A DEGRADABLE SUTURE SENSOR AND WEARABLE DETECTION DEVICE TO MONITOR INJURY SITES FOR SPORTS MEDICINE APPLICATIONS

by

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A THESIS

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Sports injuries, specifically soft tissue injuries are very common and oftentimes require the use of sutures to aid in the rehabilitation of muscles, tendons, and ligaments that have been torn. Sutures are crucial to the field of sports medicine as they provide a mechanical basis to hold bodily tissues together after surgery. Following surgery, patients begin recovery by participating in postoperative orthopedic rehabilitation programs. These programs rely on qualitative approaches such as the patient's pain level and tissue swelling to guide the process, which results in suboptimal recovery outcomes. To address the lack of effective biofeedback for personalized rehabilitation, the sensitization of orthopedic implants has been performed to postoperatively monitor mechanical conditions at the surgical site. These new technology developments have demonstrated that sutures can be sensitized, allowing them to monitor surrounding conditions in real time. While these early proof-of-concept developments are encouraging, very few sensitized sutures have been developed thus far because of limited clinical practicality. This work focuses on the development of a biocompatible suture that contains wireless sensing abilities and is made of biodegradable materials. In addition to this, a wearable device capable of collecting data wirelessly from the sensor was fabricated.

Acknowledgments

I would like to thank Dr. Keat Ghee Ong and Kaylee Meyers for mentoring and leading me through this field of study. With their expertise, I was able to gain a deeper understanding of this topic. To Kaylee, thank you for always taking the time to walk me through procedures and supporting me in whatever way you could. To Dr. Ong, thank you for providing me with the ability to become an undergraduate researcher in your lab and for pushing me to expand my skills as a researcher and presenter. Additionally, thank you to Dr. Corinne Bayerl for dedicating your time to serve as my Clark Honors College representative. I had you as a professor for more than one course at Clark Honors College and enjoyed every single one of them. Your courses taught me so much and will remain some of my favorite ones that I have ever taken in my time at the University of Oregon. Lastly, I would like to extend another thank you to Dr. Mike Hahn for serving as the third member on my thesis committee.

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Introduction

Athlete Injuries and Current State of Rehabilitative Processes

In the United States, 33 million musculoskeletal injuries occur every year with half of them being tendon and ligament injuries (Wu et al., 2017). These soft tissue injuries most often occur through a variety of sports and are one of the leading causes of athlete injuries. These injuries occur due to the repetitive motions and traumatic injuries that athletes sustain over time. Often, the damage done to tendons and ligaments requires the surgical use of sutures to aid in rehabilitating the injury site. Surgical sutures, also known as stitches, are a type of thread that holds damaged soft connective tissues together by sewing the thread through an injured site. The sutures hold tendons, ligaments, and muscles together to close what the injury has torn. Many types of these sutures are versatile with some either being permanent or temporary within the body and composed of biodegradable or non-degradable materials (A. DeRouin et al., 2016). Current permanent sutures are made out of non-biodegradable materials such as polyester and polyamide while temporary sutures are made out of materials such as silk and monocryl that degrade within the body over time (Wu et al., 2017). Due to the variance in the types of severity and location of injuries large amounts of tensile forces can be acted upon the sutures which often leads to failure of the suture or tearing through the tissue. Therefore, monitoring of the injury site post-operation is vital to prevent tearing of the suture and to receive data that could improve current surgical techniques (DeRouin et al., 2016).

Additionally, the healing process of these injuries poses a challenge for specialists such as orthopedic surgeons and physical therapists. Furthermore, the methods used to create modern post-operative physical therapy rehabilitation plans are often inconsistent and rely on qualitative factors such as tissue swelling or patient pain tolerance. Basing rehabilitative exercises on such qualitative factors can prevent optimal healing outcomes due to the variability between the patient and the medical provider. In addition to basing rehabilitative exercises on qualitative factors, imaging techniques such as ultrasounds and MRIs are only able to provide little information regarding the healing status of an injury. As the number of participants in sports activities increases, so does the need for awareness and research regarding new treatment plans surrounding musculoskeletal injuries (Barroso et al, 2015). Sports injuries will continue to increase throughout the years which will result in a greater demand for improved post-operative physical therapy.

Current State of Suture Technology

Recently, new technology developments regarding suture accessories have demonstrated that they can be sensitized, allowing them to monitor surrounding conditions in real-time. Some studies have attempted to sensitize suture accessories such as suture anchors, pledgets, and buttons. Suture pledgets are small structures made out of silicone usually that help distribute force across a suture to reduce the risk of the suture tearing. On the other hand, suture buttons are small circular plastic or metal structures that anchor sutures to bones and dense tissues. Both of these suture accessories provide ways to strengthen the sutures in areas of the body that experience high levels of stress or tension and aid in preventing any additional tearing of tissue.

The studies that have tried to sensitize suture accessories have shown that they are capable of monitoring temperature, tension, and pressure at wound sites. In one study done by DeRouin and colleagues, they fabricated a wireless sensor that they then implanted in *ex vivo* models to test its functionality. In another study by Kalidasan and colleagues, they were able to implant their device in rat models and record data. Both of these studies highlight the possibility of applying this technology to different suture types and sizes as well as demonstrated the possibility of developing a wireless sensor that can detect different tensile forces at an injury site within the body.

While these early proof-of-concept developments are encouraging, very few sensitized sutures have actually been developed thus far. They are only applicable to surface injuries due to their non-biocompatibility and/or non-biodegradability. Additionally, most of these developments are only successful in benchtop settings and cannot be translated into clinical settings due to the external equipment needed to function. This limits their application to only surface wounds and injuries.

By fabricating a biodegradable sensor with the capability to sense stress at an injury site, the suture can provide important biofeedback aiding in the study of regenerative rehabilitation within sports medicine. This research aims to overcome the limitations of current suture technology by establishing the groundwork for a biodegradable suture sensor capable of sensing conditions, such as tension and stress, at an injury site and developing a compatible detection system to go along with it. The research described in this thesis was aided by graduate student, Kaylee Meyers.

Broader Implications of This Research

A majority of current suture sensors usually require additional surgery to remove them post-surgery due to their partial biocompatibility within the body. If current suture sensors are not surgically removed, scar tissue can build up around the remaining suture accessory. These conditions can considerably increase the possibility of unwanted secondary effects within the body. The creation of a biodegradable and biocompatible sensitized suture pledget will aid in the field of sports medicine as well as enhance rehabilitation time in athletes based on real-time data received from the injury site. Not only will it improve the field of sports medicine, but this research will also apply to the monitoring of a number of musculoskeletal areas, such as the anterior cruciate ligament (ACL), Achilles tendon, and mediate cruciate ligament (MCL), post-surgery.

The broader implication of this research is to provide and create improvements in regenerative rehabilitation for sports medicine applications. Current rehabilitation methods for sports injuries lack the accuracy and ability to directly suit the needs of an injury site post-surgery. As mentioned before, most current suture sensors require wires and batteries to operate which can lead to adverse effects within the body, and thus most of these suture sensors aren't compatible with the body. This research will improve current rehabilitative techniques to provide the most accurate information possible regarding the healing process of a site post-surgery. While sports medicine is the Primary target of this research, the same technology can also be applied to the general population.

Materials and Methods:

Fabrication of the Suture Sensor System

This research employed previously established fabrication processes used to create battery-free implants to fabricate this wireless suture sensor. Development of the suture sensor system began with the design of a wireless pledget sensor using Autodesk, a computer-aided drafting (CAD) software. The different components of the design were then 3D printed using polylactic acid (PLA). PLA is a biodegradable polymer that has been used in the production of orthopedic devices, implants, drug delivery systems, etc., (Vincent DeStefano et al., 2020). The degradation rate of PLA is influenced by many factors such as the size of the implant, the type of PLA used, and the chemical structure (Castañeda-Rodríguez et al., 2023). 3D printing was the method chosen due to its relatively quick fabrication process. Despite this though, 3D printing does not yield high-quality work, and as such it made it very difficult to print small designs such as the one needed. Since 3D printing is not always a viable option due to poor design detail, the process of injection molding was experimented with. Injection molding requires the use of a metal mold that gets heated before a material (typically plastic) has been injected into the mold. In this case, the material used was PLA. The first step in fabricating our mold was the uploading of our pledget design into a computer software within a computer numerical control (CNC) machine. This machine works by utilizing the automated control of tools such as drills and routers to mill the design into a metal, most commonly aluminum due to its ease of shaping. Once our suture pledget design was milled from aluminum, we tested it by injection molding PLA into it. In addition to injection molding, 3D prints of the pledget were fabricated and then fused via thermal fusion. Thermal fusion occurs when materials are melted and fused using pressure to form a single, solid piece. Below shows a prototype of the pledget sensor using thermal fusion.

After the fabrication of the pledget sensor body (Figure 1), an inductor-capacitor (LC) circuit pattern was created. A common technique to create an LC pattern is through the process of photolithography where a photosensitive polymer is exposed through a mask to leave a latent image of the pattern on a flexible substrate such as polyimide. Once the circuit was fabricated it was then fused between the PLA pledget design via thermal fusion at 200℃. Concentric holes on either side of the pledget were incorporated into the design so that the sutures could pass through the sensor. The figures below represent what the entire system will look like once fused. Figure 2 is provided by Kaylee and shows a breakdown of what the pledget sensor components will look like when fused together (Meyers, 2022).

Figure 1. Prototype of the battery-free orthopedic pledget sensor body using 3D printing and thermal fusion injection molding.

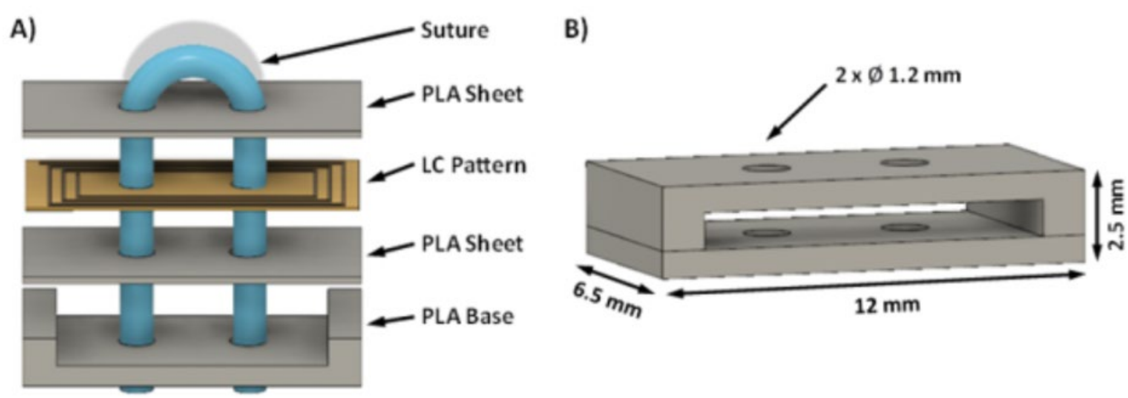

Figure 2. Pledget suture sensor components created via CAD with placement of a suture through the concentric holes (**A**). Dimensions of the suture pledget sensor created in CAD (**B**).

Sensor Functionality

The sensor responds to changes in suture tension or loading due to the distortion of the LC circuit. The LC circuit resonates at a certain frequency which is influenced by the capacitance and inductance of the circuit. The sensor can detect changes in the environment such as force because in response to force the circuit will bend, affecting the inductor and capacitor, effectively changing the resonance frequency of the sensor (Q. -A. Huang et al., 2016). The change in resonance frequency can be measured and used to characterize the changes in suture tension and loading and then can be wirelessly transmitted to a coil antenna.

Mechanical Testing (Tensile strength)

To determine the functionality of the pledget sensor, Kaylee performed a tensile load study via a mechanical testing system. To reduce the effects of plastic deformation on results a 110% pre-stress was applied to the 3D printed pledget sensor. From there, a load was applied to the pledget sensor starting at 2 N and was increased to 12 N by a step of 2N each time. This was done a total of three times. The suture used for this study was made of polyester, a non-degradable material.

Wearable Detection System

The wearable detection system consisted of modifying a Nano Vector Network Analyzer (VNA) circuit board to be compatible with a Bluetooth Low Energy (BLE) Chip (Figure 3). The Nano VNA was chosen due to its ability to wirelessly measure sensor signals and because of its relatively small size. Once the circuit board was stripped from its original casing, a BLE Chip was attached to the Nano VNA circuit board via Printed Circuit Board (PCB) soldering. The BLE Chip had to be programmed to send the data picked up from the sensor to the computer app. Attached to one of the circuit board's ports is a coil antenna made by wrapping a copper wire around a 3D-printed antenna body. The size of the antenna has a big impact on the detection of the sensor and thus its size was matched to the size of the sensor. When the antenna is placed over where the sensor is in the body it will pick up a signal from the sensor and send it to the computer app.

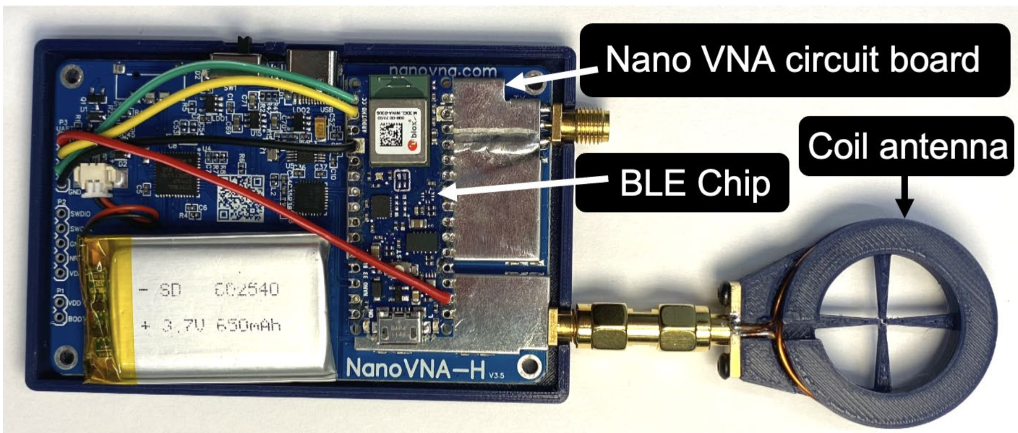

Figure 3. Wearable device model with coil wire antenna attached.

Operation of the Wearable Detection Device

As stated previously, within the sensor is a LC circuit pattern that is integrated within the pledget. When the antenna of the wearable detection system is placed over the area where the sensor is embedded within the body, a signal is picked up by the device and then sent to a computer app via the BLE Chip. The wireless data from the sensor is represented as resonance curves within the computer app. A resonance curve is a graphical representation of the response of a system to certain frequencies. The wearable device can create resonance curves that can show changes in the amplitude or shift in the resonance curve. For this research, changes in the shift of the resonance curve apply more to the sensor as shifts are indicative of changes within the external environment.

Wearable Detection System Case

Once the components of the wearable detection system were developed, Autodesk was once again used to develop a case that would house the system. The case was 3D printed from PLA and based on the design of the case the Nano VNA originally came in. This design made sure to include the following, an on/off switch hole, an LED indication hole for knowing if the device is on/charging, and a USB port for charging. In addition to the PLA casing, Velcro strips were then attached to the back of the case. This was done to ensure the wearable detection device would be compatible with standard orthopedic braces/supports (Figure 4).

B)

A)

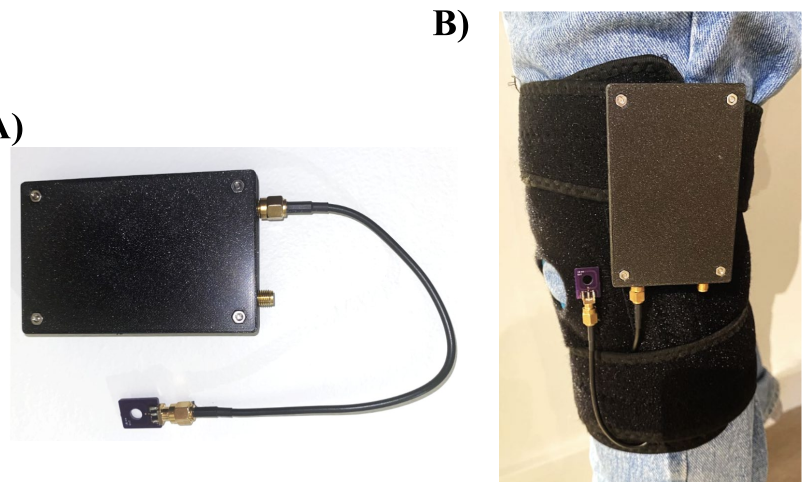

Figure 4. The wearable device enclosed within a 3-D printed PLA case (a) attached to a standard orthopedic knee brace (b).

Computer App

A computer app was developed using a software development called Visual Studios. The initial computer app features the ability to visually show the data through graphs, measure/reset background settings, and sweep for a range of frequencies among other abilities (Figure 5). A more friendly version of the computer app will be designed so that healthcare professionals and patients will have a better understanding of the data.

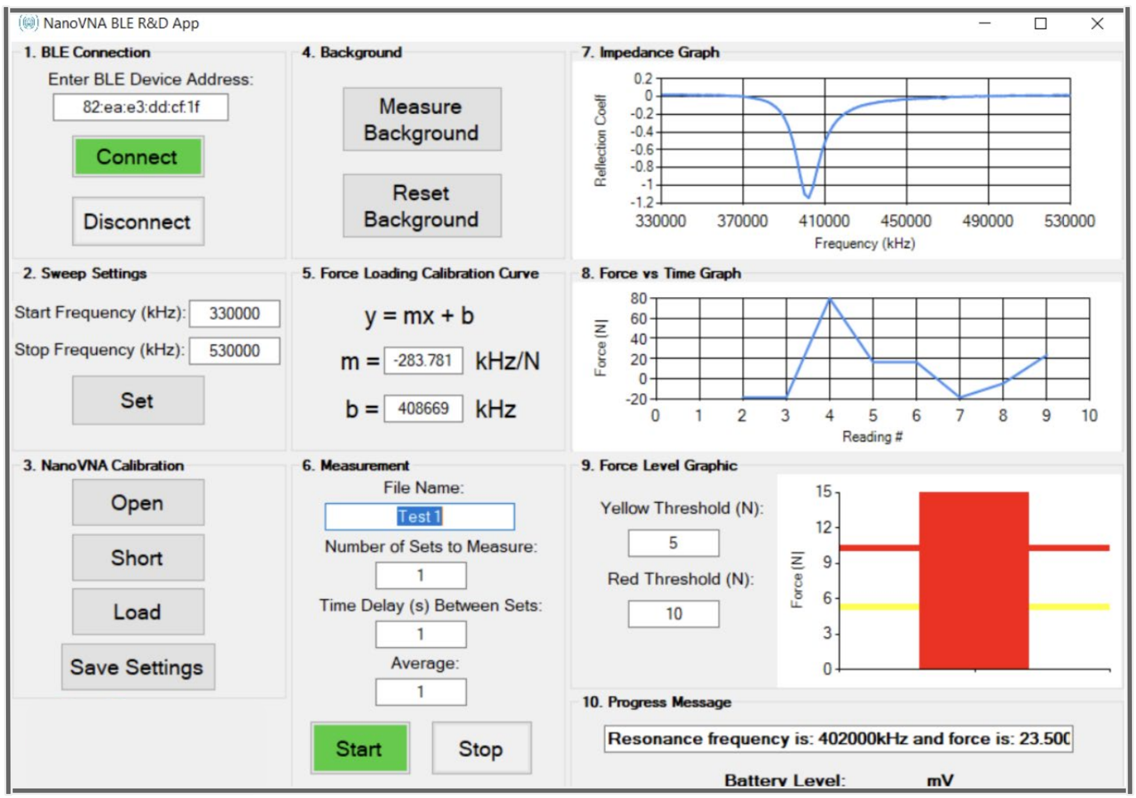

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Figure 5. Image of the computer app settings

Detection Distance Within Skin and Alignment

As part of the characterization tests, the sensor's ability to send signals through varying tissue thicknesses was determined. To do this, a synthetic gelatin called ordnance gel was used to mimic tissue due to its ability to simulate living tissue and its use in ballistics testing (Mendez-robst et al., 2010). Various thicknesses of the synthetic gelatin were placed between the sensor and the detection system's antenna to characterize the strength of the signal. Additionally, sensor alignment was characterized in two directions: radial and tilt. The radial direction was defined as the movement of the sensor in the horizontal plane while the tilt direction was defined as increasing the angle between the antenna and the sensor. A tilt angle was created by tilting the antenna, which was fixed by a clamp, at varying angles measured by a protractor for accuracy.

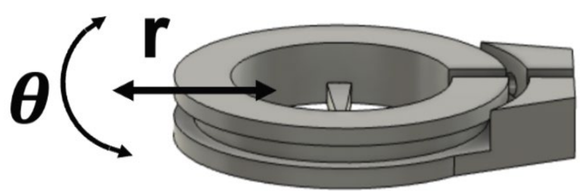

Figure 6. Layout of the coil antenna where r is the radial direction and θ is tilt angle.

Discussion and Results

Fabrication of the Suture Sensor System

When injection molding was used to fabricate the prototype, the results were promising, as the edges of the mold seemed to seal together fairly well. This was not the case every time though and oftentimes the sides of the pledget design would get stuck in the mold, making it difficult to remove. While injection molding could be a viable way to create the prototypes, more work still needs to be done to make the results of this process reliable a majority of the time. 3D printing followed by thermal fusion seemed to be the best way to fabricate the prototype as the edges fused well and there were no issues related to removing the prototype afterwards.

Tensile Strength

The data from these tests were provided by Kaylee and helped characterize the pledget sensor's ability to bear force and its sensitivity. In Figure 7, the data showed a linear relationship between the sensor's resonance frequency and loading and unloading. In Figure 8, the sensor was exposed to repetitive loading to test for changes in the sensitivity of the pledget sensor over time. The results showed that repetitive loading did not affect the sensitivity of the pledget sensor over all trials. This is an important finding because the final pledget sensor will need to be able to perform under the repetitive motions of ligaments and tendons.

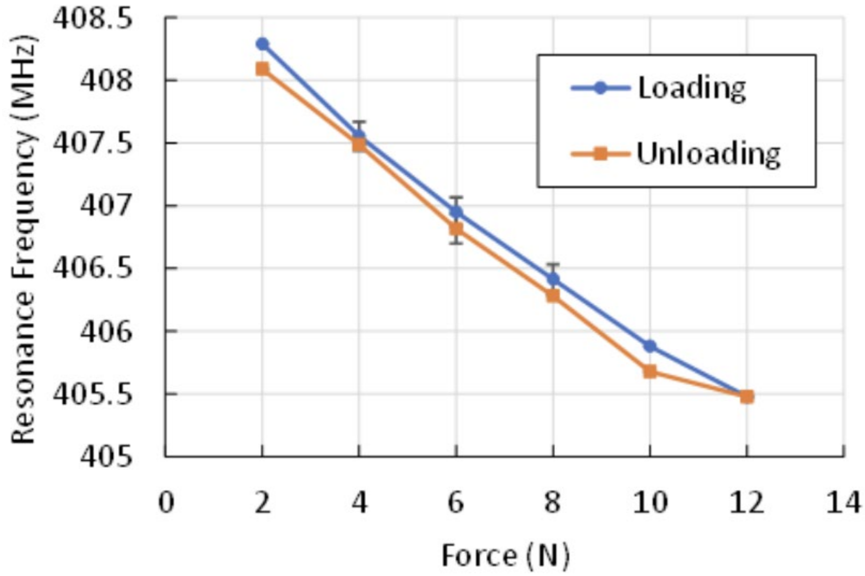

Figure 7. Sensor resonance frequency during loading (blue) and unloading (orange)

The standard deviation is represented by error bars (n = 3). Sensor resonance frequency decreases linearly with both loading and unloading.

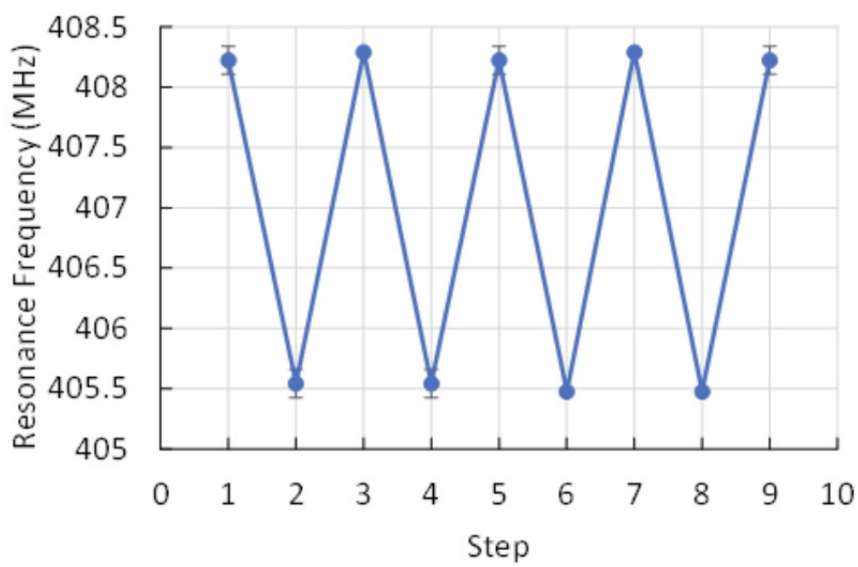

Figure 8. Sensor resonance frequency during constant loading from 2N to 12N.

The standard deviation is represented by error bars (n = 3).

Detection Distance

To determine the effect of tissue thickness on the resonance frequency of the sensor, three trials were conducted where the wearable device was used to measure the frequency of the sensor through varying tissue thicknesses. As previously stated, ordnance gel was used to mimic tissue and increased in thickness by 2 mm up to 10 mm every trial for a total of three trials. The average of the resonance frequency and real reflection coefficient values over all trials were calculated and are shown in Figure 5, respectively. The resonance frequency is being monitored to correlate with suture tension. The real reflection coefficient tells us how well the antenna can pick up the signal from the sensor. The graph below shows that as tissue thickness increases, the real reflection coefficient begins to decline, and resonance frequency stays relatively constant until it dips off when tissue thickness is 8 mm. This makes sense because as the distance between the sensor and antenna increases, the signal would have to travel farther and thus leading to a decrease in the ability of the antenna to pick up the signal. Therefore, there is a logarithmic decrease in the real reflection coefficient values. The resonance frequency dropped at a thickness of 8 mm most likely due to a distortion of the signal which makes it difficult to accurately measure the sensor's resonance frequency and thus the suture tension.

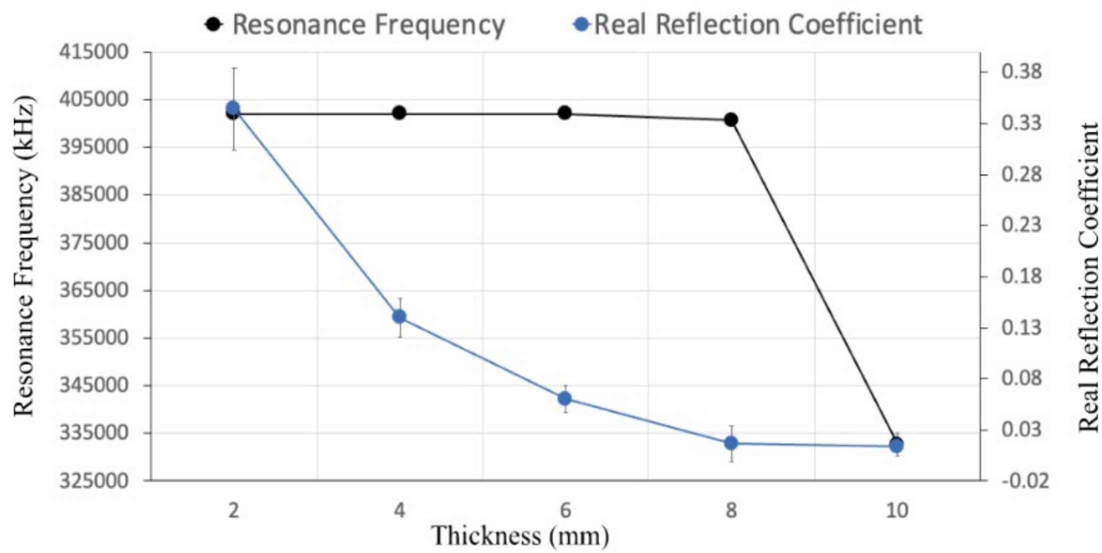

Figure 9. Effect of tissue thickness on resonance frequency and the real reflection coefficient

As tissue thickness increases from 2 to 10 mm (*n* = 3) the real reflection coefficient decreases and resonance frequency drops at a thickness of 8 mm.

Alignment

The results from the alignment trials are shown below in the following figures. In Figure 10, the tilt angle was increased by 10 degrees for each trial up to 50 degrees. Three trials were done for this characterization test and the average values are graphed below. As the tilt angle increased, the resonance frequency stayed relatively constant until 30 degrees when it completely dropped down to 330000 kHz. From there, the resonance frequency remained at that kHz to when the tilt angle measured 50 degrees. This testing method proved to be consistent as there was very little standard deviation as shown by the error bars.

For the radial distance (Fig. 11), the antenna was moved horizontally away from the sensor in 1 mm increments. Three trials were run, and the average values of the variables are shown in the graph below. The resonance frequency had a downward trend until around 7 mm where it completely dropped off until 9 mm. According to the data, around 7 mm is the limit for reliable readings from the sensor. This most likely happened because as the distance between the sensor and antenna increased, the coupling between the two was affected causing there to be a change in measured impedance. Thus, if the impedance of the sensor is affected, then the sensor's resonance frequency will shift. There is also a logarithmic downward trend of the real reflection coefficient. This is because when the distance between the sensor and antenna is increased, the amplitude of the signal that is transmitted to the antenna is decreased as it travels over the distance.

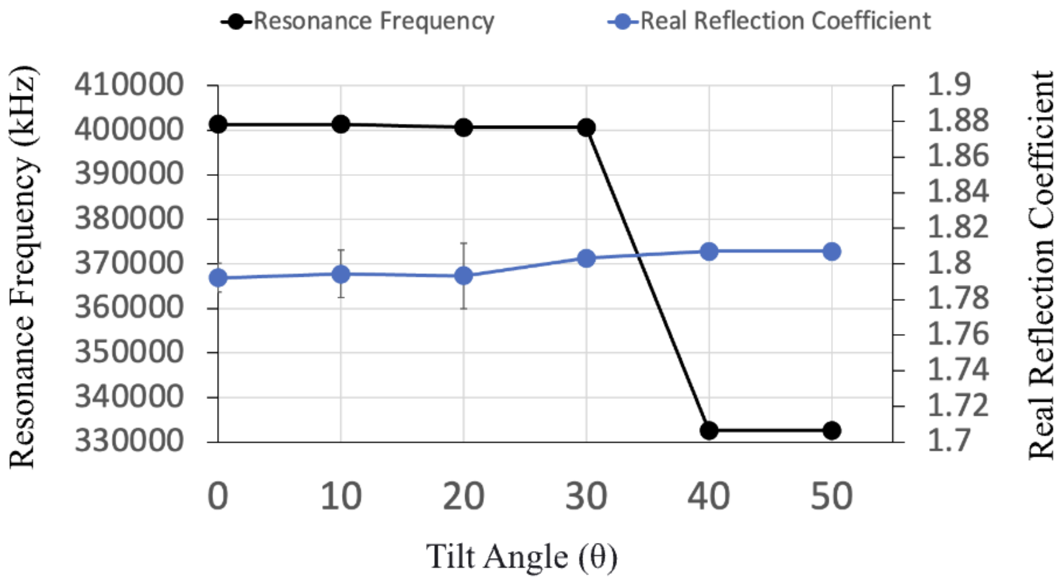

Figure 10. Effect of tilt angle on resonance frequency and the real reflection coefficient

As the tilt angle increases from 0 to 50 degrees (*n* = 10) the real reflection coefficient increases slightly while resonance frequency decreases.

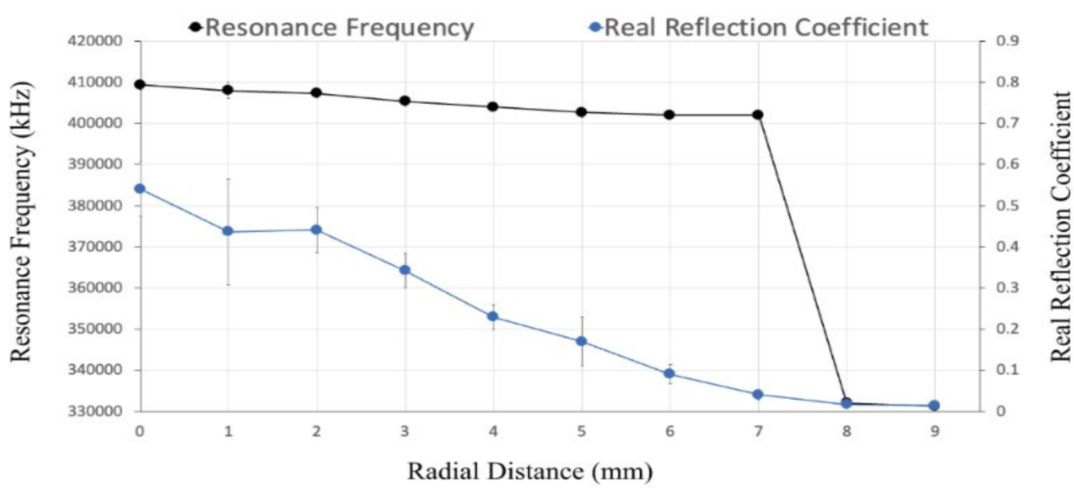

Figure 11. Effect of radial distance on resonance frequency and the real reflection coefficient

As radial distance increases from 0 to 9 mm (*n* = 3) the magnitude of the real reflection coefficient and resonance frequency decreases.

Future Direction

The results of this research indicate that sensitizing suture pledgets have the capability to provide relevant information regarding the development of personalized rehabilitation programs. Our device has shown that it is possible to measure the amount of tension/stress at a specific site as well as the status of the suture, though there is still work to be done.

The miniaturization of the wearable detection device is one of the next steps that will progress this work. Minimizing the size of the wearable detection device will make it more comfortable for the patient and will reduce any potential disturbance during data collection. Additionally, the smaller size will provide for easier storage, use, and transportation.

In regard to the computer app created by Kaylee, a simplified version of the app will be designed for patients and healthcare professionals so that they are able to easily navigate the data. Additionally, a phone app is currently being designed to provide more flexibility for the users.

Further work for the pledget sensor includes the completion of making the pledget sensor fully biodegradable. This begins with the development of the LC circuit coil design. The most common way that coil designs are produced is through the method of photolithography. An issue arises with this as the coil design must use a degradable conductive metal for the sensor to make the device fully biodegradable. Such metals that would be taken into consideration would be zinc and magnesium. The decision between which metal to be used will be difficult as zinc has a slower degradation rate within the body but has a much lower conductivity. On the other hand, magnesium has a higher conductivity but degrades twice as fast as zinc in the body. These metals would have to go through various tests and would need to be outsourced from a different company as the current metals we have to sputter coat or electroplate, gold, and titanium are expensive to work with and are nondegradable compared to zinc and magnesium. Sputter coating and electroplating are different processes in which a thin layer of material is deposited onto a substrate. Sputter coating does so by bombarding a material with protons that cause atoms to eject onto the surface of the substrate and electroplating uses an electric current to deposit a thin layer of metal onto the substrate (Merlo & Léonard, 2021).

Furthermore, research into developing an electrically conductive suture will be included in the future. Tentative plans include making the suture from a biodegradable material such as silk and then coated with an electrically conductive polymer. As soon as a prototype of the suture sensor system is fabricated, its full functionality will be tested to ensure its mechanical strength, biodegradability, and biocompatibility. Finally, once the prototype has been fully developed, the next step would be to implant the suture sensor within rodents subcutaneously to validate its functionality and degradation profile within animal tissue.

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