Growth Plate Measurement Device

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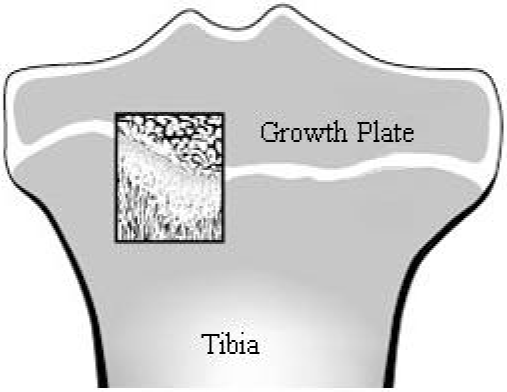

Abstract

For this project we looked at methods to measure the differential elongation of the growth plate to quantify the timing pattern for a given rate of bone elongation in a lamb's tibia. Past methods of measurement involved the use of fluorescent dyes and a Contact DVRT. These methods became inadequate in trying to precisely examine differential growth. For accurate measurements a device is needed that does not impede natural movement in its host or span the growth plate, measures up to 10 mm, produces a time intensive sampling rate every 1 to 5 minutes, and has an accuracy within 10-20μm per measurement. We have created a prototype consisting of a pair of inductors that are implanted on either side of the growth plate. One inductor has a controlled voltage passing through it that is detected by the second inductor. Displacement can be measured by the strength of the signal received by the second inductor.

Design Problem

Create a device to measure rate of growth across single growth plate in a young, actively growing lamb by time intensive sampling.

Summary of the Design Information

The first step in this project was to study the prior methods of bone growth to build upon existing concepts. The first method studied was the fluorescent dying. This consisted of precisely timed injections of oxytetracycline, a chemical that adheres to cells only in the growth plate (Figure 1). This chemical would be left behind as the bone grows so a second injection would show a displacement between the two bands of oxytetracycline in the bone. Dividing the displacement by the time between the two injections provides a growth rate. Dr. Norman Wilsman and Ellen Leiferman used this method of measurement. They found that this method had drawbacks, as it was not very precise. It only gave one measurement and the lamb would have to be killed in order to get the measurement.

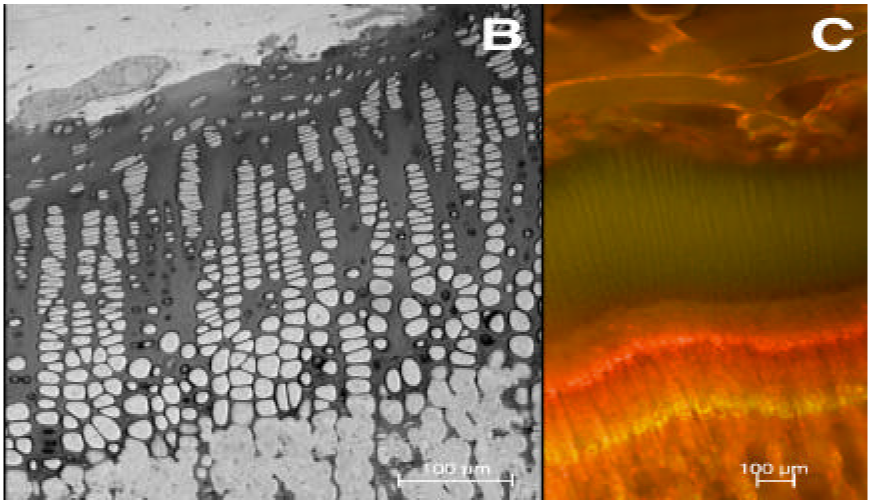

Figure 1: This picture is a close up of the growth plate. The image on the right shows the two lines of fluorescent dye. These lines are then measured to get a growth rate (Wilsman et al., 2002).

The second method used to measure growth was the Contact DVRT built by Microstrain (www.microstrain.com). This device had an element spanning the growth plate in a lamb tibia and was attached by bone screws (Figure 2). It would send a signal of differential reluctance through leads to a computer outside the lamb. This could be translated into a growth rate. This system worked, but only for a maximum of a 3-day span. After that time the device would become over-grown with immune system cells and lose its function. It was also prone to lose its signal while the lamb was on its feet or moving around. This caused the data gathered during that time to be disregarded for study purposes. A plastic sleeve was slipped over the device in an attempt to stop the build up of scar tissue, but this did not work. Immune system cells still broke down the material and adhered to the device.

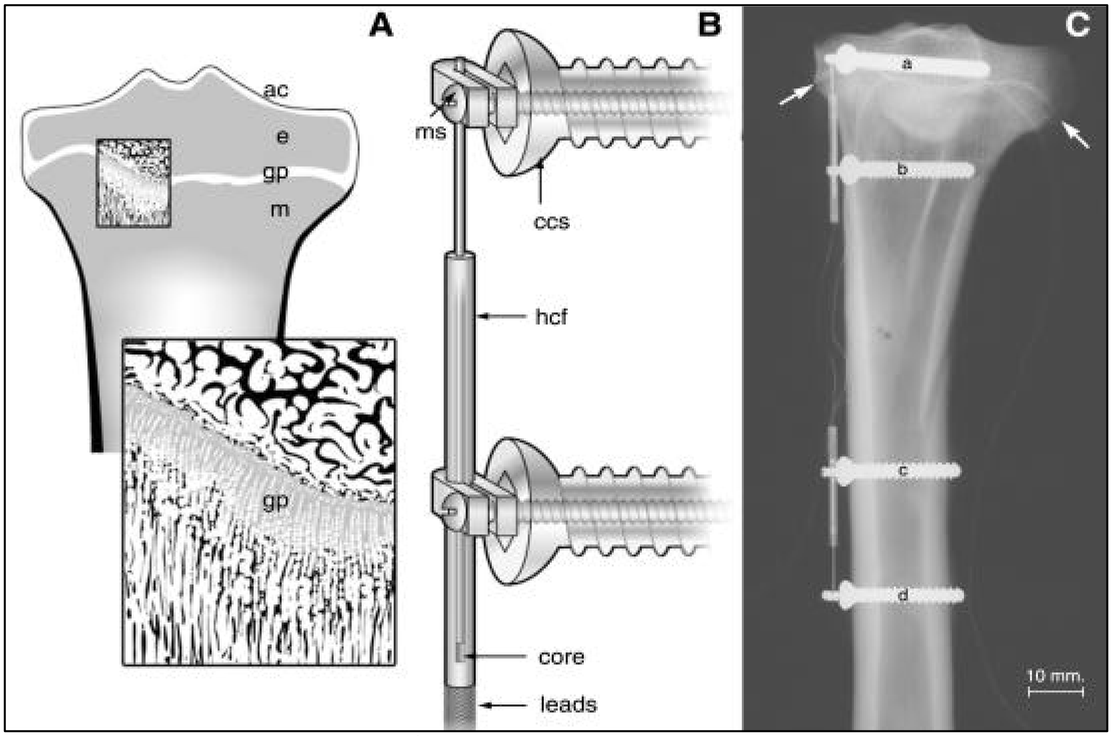

Figure 2: This is a diagram of the Microstrain Contact DVRT. It is attached by two bone screws and has an element spanning the growth plate that is capable of measuring displacement by detecting the coils differential reluctance (Wilsman et al., 2002).

Since the second method of measurement worked well except for a few drawbacks we decided to use that idea and improve upon the design. We did not want an element spanning the growth plate that could be disrupted by fibrous tissue, so we used magnetic wire to create coils. When a current is passed through the coil a magnetic field is produced that can be detected by a second coil. Therefore if we had two coils separated by a known initial distance a current could be passed through one coil and the resulting voltage could be sensed by the second coil. This provides a method to measure displacement in the growth plate of an elongating bone.

Specifications

While thinking of ways to approach the design of our device, our group thought a good place to start would be to make a list of all of the important specifications we needed to follow. One of the most important specifications that the device must follow is that it should not have any effect on the natural movements of the lamb. Currently a telemetry unit hovers above the lamb as it moves around its pen. There are no wires or leads that would cause the lamb to trip. The next specification that our device must follow is that it should have the ability to accurately measure displacement up to 10 millimeters. There are no other current non-contact devices that we found in our research that can make accurate measures of displacement at 10 millimeters. The accuracy of the device we create is also an important factor. In current contact devices, used in measuring displacement, average resolutions are between 10-20 micrometers per measurement. The accuracy of our device should be within this range. Another important aspect of the device is that it has the ability to make rapid measurement rates. The optimal rate of measurement would be about one measurement every two minutes. Rapid sample rates are very important for the application of this device because the purpose of the device is to show that growth of the tibia occurs in rapid spurts. The final important specification for the device is that it should not span the growth plate. Current contact devices have a limited period utility due to the fact that after short periods of time being exposed to physiological type environments fibrous scar tissue begins to encapsulate the device. To solve this problem, our group plans to implement a non-contact type device that eliminates this problem.

Design Options

Three alternative solutions were further analyzed beyond the brainstorming phase. These three alternatives were modifying the current design (contact DVRT), use a non-contact DVRT, or design a new non-contact device. Ideally the current device would be modified because it currently fits most of the specifications and this would also keep the cost down. As mentioned previously the current design does not operate as well after implantation because of tissue growth on the device, among other factors. The DVRT contains a ferrite core which has a tendency to shift within the body of the device. After implantation fibrous tissue growth can begin affecting the growth rate. A possible solution to this would be to encase the device in a biocompatible polymer to reduce the effects of tissue growth. The current device also contains an element which spans the growth plate which could not be modified while keeping the current contact DVRT. This is a major factor in the tissue growth as well. There would not be as significant of a problem if the device did not span the growth plate. For this reason the modification of the contact DVRT was ruled out.

Microstrain, the company that designs the contact DVRT currently in use, designs a non-contact DVRT. A major benefit of using the Microstrain non-contact DVRT is the fact that it is compatible with all of the electronics the contact DVRT uses. This reduces the cost because only the non-contact DVRT itself would need to be purchased. Using the non-contact DVRT would also solve the problem of having an element spanning the growth plate, which is a primary specification. However, a chief drawback of the non-contact DVRT is its size. When measuring distances up to 9mm, which is what is required to satisfy the specifications, the diameter of the device becomes 3.6cm, which is much too large for our application. Because the device is implanted just underneath the skin it cannot be so large as it would effect the lamb's movement. This eliminated the non-contact DVRT as a design option.

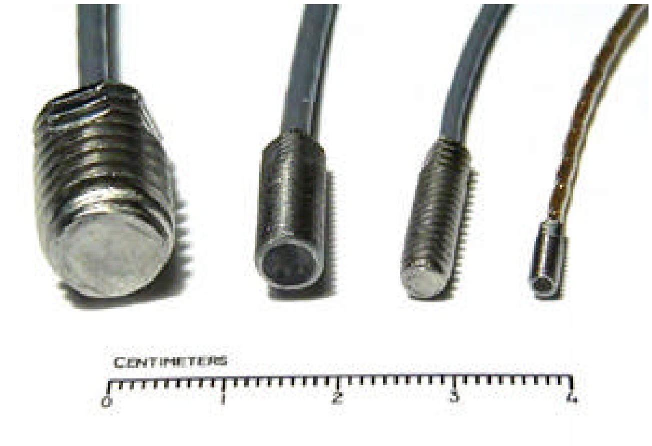

Figure 3: Various sizes of non-contact DVRT's. The largest can only measure distances a little over 3cm, much too small for our application (Microstrain, 2001).

Elimination of the previous two ideas led to the need for a new non-contact device to be designed. The two inductor design consists of two handmade inductors that are completely separate. An inductor is a passive electronic element that stores energy in the form of a magnetic field. In its simplest form, an inductor is a coil of wire. For testing purposes one inductor is fixed and the other is able to move. The fixed inductor would be implanted in the distal end of the tibia relative to the growth plate and the mobile inductor would be implanted in the proximal end. In this conformation when the mobile inductor moves away from the fixed inductor it mimics the bone growing and the proximal inductor moving away from the distal inductor. The distance between the two inductors is measured by inducing a voltage difference across the fixed inductor. This causes a magnetic field to be produced and the magnetic field induces a voltage across the mobile inductor. Strength of magnetic fields is a function of the inverse square of one's distance from it. As the mobile inductor moves away from the fixed inductor the magnetic field felt by the mobile inductor is reduced and hence the voltage drop across it is also reduced. This drop in voltage is then measured by a voltmeter and a relationship can be formed between an induced voltage and the distance between the two inductors.

The two inductor design would fit all design specifications. The inductors can be made to be small enough to meet specifications. A polymer can be used to encase them to reduce effects from tissue growth in the lamb. And most importantly the device would not span the growth plate.

The Solution

Due to the well-defined specifications of the project, we felt that a non-contact device was essential. It seemed that any device that spanned the growth plate would only result in the same problems experienced by our client previously. We found that a commercial non-contact DVRT was not an option and therefore used that theory to engineer our own device.

The design is actually quite simple. It consists of two inductors; one that induces a magnetic field and one that detects that magnetic field. The inductors were covered in a plastic coating for protection and mechanical integrity. The two inductors are then attached to the bone in a way that is similar to the current attachment method. Each inductor is wrapped in a nylon bracket which is then screwed into the bone using bone screws. It is important that the orientation of the inductors is end-to-end in order to maintain the induced voltage-displacement relationship.

The device itself consists of two inductors each containing 100 winds, measuring approximately 0.325” in length, 0.125” in inner diameter, and 0.250” in outer diameter. Each end of connecting magnetic wire is then soldered to a 3” length of copper wire for easy power source attachment. Each inductor is attached with a 0.250” diameter clamp. The rest of the prototype is simply a setup to show attachment to the bone and enable easy movement to display voltage detection with displacement. All prototype base components are made of clear plastic held together with stainless steel screws. It is for display only, but a drawing of the entire setup can be found in the appendix. A detailed list of the cost of the device components only can be seen in table 1.

Table 1: Approximate costs of device components.

Component	Cost
Magnetic Wire	Free (obtained by Dr. Webster)
Plastic Coating	$3.98
Nylon Brackets	$1.99
Stainless Steel Screws	$3.00
Power source	supplied
Multimeter	supplied
Approximate Cost (Device only):	$8.97

Part of the design process included choosing materials that were biocompatible. Because stainless steel was used in the contact DVRT, we used stainless steel screws as our mode of attachment. The copper magnetic wire, although it is coated, would not handle the biological environment very well. For this reason, we coated the wire with a shrinkable polyurethane plastic. Nylon clamps were chosen instead of metal so that they would not interfere with the inductors and to aid in the biocompatibility of the device.

The 100-turn inductors were chosen for several reasons after testing other coil sizes. The 100-turn set of inductors produced a signal that was strong enough to measure displacements up to 10mm and beyond. Data was obtained from five test trials in air and ten test trials in saline. At a displacement of 1mm a voltage was induced across the mobile inductor of 15.89mV in air. The voltage decreased to 1.98mV at a displacement of 10mm. The curve formed by the data between 1mm and 10mm resembled that of a second or third degree polynomial. The standard deviation observed for this data ranged from 0.025 to 0.682. These results can be seen in Figure 4. When immersed in saline, the inductors performed with similar accuracy but reduced strength. However, the induced voltage was still strong enough to give accurate measurements at 10mm. At a displacement of 1mm a voltage was induced across the mobile inductor of 11.56mV in saline. The voltage decreased to 1.05mV at a displacement of 10mm. Again, the curve formed by the data between 1mm and 10mm resembled that of a second or third degree polynomial. The standard deviation observed for this data ranged from 0.027 to 0.254. These results can be seen in Figure 5. Standard deviations are shown as bars in both figures.

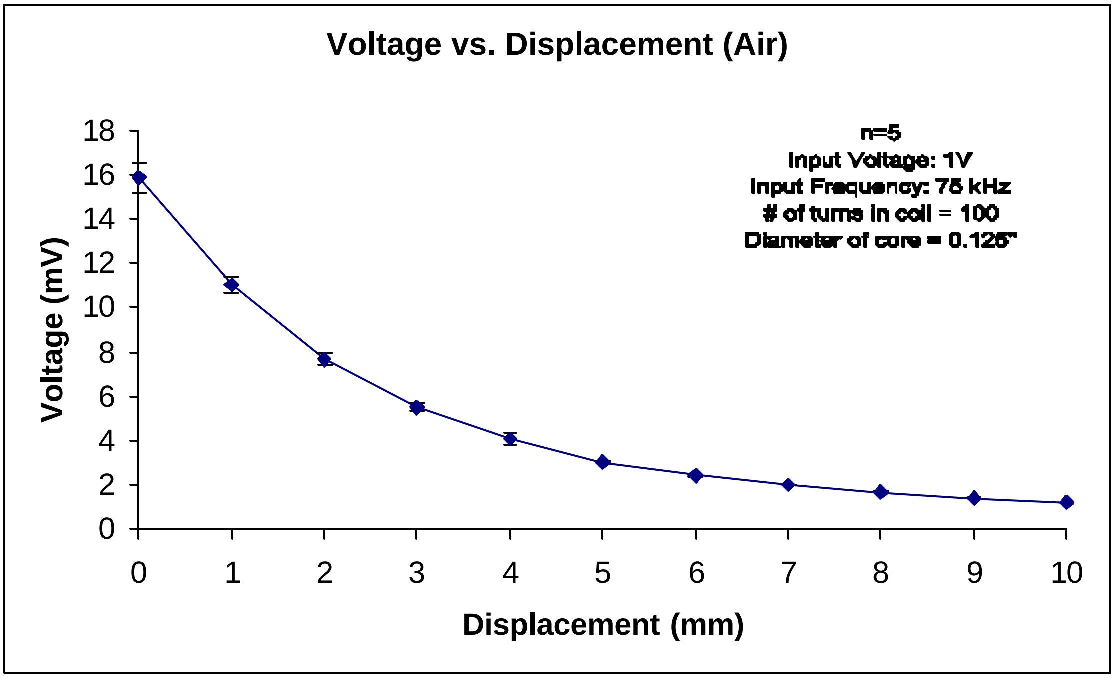

Figure 4: Plot of induced voltage as a function of displacement. Measured in Air.

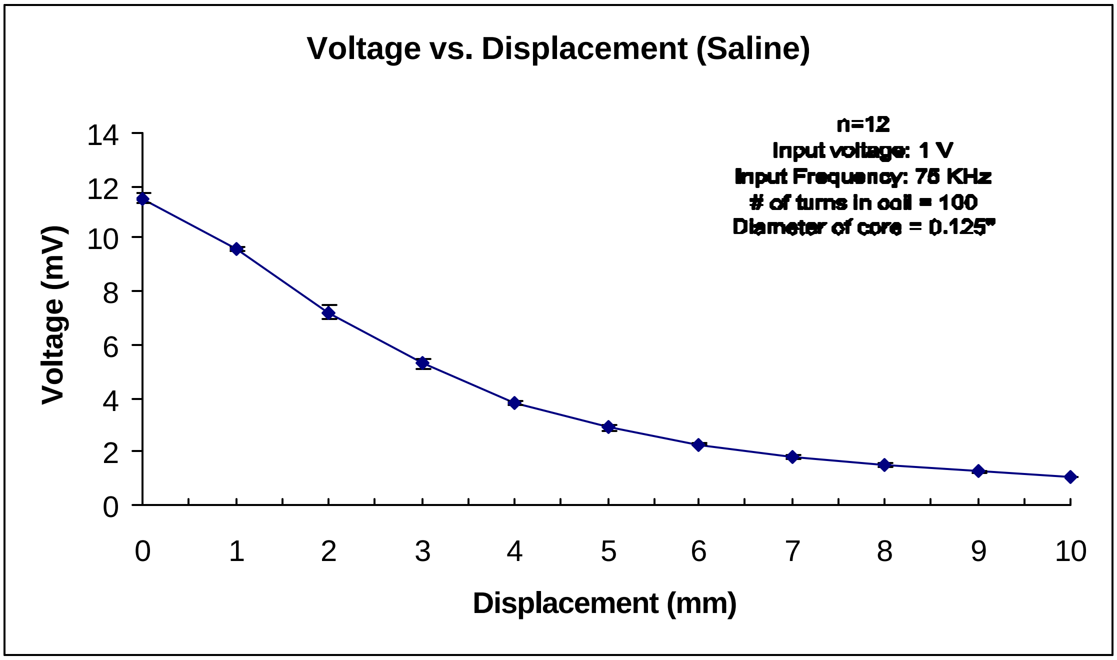

Figure 5: Plot of induced voltage as a function of displacement. Measured in saline.

Conclusion

Ethical Issues:

The main ethical issue that should be taken into account when working on this device is the safety of the animals being tested on. Several agencies around campus set strict regulations on the type of testing that can occur. One of the issues that should be taken into account when performing testing on animals is the best time to end a trial. The investigator should know when an amble amount of data has been taken and at that point should decided to terminate the study. Another issue that must be considered when developing our device is that proper testing in various different conditions occurs. Testing should be done to verify that the temperature of the device is constant. Other factors such as pH, amount of current leakage, and general device biocompatibility should also be closely monitored. A final step that should be taken after completion of testing is application for FDA approval. These steps should help ensure that the device complies with all stringent ethical standards.

Future Considerations:

The major future consideration that must be handled for this device is finding the safest and most efficient way to mechanically attach the device to the bone. Attachment to the bone on either side of the growth plate is a paramount issue, because the accuracy of the device is dependent on the stability of the components of the device. If the device shifts one millimeter in any direction it could cause large variations in measurements. This problem is one that our group considered throughout the semester but never completely figure out how to solve. The main objective of the next semester of work on this project should be focused on solving this problem. Other issues that should be considered in future work on this device are first finding ways to keep low input voltages while increasing output signal, and also continued testing. The continued testing of the device could lead to high levels of accuracy by determining the exact amount of output voltage at each small distance. After modifying certain small aspects of our device, it could be a very powerful tool in various research applications.

References

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2.) Microstrain, Inc. Manufacturer of microminiature sensors [Company web site]. ©2002 Available at: www.microstrain.com Accessed October 15, 2002

3.) Breur G, VanEnkevort B, Farnum C, Wilsman N. Linear Relationship Between the Volume of Hypertropic Chondrocytes and the Rate of Longitudinal Bone Growth in Growth Plates. J of Orthop Research 1991; 348-359.

Appendix

Growth Plate Measurement Device

Product Design Specifications (PDS)
10/1/2002

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Function of Device:

The growth plate measurement device should sense the rate of growth across a single growth plate in a young, actively growing lamb by time intensive sampling. The device should be able to produce readings continuously over a four week period. It will help to answer the questions about the rate of growth in mammals. It is not known whether growth occurs continuously during development or if it comes and goes in spurts.

Client Requirements:

- Be innocuous to the lamb and its natural movements
- Capable of measuring 10 millimeters of growth over a one month period
- Have the accuracy of 10-20 micrometers per measurement
- Capable of time intensive sampling rates-measurements every 1-5 minutes
- *Device should have no element spanning the growth plate

*Current method has a transducer coil spanning the growth plate which is a major limitation. Its accuracy is compromised after a few days due to cell growth and animal movements.

1. Physical and Operational Characteristics

a. *Performance requirements*: There will be a few specific performance demands on this device. Initially, it is expected that each growth plate distance measurement unit that is placed in the lamb will be discarded after one use so the sterile conditions are more likely, however, this may change after more cost analysis. The device will also have to endure some loading from surrounding tissues while implanted in the lamb.

b. *Safety*: Safety issues are a very important part of the design process for this device. The device must be sterile to ensure it does not cause harmful reactions. Upon introducing a foreign material numerous infectious, and host response reactions are possible. A sterile device would help to lower the probability of these types of reactions.

c. *Accuracy and Reliability*: While measuring the change in distance in the two separating phases of the bone growth plate, the device is expected to maintain accuracy of within 10-20 micrometers per measurement.

d. *Life in Service*: The device is expected last for about three weeks which is the duration of the experiment. It is also expected that the device will be able to measure up to 1 centimeter in total length over the period of the experiment with the capability of time intensive measurement sample rates. (about 1 every 2.5 minutes)

e. *Shelf Life*: This device should not be stored in extreme temperatures because this may compromise many of the electrical components of the displacement sensor.

f. *Operating Environment*: This device will be exposed to physiological type conditions while operating. This means temperatures around 37º C, and a pH of about 7.4-7.6. Although stainless steel, a highly non-corrosive material will likely be used in this device, overtime corrosion of this material could occur due it's implantation in the extracellular fluid of the lamb. The people who will handle this device are veterinarians who implant it into the lamb.

2. Production Characteristics

a. *Quantity*: Initially, one complete unit will be needed. This will include all components. Because the fixation components will be the most replaceable pieces, a few extra could be considered.

b. *Target Product Cost*:

Component	Cost
Magnetic Wire	Free (obtained by Dr. Webster)
Plastic Coating	$3.98
Nylon Brackets	$1.99
Stainless Steel Screws	$3.00
Power source	supplied
Multimeter	supplied
Approximate Cost (Device only):	$8.97

3. Miscellaneous

a. *Standards and Specifications*: No FDA approval necessary, however specifications for the operation of the non-contact DVRT and related components are guaranteed.

b. *Customer*: Several aspects must be considered. The device should:

- Be innocuous to the lamb and its natural movements
- Capable of measuring 9 millimeters of growth over a one month period
- Have an accuracy of 10-20 micrometers/measurement
- Capable of time intensive sampling rates

- Have no element spanning the growth plate
- Take accurate measurements when the lamb is in any position
- Provide a signal that is not effected by movement of the lamb

c. *Patient-related concerns*: For each study, the device will be implanted for approximately 3 weeks. At the end of the 3 weeks the device is to be removed and then have the ability to be reused. The device must be sterilized before each implantation and thoroughly cleaned and sterilized after each extraction. In addition, because the patient is a lamb whose movements cannot be controlled, the device itself must have the ability to move with the lamb and in turn cannot be affected by the lamb's movement.

d. *Competition*: We will be using our design in combination with components that are commercially available. For this reason, there is no competition that we see at this time.

Appendix (cont.)

Drawing of Prototype