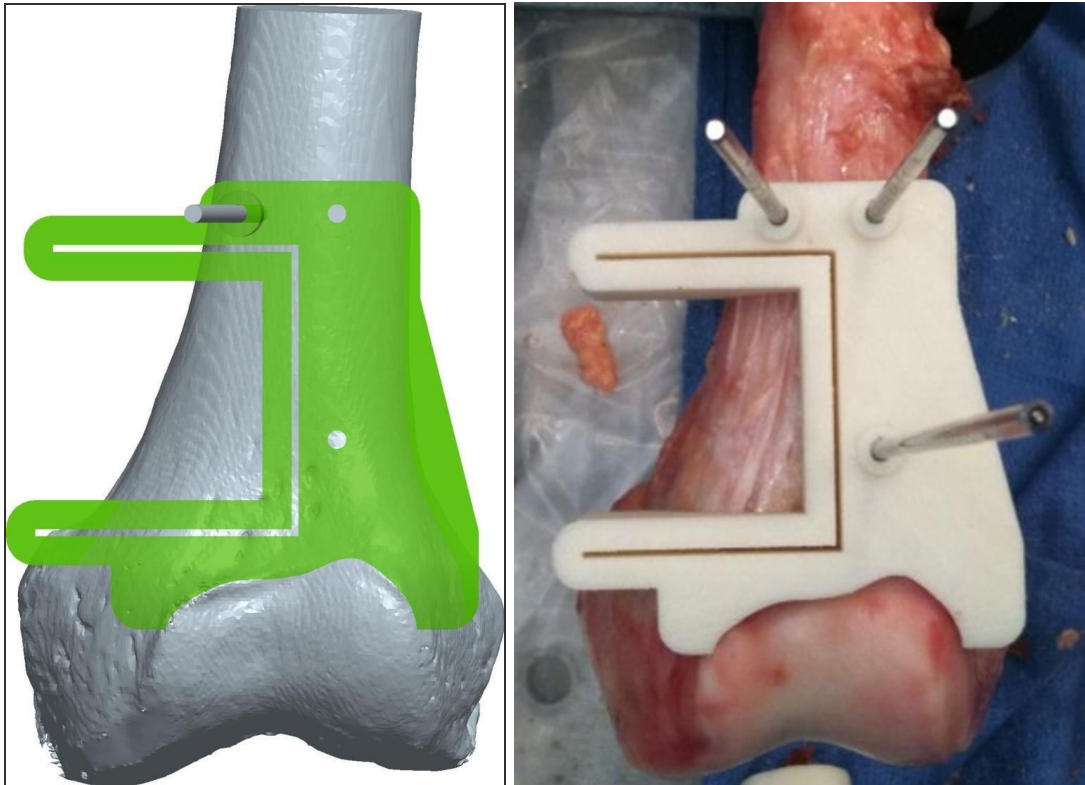


3D Printed Orthopedic Cutting Guides for Veterinary Surgery



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12-7-17

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Executive Summary

Veterinary surgical procedures used to fix deformities in animal bones have traditionally relied on the surgeon's freehand cutting abilities. With the aid of 3D design software and CT imaging surgeons can now map out their surgeries quite accurately but the actual accuracy of the cuts is left entirely to the competence of the surgeon. Herein lies the motivation for our project. This report aims to present the progress of our attempt to collect data to determine the feasibility of using 3D printed cutting guides to increase the accuracy of these cuts.

Orthopedic cuts are generally quite complex for instance a cut may be oriented 23 degrees from the sagittal plane and 14 degrees from the frontal plane. Using a cutting guide the surgeon would be able to perform this cut with accuracy and precision. Ideally, this improved accuracy could provide an improved recovery both in the long-term and short-term. However, there is very little research on this subject that demonstrates safety, and the long-term effects cutting guides have on the health of the animal. Our research aims to accomplish three goals: to quantify the safety of the cutting guide with wear and thermal tests, the accuracy with metrology, and if the first two goals are met, determine if the improved surgical accuracy has improved either short-term or long-term health benefits to the dogs which surgery was performed on.

Our research this semester accomplishes most of our first goal of determining the safety of cutting guides for use in surgery. The main concerns with safety were heat and wear. Since, the cutting guides are made out of plastic we hypothesized that the friction of the saw blade moving on the cutting guide surface could generate enough heat to deform the cutting guide. In our testing we found that no significant increase in temperature occurs on the cutting guide surface. Our client pleased with this results then requested that as part of our research next semester, we would quantify the heat generated in the bone of the dog. This will be important in order for the surgeon to know the pace at which they must cut at because avascular necrosis or the death of bone tissue is extremely detrimental to the recovery of the animal. When we quantify the heat generated in the bone, we will accomplish our goal of demonstrating the safety of the guide.

Our second concern regarding safety was wear based. We were able to conduct our test parallel to our heat test and found very little material was lost during cutting. This means that our client can safely cut knowing that polymer material is not contaminating the wound of his patient.

In the future, along with quantifying the heat generated on the bone do to cutting, we will run tests on cadaver bones and 3D printed bones in order to quantify and show hypothesized increases in accuracy when compared to free hand cuts. At this point we will publish our data and our client will perform long-term studies to determine the effect the use of cutting guides has on the short-term and long-term recovery of his patients.

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Introduction

Deformities in the bones of animals can cause severe pain, infections, and can threaten the animal's ability to move on its own power. The surgical procedures required to fix these conditions require a very high level of accuracy and it is often left up to the skill of the surgeon's freehand cutting ability alone to achieve. The UW-Madison school of Veterinary Medicine performs around 160 of these types of procedures in a given year. This proposal will describe how we wish to investigate the feasibility of using 3D printed methods within the University of Wisconsin-Madison to create patient specific orthopedic cutting guides to aid in these surgeries.

There are already examples of this kind of technology being utilized in both animals and humans; however, most of these cutting guides are created by 3rd party sources^[2,4]. The problem with ordering a guide from an outside source is the cost, which in the case of animals, can often deter owners from having the procedure done on their pets.

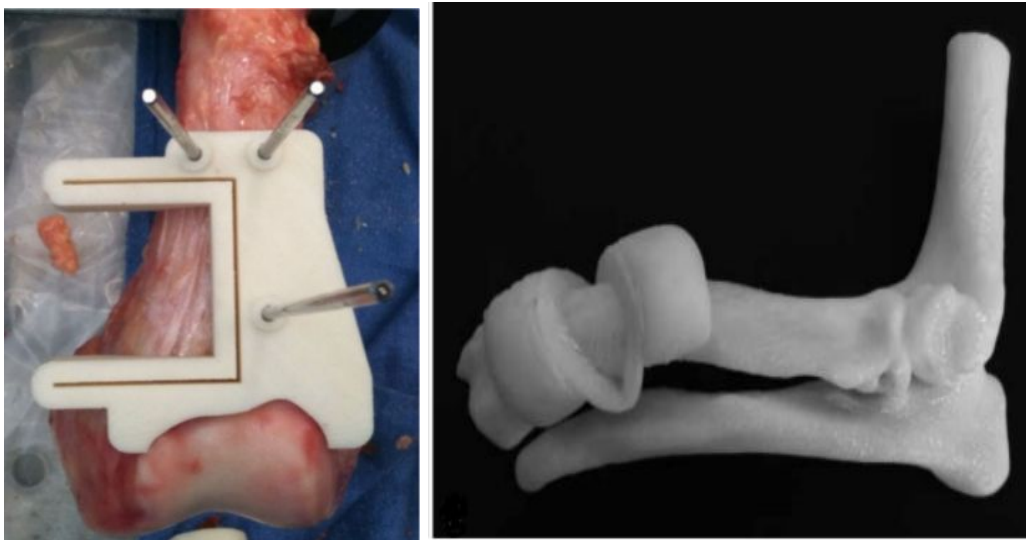


Figure 1: Right) Example of 3D printed cutting guide mounted on a 3D printed dog forearm. Left) Example of a 3D printed cutting guide being tested on cadaverous human bone^[2,4].

Figure 1 shows examples of existing 3D printed cutting guide concepts. While these guides exist there still is not a large amount of data regarding the safety and overall efficiency. This prevents the guides from being used regularly in surgery. This proposal will outline the testing plan for analyzing the safety, accuracy, and applicability of 3D printed cutting guides. The safety testing will be concerned mainly with heat and wear of the material during the cutting operation. Heat could cause the material to melt and deform which could lead to inaccuracies and wear can leave particulates of material in the patient which may cause any number of side effects.

Problem Statement

Any pet owner will agree there is something special about seeing their pet happy and healthy and able to roam, run, and play. Imagine having to see your pet unable to fulfill its desires due to a deformity in their bone growth, which is the unfortunate reality of many household pets. Bone deformities in both animals and humans can often lead to future problems such as pain, infection, and loss of mobility and these issues can be exacerbated by a lack of surgical precision. Because of this, our client Jason Bleedorn, a surgeon within the UW Veterinary Department, is seeking a cost efficient way to reduce the chance of surgical error in the form of an orthopedic cutting guide to aid the removal of bone deformities in animals. Currently, methods to obtain an accurate cutting guide can cost up to \$10,000, which is too expensive for an average pet owner. This leads to the surgeon relying on his/her freehand cutting abilities which have a larger margin of error. We hope to utilize in-house 3D printing as a less expensive alternative to provide these guides to Jason Bleedorn and his colleagues; with the intent to increase the general quality of orthopedic care for animals over time.

Background

Bone Deformities

Bone deformations may occur during the congenital phase of life (birth), during the developmental phase, or may result from some traumatic event such as damage to the growth plate. In addition, the type of bone deformation varies. There can be an angulation deformity (bend in the bone), rotation or twist of the bone, displacement of the bone, or a length discrepancy^[17]. Fixing these bone deformities requires a fine degree of accuracy by the surgeon, as well as adequate materials for surgery.

According to the Heidelberg bone correction surgery^[6], a 3 step process is used to fix a two stage bone deformity in humans, however this process can be mimicked on any animal bone as well. The process is as followed: the surgeon first identifies the CORA (Center of Rotation of Angulation) which is where the proximal and distal axis of the bone meet as shown in figure 2. Then, the surgeon uses a bone saw to move the bone and align the anatomical axis of the bone. The final step is to plate and screw the bone in the correct place using double locking screws, to allow for a proper heal and correction of the bone deformity. This process is very similar to that of Jason Bleedorn, a Veterinary Surgeon at the UW Veterinary Hospital.

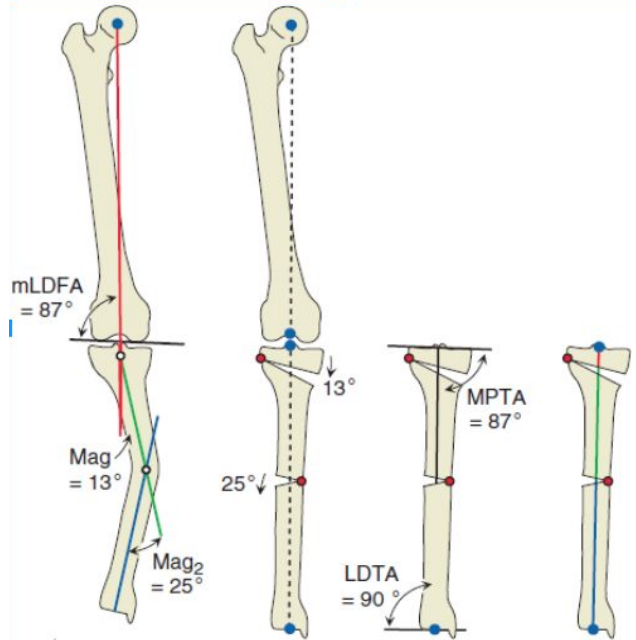


Figure 2: Bone Deformation Correctional Surgery. CORA(s) located at white dot.

Existing Methods

There are currently third party companies that manufacture orthopedic cutting guides that can be used to assist the surgeon when making the bone cut. A process called Visionaire (figure 3) was developed by a team of engineers at Smith and Nephew. This process allows radiologists to take CT images and x-ray images of a patient's deformed bone, and create a specific cutting guide for that individual. However, this is only used in human knee replacements and not for correcting bone deformities^[9]. One key step in Visionaire's process is manufacturing the cutting guides. Currently, their main method of production is by using a CNC (computer numerically controlled) machine. This can be very time consuming and costly, as there are many alternative approaches, namely 3D printing, that could be taken.



Figure 3: Visionaire Company



Figure 4: Stratasys 3D printing Company

Stratasys is a 3D printing company and manufacturer of 3D printing materials (figure 4)^[8]. 3D printing technology is still relatively new having come out in the past few decades. It offers an incredibly intricate and promising solution to time consuming machining. This technology can be used to 3D print a cutting guide for a particular animal or patient. Using CT scans and the software CALYPSO, we will be able to send a geometric model to SolidWorks, which will then

be uploaded to a 3D printer.

In addition to a patient specific process such as Visionaire, 3rd party 3D printed guides, there are more general cutting guides on the market. For example, there is a device produced by Johnson & Johnson in which surgeons may attach different sized cutting slots on to a mechanism which allows a variety of different angles and sizes of cuts to be made^[18].

Marketability

Veterinary surgeons would primarily benefit from having a patient specific orthopedic cutting guide, as it would allow for a much more accurate and precise cut when correcting the bone. By importing an image of the bone geometry, and using 3D printing technology, the cutting guide will be able to fit snugly with little or no human error. The guide would also help the animal with recovery time, as a more precise and efficient surgery will make the bone heal more quickly. Finally, the animal owners in turn will have more trust in the surgeon if proper instruments are used in surgery. Overall, the cost of transitioning into a more patient specific approach to correcting bone deformities is unknown currently, as there hasn't been enough research on the topic; with that said, the opportunity cost of the surgeon will go down because of a quicker surgery.

Objectives

The aim of this project is to collect data and determine the feasibility of 3D printed cutting guides using resources within the University of Wisconsin-Madison. The three main areas of interest are safety, accuracy, and applicability. This was done by creating a standardized testing specimen which we can use to collect consistent data. Next semester we will be testing on actual bone and with custom cutting guides.

Biocompatibility

With any cutting process there will always be material lost in the form of dust particulates. In our case there will be dust from the bone being cut and potentially from the cutting guide itself depending on the toughness of the material. If there are particulates coming off of the guide we must determine how much is being lost and what are the acceptable levels of that specific material getting into a surgical wound if there are any.

Accuracy

A major goal of this research is to provide surgeons with a way to increase the accuracy of their cuts compared to their freehand cuts. This semester's objective regarding accuracy consisted of creating an optimal testing environment and do initial planning for future testing.

Applicability

The design and implementation of custom cutting guides must be applicable to any or most small animal long bones.

Testing Guide Designs

Preliminary Designs

We began by creating a few different testing specimen geometries, with varying gap widths, to be attached to bone analog substitutes provided by Dr. Bleedorn. These widths were varied by 0.05" starting at 0.15" greater than the blade thickness. Figure 5 shows our first testing specimen. It is designed such that there are only two wear surfaces during cutting to reduce heat by friction. It also has holes at each end of the guide to help mount it to the test piece as well as holes in the front faces of the guides to allow for temperature probes to be embedded in the guide.

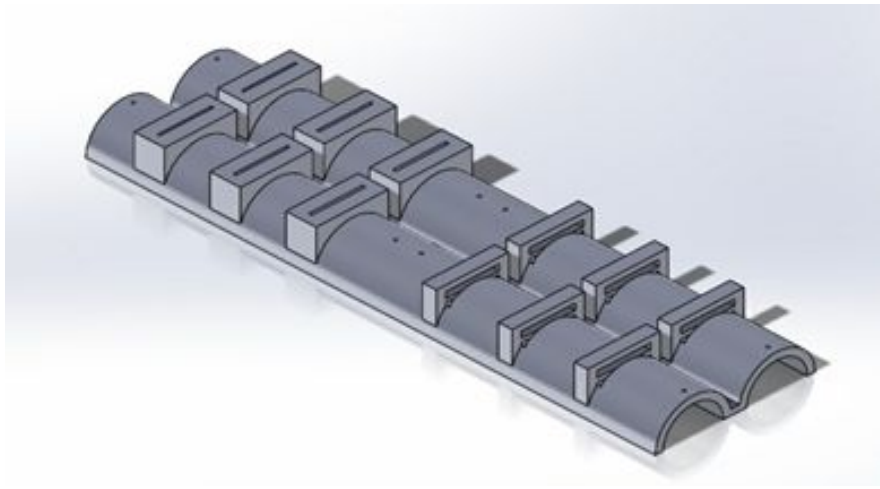


Figure 5: First cutting guide test specimen with one and two sided guide concepts, the part is arranged such that we could maximize the number of guides we can achieve with one 3D print.

Current Design

As seen in Figure 6, we made some improvements on how the part will be mounted on the test piece, mainly by extending the sides of the guide to touch the work surface during testing. Additionally, we changed the test piece from bone analog to a pine wood tube. We also widened the gap for the saw blade as well as added gaps on the side of the guide to allow debris to escape instead of falling back into the wound. The holes for the thermistors were also widened in order to allow for a better fit for our thermistor circuit.

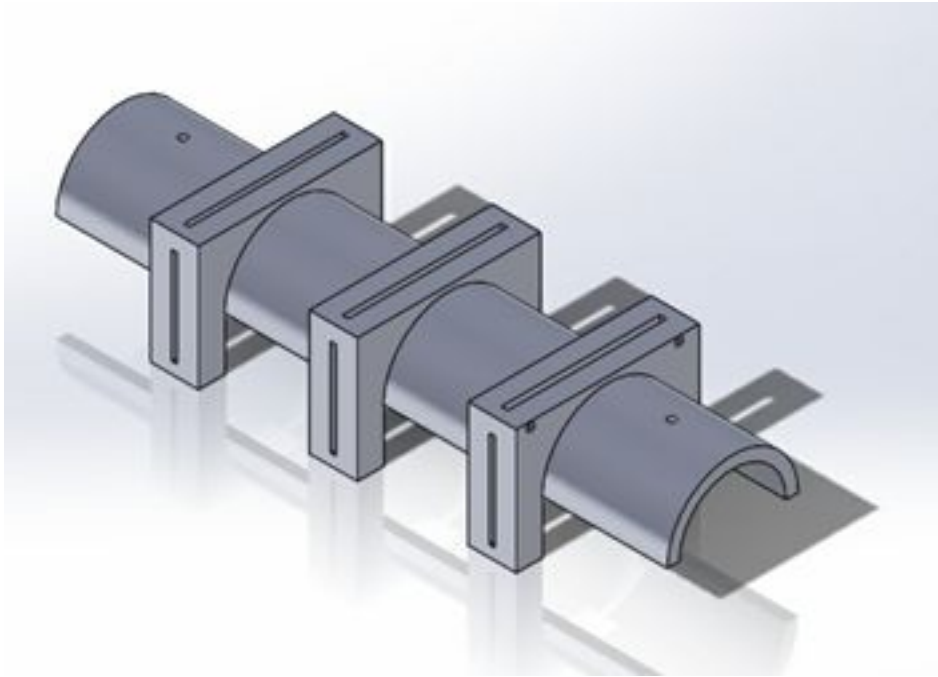


Figure 6: 3D model of the current test specimen.

Testing

Volumetric

The volumetric analysis is meant to determine how much material is lost after a cutting process. This test process is as follows:

1. Perform a CT scan of one of the test guides and record the volume.
2. Carry out a cutting test with the same guide.
3. Perform another CT scan of the post-cut part and record the volume.
4. Compare the volume of the original part with the new post-cut volume to determine how much material was lost and where it was lost from.

Weight

Like the volumetric test, this test quantifies the amount of material lost in the cutting process. The test is as follows:

1. Weigh the part before cutting.
2. Carry out a cutting test.
3. Weigh the part post-cut.
4. Compare before and after.

Heat

The thermal analysis involves using thermistors embedded in the test guide which actively measures the wear surface temperature during a cut. We wish to measure this because if the guide becomes too hot during testing it could deform the guide leading to inaccuracies in cutting. The thermistors will be set up in a voltage divider circuit with a known resistance, as seen in figure 7, and connected to a data acquisition system (DAQ).

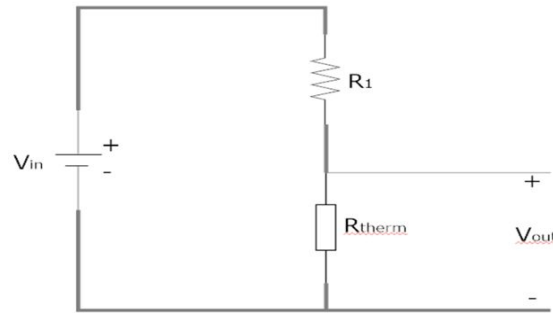


Figure 7: Voltage divider circuit used to determine temperature.

The DAQ will read the voltage of the thermistor (V_{out}) and the input voltage (V_{in}) into Labview to determine the instantaneous resistance of the thermistor, shown in figure 8. Thermistor resistance is calculated by:

$$R_{therm} = \frac{R_{known} * v_{out}}{v_{in} - v_{out}} \quad (1)$$

For our testing, we used NTC thermistors which had a pre-defined curve relating resistance to temperature. This curve was calculated using the equation:

$$T = \frac{B}{\ln\left(\frac{R}{r_{\infty}}\right)} \quad (2)$$

Equation 2 was then input into the LabVIEW VI (Appendix B) to obtain a continuous temperature read-out.

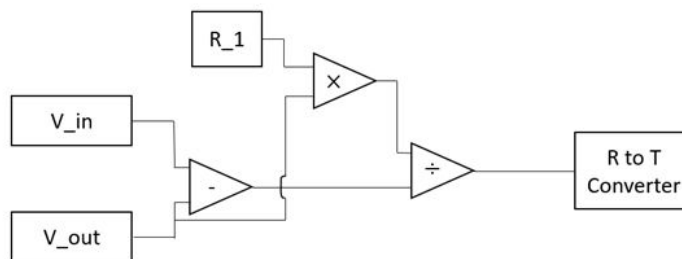


Figure 8: Block diagram representing the calculations being done within LabVIEW. The full VI can be found in the Appendix.

Results

Of the tests listed above we were able to finish carrying out the thermal analysis and weight measurements due to issues with volumetric analysis software. The test showed that there was no significant increase in the temperature of the wear surface of the cutting guide during cutting. The data is summarized in figure 9. From the data it is clear that cutting does not affect the material in any way as the temperature increases were on the order of $\sim 0.1^{\circ}\text{C}$.

The weight measurement results were not what we expected because it showed a 3% weight loss. We suspect that this data may be flawed. We will need to examine the volumetric losses with the CALYPSO software in the future.

	Before Cutting	After Cutting
Weight (mg)	21027.4	20379.8
Weight difference (mg)	647.6	
Weight loss percent (%)	3%	

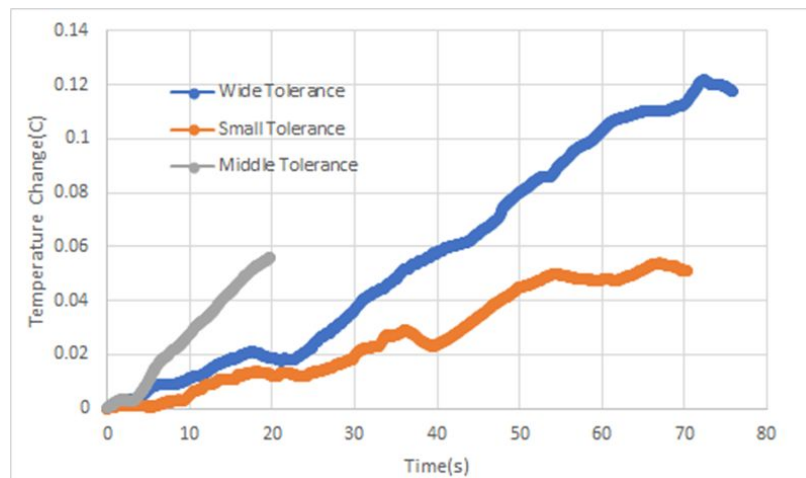


Figure 9: Graph of the temperature change of the cutting guide vs cutting time.

Conclusions

In conclusion, we have executed our goals as far proving the safety of the guide for use in surgery, and have planned out what we want to accomplish next semester. The safety of the cutting guides was proven with thermal, volumetric, and weight tests. Our client asked us to further investigate the thermal effects that cutting has on the bone of the animal. We will test this along with accuracy next semester which we will print all our test cutting guides for either

cadaver bones or 3D printed bone geometries.

Future Work

Keeping our initial results and limitations in mind, and after having a conversation with Dr. Bleedorn, next semester will focus on testing with real cadaver bones and creating guides that fit actual bone contours.

One of the elements that our client was most concerned with in this procedure is the amount of heat that is generated on real bone. To analyze this, we will drill holes in the cadaver bones (provided by our client) and insert our thermistors in strategic locations to measure the heat generated while cutting. This will mimic our thermal testing done in the guides but with the focus of analyzing the heat transferred to a real bone. This element is important to us and our client as it will be a big factor of the patient's recovery time.

We plan on printing guides that fit real bone replicas. Dr. Bleedorn has an archive of CT scans that will make available to us. From this archive, we will select models to 3D print and serve as our test models for the remaining of the project. These test models will be used with the guides to perform accuracy tests. This will determine how beneficial these guides can actually be in a real case scenario.

Our accuracy tests will determine the feasibility of different cuts in "hard" angles to cut for a surgeon. In this test, the 3D printed bone will be cut without the use of a guide. The same cut will then be performed on an identical bone using the guide. Both cuts will be scanned and compared against the initial planned cut using CALYPSO software. This planned standard will be given to us by Dr. Bleedorn and will allow us to determine if 3D printed cutting guides offer a significant increase in accuracy over free-hand cutting.

Appendix

A. Equations

Thermistor resistance in voltage divider (1):

$$R_{therm} = \frac{R_{known} * v_{out}}{v_{in} - v_{out}}$$

Where v_{in} and v_{out} are measured directly from the circuit via a portable DAQ.

□-parameter Equation (2):

$$T = \frac{B}{\ln\left(\frac{R}{R_0}\right)}$$

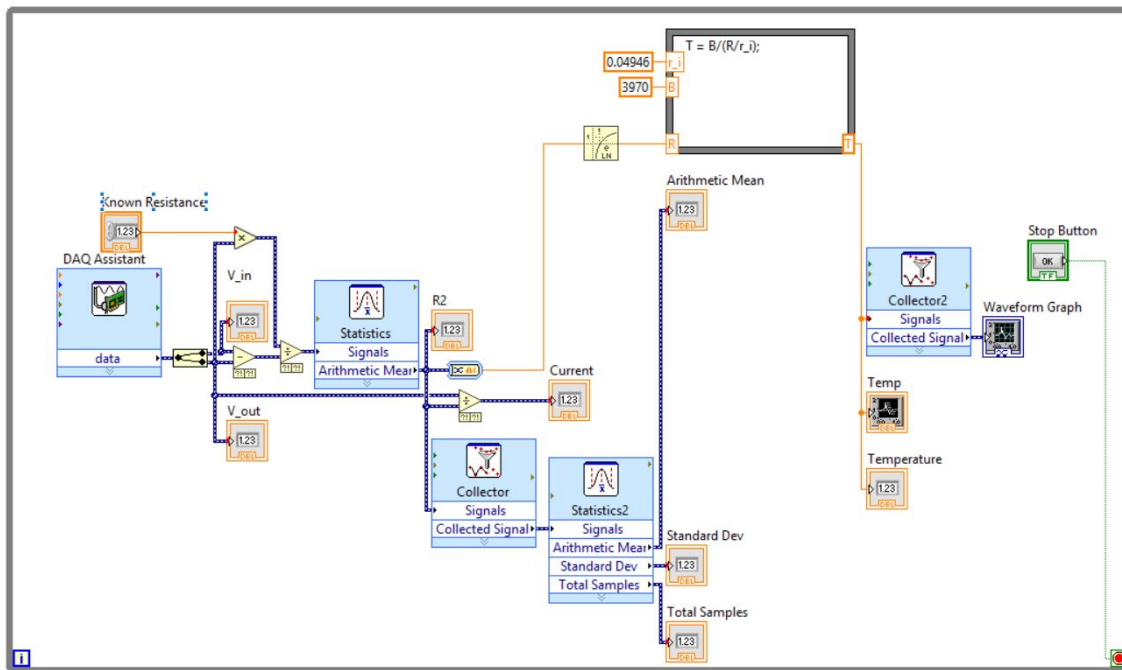
$$R_\infty = R_0 e^{-\frac{B}{T_0}}$$

This function is used to convert the resistance measured via Equation 1 into a readable temperature. The constants of the equation were determined from the provided datasheet which came with the thermistors.

B is the β -parameter, a given constant unique to the thermistor; T_0 is the reference temperature; and R_0 is the resistance value at that temperature. Their values are as follows: $T_0 = 298.15$ K, $R_0 = 30,000 \Omega$, and $B = 3970$.

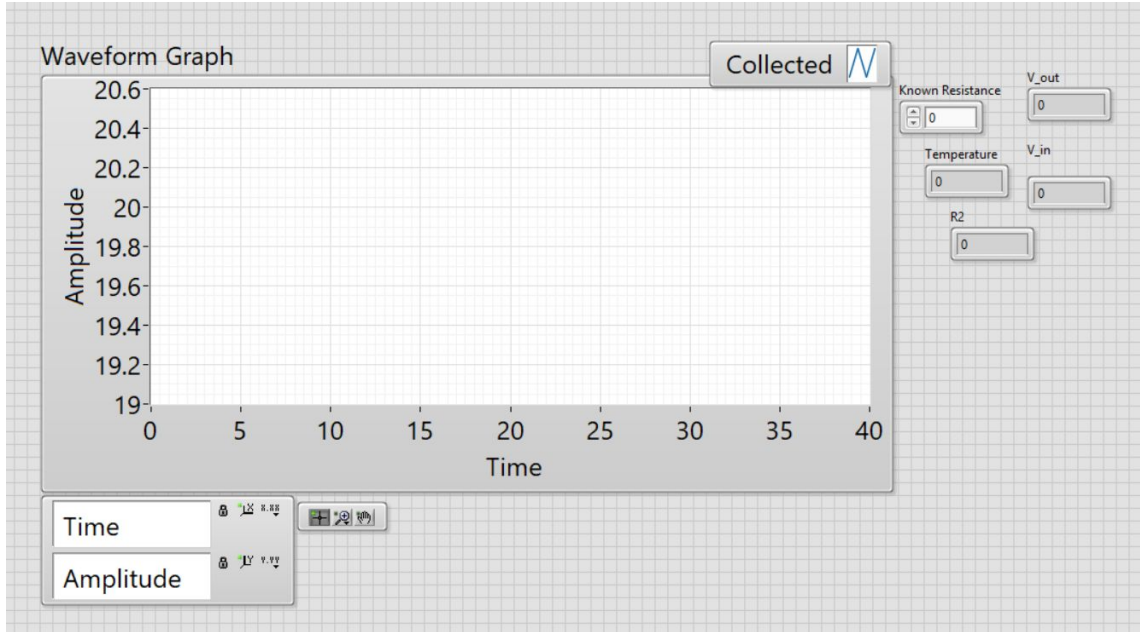
B. Code

Thermistor VI Block Diagram:



Once started, the LabVIEW VI takes continuous data from the DAQ consisting of V_{in} and V_{out} . From these values, the resistance of the thermistor is calculated. The standard deviation and sample number of this resistance are calculated throughout the test duration. At the same time, thermistor resistance is converted into a temperature via the β -parameter equation (Appendix A). This temperature is then recorded and graphed. This cycle continues until the stop button is pressed.

Thermistor VI Front Panel:



The front panel of the VI contains the temperature and circuit information as well as a continuous graph of temperature over time. The known resistance value used in calculations can be changed on the right of the graph. This allows the VI to work with different resistor values.

C. Gantt Charts

Fall Semester:

Schedule for first semester of project		October				November					December			
		5	12	19	26	2	9	16	23	30	7	14	21	28
Meetings	Team	X	X	X	X	X	X	X	X	X	X			
Meetings	Faculty Adviser	X	X	X	X	X	X	X	X	X	X			
Meetings	Client					X		X		X				
Meetings	CT scanner training				X									
Deliverables	Final Progress Report											X		
Deliverables	Progress Report	X	X		X	X	X	X	X	X	X	X		
Deliverables	Fall Design Review				X							X		
Deliverables	Symposium Registration/Event											X		
R&D	General Research	X	X	X	X	X								
R&D	Testing proposal (faculty adviser)			X	X									

R&D	Testing									X	X	X		
R&D	Analysis										X	X		
Phase 1 End	Deliver recommendations/plan for next semester										X	X		

Spring Semester:

Schedule for 2nd semester of project		Jan.		February			March					April			
		22	29	6	13	20	27	6	13	20	27	7	14	21	28
Meetings	Team														
Meetings	Faculty Adviser														
Meetings	Client														
Deliverables	Final Progress Report														
Deliverables	Progress Report														
Deliverables	Spring Design Review														
Deliverables	Symposium Registration/Event														
R&D	Testing														
R&D	Analysis														

The schedule for the Spring semester is currently tentative as we have get to receive the class schedule. Because we have a working guide design, the majority of the semester will be spent on testing and analysis.

D. PDS

3D Printed Orthopedic Cutting Guide

Team Members: Andrew Knoepfel, Anuar Acosta, Chelsie Metz, Daniel Simmons, Thomas Friesch

Function:

Bone deformities in both animals and humans can often lead to future problems such as pain, infection, and loss of mobility. These issues can be exacerbated by a lack of surgical precision. Our client Jason Bleedorn, a surgeon within the UW Veterinary Department, is looking for a cost efficient way to fabricate an orthopedic cutting guide to aid the removal of bone deformities in animals. Currently, methods to obtain an accurate cutting guide can cost up to 10k, which normally is too expensive for an average pet owner. We hope to utilize 3D printing

as a less expensive alternative to provide these guides to Jason Bleedorn and his colleagues and to increase the general quality of orthopedic care for animals over time.

Client Requirements: The cutting guide will be created using a pre-made CAD model specifying the specific dimensions of the specific animal bone, and we will be downloading the CAD models to a 3D printer. The client will only need a few before the end of the semester, as Jason only has a couple bone deformation surgeries scheduled.

Design Requirements: The following list is a set of requirements that must be fulfilled by the final product.

1. Physical and Operational Characteristics

1.0 *Performance requirements:* The cutting guide must be used once for each specific animal surgery. It must be able to withstand high amounts of heat and pressure from the sterilization process, as well as heat and physical stress from when the saw blade moves along its edge. Most importantly this product must be produced in a more cost efficient way than the normal manufacturing process.

2.0 *Safety:* This product will be made of a polymer so it can withstand high temperature and stress. The product must be sterilized before use in a surgical setting and the manufacturing process must be user friendly and non hazardous. Any mixing of polymers or handling of the 3D printer should be done with caution.

3.0 *Accuracy, Quality and Reliability:* The manufacturing process must reduce the cost of production by 30%. This process must be repeatable in a timely fashion to ensure maximum manufacturing efficiency.

4.0 *Life in Service:* This process will be implemented and used indefinitely if it turns out to be more efficient than the current cutting guide manufacturing process. The guide itself will be used once on each specific patient case and then recycled.

5.0 *Shelf Life:* The process does not have a shelf life however the cutting guides will maintain their appearance and performance for long periods of time, as plastic is not easily corrodible.

6.0 *Operating Environment:* The process must be operable in any location with access to a 3D printer, electricity, and the correct polymer. The guide itself must be operable in a surgical setting. The guide must be able to withstand exposure to light, bodily fluids, metal, radiation

from imaging, and physical stress. The guide must also be able to withstand the 121°C and 15 psi used in the sterilization process.

7.0 *Ergonomics*: The process is mainly computer operated. A CAD application must be accessible to create the design, and a human must import the CAD model to the 3-D printer. The cutting guide itself must be user friendly and easy to handle for the surgeon and any surgeon assistants in the operating room.

8.0 *Size*: The manufacturing process is to ideally be large scale if it is economically efficient. The cutting guide's size will vary based on the specific case, however it must be large enough to allow for an accurate cut of the animal bone

9.0 *Weight*: The process does not have a weight, however the cutting guide's weight should be light enough to be easily handled, and durable enough to withstand force.

10.0 *Materials*: The process is to be made using CAD models, a 3-D printer, and a polymer.

11.0 *Aesthetics, Appearance, and Finish*: The produced cutting guide is to be smooth and precise.

2. Production Characteristics

12.0 *Quantity*: The number of units needed during this process is one per surgical case. However, this production method will take place at a large scale.

13.0 *Target Product Cost*: The production cost of this method is to be 30% less than the standard manufacturing method.

14. *Testing*: We will test the different polymers in order to determine which is the best to use under the given stresses. We will then conduct a feasibility test in order to determine how much more efficient a 3-D printed cutting guide is compared to the normal CNC manufacturing method.

3. Miscellaneous

15.0 *Standards and Specifications*: Cutting guides produced via this method must meet FDA regulations for use in a surgical setting.

16.0 *Customer Requirements*: This production method must be cheaper, faster, and more precise than the traditional method.

17.0 *Competition*: The current method of producing cutting guides is to mill them using CNC.
(source needed)

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