduction ($+40^0$)

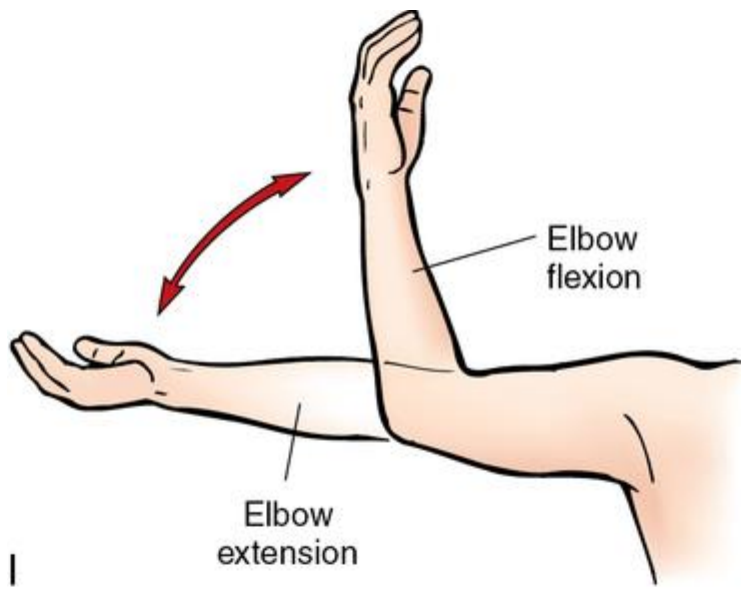
Note. Forner-Cordero et. al 2008. Kinematics and dynamics of wearable robots. Wearable robots: biomechatronic exoskeletons

The emerging field of soft/textile exoskeletons branches off from the rigid body exoskeleton design, and we are hoping to contribute to the research by constructing our own soft exoskeleton for an arm. Some conditions can cause reduced arm mobility, or complete loss of functionality entirely. Our exoskeleton is aiming to aid those with reduced arm mobility, with people with early ALS being a prime demographic. Rigid body exoskeletons are usually limited to only a couple degrees of freedom and are extremely bulky. With a soft exoskeleton, there is hope to have at least the same number of degrees of freedom and in a unit that the patient can actually wear around without it getting in the way of day-to-day functions.

As for a deliverable, we are aiming for our exoskeleton to have one guaranteed degree of freedom in the elbow. We are planning on providing extension/flexion as our supported degree of freedom, which allows the forearm to be moved up and down. Our prototype will be using Bowden cables in order to aid the movement of the user's arm. Bowden cables consist of a sturdy hollow tube with a wire running through the center of it. The wire can be pushed and pulled through the tube in order to achieve motion and accomplish tasks. A common use for Bowden cables can be seen on bicycles, where they are used for changing gears.

Figure 2

Motion of extension/flexion of the elbow

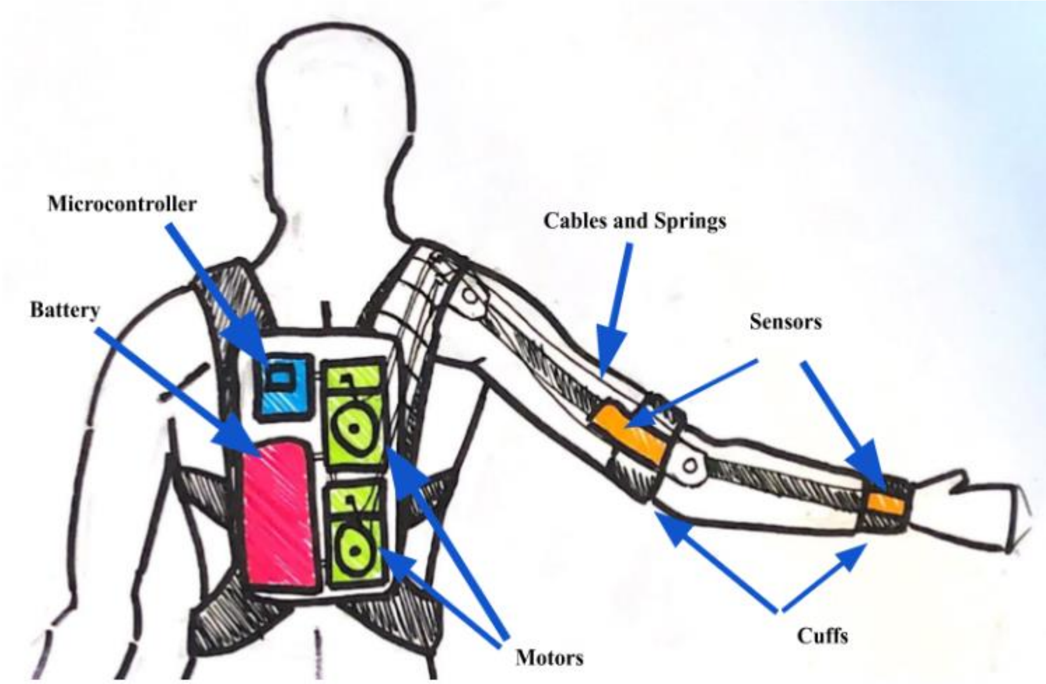


Note. Themes, U. F. O. (2016, June 22). Anatomy and physiology. Retrieved from Musculoskeletal Key website: https://musculoskeletalkey.com/anatomy-and-physiology/

We are using Bowden cables for the actuator, and will achieve actuation using a motor that will be housed in a small back pack that the user will wear. The motor will be battery powered and will use an Arduino to process information from the sensors on the arm. For sensors, we are using EMG and IMU sensors attached to the arm. The EMG sensor is used to sense when the user sends an electrical impulse to their muscle, indicating that they want to move it. The IMU will be used to keep track of the user's arm position. A rough drawing of our plan can be seen below.

Figure 3

Prototype Drawing



Note. Prototype drawing our capstone group drafted.

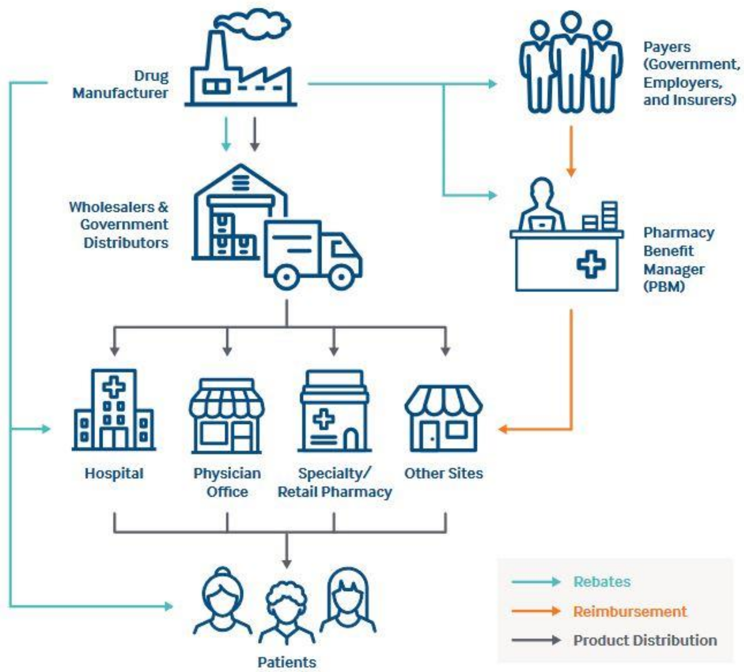
This technical project comes with some large challenges. The first challenge is that soft exoskeletons are a relatively novel field, and have not had a huge amount of research done yet. However, there are a few instances of Bowden cables being used in both lower limb and upper limb exoskeleton prototypes. While there certainly will be challenges, we believe that getting a prototype that can replicate the motion of the elbow will be achievable.

STS Topic

Type 1 diabetes is a genetic disorder that is caused when the pancreas is unable to produce insulin, or does not produce enough of it (CDC, 2021). Being diagnosed with type 1 diabetes used to be a death sentence due to there being no treatments for it. This is why the discovery of insulin isolation was such a life changing discovery, it gave type 1 diabetics a chance to live. Insulin therapy first became a valid treatment for diabetes when the isolation of insulin was accomplished in 1922 in a lab in the University of Toronto (Lewis & Brubaker, 2021). The University of Toronto had hoped to produce and provide insulin to those who need it at little to no cost once this discovery was made, but the labs in their health department quickly began to lack the output capability to meet the current demand at the time. (Beran et al., 2021) This need to outsource is one of the first steps that leads to the essentially oligopoly that we see today. My STS research will be aiming to look into the situations around decisions like these made by the main insulin manufacturers to see what sort of consequences these decisions have on those that rely on the product. Currently, the top 3 insulin manufacturers have had patents on their products that have lasted for about 100 years, since the discovery of insulin. (Hayes & Barnhorst, 2020). These patents have prohibited other manufacturers from joining the insulin production space, which allows for predatory choices to go unchecked from those main three since there is no competition offering competitive pricing or products.

Figure 4

Pharmaceutical Drug Development Flow Chart



Note. Glied, S., & Zhu, B. (2020). Not So Sweet: Insulin Affordability over Time. Retrieved from https://www.commonwealthfund.org/sites/default/files/2020-09/Glied_not_so_sweet_insulin_affordability_ib.pdf

Figure 4 shows the levels of the distribution of a pharmaceutical drug. As seen in the image, the drug manufacturer controls every aspect of the sale of the drug. This visual helps to show just how much control those main three manufacturers have on the industry. One of the reasons that insulin prices are so high is because of the population that needs it. Type 1 diabetics need insulin to survive, so they are more willing to pay money for insulin, because they don't have any other choices. Manufacturers are taking advantage of a vulnerable population in order to make profit (Rajkumar, 2020). Additionally, year after year the prices are getting higher, and while there can be some governmental influence in the short term, the root of the problem needs to be taken care of to solve it: “[We] need some systemic changes to try to address the problems that are driving drug prices higher in general, and insulin prices higher specifically” (Chesak, 2020).

After compiling information on the background and current situation of insulin treatment, I will apply that to an ethics framework analyzing the actions of the manufacturers. The ethics framework that I am using for duty ethics, otherwise known as Kantian ethics (Johnson, 2020). Immanuel Kant was a German philosopher that was the first to postulate this line of thought. Kantian ethics has states that an action is morally correct if it conforms to a list of duties which are meant to uphold respect for others. In short, Kantian ethics evaluates actions based on if it respects other people or not.

Although this topic can be greatly beneficial for newly released medical devices and technology, there may be some difficulties that may impact research. The policies and deals that the manufacturers make are much more difficult to find compared to things such as governmental policies that are implemented. With that being said, the intention with this research is to yield an analyzed history of insulin pricing and policies made by those involved with insulin manufacturing, as well as using an ethical framework to analyze what impacts these have on society as a whole.

Research Question and Methods

My research question is, How are necessary medical technologies distributed by their manufacturers and made available to those who need them? I will be conducting a historical analysis of insulin treatment from when it was discovered, to the present day. In order to gather this information, I will be using journal articles and documents that illustrate the discovery of insulin and everyone that was involved. Additionally, I will look into policies and deals that are made between those involved with insulin manufacturers that either change the dynamics of who manufactures insulin or deals that block others from entering the space. With this gathered information, it will allow a deeper understanding of what decisions lead to the current situation surrounding the access to insulin. Using the information learned from that analysis, I will apply it to an ethical framework to understand the social implications that come from price gouging, in this case, life-saving medicine on both the side of the manufacturers, and those diagnosed with type 1 diabetes. The ethical framework I am choosing to apply to this situation is duty ethics, otherwise known as Kantian ethics. Some critiques to this framework are that it fails to take into account any exceptions to the rules that might have to be made in order to take the morally correct path, such as lying to protect someone, as wells as the fact that it does not take into account the consequences of the actions taken (Schinzinger & Martin, 2000).

Conclusion

For my technical work, we are hoping to deliver a prototype soft/textile exoskeleton for an individual's arm, that supports two degrees of freedom. The target demographic would be primarily ALS patients that are beginning to, or have lost motor functions in their arm to improve their range of motion. For my STS research, I am planning on figuring out how the process of patenting and distributing newly discovered medical treatments affect the pricing and accessibility of that treatment over time. Researching this will help give insight into making the distribution and pricing decisions more equitable for future medical technology/devices. If successfully completed, the soft exoskeleton would be one of the life changing medical devices that we could implement the framework observed from the STS portion to make it available to everyone who could benefit from it, regardless of financial situation.

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