AN UPDATED TELEMETRY SYSTEM FOR RELIABLE POWERING IN VIVO COUPLED TO A TABLET COMPUTER

by

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DEDICATION

This thesis is dedicated to my parents Diane and Gary Ouellette.

**Thanks Dad for turning me into a do-it-yourselfer,
and for sharing with me the satisfaction of a job well done.**

And Mom, thanks for everything; I can’t say in words everything you taught me.

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ABSTRACT

Accurate and reliable *in vivo* measurement systems for orthopedic applications will allow a better understanding of native joint loading, gait patterns, and changes during healing and tissue regeneration. Robust and reliable telemetry units with an implantable transmitter and data acquisition software are necessary to insure long-term measurements. It was the goal of this study to update the current implantable telemetry system. Updates included using a new tablet computer for increased rates of data acquisition and encasing transmitters in a new waterproof casing.

Software was developed using Labview on a Windows based Acer Iconia Tab. The Labview program allowed the user to save data to a measurement file and view the data in real time. The increased processing power of the tablet resulted in an increase in data collection rates from 29Hz to 87Hz. Interfacing the tablet computer with the telemetry system required the use of a RS-232 protocol to USB adapter. The newly developed tablet computer system was also used for load measurement collection during the most recent *in vivo* study.

In order to insure transmitter function *in vivo* it was necessary to characterize the factors affecting transmission *in vivo* and develop transmitter and power coil designs that operated reliably. In the past implantable transmitters were noted to operate properly during bench top testing, but often failed after being placed *in vivo*. The two factors studied that limited power transfer to the transmitters were immersion in an aqueous environment and exposure to elevated temperatures. An aqueous environment significantly decreased power transfer by 11.9% (p-value = 0.014) relative to testing on

the bench top. Additionally, a temperature increase to 40°C decreased power transfer by 6.2% (p-value = 0.017) when compared to power transfer in room temperature air.

A solution that restored transmitter function required encasing transmitters in a new waterproof casing. Different casing designs made of silicone and semi-solid triglycerides were developed and tested on the bench top. Two different casing designs were used during *in vivo* testing and implanted into test animals. One casing design insured transmission while the other separated *in vivo* and did not facilitate transmission.

1 INTRODUCTION

Implantable sensors coupled with telemetry systems have been used as research tools throughout the medical field. The fields of Orthopedics, Pharmacology and Toxicology, Neuroscience, and many others have used implantable sensors and telemetry to monitor a variety of *in vivo* information. The main use of medical telemetry in orthopedics has been as a research tool, but real-time *in vivo* information would be an invaluable clinical tool. Physicians could make more informed individualized decisions for a patient if they had access to *in vivo* data. Implantable sensors and telemetry offer these advantages, but challenges remain in moving many of these systems into clinical practice.

Telemetry systems have been used in animal models to monitor physiological signals to help with drug assessment and to evaluate seizures. A telemetry unit has been used in mice to monitor heart rate for drug toxicity studies [1]. The animal was fitted with a telemetry system that monitors heart rate to allow measurement collection without handling the animal. A drug can be administered to these animals and heart rate can be monitored without introducing stress as a confounding factor. Additionally, telemetry units have also been used to monitor rat electroencephalograms (EEGs) in order to study seizure progression and epilepsy [2]. In both cases telemetry allowed data collection in a more natural environment to better understand the effects of drugs or a disease state.

In the field of orthopedics implantable sensors have been used in order to understand both basic processes such as load induced bone remodeling [3, 4] and clinically relevant measurements such as forces on implants [5-7], loads affecting spinal fusion rates [8, 9], and loads on native bones [10, 11]. Additionally, better total joint replacement hardware has been developed with the loading information collected by the use of telemetry coupled with instrumented total joints [12-14]. Loads collected in an *in vivo* setting can also be used to validate current measurements collected using gait analysis and kinematics [15-17].

Telemetry and *in vivo* sensors offer opportunities in personalized rehabilitation. Real time *in vivo* information could help a physician to make better treatment decisions for a patient and personalize the rehabilitation process. Currently all patients who require orthopedic surgery are generally prescribed similar post surgical therapy regardless of age, size, and activity level; even though few studies have been performed to assess the long term benefits of current post surgical therapy routines [18]. Better therapeutic standards could also be developed as a result of the insights gained by monitoring healing under a variety of conditions. [8, 19].

An accurate knowledge of *in vivo* forces will provide the basis for alternative regenerative approaches and tissue engineering techniques. Osteoarthritis is a common, and painful, disease of the synovial joints. It affects between 12-15% of people between 25-74 years of age and osteoarthritis is radiographically observed in over 70% of the population over the age of 65 [20]. Osteoarthritis is characterized by the breakdown of cartilage in joints and once the cartilage has been destroyed the bone surfaces touch each other leading to pain and inflammation of that joint. Total joint replacement is the standard of care to eliminate pain and return range of motion to the patient. However, treatment with total joint replacement has drawbacks and it would be better to regrow specific areas of a patient's cartilage instead of replacing the entire joint.

In vivo sensors can be used to provide measurements in order to overcome some of the challenges associated with cartilage regeneration. Cartilage tissue engineering is difficult due to the need to reproduce the exact structure of the tissue and the fact that cartilage does not regrow spontaneously [21]. Cartilage is a highly organized tissue and requires appropriate loading and scaffold structure in order to grow into its original shape with its original organization [22]. Sensors and telemetry can be attached to scaffolds for tissue engineering to accurately characterize joint loading during cartilage growth[23, 24]. These scaffolds can be seeded with cells to grow cartilage *in vivo* and once cartilage regeneration is better understood such "sensate" scaffold systems can be used as feedback to allow a patient to monitor loading of the cartilage during rehabilitation.

For tissue engineering repair and other orthopedic applications, one commonly used sensor is a strain gauge [25-27]. Strain gauges are small, inexpensive, robust, and sensitive to very small deformations. They can be readily attached to orthopedic implants or musculoskeletal tissues to measure forces and moments [28-30]. They can also be attached to scaffolds to monitor joint loading during tissue regeneration and repair [23, 31, 32]. Strain gauges allow real-time, *in vivo* strain monitoring and, with precalibration, can provide load information.

In order to collect measurements from implantable strain gauges they must be connected to signal conditioning electronics and a separate or integrated transmitter unit.

A telemetry system used for *in vivo* measurement collection consists of measurement circuits, a transmitter, and an inductive coil to power the circuitry [33]. Many challenges remain in designing and manufacturing these telemetry systems so that they are robust and reliable [34]. Although, implantable transmitters have been used to measure and transmit *in vivo* data for several years [24], these systems have not always been dependable and are often expensive because they must be custom made. This currently limits the extensive use of implantable transmitters and consequently very little direct measurement information has been published [35].

Powering of the transmitters represents one major challenge for the development of robust implantable systems. Many research studies and some clinical systems utilize an internal battery. This may be acceptable if the device can be large or has a short implanted lifespan. However a small device that is expected to last the lifespan of a person must utilize another source of power. One option used in orthopedic implants and potentially in retinal implants is the use of an external power coil [36, 37].

In order to power long term implants, external power coils have been utilized and power is supplied through a wireless transcutaneous source. This can be done by magnetically coupling an external power source with a magnet wire coil to an implanted coil that powers the transmitter’s electronics. These types of systems can provide constant power allowing continuous and extended monitoring of *in vivo* measurements. Such coils have been proven commercially affective in recharging pacemaker batteries as well as supplying power to total artificial hearts [38-40].

The goals of this study were to upgrade the telemetry system used in previous orthopedic animal studies to allow more reliable *in vivo* measurement collection. This goal was achieved by updating the current data collection device and ensuring sufficient power transfer to implanted transmitters. The newly developed data acquisition software was developed using Labview and was designed to run on a tablet computer. It allowed increased rates of load measurement collection and a more advanced user interface. Additionally, *in vivo* factors that affected power transfer to the transmitter were examined. These included temperature variations, environmental conditions and power coil design.

The results of this study will allow future *in vivo* measurements to be more reliable and will support experiments testing additional hypotheses. The upgrades to the telemetry system will insure stable reliable powering of the transmitters and allow increased rates of measurement collection. In this study ideal power transfer was achieved by adjusting the power coil configuration and encasing the transmitter unit in a specific type of waterproof casing. This new type of casing prevented water from surrounding transmitters to allow for more efficient power transfer. The new data collection system will also be easier to use, provide more visual information to the user, and maximize measurement collection from the transmitters.

2 MATERIALS AND METHODS

2.1 Overview

2.1.1 In vivo measurement system and telemetry components

The telemetry system (Microstrain Inc., Burlington, VT) used for this research was custom-made to allow *in vivo* load measurement collection and transmission. The overall system consists of an implantable transmitter, a power coil and function generator for power, and a receiver unit connected to a computer for data analysis. (Figure 1) The implantable transmitter contained an onboard signal conditioning system, a pickup power coil, and a radio frequency (RF) transmitter. The transmitter was also modified to use a magnetic switch for *in vivo* baseline balancing. (Figure 2)

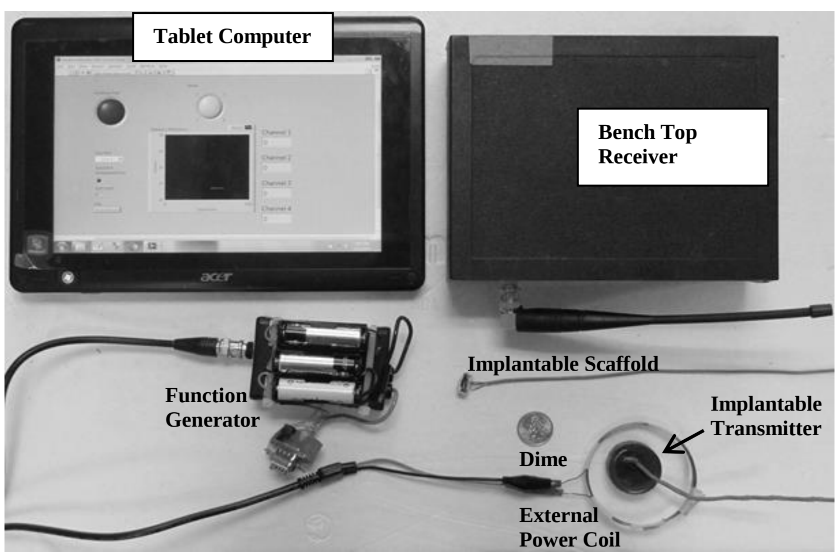

Figure 1 – Components of the telemetry system. The transmitter, connected to the scaffold, was implanted *in vivo.* The function generator and external power coil supplied power to the transmitter via magnetic coupling. The bench top receiver was connected to the computer for measurement collection and analysis.

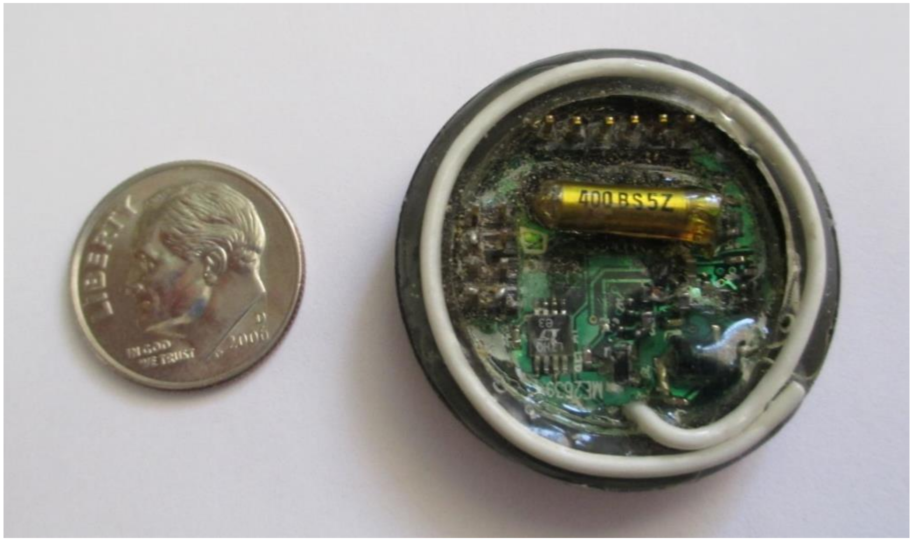

Figure 2 – Implantable transmitter used with strain gauges to monitor joint deformations. The transmitter consists of signal conditioning electronics, a RF transmitter unit, and a zero baseline switch.

The implanted transmitter was powered by magnetic coupling. An external power coil made of magnet wire was placed around the transmitter during data collection and a function generator supplied an alternating current signal to the external coil (Figure 3). Through magnetic coupling the signal from the external coil was transferred to another magnet wire coil surrounding the transmitter. In this way, the transmitter could continuously transmit data as long as the external coil was positioned properly and supplying power to the transmitter.

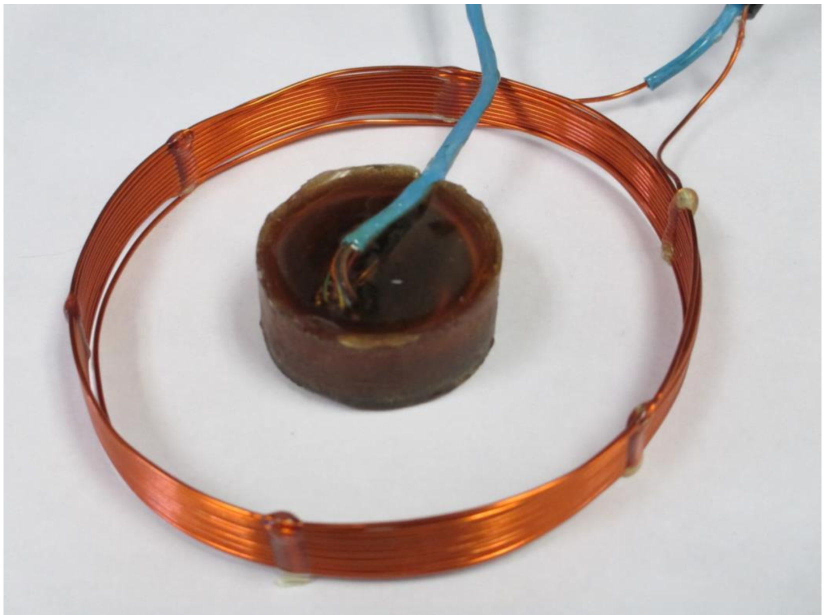

Figure 3 – An external power coil placed around a transmitter. A function generator was connected to the external coil and sent an alternating current signal through the coil. Another coil within the transmitter picked up the signal from the external coil through magnetic coupling to power the transmitter.

The transmitter sent data to a bench top receiver (Microstrain Inc., Burlington, VT) which was connected to a computer for measurement storage and data analysis. Previously a Dell handheld computer was used for this purpose. As part of the current research project a tablet computer was used to upgrade the overall system. Both platforms utilized Labview as the programming language, but a completely new program designed for the Tablet-PC was written from scratch. Limited amounts of code could be reused from the handheld computer because it was originally written in an abridged version of Labview called the Mobile Module.

2.1.2 Sensor and telemetry coupled with an implantable scaffold for tissue engineering

Implantable scaffolds can be used to increase the understanding of how loads affect tissue engineering when equipped with sensors to monitor joint loading during tissue repair. Stem cells can be differentiated into cartilage cells after being placed on scaffolds and will form joint tissue when appropriate loads are applied. Loading was monitored by attaching strain gauges (Vishay Measurements Group, Raleigh, NC) to the polybutylene terephthalate (PBT) scaffolds and gauges were calibrated prior to implantation of the scaffolds. A strain gauge is a passive device that changes its resistance in response to a deformation change. Implanted scaffolds with strain gauges can monitor tissue deformation, and with pre-calibration, report loads placed on a native joint (Figure 4). The strain gauges on the 'sensate' scaffolds were connected to the implanted transmitter by a mini connector (Digi-Key Corporation, Thief River Falls, MN) and load measurements were relayed to the computer by the telemetry system (Figure 6, Figure 7).

Figure 4 – A variety of different types and sizes of polybutylene terephthalate (PBT) scaffolds used for cartilage tissue engineering. Strain gauges can be attached to these scaffolds to monitor deformation change *in vivo*.

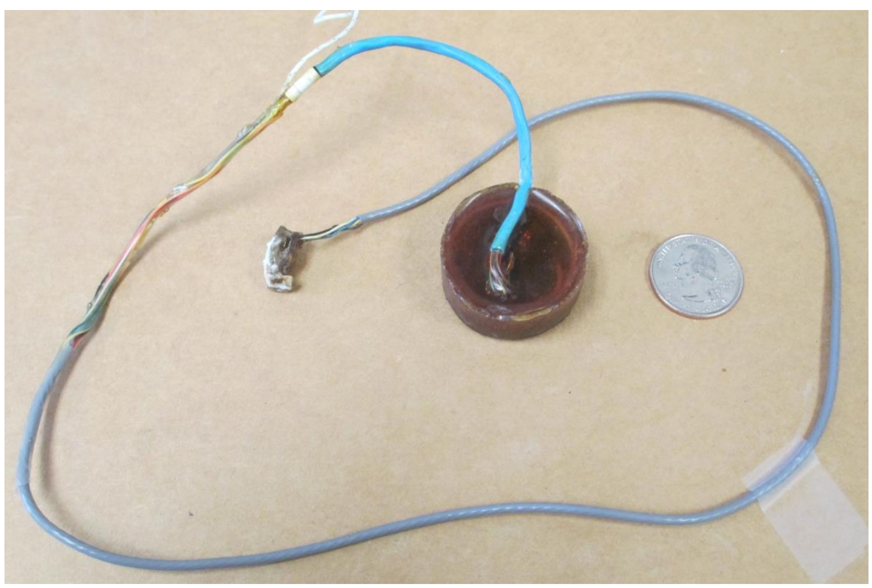

Figure 5 – A scaffold for tissue engineering connected to a transmitter. Both the scaffold and transmitter are implanted; the wires are connected and then also implanted.

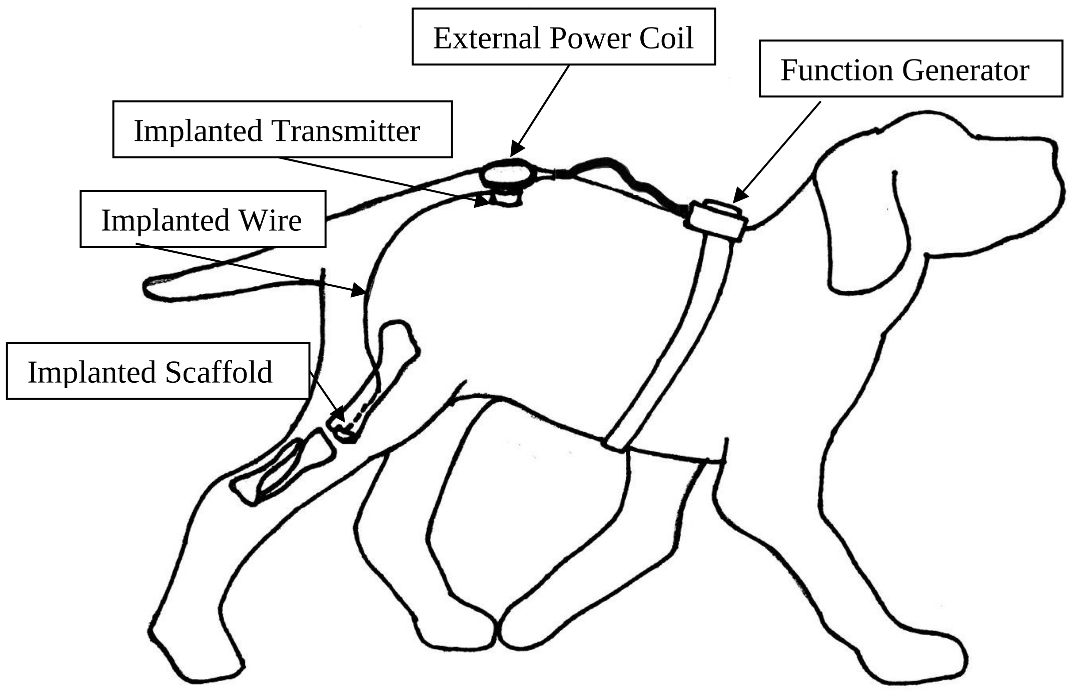

Figure 6 – Implantable scaffold and transmitter placement in a canine test animal.

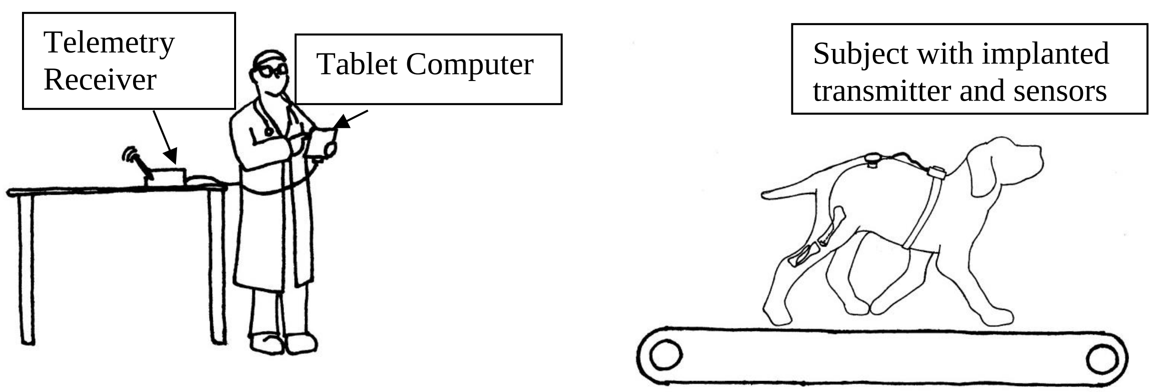

Figure 7 – Representation of the setting in which measurements from an implantable scaffold in a canine test animal were collected.

2.2 Design of a new strain monitoring system on a Tablet-PC

2.2.1 Table-PC capabilities compared to a former handheld computer system

Moving to a tablet computer significantly increased the capabilities of the load monitoring system when compared to the handheld computer. The tablet selected (an Acer Iconia Tab) could be converted into a netbook by use of an attachable keyboard (Figure 8). The Acer tablet ran Windows 7 Home Premium using an AMD C-60 1.00 GHz processor with 2GB of Random Access Memory (RAM). The software was developed using Labview 2009 (National Instruments, Inc, Austin, TX) and was programmed directly with the tablet computer.

Figure 8 – Acer Iconia Tab in 'laptop' mode with an attachable USB keyboard.

The Acer Iconia Tab offered many benefits compared to the Dell handheld including:

1. The processesor of the Acer tablet was over twice as fast as the Dell handheld (Acer Tablet – 1.00GHz, Dell – 416MHz) and had 32 times more random access memory than the handheld (Acer Tablet – 2GB, Dell – 64MB). However, the Acer Tablet did have half the amount of hard drive storage space compared to the Dell (Acer Tablet – 32MB, Dell – 64MB). In spite of the reduced storage space, the tablet could easily transmit data to the lab server using a Wi-Fi connection, increasing the effective storage capacity.
2. The Acer Tablet ran Windows 7, which is familiar to many users. The tablet allowed a user to perform data analysis on the tablet directly, access the laboratory server, or use the tablet as a fully functional computer.
3. A full version of Labview 2009 could be utilized while only the limited Labview Mobile Module could be used to program the Dell handheld. Software developed for the Dell had to be written on a desk top computer and ported to the handheld. In contrast all tablet programming and troubleshooting was performed directly on the tablet computer.
4. The Acer tablet has two USB ports to interface with the receiver or other devices as well as an attachable keyboard. The Dell handheld had a single compact flash slot configured as a serial communication port.
5. The Acer Tablet had 4 hours of battery life in highly demanding video applications and up to 8 hours for low demand activities. At the time of the

handheld to tablet upgrade the Dell handheld battery was only able to provide power for 15 minutes of continuous use.

2.2.2 Interface between the Tablet-PC and telemetry system

The telemetry system interfaced with the Tablet-PC by use of RS-232 serial port communications. The telemetry receiver has an RS-232 output that was attached to the Tablet-PC through a USB connection. The receiver sent data in packet form and each data packet contained 11 bytes of information from the transmitter (Table 1). Each data packet began with a header byte with a value of 255, and included data from the four transmitter channels, as well as two check sum bytes.

Table 1 – Data contained in one data packet from the telemetry receiver

Header 255	Channel 1 MSB	Channel 1 LSB	Channel 2 MSB	Channel 2 LSB	Channel 3 MSB	Channel 3 LSB	Channel 4 MSB	Channel 4 LSB	Checksum MSB	Checksum LSB

The value of a single channel was calculated by multiplying the most significant byte (MSB) by 256 and adding the value of the least significant byte (LSB) (Equation 1). The checksum values were used to determine if the data packet received was valid. The value of the data channel bytes were summed and compared to the checksum bytes (Equation 2). If the sum did not equal the checksum value then the packet was discarded since an error occurred during transmission.

Equation 1 – Equation to solve for a single channel strain value based on the data stored in the received bytes.

$$CHn = MSBn * 256 + LSBn$$

Equation 2 – Equation to determine if a valid data packet was received. If this equation was not true the packet was discarded.

$$Checksum(MSB) * 256 + Checksum(LSB) \equiv \sum_{N=1}^{4} ChN(MSB) + ChN(LSB)$$

The RS-232 protocol used by the telemetry receiver is now considered a legacy device. As such the Tablet-PC could not interface directly with the receiver. A commercial RS-232 to USB converter (Tripp Lite, Chicago, IL) was used to allow information from the receiver to be sent to the tablet computer. The drivers for the converter were automatically installed when first connected to a Windows based computer. Labview then initialized the serial port and handled all data received from the emulated RS-232 serial port.

2.2.3 Software design

The software was designed in Labview to facilitate strain measurement collection, initial analysis, data storage, and data visualization (Figure 9). The software performed five main functions; initialization, data collection, initial strain analysis for each channel, a valid data retrieval check, and data display (Figure 10). Upon initialization, the serial port continuously received data and the data was scanned until a complete data packet was collected. Once a full packet was found the four strain channel values were calculated. If a complete and reliable data packet was collected the data was displayed to the user and stored for later use. Once 500 data points (approximately 5 seconds) were collected the tablet automatically saved the data to a text file. This process continued until the user pressed the “Stop and Save” button.

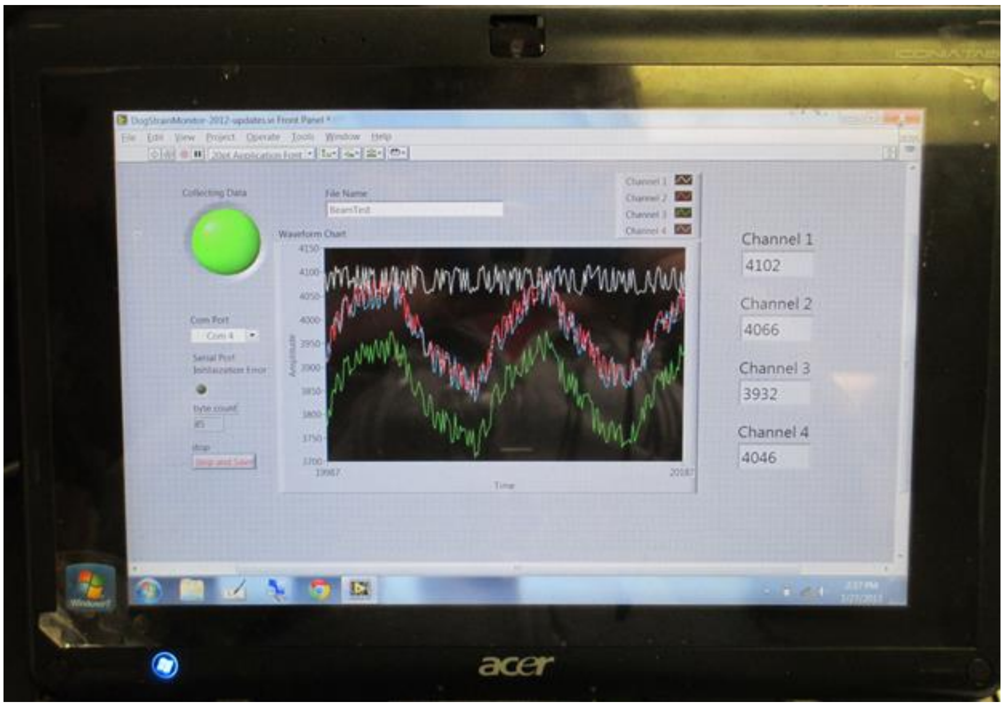

Figure 9 – User interface for the Strain Monitoring Labview software.

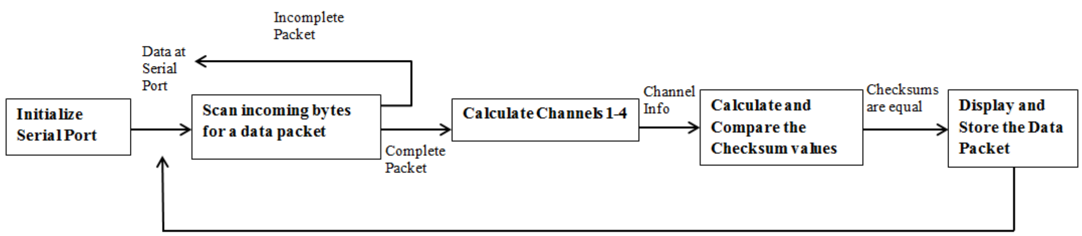

Figure 10 – Flow diagram for the tablet computer Labview software. Data collection was continuous until ended by the user.

The following paragraphs describe the main functions of the measurement collection program in depth.

Initialize Serial Port: The serial port was initialized when the user turned the program on. The parameters used to open the serial port corresponded to the bench top receiver settings (Table 2). The communications port (COM) utilized for data collection depended on input from the user, and each USB connector on the tablet corresponded to a different COM port (Figure 11). COM2 was the lower left USB port, COM3 was the lower center USB port, and COM4 was the left USB port on the keyboard. COM4 was only accessible when the tablet was connected to the keyboard dock. If the serial port was not successfully initialized a “serial port initialization error” indicator turned on.

Table 2 – Serial port communications parameters determined by the receiver

Parameter	Value
Baud rate	9600
Data bits	8
Stop bits	1 bit
Parity	No parity

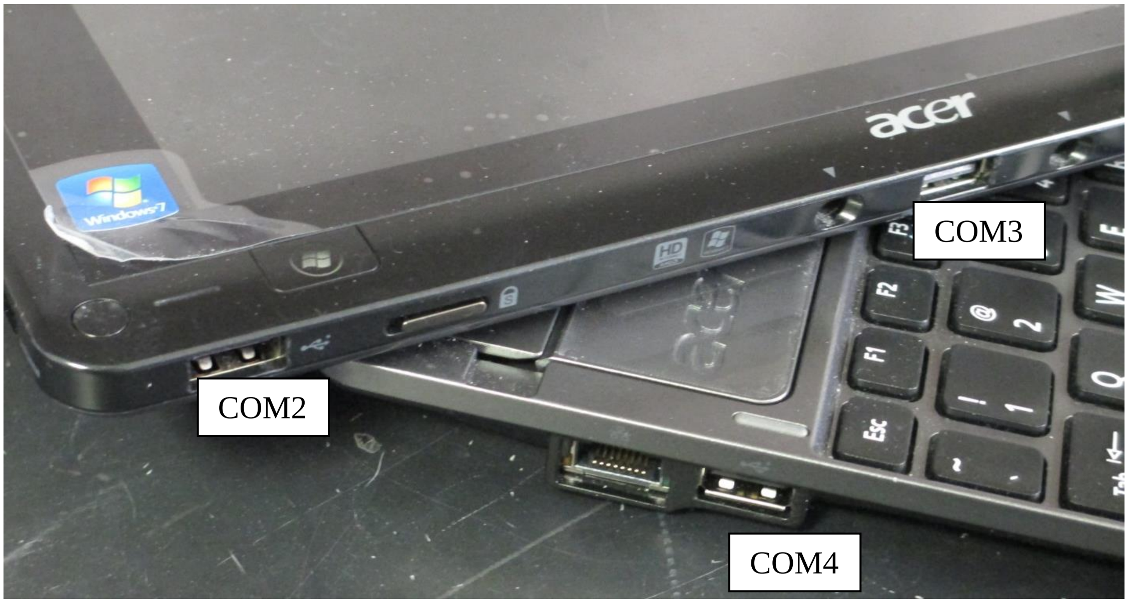

Figure 11 – Available COM ports on the Acer Tablet and attachable keyboard. When the keyboard was attached the only port available was COM4.

Scan incoming bytes for a data packet: Once data had been received at the serial port the program scanned each byte for the beginning of a packet. If the value of the byte was 255, the start byte, the program waited until a full 11 byte packet was collected. If the value was not equal to 255, the byte was discarded and the next byte was read. Once a full packet was collected all 11 bytes were temporarily stored to be analyzed.

Calculate Channels 1-4 and check for overloading conditions: Once a full packet was collected the 11 bytes were analyzed and used to calculate the values on each of the four channels. Each channel was calculated from the most significant bit and the least significant bit. The values for channels 1-4 were temporarily stored for later display to the user.

Calculate and Compare the Checksum values: In each data packet there were two checksum bytes. The checksum bytes contained a summary of the data transmitted in the data packet to validate transmission. If the checksum values were correct the stored channel strain values were sent to be displayed.

Display and Store the Data Packet: The channel information was displayed in a variety of ways (Figure 12). The actual values received from the packet were displayed in both graphical form and numerical form. The strain data was graphically displayed with the four channels simultaneously plotted on a chart. The chart displayed strain data, in μstrain, versus the packet number since the initialization of the program. Because the sampling rate was constant, the data packet number was equivalent to a time scale. This display was an estimate of the loading pattern versus time. The values of strain for each channel were also displayed numerically and a green light turned on to indicate to the user that load information was being successfully collected.

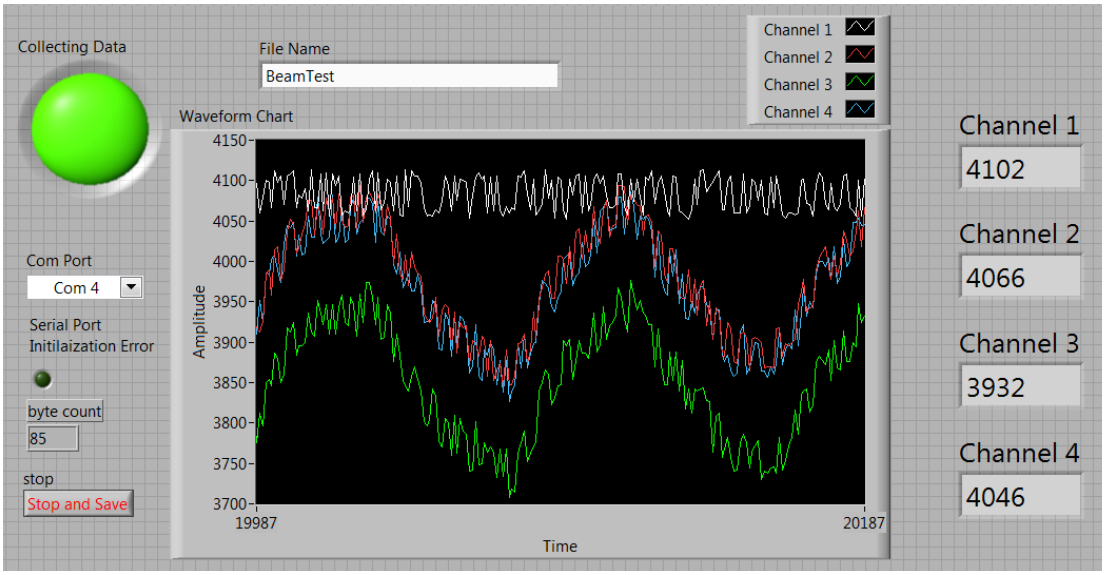

Figure 12 – Tablet software Graphical User Interface. Strain data was displayed to the user numerically on the right (in µstrain), and graphically as a chart (µstrain vs. time). If data was successfully collected the 'Collecting Data' indicator (upper left corner) turned green.

2.2.4 Validation of the new software system

Once software development was completed the functionality of the new tablet computer was compared to the old Dell handheld system and an established desktop system. A telemetry unit was connected to strain gauges attached to a beam. The telemetry unit was then powered and measurements were collected during loading using either the Dell handheld or the tablet computer. Data collected by the desktop system was collected using a hard wired data collection system directly from the strain gauged beam. Data was collected continuously for one minute while the beam was being loaded in compression. Loading was performed by applying a sinusoidal load waveform to the beam at 1Hz, 3Hz, and 5Hz. The sampling frequencies of the handheld and tablet were then calculated based on the number of data points collected during the time period tested. Data collected by the tablet computer was also compared directly to data collected by the desktop computer. After desktop validation the tablet computer system was used to collect *in vivo* data during a cartilage resurfacing and knee joint loading study.

2.3 Evaluation of power transfer to transmitters and methods to ensure reliable powering

In past experiments transmitters would fail after some period when placed *in vivo*, even when preliminary bench top testing demonstrated that transmitters functioned properly. The approach in the methods was to understand the effects of an *in vivo* environment on transmitters and attempt to find solutions to restore transmitter function. Two factors studied that distinguish an *in vivo* environment from the bench top were elevated temperature and aqueous surroundings. In the test animals commonly used for joint research the physiological temperature is approximately 39°C. As such the temperature range of 40°C ± 2°C was selected to test the effects of physiological temperatures on power transfer. The effects of water, saline and other physiologically relevant solutions were also tested.

2.3.1 Power coil development and production

Power transfer to the transmitter appeared to be a limiting factor which prevented proper function of transmitters *in vivo*. In order to increase the amount of power delivered to the transmitter a variety of power coil designs were constructed and tested. The shape that resulted in the highest power transfer was a flat ring style coil (Figure 13).

Nine sizes of this coil style were built in three different diameters; 6cm, 8cm and 10cm; with three different wire sizes; 20 gauge, 24 gauge and 26 gauge (Figure 14). The coils were created by wrapping the wire around a beaker of the appropriate size.

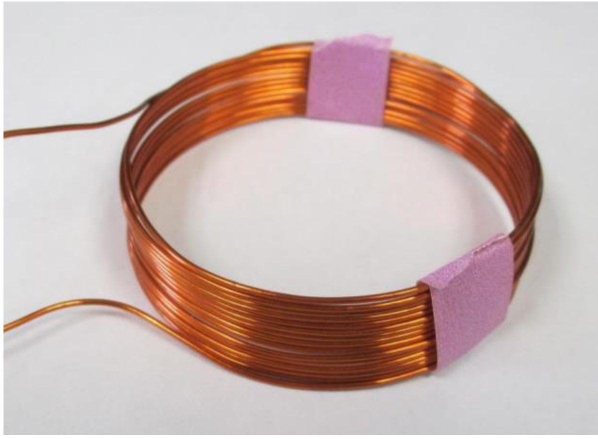

Figure 13 – Power coils were made by stacking rungs of magnet wire. Shown here is a 6cm diameter coil made with 20 gauge magnet wire.

Figure 14 – All nine of the power coil sizes tested are shown in this picture. Top to Bottom: 26G, 24G, 20G magnetic wire diameter power coils. Left to Right: 10cm, 8cm, 6 cm diameter power coils.

The flat ring style power coil formed a solenoid, and the magnetic field, B, inside the center of the ring can be estimated from the height of the ring, *h*, the current through the wire, I, the number of turns in the coil, *n*, and the magnetic constant of the wire material, μ_0 (Equation 3). The height of the coil was limited by size considerations and smaller diameter wires would allow for more turns in the coil, which would increase the magnetic field. However, the amount of current that can pass through magnet wire was limited by the diameter size of the wire used. Larger diameter wires allowed more current to flow than smaller diameter wires, but created a larger coil. Due to these variations, nine power coils in the form of a solenoid were built and power transfer was experimentally tested.

Equation 3 – Magnetic field generated by a flat ring style power coil.

$$B = \mu_0 \frac{nI}{h}$$

The power coils were built to have between 10 and 15 rungs. The number of rungs used was determined experimentally for each type of coil. Power transfer was assessed by use of a model transmitter coil connected to an oscilloscope (Figure 15). The model transmitter coil was made to have the same shape, wire size, and rungs as the power coils used in the transmitters. Actual transmitters could not be used for this test as the transmitters could not be connected to the oscilloscope. The model transmitter coil was connected to the oscilloscope and the amount of voltage delivered by the external coil was measured. For each of the nine coils the number of rungs that lead to the highest power transfer to the model transmitter coil was selected for further testing.

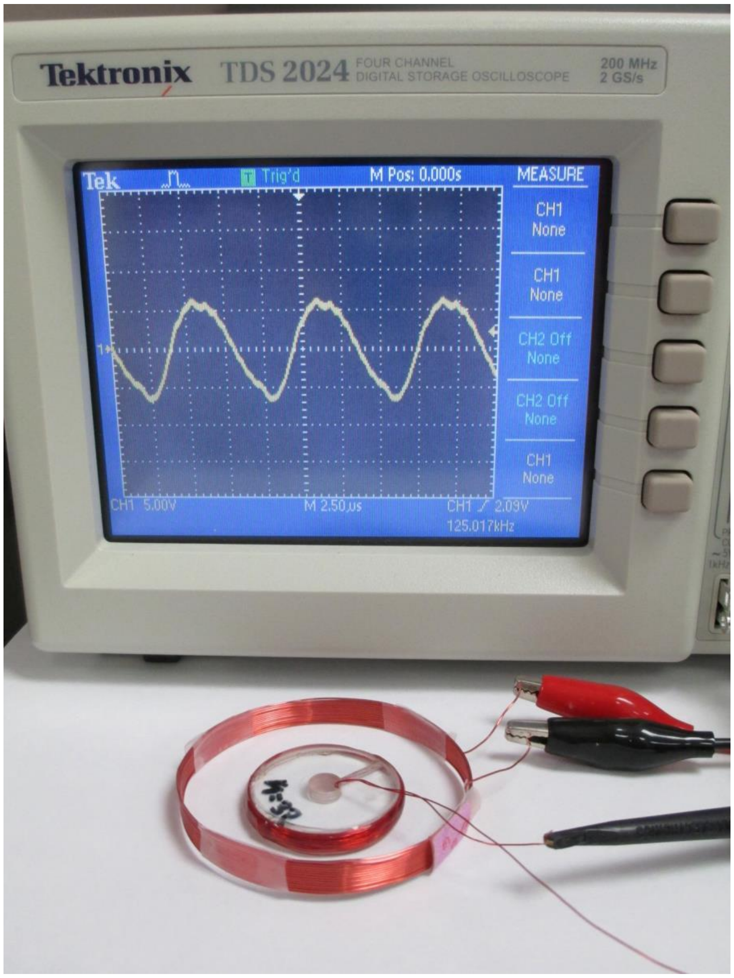

Figure 15 – Signal delivered to the model transmitter coil measured by an oscilloscope. The power signal was delivered through magnetic coupling from a 6cm coil made with 26 gauge magnet wire.

2.3.2 Development and formulation of the temperature and water bath tests for power transfer measurement to model transmitter coils

In order to begin to assess the changes in power transfer in an *in vivo* environment, tests in elevated temperature and in water were performed. Tests were performed in 40°C air, in room temperature water and in 40°C water and compared to a control test in room temperature air. For each test the amount of voltage measured from the model transmitter pickup coil was recorded. Each test was performed three times with the average taken to be the voltage delivered by that size external coil in that environment.

All water tests were performed in a water bath. For the 40°C test the water bath was able to maintain a temperature within 1°C of the set point. For the room temperature air test the water bath remained off until the bath cooled to room temperature. For all moisture testing the model coil was submerged under 5mm of water and the external coil was placed around the transmitter. The elevated temperature tests were performed by using a heat gun to heat the inside of an aquarium to 40°C ± 2°C. Because the heat gun had to be manually turned on and off the range of acceptable temperatures was larger than those from the water bath.

2.3.3 Development and formulation of the in vivo simulator

The *in vivo* simulator was designed as a means to confirm transmitter function before implantation into an animal model. The first design of the simulator involved using a water bath and sliced porcine tissue to simulate test animal tissue. After this setup was confirmed to work, a more permanent design was developed. The final design used a glass container placed on top of a hot plate (Figure 16). Different materials were selected as model tissues to represent the skin layer that the transmitters would be implanted under. The tissues tested included pork loin, sliced porcine tissue and chicken skin.

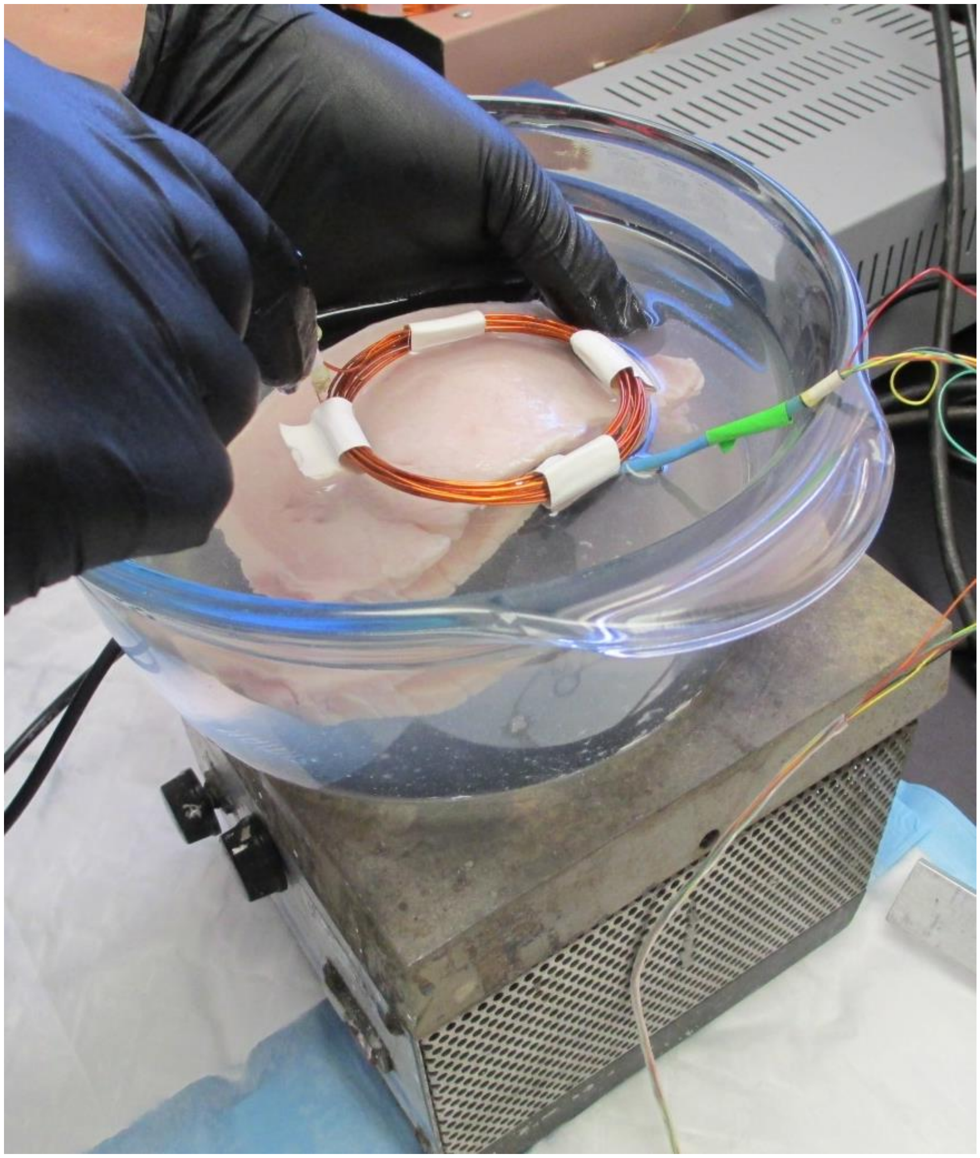

Figure 16 – *In vivo* simulator in use. The transmitter is placed in the center of the pork loin and placed in water heated to 40°C.

2.3.4 Developing solutions to transmission problems

Initial investigations were performed using the *in vivo* simulator and were aimed at determining what environments prevent the transmitters from operating correctly. For each of these tests the transmitters were powered for one minute. Transmitters passed if transmission was not affected by that environment and data was acquired for the entire minute. Transmitters were considered to function intermittently if transmission occurred but data was not recorded for the entire minute, and transmitters failed if no data was collected for that test.

Control tests were performed by testing transmitter function in room temperature water, 40°C water and using the *in vivo* simulator. For the water bath testing the transmitter was left in the bath for 1 hour prior to data collection and the transmitter was held under 5mm of water. When using the *in vivo* simulator the transmitter was placed beneath up to 5mm of moist tissue and the external coil was placed over the tissue. For all other tests the coil was placed around the transmitter. Possible solutions to transmission problems compared transmitter function to these control tests.

In order to investigate the impact of liquid on the transmission, different solutions were tested. Transmitters were tested in isotonic saline and a sugar solution to represent some of the molecules present inside the body. Transmitters were also tested in oil to determine whether the polarity of the liquid affected transmission. To simulate the ions present in an *in vivo* environment a 0.9% NaCl saline solution and a 3% agarose sugar solution were used and vegetable oil was used as a non-polar liquid for comparison to these solutions. Transmission was determined by following the same pass/fail system as the control tests.

These preliminary tests suggested that the presence of an aqueous solution prevented proper transmitter function. Transmission was successful in a hydrophobic liquid and solutions that limited water from surrounding the transmitter were further explored. The first test was performed using a triglyceride ring, in the form of porcine lard, to prevent water from surrounding the transmitter (Figure 17). This material was selected because it was a semi-solid non-polar easily moldable material.   A transmitter surrounded with 1cm of lard on all sides was tested in a 40°C water bath and transmission was assessed using the pass/fail system.

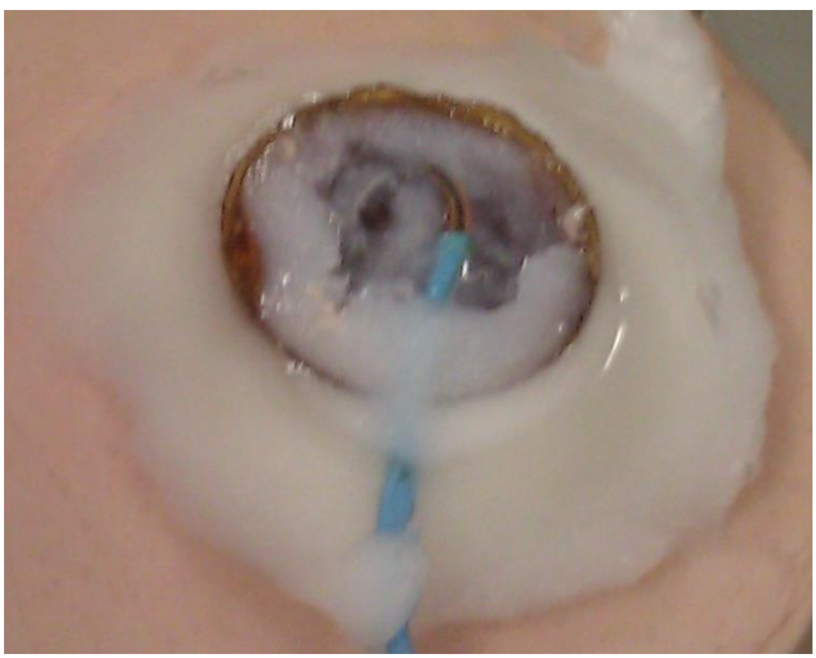

Figure 17 – Transmitter surrounded by the triglyceride ring to prevent water from surrounding the transmitter power coil.

2.3.5 Design of waterproof silicone casings

After some success with the triglyceride ring a more permanent device was investigated in the form of a silicone mold. Silicone molds were made using Sylgard® 185 silicone (Dow Corning Corporation, Midland, MI) and molded into a variety of configurations. During each trial the silicone elastomer base was mixed with the silicone elastomer curing agent in a 10:1 ratio according to the manufactures instructions. The mixed silicone was then poured into a mold and allowed to cure for 24-48 hours. The first mold design consisted of one piece that surrounded the transmitter on all sides and the bottom (Figure 18). The second design completely enclosed the transmitter on all sides. This casing was made in two parts, an inner shell and an outer ring (Figure 19, Figure 20). Transmission was assessed with both of the silicone casing designs using the pass/fail system.

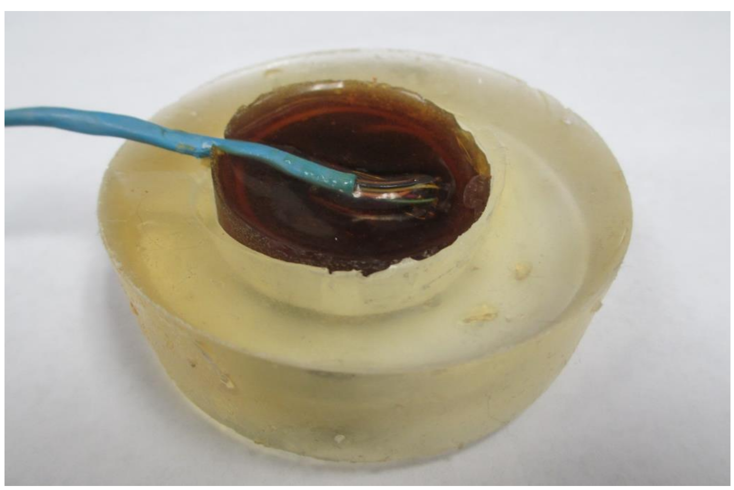

Figure 18 – Bottom and side covering style of silicone mold.

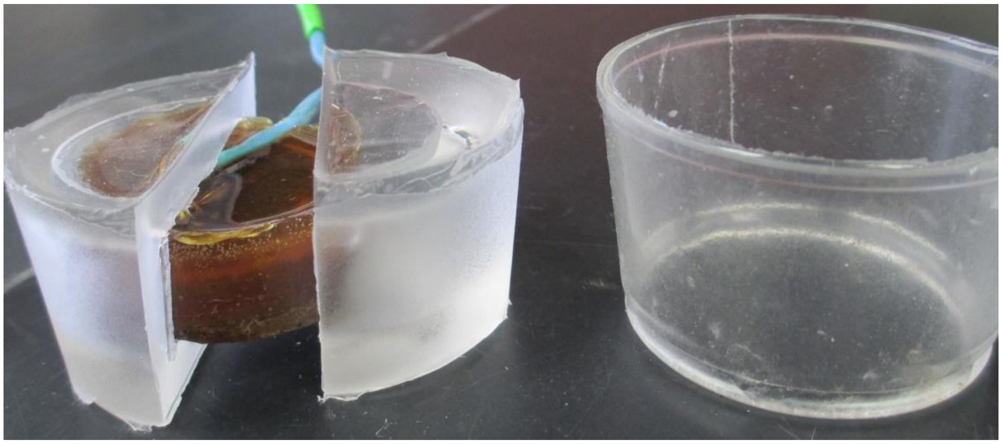

Figure 19 – Transmitter with the three piece silicone mold. The two pieces of the inner shell completely encase the transmitter and the silicone ring was placed around the shell to hold it together.

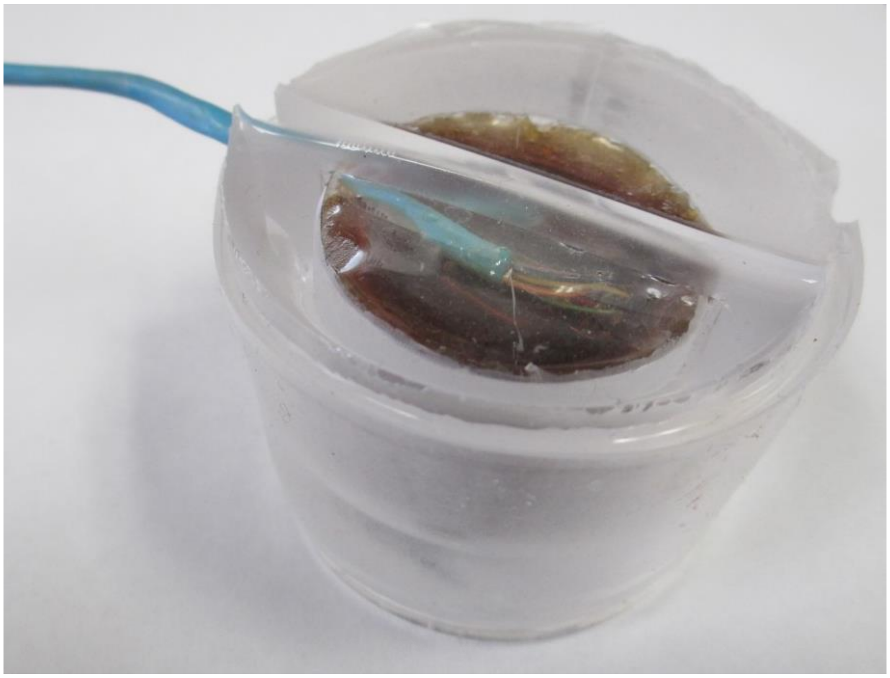

Figure 20 – Transmitter placed in the three piece completely encasing mold.

2.3.6 In vivo testing with silicone mold casings

During the silicone casing design process two test animals were being used for a knee joint loading study using implanted telemetry. Sensate scaffolds and the telemetry systems discussed in this work were implanted into the two 30kg hounds in order to monitor knee joint loading during cartilage tissue repair. The newly developed tablet computer data collection system was used for this study. A transmitter unit, with or without a silicone mold, was implanted at the same time as the scaffold and joint loading was monitored for up to six months. Transmitters, scaffolds, and molds were sterilized in ethylene oxide and double aerated before implantation. Both test animals were exercised regularly on a treadmill and knee joint load measurements were recorded when transmitters were functional.

In the first test animal a silicone mold encased transmitter was implanted. The silicone mold implanted during this surgery was the one piece design covering the bottom and sides of the transmitter. Prior to implantation the transmitter had been waterproofed and prepared using a full covering of Masterbond epoxy following laboratory standard operating procedures. The silicone mold was prepared and cured in the lab before the surgery. During surgery the transmitter was placed into the open top silicone mold and implanted into the test animal.

In the second test animal a transmitter without a silicone mold was implanted following procedures used in previous experiments in which transmitters failed to function *in vivo*. Although function was confirmed prior to implantation this transmitter was not functional *in vivo* as anticipated. A revision surgery was then performed to encase the transmitter in the three piece style silicone mold. The transmitter was surgically removed from the test animal and the mold was placed around the transmitter. The transmitter-mold unit was then reimplanted into the test animal.

After sacrifice further tests were performed to assess the effects of temperature in the *in vivo* environment. The transmitter of the second test animal remained entirely *in vivo,* and only the temperature was changed. The area around the transmitter was cooled to room temperature and measurements were taken to assess transmitter function. The transmitter was then removed from the test animal. After sacrifice both excised transmitters were reassessed for function on the bench top.

3 RESULTS

3.1 Results from the strain monitoring system on a Tablet-PC

3.1.1 Explanation of the tablet software graphical user interface

The user interface for the tablet program was designed to be simple and easy to use. The interface allowed visualization of the data collected both graphically and numerically. The user could also easily view a large green LED to check the status of transmitter function. If the LED lit green then data was being collected and stored. The user also had some control over the operation of the system (Figure 21). The user could run the program, save the program, and also give the measurement file a unique file name.

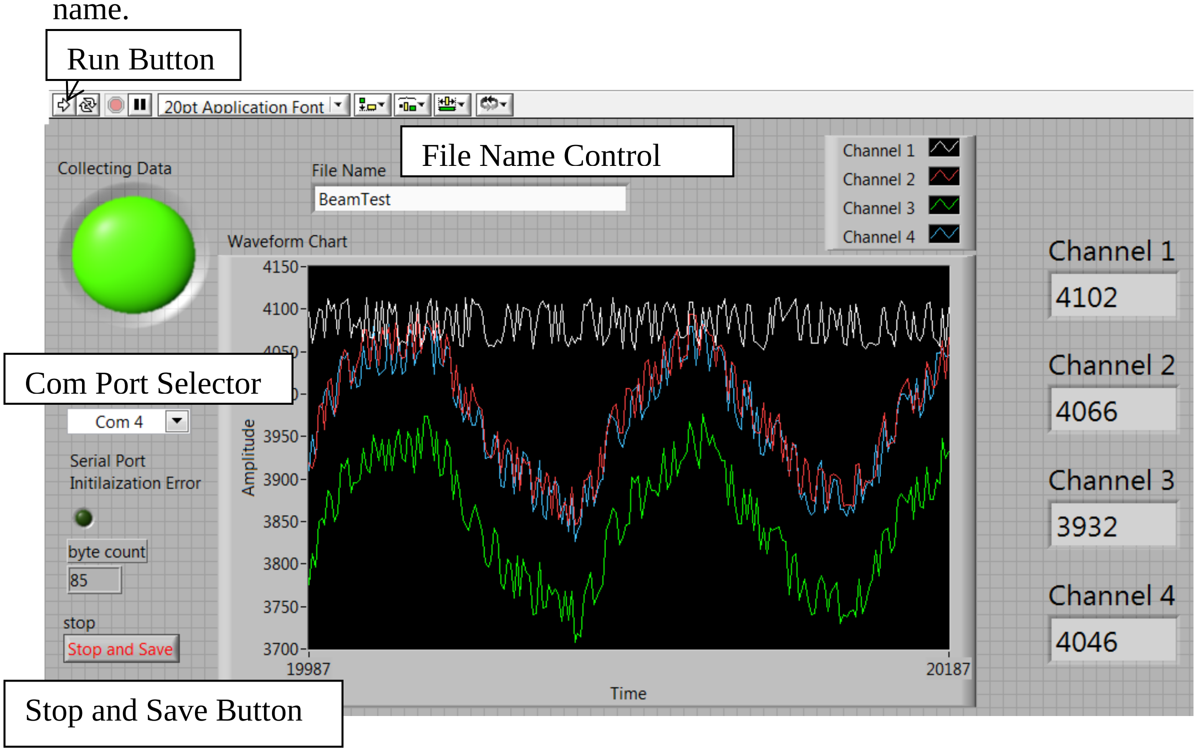

Figure 21 – Tablet Software User Interface. Controls available to the user are highlighted.

Run Button: This button was pressed to start the program. When pushed the selected communications port was initialized and data collection began.

File Name Control: This selector allowed the user to give a name to the measurement file created to store the strain data. The file name was appended with the date and time data collection began, which ensured a unique file name was given for each measurement file.

Com Port Selector: This selector allowed the user to select the appropriate communications port used for data collection.

Stop and Save Button: Stopped the program. Any data not previously stored was saved when this button was pressed and the communications port was closed.

3.1.2 Bench top validation; Comparison to a desktop computer system and the Dell handheld computer system

The new Tablet-PC data collection system was validated by comparing data collected on a desktop computer to data collected with the tablet computer. Sinusoidal strain patterns were collected at 1Hz, 3Hz, and 5Hz simultaneously with both computers (Figure 22, Figure 23, and Figure 24). The strain measurements collected by the tablet computer were equivalent to the strain measurements collected by the desktop computer and served to validate the function of the tablet computer.

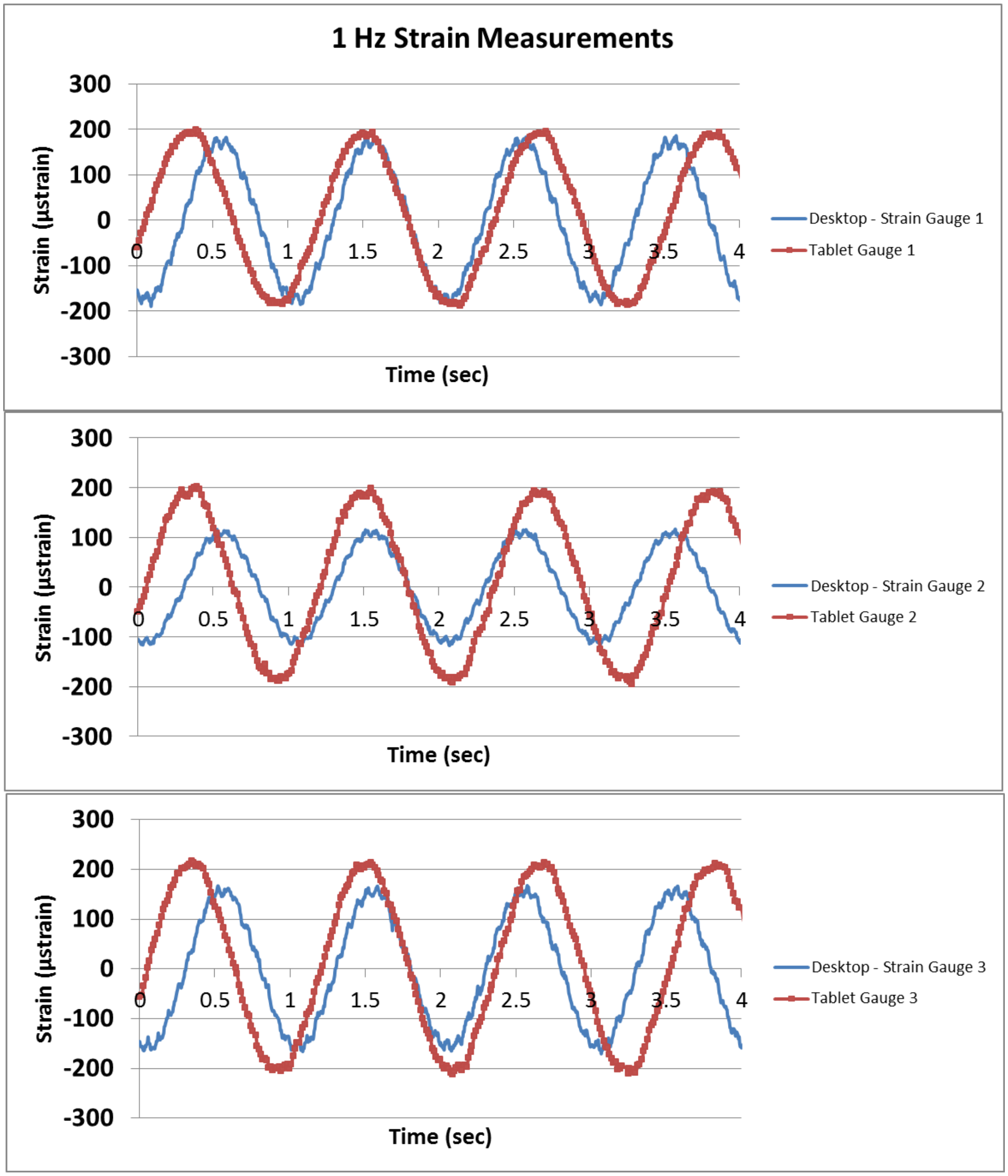

Figure 22 – Comparison of 1 Hz sinusoidal strain measured by a desktop computer and strain measured with the tablet computer coupled to the telemetry system.

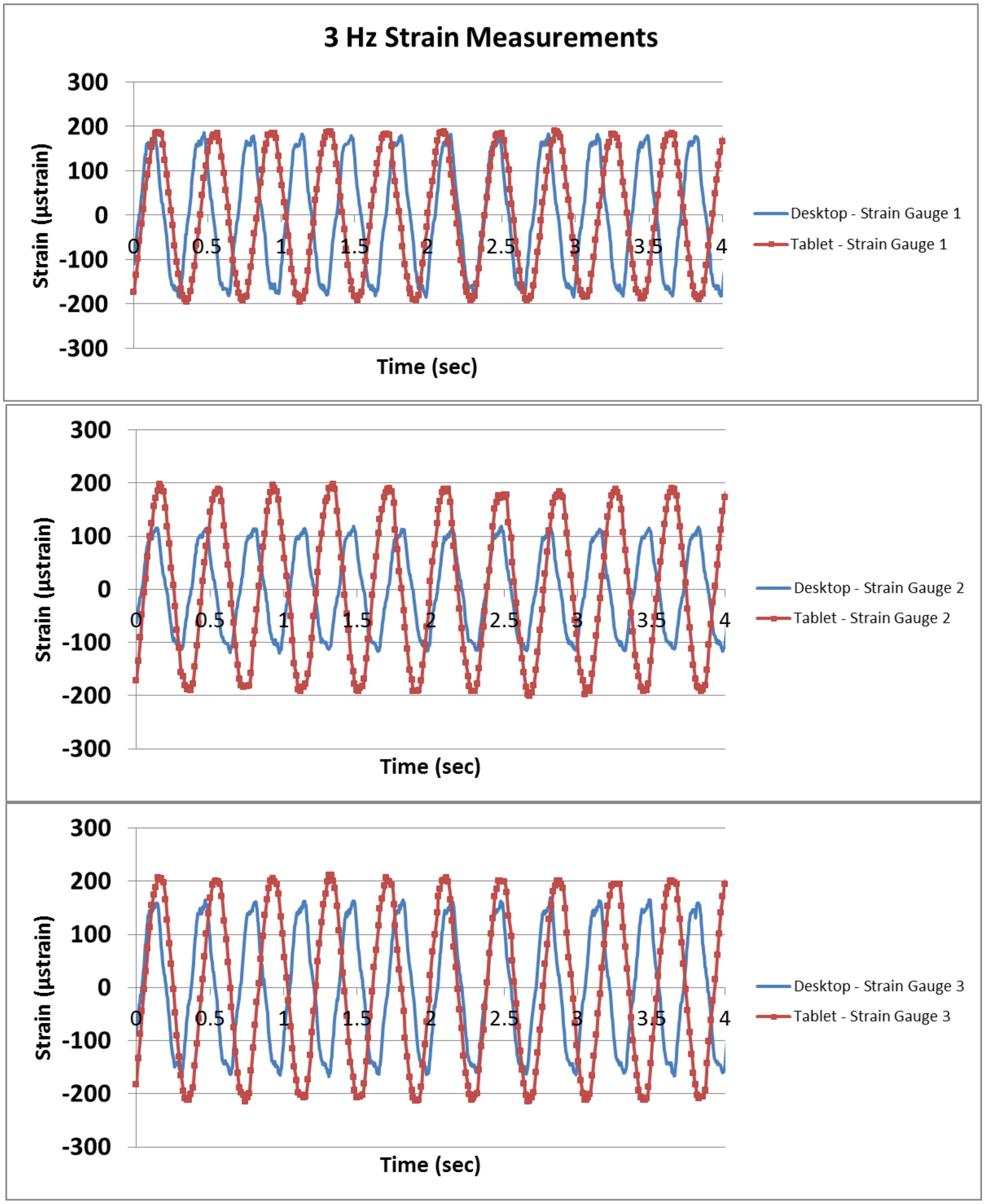

Figure 23 – Comparison of 3 Hz sinusoidal strain measured by a desktop computer and strain measured with the tablet computer coupled to the telemetry system.

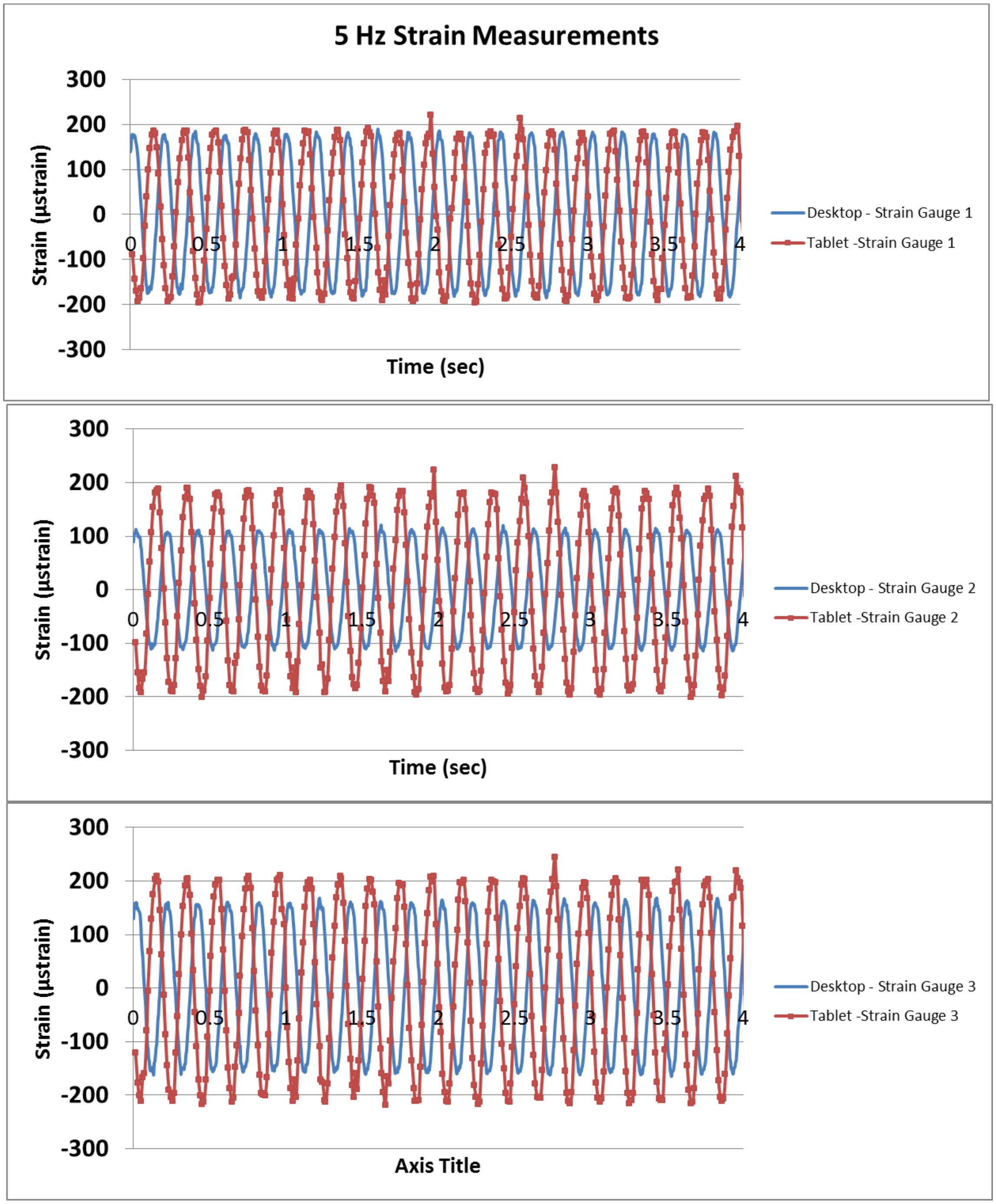

Figure 24 – Comparison of 5 Hz sinusoidal strain measured by a desktop computer and strain measured with the tablet computer coupled to the telemetry system.

The strain measurements collected by the tablet computer were comparable, but not identical to, strain measurements collected with the desktop computer used to calibrate the implantable scaffolds. Strain magnitudes were different because the transmitter electronics amplified the measured strain signals before transmission to the tablet computer. A calibration factor was applied to strains collected by the tablet computer (Equation 4). The relationship between the strain collected by the desktop computer and the tablet computer was linear. However, the exact value of the calibration factor had to be calculated before each experiment since it was different for each transmitter.

Equation 4 – Relationship between strain measurements from the desktop computer and the tablet computer.

$$Desktop\ strain \cong 0.3 * Tablet\ strain$$

Strain data collected by the tablet computer was also compared to data collected by the Dell handheld computer used in previous studies. The increased processing power of the tablet was better suited for data collection when compared to than the handheld. Because of this, the tablet was able to collect data at increased rates compared to the Dell handheld (Figure 25). The tablet computer could sample data at up to 87Hz and the Dell was only able to sample at approximately 29Hz. The increased rate of data collection by the tablet allowed more accurate load measurement collection and better analysis of loading data.

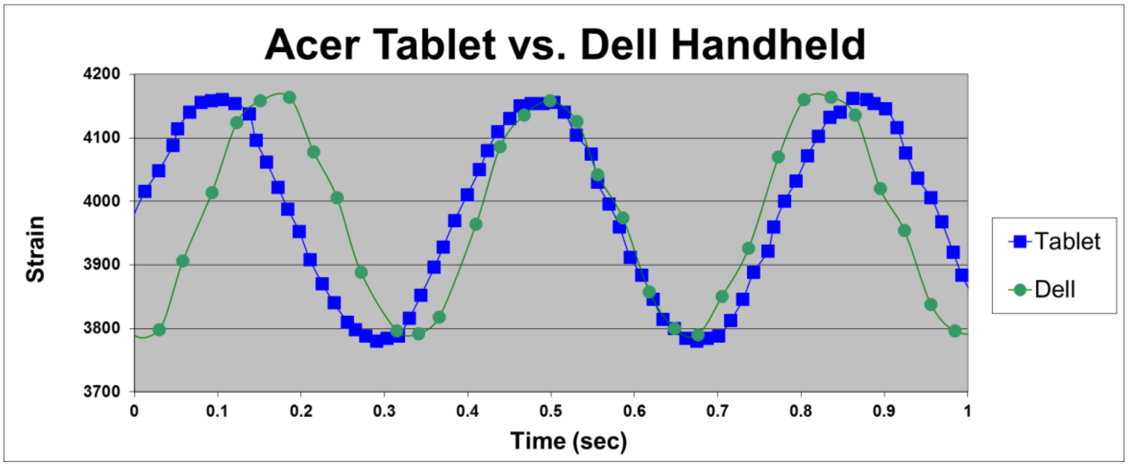

Figure 25 – Comparison of data collected by the tablet computer and the Dell handheld computer. The tablet computer sampled at 87Hz, while the Dell handheld sampled at 29 Hz.

3.1.3 In vivo strain measurement data collected from the Tablet-PC

The tablet computer was able to collect loading data from one of the three strain gauges implanted in one test animal. After transmitter removal from the test animal both the transmitter and scaffold sensors were noted to be operational, but there was added resistance in the wire connecting the sensors to the electronics. The increased resistance in the wires prevented detection of the strain gauge resistance changes *in vivo*.

Strain measurements were successfully collected multiple times per week with the tablet computer for a period of four months. The tablet computer functioned correctly for the duration of the experiment and loading data was collected from one strain gauge (Figure 26). Although additional analysis is being performed on the strain measurements, this is outside the scope of the current project.

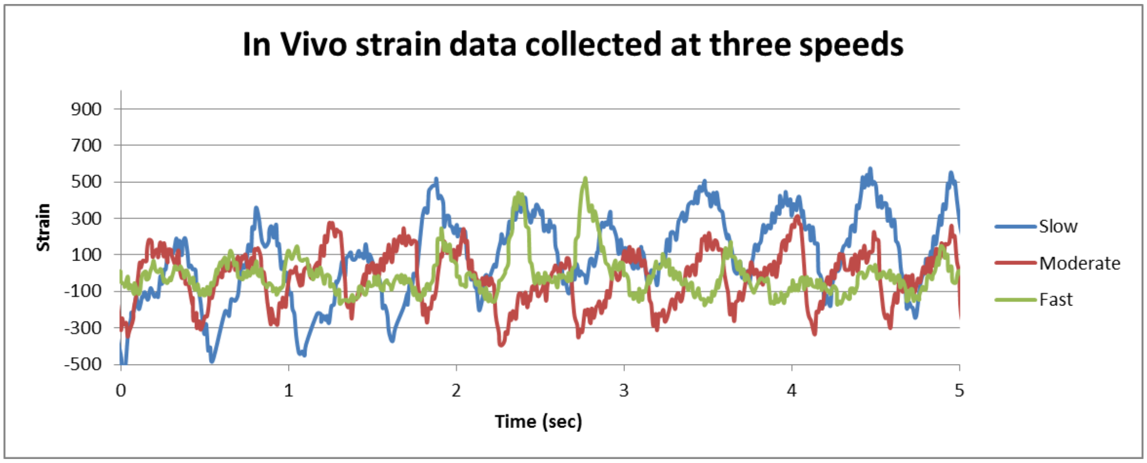

Figure 26 – Strain data collected from the tablet data collection system. Strain data was collected at three speeds during each measurement collection session. This sample of data was collected 3 months post transmitter and scaffold implantation.

3.2 Results from power transfer evaluation and powering of transmitters

3.2.1 Power coil development initial results

The amount of power delivered by each power coil depended on the diameter of the coil, the wire size used to make the coil, and the number of rungs present in the coil. Each of the nine power coils were built with the number of rungs that lead to the highest power transfer (Table 3).

Table 3 – Number of rungs that lead to the highest power transfer for each coil size

Coil Size (Diameter-wire)	Number of Rungs
6cm - 20G	11
8cm - 20G	13
10cm - 20G	11
6cm - 24G	13
8cm - 24G	12
10cm - 24G	10
6cm - 26G	15
8cm - 26G	12
10cm - 26G	11

3.2.2 Power transfer to model transmitter coils in water and at elevated temperature

The amount of power transferred to the model transmitter coil was significantly reduced by both water and elevated temperature. The amount of voltage measured from the model transmitter coil depended on which external coil was used and the environment in which it was tested (Figure 27, Figure 28, and Figure 29). When the amount of voltage measured in the room temperature air control environment was high, the voltage delivered in water or in elevated temperature was often greatly reduced. In all cases, the amount of voltage measured in water or at a higher temperature was a fraction of what was measured in a room temperature air environment.

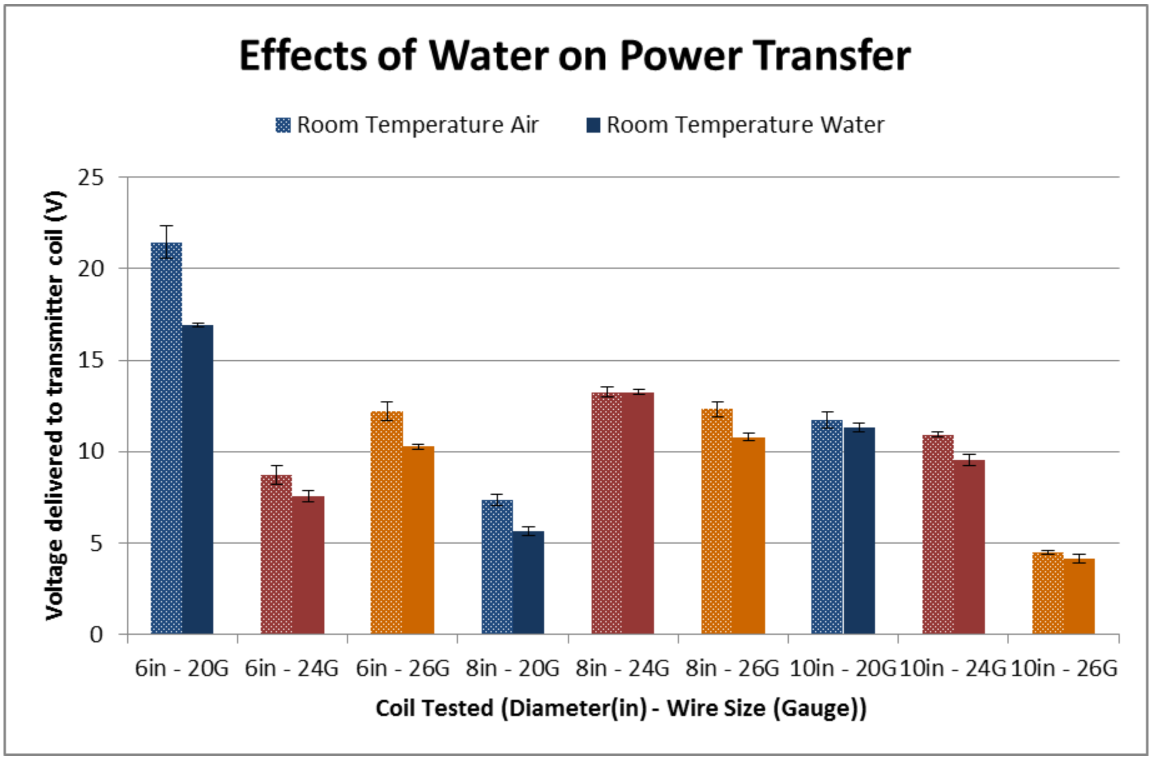

Figure 27 – Effects of a water environment on voltage delivered to the transmitter coil compared to room temperature air. The change in voltage measured in water when compared to room temperature air was significantly different (p-value = 0.014), and resulted in an average decrease in voltage delivered by 11.9%.

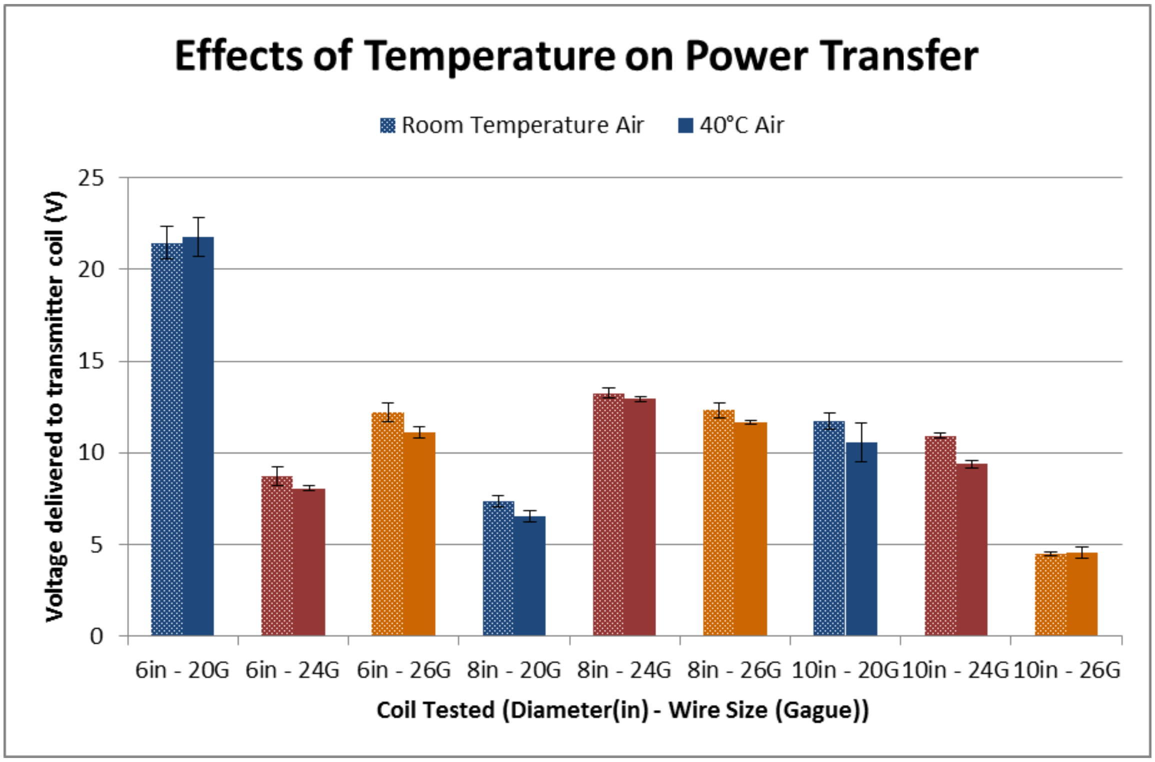

Figure 28 – Effects of a 40°C elevated temperature environment on voltage delivered to the transmitter coil compared to room temperature air. The change in voltage measured in 40°C air when compared to room temperature air was significantly different (p-value = 0.017), and resulted in an average decrease in voltage delivered by 6.2%.

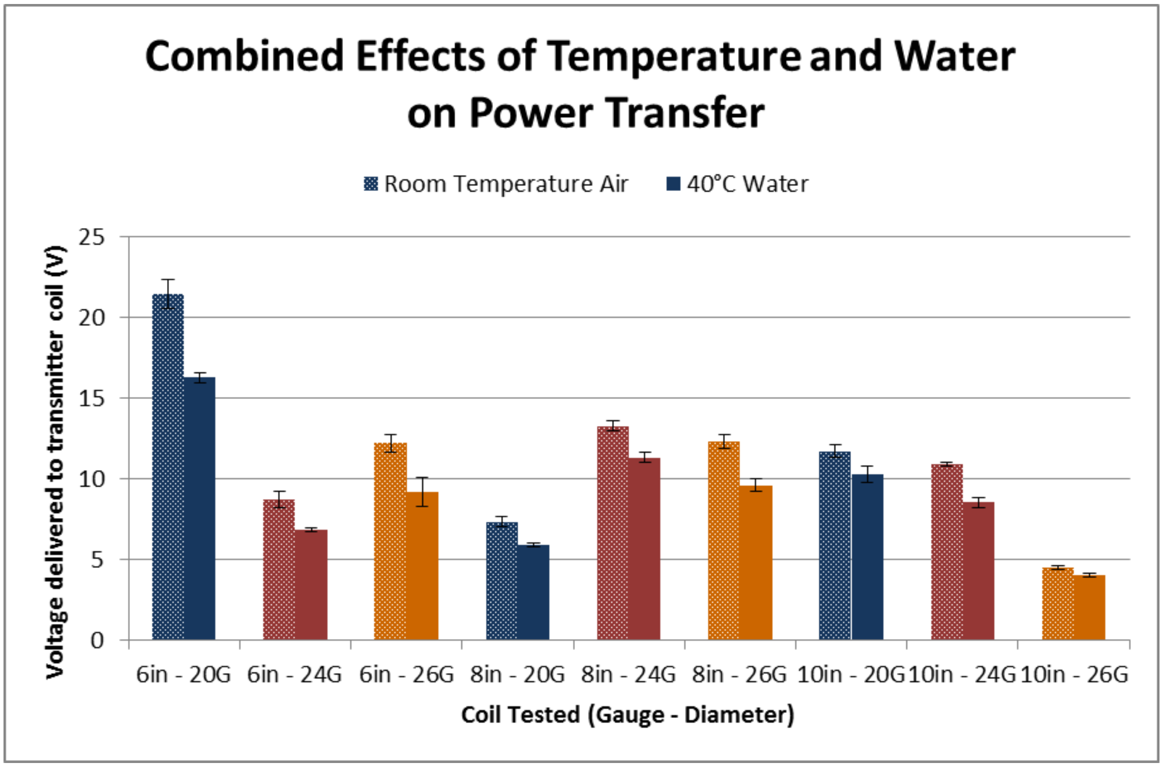

Figure 29 – Combined effects of elevated temperature and water environment, as measured in a 40°C water bath, on voltage delivered to the transmitter coil compared to room temperature air. The change in voltage measured in 40°C bath when compared to room temperature air resulted in an average decrease of voltage delivered by 18.2%.

An aqueous environment reduced power transfer to the model transmitter coil by an average of 11.9% when compared to power transfer in air. Using a paired t-test this change from room temperature air to room temperature water was significant (p-value = 0.014). Additionally, 40°C air also reduced power transfer by 6.2% when compared to room temperature air, a change that was also significant (p-value = 0.017). When compared to power transfer in room temperature air, power transfer to the transmitter coil was significantly reduced by both the presence of water and an elevated temperature.

Power transfer was further reduced by the combination of a water environment and elevated temperature, as demonstrated by a 40°C water bath. The average voltage measured in a 40°C water environment was reduced by 18.2% when compared to room temperature air. Due to the effects of both an aqueous environment and the elevated body temperature, power delivered to a transmitter *in vivo* was expected to be reduced by a similar amount.

The results showed the coil that lead to the highest power transfer was the 6 cm 20 gauge coil. However, in an animal model an 8 cm size coil was easier to use as the 6 cm size coil was too small and difficult to position around the implanted transmitter. An additional benefit of the 8 cm size coils was that they showed the lowest variability in voltage measurements when compared to the 6 cm and 10 cm sized coils. When compared to the coils made with 20 gauge and 26 gauge wires, the coils made with 24 gauge magnet wires were also the most reliable at providing the highest power transfer. As a result the best power coil design for this style of transmitter was an 8 cm diameter coil made from 24 gauge wire. The measurements demonstrated that this design was the most reliable response and provided excellent power transfer to the model transmitter coil in all environments tested.

3.2.3 In vivo simulator validation

Different types of tissues were tested in the in vivo simulator multiple times and transmitter function was assessed (Table 4). All the materials tested the *in vivo* simulator operated properly. Pork chops lead to the worst transmitter function and therefore it represented the best material for future *in vivo* simulation tests since it models a worst case scenario.

Table 4 – *In vivo* simulator observations with the different tissues tested.

Material	Test Number	Observations
Chicken Skin	1	Transmission is intermittent, transmission occurred at the end of the test.
	2	Occasional data collection, limited number of packets collected.
	3	Intermittent transmission.
Pork Chop	1	Some transmission.
	2	Light indicating powering, but no data collection. (Most similar result to in vivo conditions)
	3	Erratic transmission
Sliced Porcine Tissue	1	Intermittent transmission
	2	Unreliable transmission

3.2.4 Results from possible solutions to transmission problems

When testing with the *in vivo* simulator, both transmitters operated intermittently and consistently failed to transmit in an aqueous environment. Transmitters failed in water at room temperature and at 40°C (Table 5). Additionally, when transmitters were exposed to solutions with ions and molecules (isotonic 0.9% NaCl solution, 3% agarose solution) present in a physiological environment they also failed. However, when placed into a non-polar liquid (oil) the transmitters were operational.

Table 5 - Results for transmitters tested in various *in vivo* simulating environments

	Transmitter A	Transmitter B
25°C Water	Fail	Fail
40°C Water	Fail	Fail
In Vivo Simulation	Intermittent	Intermittent
0.9% NaCl solution	Fail	Fail
3% agarose solution	Fail	Fail
Vegetable oil	Pass	Pass

The bench top transmission results showed that water around the transmitter prevented transmitter function *in vivo*. In order to limit water from surrounding the transmitter a triglyceride ring and silicone molds were used. Both of these materials facilitated power transfer and were successful in restoring transmission in a 40°C water bath (Table 6). However, when the warm water began to breakdown the triglyceride ring transmission failed. In contrast, the silicone molds did not break down and facilitated continuous power transfer and transmission. Evaluation of the silicone molds demonstrated that water was kept several millimeters away from the transmitter pickup coil, which ensured proper transmitter powering and function.

Table 6 – Results for transmitters placed in molds

	Transmitter A	Transmitter B
Triglyceride Ring in 40°C Water	Intermittent	Intermittent
Top and Side Silicone mold in 40°C Water	Pass	Pass
Full Silicone mold in 40°C Water	Pass	Pass

3.2.5 In vivo testing results using the first design of silicone molds

After removal of the transmitter unit from the test animal with the one piece silicone mold, it was noted that the silicone mold tore at some point after implantation and a fibrous capsule had formed around the transmitter and mold. Although the mold broke *in vivo*, the fibrous capsule held the silicone mold around the transmitter throughout the study. As a result the mold remained in place and allowed the transmitter to function *in vivo* for the duration of the experiment.

In the second test animal a transmitter without a silicone mold was initially implanted and the transmitter did not function as anticipated. A revision surgery was performed to encase the transmitter in the 3 piece silicone mold, but the mold system did not remain in place. After the mold was implanted a large seroma developed at the implant site. Because of this the external power coil could not be adequately positioned around the seroma and the transmitter was unable to be powered and did not function. After two weeks the fluid was surgically removed and the coil was placed around the transmitter. However, the transmitter was only powered briefly and full transmitter function was not restored.

After sacrifice, the area around the site of the non-functional transmitter was cooled and the implanted transmitter began operating when the area reached room temperature. The transmitter remained implanted during this test, which demonstrated the effect of body temperature on transmitter function *in vivo*. After removal of the mold it was observed that the ring portion of the mold had broken after implantation and the mold separated *in vivo*. Functionality was lost because the silicone mold was not surrounding the transmitter and it could not facilitate power transfer to the implanted coil.

4 DISCUSSION

Prior to the development of telemetry, load measurements were performed by use of percutaneous leads and the first direct in vivo measurements were performed by Rydell in the 1960's [41]. Strain gauges were attached to a hip prosthesis and wires were passed through the patient's skin to signal conditioners and a chart recorder for data collection. After the completion of measurement collection the wires were surgically removed from the patient. With advances in electronics and miniaturization of transmitters the need for percutaneous wires has been eliminated.

Telemetry connected to implantable sensors started to be used as orthopedic research tools in the 1970's [42, 43]. External powering of implantable transmitters through magnetic coupling was developed and tested during these early studies by Nachemson et al. However these devices were extremely limited in function and could only record one channel of data. Subsequent research utilized devices that could record multiple channels, but the implanted devices were either large and time limited with toxic batteries [44, 45] or implantable sensors were percutaneoulsy connected to external transmitters [46].

One area of research that has benefited from the use of implantable telemetry is spine fusion research in patients with scoliosis. In the 1990's Bergman's group demonstrated the value of sensing and telemetry to monitor spine fixation devices during fusion [47]. They discovered that even after spine fusion, high loads may be placed on the fixation devices, explaining the reason that spine fixation devices can break several months after implantation. Szivek et al. expanded on this research used sensors and telemetry to define *in vivo* loading on the lamina [8, 9]. This information allowed them to monitor native tissue during spinal fusion.

"Sensate" total knee joints with sensors and telemetry have also been developed and investigated to better understand implant loading. [48]. D'Lima et al. used a customized total knee replacement with sensors and telemetry to measure loads on knee implants over an extended period of time [5]. Measurements were collected from patients during the healing process. These measurements provided loads during activities of daily living as well as during exercise activities.

Native knee joint loading has also been documented by Szivek et al. in a well-established canine model by use of telemetry [31, 49]. These studies have documented *in vivo* loads prior to and following ACL injury as well as during cartilage tissue repair [15, 16]. They noted that when given pain medication after ACL injury loading patterns were more similar to those pre-injury [50]. Knowledge of how loading changes during the healing process will help lead to better therapeutic standards and will help to personalize the rehabilitation process.

Despite the success of these projects the use of implantable sensing systems remains an academic pursuit and has not moved into widespread clinical practice [26]. One of the main challenges with *in vivo* measurement is the design of a robust and long lasting transmitter and a reproducible method for data collection and analysis. Electronics are often designed for use in dry room temperature environments and adapting these components for use in an *in vivo* environment has been a challenge.

However, recent advances in computer hardware have made the development of improved data acquisition software simpler and less expensive.

It is estimated that one in four adults in the United States owned a tablet computer in 2012 and this number is estimated to increase over the next few years [51]. A Windows based tablet computer was selected because of widespread tablet use, increased computing abilities as compared to a mobile platform, and ease of software development. Although the iPad is one of the most popular tablets on the market, Apple Inc. has many restrictions on interfacing iOS devices with non-Apple hardware, such as current telemetry systems. This necessitated the use of a non-Apple tablet and a Windows 7 device was selected because of its compatibility with Labview.

Labview is a visual programming language that is well suited to data acquisition, graphical user interface design, and data visualization and storage. The major challenge faced during programming the tablet computer with Labview was interfacing with the telemetry receiver serial port. The telemetry receiver delivers strain measurements via a RS-232 serial port, a protocol that is not directly supported by tablets. As a result a RS-232 to USB serial port adapter was necessary, but these devices are not perfect. The Labview program would occasionally freeze because it could not obtain data through the emulated RS-232 port. Although changes in the program decreased the number of times Labview froze, this problem could not be eliminated completely. If the program froze the user had to restart Labview and reinitialize the serial port. Despite this inconvenience almost no data was lost because the program saved the data every few seconds.

Upgrading the data acquisition system from a Dell handheld computer to the Acer tablet insured an increase in the sampling frequency of the system. The Dell handheld could only process data at 29Hz and as a consequence some data received from the transmitter was discarded. The increased processing power of the Acer tablet allowed data acquisition to occur at 87Hz, the sampling frequency of the hardware. The increase in sampling rate is expected to assist in data analysis of gait patterns. In order to preserve the power spectrum of human gait a sampling frequency of at least 30Hz is essential [52]. The tablet computer will collect a human gait signal accurately, while the Dell handheld creates some distortion in the gait pattern. Other implantable telemetry transmitters utilize a sampling frequency as high as 200 Hz [53]. Therefore use of the tablet with available telemetry systems will provide accurate gait pattern information collection.

In prior studies implantable sensing systems with transmitters often failed soon after placement *in vivo*, even though preliminary testing showed that they operated properly on the bench top [24, 32]. In order to ensure reliable transmitter function it was necessary to determine the factors affecting the transmitters *in vivo.* The two factors studied were immersion in an aqueous environment and exposure to elevated temperature. Immersion in water or human tissues significantly attenuated the radio frequency (RF) signals emitted from a transmitter [54, 55]. However, the transmitters used for this study were designed to transmit at an appropriate RF frequency (418.5 MHz) in an attempt to mitigate this effect.

It was hypothesized that transmitter function may be inhibited due to insufficient power delivery. The experiments utilized in this study were designed to quantify the differences in power transfer on the bench top and power transfer in a simulated *in vivo* environment. The results of this study demonstrated that power transfer to the transmitter pickup coil was strongly impacted by *in vivo* conditions. Both immersion in an aqueous environment and an elevation in the surrounding temperature to 40°C significantly decreased power transfer to a model transmitter coil when compared to power transfer in room temperature air. The combination of these factors, as in a 40°C water bath, further reduced power transfer and the implanted transmitters' inability to function maybe a result of insufficient power transfer.

A technique that either reduced the effect of the aqueous environment or that of elevated temperature was required to ensure proper power delivery. It would be difficult to alter the temperature of the implanted transmitter since the body consistently maintains physiological temperatures. Therefore methods that could alter the effects of the aqueous environment on power transfer to the transmitter were carefully examined. Transmitter function was systematically assessed on the bench top, and in various environments simulating *in vivo* conditions. Experiments with physiologically equivalent saline solutions and sugar solutions as well as with hydrophobic liquid solutions demonstrated that transmitters fail in an aqueous environment, but adequate power transfer and transmission does occur in hydrophobic liquid.

The presence of water was found to inhibit transmitter function and this may be attributed to the magnetic susceptibility of water. Due to its magnetic susceptibility water is a diamagnetic material [56], which generates an opposing magnetic field when an external magnetic field is applied. Because of this, the water attenuates the magnetic field generated by the external power coil and power delivered to the transmitter is reduced. This reduction in power transfer was preventing the transmitters from powering and transmitting *in vivo*. Limited research has been performed to quantify the affect water and saline have on magnetic induction power transfer with respect to medical implants.

Transmitter function *in vivo* can often be erratic or transmitters can be completely non-functional. Therefore, it was necessary that the *in vivo* simulator be able to model this type of transmitter performance. The material that lead to the worst transmitter function in the simulator would therefore be the best choice for future experiments. When the transmitter was placed into pork loin, transmitter function was intermittent or non-existent. This material was selected for future experiments to simulate transmitter function *in vivo*.

A solution to limit the effects of water on power transfer was developed as a method to ensure appropriate transmitter function. When triglyceride rings or silicone molds, non-diamagnetic materials, were placed around the transmitter, function was restored in a 40°C water bath. The silicone mold casing proved to be a permanent solution and was selected for additional testing in an animal model.

When the mold was properly positioned the transmitter functioned properly *in vivo*. In the animal with the single piece silicone mold, the mold remained in place throughout the experiment and loading of the tissue engineering scaffold was collected for a period of 6 months. However, in the second test animal with the three piece silicone mold a large seroma developed. This mold was larger than the one piece style and may have caused the development of the seroma. The seroma fluid likely lubricated the area between the silicone pieces and caused them to separate. Because the silicone mold was not surrounding the transmitter, load data could not be collected.

Pure silicone is a bioinert FDA approved implant material and used in a variety of implants and is a safe substance to implant with transmitters. Adequate transmitter operation was restored *in vivo* when the waterproof silicone casings were in place. However, in both of the 6-month test animal studies the silicone casings were noted to have fractured *in vivo*. The molding process used to create the molds was a custom process and additional experimentation with different mold shapes may provide a more durable design to facilitate long-term transmitter function. If a silicone mold design that remains intact *in vivo* is developed then transmitters implanted with a silicone coating should allow for more reliable data collection.

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