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Design for an Axial Lumbar Interbody Fusion Surgical Simulation

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Major Qualifying Project:
Design for an Axial Lumbar Interbody Fusion Surgical Simulation

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Spinal Fusion, Simulation, Lumbar Model

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Abstract

The AxiaLIF procedure is performed on the lowest level of the lumbar spine, the L5-S1 disc space, which is accessed through a 2 cm surgical incision adjacent to the coccyx. Due to the minimally invasive nature of this procedure, there is reduced surgical trauma, less blood loss, shorter operative time, and most importantly, faster recovery. Roughly 1,600 AxiaLIF procedures have been performed in hospitals across the United States (Aryan, H. E. et al., 2008); therefore, there are a limited number of physicians experienced in performing this procedure. Through the research conducted in the paper a biomimetic spinal anatomical model was created that can allow medical professionals to hone their skills performing the AxiaLIF surgery. The model includes the lower spine, highlighting spinal discs L3 through S5. The model also gives the learner feedback ensuring that the user does not cause any surgical complications. To ensure biomimetic capabilities, several materials were tested to see how their mechanical properties compared to those found in an actual patient; the most important biomechanical property being the density of sacral and lumbar bone, 0.120 g/cm^3.

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Chapter 1: Introduction

The Axial Lumbar Interbody Fusion (AxiaLIF) procedure is an alternative approach to traditional fusion procedures in the lumbar spine. This surgery, unlike previous fusion methods which require a ventral and/or dorsal approach, is performed from an anterior approach along an axis perpendicular to the L4 or L5 disc. The L5 to S1 disc space is accessed through a 2 cm percutaneous opening adjacent to the coccyx. The time of operation is under an hour, compared to the nearly 3 hours required in conventional fusion surgery. Due to the minimally invasive nature of this procedure, there is reduced surgical trauma, less blood loss, shorter operative time, and most importantly, faster recovery. With only about 1,600 AxiaLIF procedures completed in hospitals across the United States, there are a limited number of physicians experienced in performing this innovative method to spinal fusion.

In the field of medicine, mentorship and shadowing is the primary hands on teaching method, and until recently, there was no better way to learn new skills and techniques, other than observing more experienced physicians. Advancement in the understanding of the human body and the adaptation of technology into the medical field has allowed for simulation training to rise as the preferred method of teaching medical procedures. Simulation is defined as the use of a model to practice a task, in place of performing the task on the actual item or person. An example of this is when medical students are taught how to suture; a common simulation method is to use a needle, thread, and a sliced orange peel to simulate a skin wound. The proposed project will create a spinal anatomical model that will instruct medical students, residents and other medical learners how to perform the new AxiaLIF spinal fusion surgery.

Statement of the Problem

The client originally requested that the major qualifying project group design and create a surgical model of the AxiaLIF surgery. This surgery does not currently have an acceptable cost-effective simulation but is modeled via performing the surgery on cadavers, spinal segments from calves, or using sawbones. Although these methods allow the learner to perform the surgery, cadavers and sawbones are expensive, and calf spines are anatomically incorrect. There is a need for a simulation of the AxiaLIF surgery because it is a novel procedure that requires extremely precise and accurate movements. Any surgery, as exact as this one, would require an enormous amount practice and understanding from the surgeon. The problem is that since a cost effective, modeled simulation for this surgical procedure does not exist, learners are subject to errors and complications in surgery with live patients. Simulating this procedure could follow a variety of different paths, ranging from creating a fully simulated human with correct physiological responses to modeling an extracted spinal column containing only the absolute necessary anatomy for the surgeon to practice.

Project Goal

The goal is to use cost effective materials that are within 20% of the mechanical properties of each relevant structure in the body. Since the spinal components of the model are the focus of the surgery, it is vital that accurate to near accurate (within 20%, density: 0.0240 g/cm^3) mechanical dimensions are observed (spinal bone density: 0.120 g/cm^3) (Unosso, E., 2010).That being said, the density of the modeled lumbar and sacral bone should be between 0.0961 and 0.144 g/cm^3. The pedicle and facet joints of the spinal column are of a less concern given that the procedure is not focused on these components. The simulated colon should anatomically mimic the size and shape of an adult colon and alert the user if the colon is punctured during the simulation.

The following chapters outline the entire design process the major qualifying group followed to create a working prototype of an AxiaLIF surgical simulation model.

Chapter 2 - Literature Review

Simulation

Simulation in the medical field is defined as the artificial and simplified version of a medical procedure, where the aim is to enhance learning via teaching methods such as immersion, retrospective learning, feedback without liability (Datta, et.al., 20120). Simulation modules can also be used as a means of retraining or refreshing knowledge of a procedure (Satava, 2006). Types of medical simulation include computer simulation, video simulation, hands-on model simulation, and virtual reality simulation. Computer and video simulation models can be simple presentations teaching the user about how to use cardiovascular imaging effectively or they can be interactive systems which allow the user to manipulate physiological or pharmacological variables and learn to discover trends based on feedback from these simulations (Bradley, 2006). Hands-on model simulations cover all aspects of medicine from simulated blood pressure readings to ultrasound compatible central venous access training systems (Figure 1).

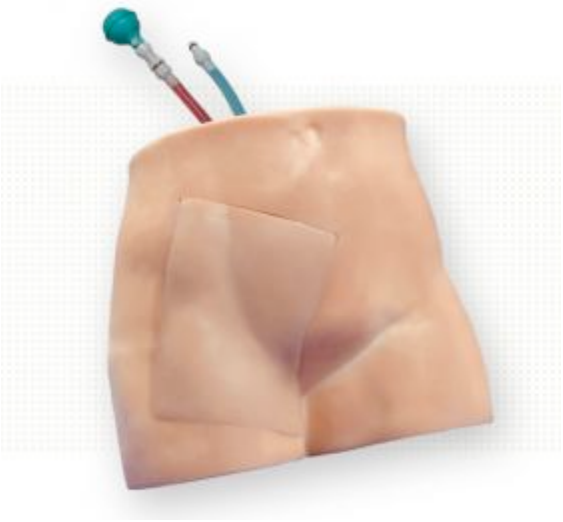


Figure 3: Central Venous Access Simulation (Simulab Corporation, 2012)

Virtual reality systems are the state of the art for medical simulation. These systems can be very expensive; however they are a very effective simulation tool as they incorporate haptic technologies involving force feedback within the virtual reality scenario. For example, if the user performing a surgical incision were to poke around the incision site, a force will only be felt when the scalpel virtually comes in contact with the computer model (Figure 2).

Figure 4: Virtual Reality Simulating a Surgical Incision (Universiteit Twente. 2012)

In a review of simulation studies by Sutherland it was concluded that computer and video simulation were not more effective than standard training procedures, however model simulation and cadaver training may have been better than standard training (Sutherland et. al., 2006). Standard training in this procedure was defined as the development of cognitive, clinical, and technical skills which are acquired during mentorship.

Benefits of Simulation

Simulation systems are attractive because they relinquish the need for patients in need of specific procedures, as well as because of their cost-effective nature. There are endless patients on which a student can learn how to take a blood pressure correctly, though there will not be as many opportunities to learn procedures such as complex surgeries. Simulation eradicates the need to wait to learn procedures. The average cost of training a surgical resident in an operating room for a duration of 4 years was determined to be $47,970 between the years of 1993 and 1997 due to the loss in operating room time (Bridges et.al., 1999). Even though modern medical simulators can cost up to $200,000, they are cost-effective when compared to the price of teaching residents in an operating room. When simulation models are compared to live animal or cadaver models, which can cost up to $5,000, for learning, it was proved that the quality of the technical skills learned were equivalent, and therefore the simulation model was the cost-effective method (Anastakis et.al. 1998). A main goal of simulation models is to create a comfort level for a user with respect to a medical procedure. For example, the first time a patient performs a spinal tap they will be nervous about the risks in the procedure. Simulation models act to reduce the fear of a procedure and calm nerves of an anxious medical professional. It was shown in a study which tested the operating room performance of students with simulation experience compared to students without simulator experience it was shown that simulator training positively affects initial operating performance in regards to instrument manipulation and confidence in surgical procedures (Edmonds et.al., 1997). The effectiveness of surgical simulation has led to the development of simulators for a wide variety of surgical procedures.

Drawbacks of Simulation

The use of medical simulations to teach, or reteach a procedure is very beneficial to the learner and the only downside of simulation that has been noted is the lack of realism presented in the modules. Simulators must sacrifice realism because of the complexity of the human body, and because a completely realistic model is not necessary to learn the necessary skills of a procedure (Satava, 2006). As an example, a simulation focused on helping a user learn how to suture does not need to perfectly match the biomechanics of human skin and therefore an orange peel is commonly used as a simplified, cost-effective alternative to a skin-like substance.

AxiaLIF Procedure Simulation

Currently the standard for learning the AxiaLIF procedure is through a variety of simulation modules including cadavers, calf-spines, and sawbones. The company hosts these training sessions and not only do they occur very infrequently but cadavers are expensive and are not feasible for more than one surgery; calf-spines do not exhibit the same anatomy as a human lumbar spine and sacrum, and sawbones, though they cost under $100, can be considered expensive if the simulation were to be used numerous times (Sawbones, 2012).

Chapter 3 - Project Strategy

Initial Client Statement

The initial client statement reads as follows:

Design and develop an anatomically correct surgicalffigure model of the AxiaLIF surgical procedure.

Objectives and Constraints

Client's Original Objectives

The client's original objective was given to us as a very broad request to create a surgical model of a procedure which currently does not have a cost-effective simulation model. As stated earlier, simulating this procedure could follow a variety of different paths, ranging from creating a fully simulated human with correct physiological responses to an extracted spinal column containing only the necessary anatomy for the surgeon to practice. Due to the ambiguity of the initial client statement our design group had quite a few questions:

- What exactly is the AxiaLIF surgery?
- What is the ideal surgical simulation that the client is asking for?
- How realistic does this model need to be?
- Who will be using this model? etc.

These questions were compiled and asked to a panel of clients, Dr. Melinda Taylor, Dr. Brian Sweeney, and Dr. Frederik Pennings. This client meeting led us to creating a revised objectives tree (Figure 3) and client statement based on their responses.

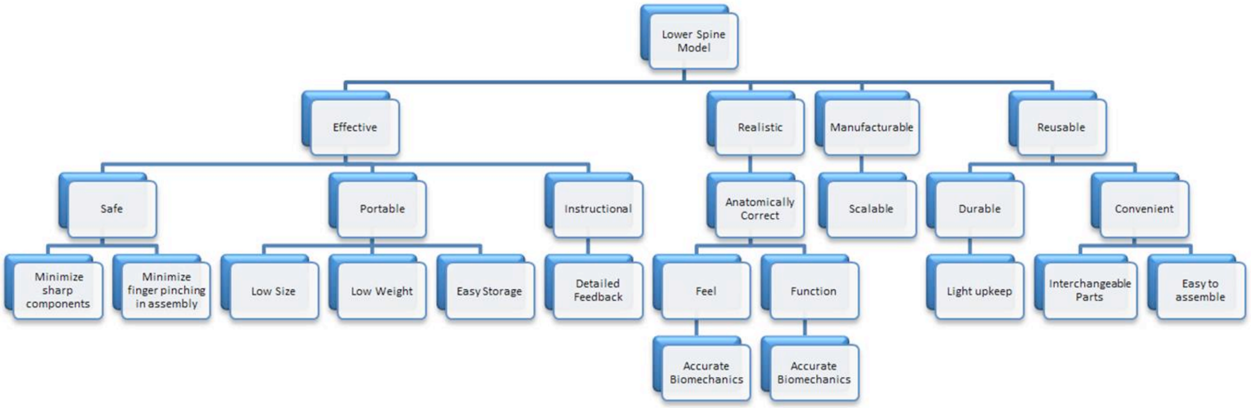


Figure 3: Revised Objectives Tree

Explanation of the Revised Objectives Tree

The AxiaLIF surgical model should be effective in relation to its typical usage. The model will match desired effectiveness if the model is safe, portable and instructional to an adequate degree. The model should be safe because the learner should not be harmed when completing the learning exercise. The model should present no threat of danger as the focus of the learning exercise should be on the procedures being taught. Any lapse in safety will distract the learner from understanding how to complete the taught procedure correctly. The model should be portable because the advisor's instruction space is limited and simulation models are stored in a separate area when not in use. Portability will thus increase the value of the model. The model should be instructional, to suit the needs of the learners, the hosting facilities, and ultimately the patients. In order to avoid future complications, the learner should be able to complete the exercise with a full understanding of what will be expected during surgery and how to properly run the procedure.

The model should be realistic. To serve as an effective teaching model, the AxiaLIF surgical model should be anatomically correct in feel and function. If the model is realistic in feel and function most if not all observations made in the model procedure will closely match those observed in the actual procedure, thus, allowing the learner to have foresight as to what the actual procedure will be like. In order to create a realistic feel for the learner throughout the model procedure, the biomechanics of the material components in the model should align with the actual biomechanics of an average patient. The model should be equipped with realistic bodily functions so the learner will be able to observe relationships between several different body parts throughout the duration of the procedure.

The model should be manufacturable so the client can have the option of producing the model in mass quantities. It should also be scalable to simplify the manufacturing process. The model will provide instruction on the AxiaLIF surgery but it will also include the option of varying the fusion disk space and the types of degenerative disks present. This allows for a larger group of learners to benefit and it reduces the need for additional models to be designed and manufactured.

The model should be reusable. If the model allows for multiple usages without failure it will also prove to be cost effective. This objective is very important considering that the model will provide instruction for multiple procedures. The model should be durable and persist with light upkeep despite normal facility use. To make the model more convenient, interchangeable parts should also be incorporated into the model's design, granted that these parts are easy to assemble and disassemble. This also increases cost effectiveness while allowing for reusability. Used parts may also serve as instructional 'take aways' for the learners.

Table 1 below highlights the Pairwise Comparison Chart that the project group used to arrange the objectives in order of importance.

Table 1: Pairwise Comparison Chart

Pairwise Comparison Chart					
	Effective	Realistic	Manufacturable	Reusable	Total
Effective		1	1	1	3
Realistic	0		1	1	2
Manufacturable	0	0		0	0
Reusable	0	0	1		1

Revised Client Statement

Design and develop a cost-effective, anatomically correct spinal model allowing surgeons to simulate the minimally invasive surgical procedure known as AxiaLIF.

Project Approach

The major qualifying project group intends to design and develop an anatomically correct spinal model allowing surgeons to simulate the minimally invasive surgical procedure known as AxiaLIF. The model will be completed by April 2012 and the model will meet all budgetary requirements. Several needs and functions will be developed to further develop and ensure the end effectiveness of the model. The project clients and advisors will be enlisted regularly for any advice and suggestions throughout the research and design portions of the project.

Chapter 4 - Alternative Designs

Needs Analysis:

The project group recorded several needs that must be met in order to solidify the model's success. The model needs to have incorporated parts that are near if not accurate to anatomic dimensions in size, shape, and function. The model needs to include the lower spine, highlighting spinal discs L2 through S5, as well as include the colon. The model needs to give the learner feedback of incorrect tooling trajectory and colon perforation. A schematic and instructions for production or a working prototype of the model also needs to be created by April 2012. The major qualifying project group created several design alternatives that meet all of the stated needs (Table 2). The selected design is identified by highlighted typeface.

Table 2: Needs/Design Matrix

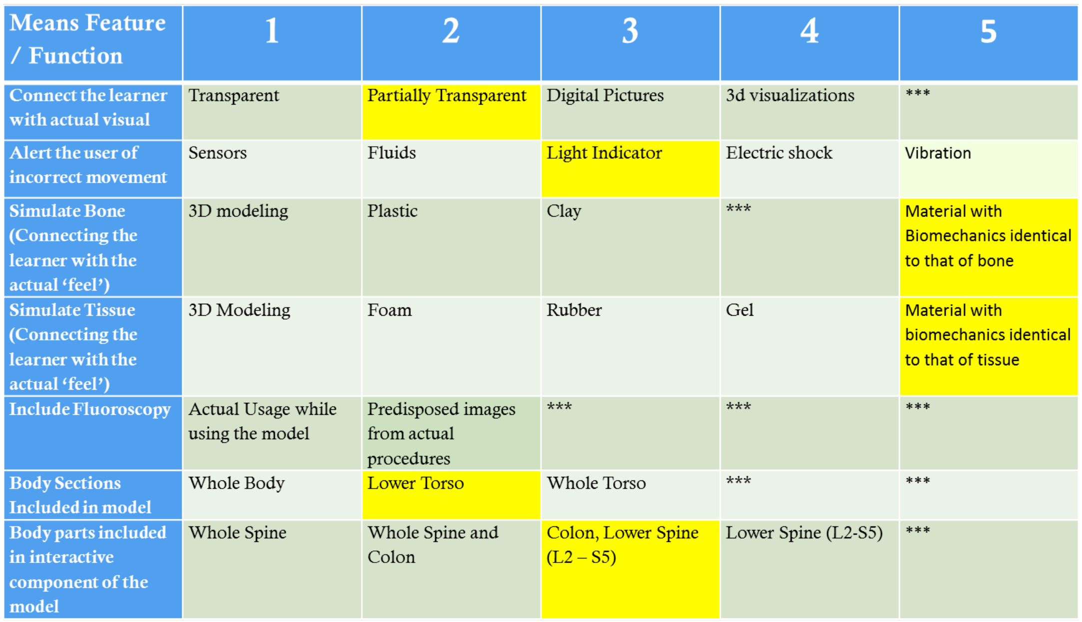
Design Alternatives	**Are the following needs feasible?**				
	Near accurate in dimensions	**Aesthetically Realistic?**	**Include Lower Spine (L2-S5)**	**Constant Feedback**	**Honor time commitment**
Alternative Design 1: Semitransparent Model	Yes	Yes	Yes	No	Yes
Alternative Design 2: "Operation Model"	Yes	No	Yes	Yes	Yes
Alternative Design 3: 3D Virtual Reality Simulation	No	No	Yes	Yes	No

Alternative Design 4: Opaque Model with Electrical Feed Back and Pressurized Colon Feedback System	Yes	Yes	Yes	Yes	Yes

Functions and Specifications

The model should perform several functions upon its completion. The model should connect the learner with an actual visual of the finished model procedure, alert the user of incorrect instrument trajectory and depth, simulate bone (connecting the learner with the actual 'feel'), simulate tissue (connecting the learner with the actual 'feel'), give the learner feedback throughout the model procedure, show the learner relevant body sections and allow learners to interact with relevant body parts in an interactive component of the model. The project group also created a Function and Means Chart (Table 3) to evaluate possible means for the functions listed above. If all of these functions are met the model should prove to be successful.

Table 3: Function and Means Chart



Means Feature / Function	1	2	3	4	5
Connect the learner with actual visual	Transparent	Partially Transparent	Digital Pictures	3d visualizations	***
Alert the user of incorrect movement	Sensors	Fluids	Light Indicator	Electric shock	Vibration
Simulate Bone (Connecting the learner with the actual 'feel')	3D modeling	Plastic	Clay	***	Material with Biomechanics identical to that of bone
Simulate Tissue (Connecting the learner with the actual 'feel')	3D Modeling	Foam	Rubber	Gel	Material with biomechanics identical to that of tissue
Include Fluoroscopy	Actual Usage while using the model	Predisposed images from actual procedures	***	***	***
Body Sections Included in model	Whole Body	Lower Torso	Whole Torso	***	***
Body parts included in interactive component of the model	Whole Spine	Whole Spine and Colon	Colon, Lower Spine (L2 – S5)	Lower Spine (L2-S5)	***

As for the model's specifications, the chosen material components should be within 25% of the mechanical properties of each relevant structure in the body. Since the spinal components of the model are the focus of the surgery, it is important that mechanical characteristics are within 20% (density: 0.0240 g/cm3) of that recorded in an average lumbar and sacral, biomimetic model (recorded spinal bone density: 0.120 g/cm3 [4], i.e. Sawbones). That being said, the density of the modeled lumbar and sacral bone should be between 0.0961 and 0.144 g/cm3. The mock colon and soft tissue should be able to be punctured and incised respectively. There should also be a mechanism to alert the learner if the colon is punctured.

Conceptual Designs:

Originally the board game Operation was used as a diving board when brainstorming specific means and designs for the AxiaLIF model. In this board game a simple circuit is connected to a system of buzzers and lights that alert the player of an incorrect movement. Tweezers are used as a surgical tool in this board game is connected to the internal circuitry by a wire. Touching the tweezer to the metal pieces on the game board closes the loop of the circuit and an LED lights up indicating an incorrect movement. The project group decided that the electrical circuit in the board game could be incorporated into to the AxiaLIF model. Pictured below is an image of the circuit used in the board game (Figure 4).

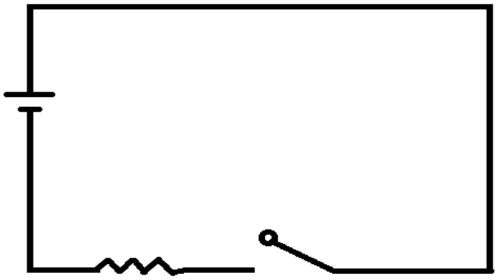


Figure 4: Simple Open Loop with Switch

The project group also saw the need for the inclusion of a representation of the colon in the AxiaLIF model. The colon plays a major part in the instruction of the surgery since it presents such a large risk due to its proximity to the sacrum and puncturing the colon can cause infection of the surgical site. Therefore it was decided at the beginning of the design process to include a representation of the colon in its accurate size and shape.

Preliminary/Alternative Designs

After the project group conceptualized the design of the AxiaLIF model, four alternative designs were developed that included all aspects that were deemed vital in our functions, needs and specifications.

Alternative Design 1: Semitransparent Model

This design composed of a model of the lower torso in which a replaceable spine incased in a transparent gel could be inserted into the lower back. The torso was intended to be made of a rubber, including a rubber flap on the back of the model covering the spinal insert while the learner attempted to perform the surgery. This rubber cover allows the learner to practice surgical procedure with minimal imaging. This design includes the vertebrate from L3 through the end of the sacrum. With the use of this design, mock surgeries can be practiced in a very deliberate and hands on manner. The learner will also be able to see the repercussion of the direct insertion of the tooling into the S1-L5 disk space. Although it has several benefits, this design is not effective for realistically practicing trajectory and avoiding surgical errors.

Alternative Design 2: Transparent Model with "Operation Feedback"

This design includes a completely transparent variation of the spine held within a mannequin, depicting the full flesh from the torso to the mid-thigh region. This model would be beneficial for a first time user or someone who wants to become familiar with the mechanics behind the surgery. To adapt this model to create more realism, an opaque rubber skin could be used to coat the transparent model. The spinal column would be composed of the spinal discs ranging from the L3 to the S5 disc space, which would be buried inside of the model at the anatomically correct position. The vertebrate will be created in the same manner as the first alternative design, from a silicon mold and with epoxy resin.

A major difference between this model design and the first is that this design contains metal pieces surrounding the working channel of the vertebrate for the AxiaLIF surgery. These metal pieces act in a similar manner to the board game Operation, where when touched by a surgical tool, they will act to complete the circuit and ignite a light. This light will act as a notification to the user that the angle of insertion of the tooling is incorrect and must be readjusted. Two means for the manifestation of the metal sensors are: to be included as a coil around the working channel or as a series of coradial metal sensors. The coil would act to show that an incorrect angle of insertion was performed. The series of coradial metal sensors however, can act to show the exact incorrect direction of the trajectory that was performed. Each metal sensor can be connected to a different light bulb indicating the degree of error.

The surgical tooling used in this model would need to be composed of conductive material, and since the tooling used in the actual surgery are composed of titanium, either new instruments would need to be fabricated or the original instruments would need to be coated in a conductive material. An important implementation into this design is integrating computer software to make the surgery more realistic. When an incorrect movement is performed, not only would a light be ignited, but a simulated fluoroscopy image would be depicted on a makeshift surgical monitor. Since fluoroscopy is used throughout the surgery, this would create an added sense of realism. When the surgery is complete, the bones can be placed back into the silicon mold and epoxy can be added to fill in the channel created in the simulation.

Alternative Design 3: 3D Virtual Reality Simulation

In this design a 3D force feedback virtual reality simulation replaces the entire physical model. The positive aspect of this design is that the user can see exactly what is going on and gain a great visual experience from it. This design incorporates the use of "real time" imaging that would include fluoroscopy images of what the learner would see if the surgery was actually being performed on a live patient. Expense is the largest drawback for this design alternative. This design also limits end understanding of what the surgery will feel like and how much pressure will be needed to be applied to the tooling throughout the entire procedure.

Alternative Design 4: Opaque Model with Electrical Feed Back and Pressurized Colon Feedback System

The final and preferred alternative design models the second alternative design; however due to budget constraints this model does not incorporate the use of fluoroscopy. This design features electrical and pressurized colon feedback systems. The electrical feedback will alert the user when an undesired action in the surgery is made through the use of indicator lights. Metal sensors located in the L5 vertebrae and the L5-S1 intervertebral disc will notify the learner if they were entering the modeled sacral bone at an incorrect point or angle. The surgical tooling could be modeled in SolidWorks 2011 and then constructed using a combination of rapid prototyped ABS plastic coated in epoxy and conductive paint, as well as prefabricated stainless steel parts. When the surgical simulation is over, the L5 to S1 fusion will be removed so the user can observe the completed surgery. New vertebral bones can be placed into the spinal gap and gelatin can be added to fill in the channel created in the simulation. The project group listed blended gelatin in a silicone shell as a favorable mean to model the inter-vertebral disc (nucleus pulposus and annulus fibrosus respectively) and a blend of polyurethane to model the mechanics of the bone observed in the spinal column.

Feasibility Study/Experiments

To test the structural feasibility of using polyurethane in the most vital aspect of the model, the densities of eight different variations of a polyurethane (PU) mix will be calculated, all having different proportions of hydroxyl and isocyanate groups and different mix times. The project group also created qualitative metrics and modeled key components of the design to further test its feasibility.

Metrics

The project group created a system of metrics to test the feasibility of the final design (Table 4). The following table highlights the metrics that were created and the scores that were given to the model after it was manufactured.

Table 4: Qualitative Metrics for the AxiaLIF Lumbar Spinal Fusion Simulation Model

Safe:		
No possibility of injuring user	100	X
Slight possibility of injuring user	40	
High possibility of injuring user	10	
Complete chance of injuring user	0	
Portable:		
Simulation can be moved at will	100	X
Simulation can be moved, with some trouble	60	
Simulation is movable, but with much difficulty	30	
Simulation is immobile	0	
Instructional:		
Simulation completely teaches the procedure	100	
Simulation models the surgery, but may be incorrect in some aspects	75	X
Simulation slightly resembles surgery	20	
Simulation does not model surgery by any means	0	
Feel:		
Feel of the simulation is exactly that of the human body	100	
Feel of the simulation is similar, but does not exactly mimic to the human body	80	

Feel of the simulation is barely mimicking the feel of human organs	40	X
Feel of the simulation does not mimic human organs at all	0	
Function:		
Simulation parts move the way they naturally do	100	
Simulation parts mimic most of the movements of natural parts	75	X
Simulation parts barely mimic the movements of natural parts	25	
Simulation does not mimic natural movements	0	
Durable:		
Simulation is useable for 5-10 years	100	
Simulation is useable for 1-5 years	75	X
Simulation is useable for 6 months -1 year	25	
Simulation is useable for <6 months	0	
Interchangeable Parts:		
Each necessary part is completely interchangeable	100	X
Most necessary parts are interchangeable	75	
Some necessary parts are interchangeable	25	
No parts are interchangeable	0	

Modeling

The project group created a schematic for the Final Design (Figure 5) highlighting the dual feedback feature comprised of the electrical and pressurized colon feedback systems.

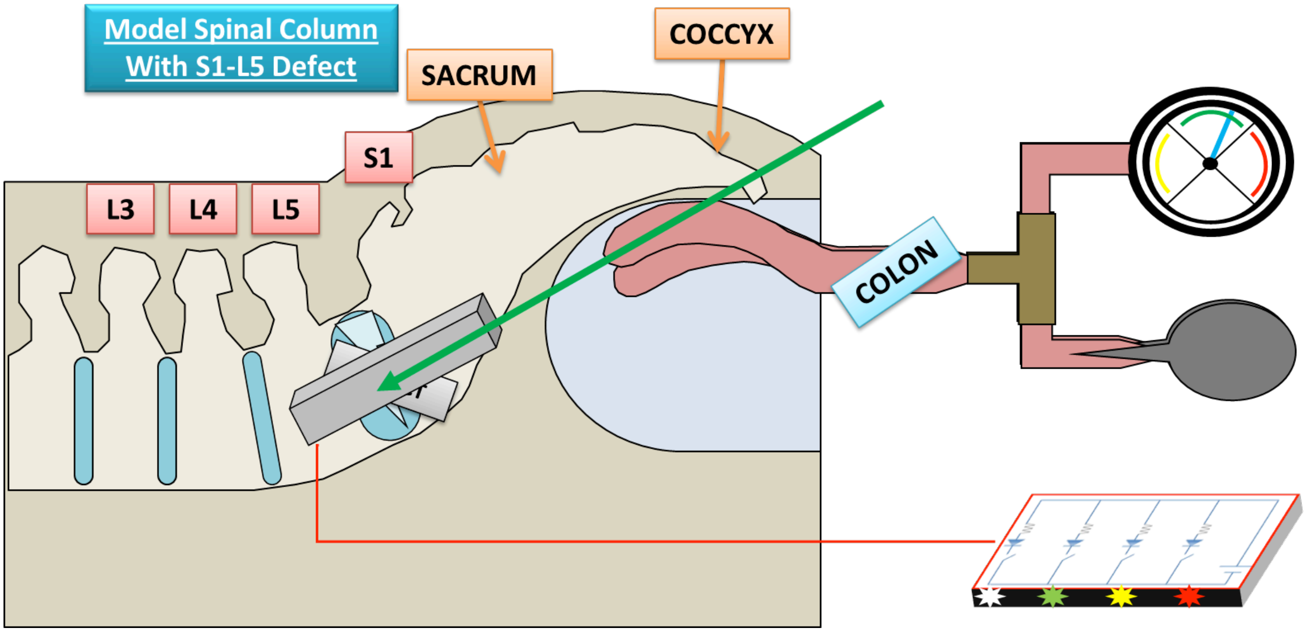


Figure 5: Final Design Schematic (Microsoft Office 2010)

The surgical tooling was modeled in SolidWorks 2011 after directly measuring the instruments provided by the company. The tooling which was too complex to manufacture using metal parts, and strong enough to withstand the forces presented by the surgery were printed using rapid prototyping. Being that ABS plastic is not electrically conductive, conductive paint was used to coat the parts of the tooling that could come in contact with the sensors in the vertebrae as a means of completing the electrical circuit. The tools which required greater strength were created using stainless steel tubing and stainless steel rods, or a combination of ABS plastic and stainless steel. These tools were either entirely electrically conductive because they were manufactured using stainless steel or they were made conductive by applying conductive paint. The 9mm Drill modeled in SolidWorks was manufactured by epoxying a stainless steel drill bit to an ABS plastic handle (Figure 6).

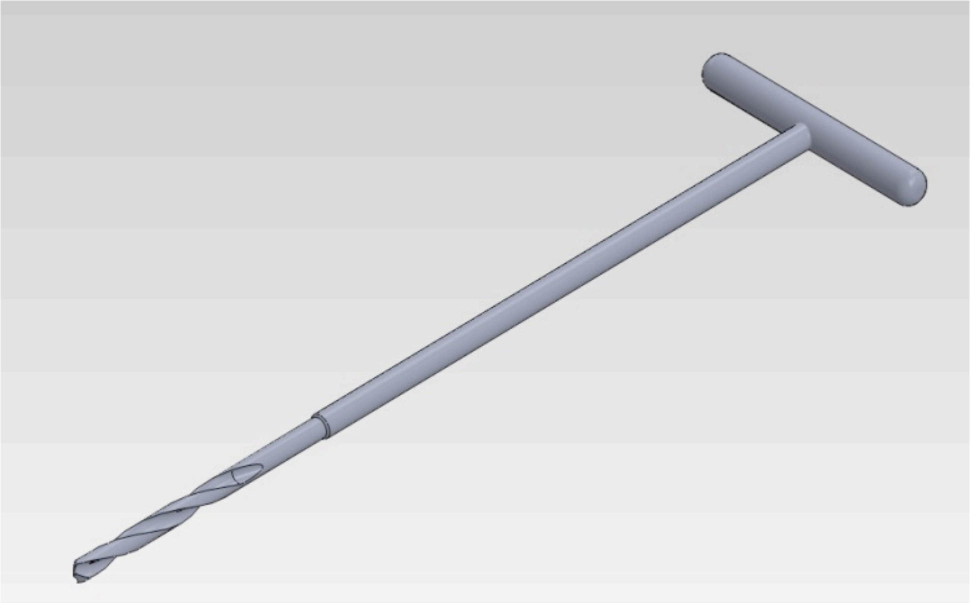


Figure 6: CAD Drawing of 9mm Drill (Solidworks 2011)

The 30 degree exchange cannula was modeled in SolidWorks, and due to its complexity and strength was able to be rapid prototyped (Figure 7).

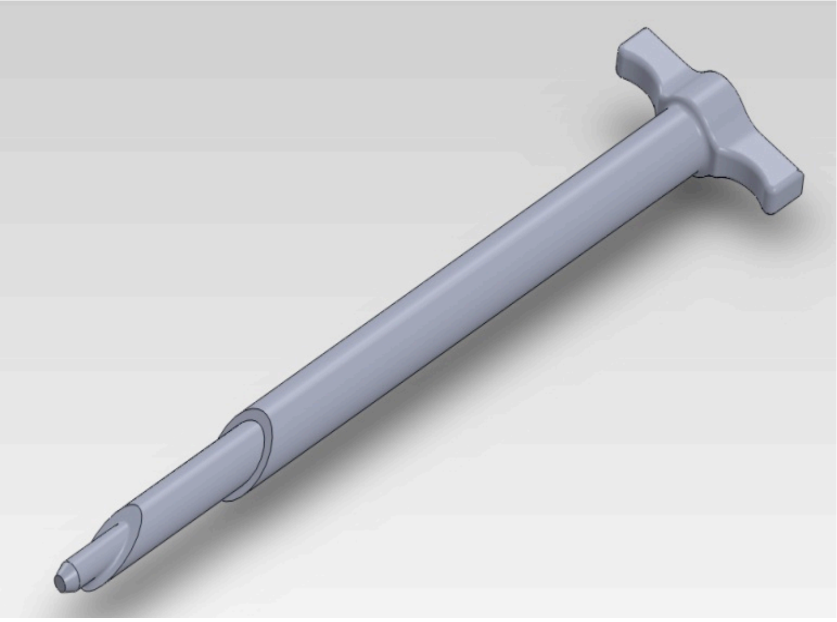
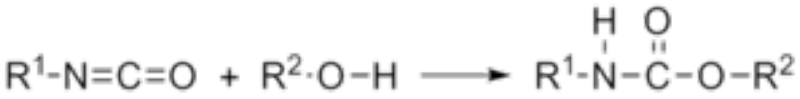


Figure 7: CAD Drawing of 30 Degree Exchange Cannula (Solidworks 2011)

Chapter 5 – Design Verification

Polyurethane Foam

The densities of eight different variations of a polyurethane (PU) mix were calculated, all having different proportions of the hydroxyl group to the isocyanate group or a different mix time varying from 10 to 30 seconds (Figure 8). The variations of PU that were mixed for 10 seconds (all groups labeled A) all displayed an end density higher than those that were mixed for 30 seconds. The average density of each mix (identified by the red data markers) increased as the ratio of the polyisocyanate added to the mix increased.



$$R^1\text{-}N=C=O + R^2\cdot O-H \longrightarrow R^1\text{-}\overset{\overset{H}{|}}{N}-\overset{\overset{O}{\|}}{C}-O-R^2$$

Figure 8: Generalized polyurethane reaction note that the isocyanate group is shown first in the equation, followed by the hydroxyl group (Seymour R. B., Kauffman G. B., 1992).

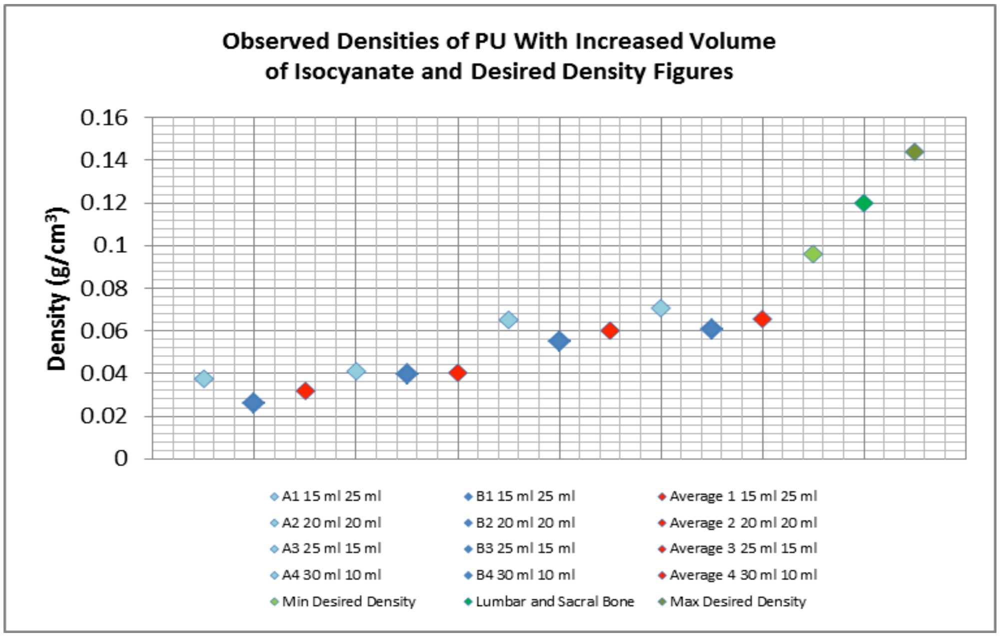


Figure 9: Observed densities of PU blends (containing varying amounts of isocyanate and hydroxyl components) and the values of desired density

Table 5: Densities of PU mixes

Sample:	**Isocyanate (Part A)**	**Hydroxyl**	**Density (g/cm^3)**	**Mass (g):**	**Volume (cm^3):**
A1 (10 Sec.)	15 ml	25 ml	**0.0376**	1.579	42.054
B1 (30 Sec.)	15 ml	25 ml	**0.0262**	1.293	49.313
Average 1	15 ml	25 ml	**0.0319**	1.436	45.684
A2	20 ml	20 ml	**0.0411**	1.882	45.823
B2	20 ml	20 ml	**0.0397**	2.150	54.089

Average 2	20 ml	20 ml	**0.0404**	2.016	49.956
A3	25 ml	15 ml	**0.0652**	2.626	40.307
B3	25 ml	15 ml	**0.0551**	2.258	40.997
Average 3	25 ml	15 ml	**0.0602**	2.442	40.652
A4	30 ml	10 ml	**0.0707**	1.479	20.930
B4	30 ml	10 ml	**0.0605**	1.637	27.044
Average 4	30 ml	10 ml	**0.0656**	1.558	23.987
Min Desired Density			**0.0961**		
Lumbar and Sacral Bone			**0.1200**		
Max Desired Density			**0.1440**		

Sensor Feedback System

A nine-volt battery powers the electrical component of the feedback system. It is set up so that the LED lights and sensors were set up in parallel from each other (Figure 10). A 1k-ohm resistor is placed by each LED, dropping the voltage so that the LED lights will not burn out. The surgical tools are connected to the breadboard by an alligator clip. There is only one alligator clip, so it must be unclamped from a tool after being used and connected to the next instrument being used. The operating tool functions as a switch that completes the circuit when in contact to a sensor. The system functioned properly and the indicator LED lights came on for each individual sensor.

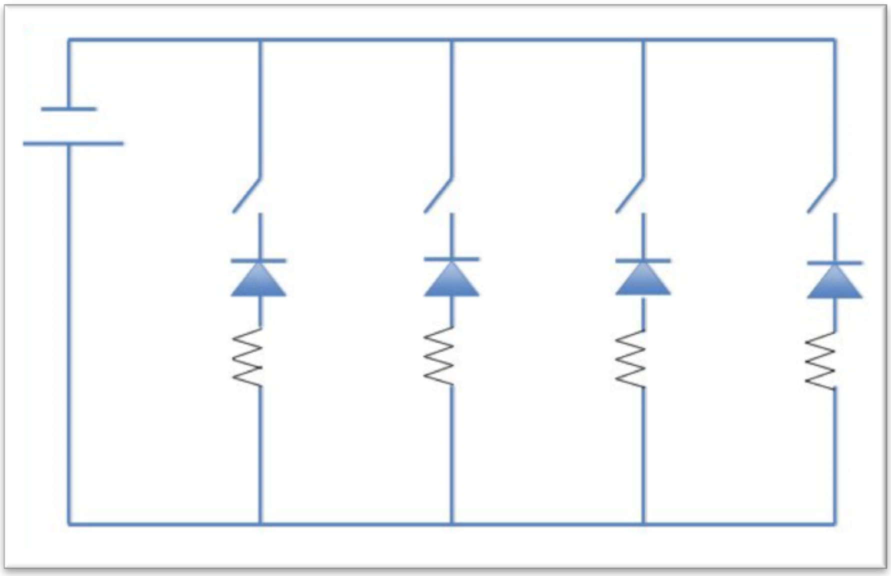


Figure 10: Electrical circuit schematic

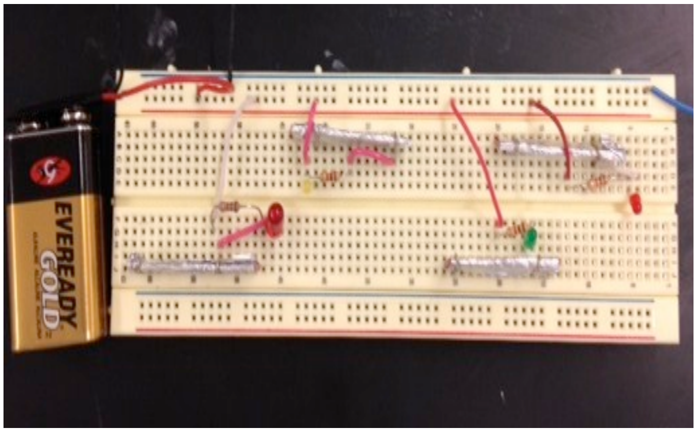


Figure 11: Final Sensor Breadboard

Pressurized Colon Model

The pressurized colon feedback system is composed of a stretched balloon, a crimp tee, a hand pump and a pressure gauge. The balloon is inflated to 2 inches in diameter and is hand-guided through paper clip loops which act to shape the colon in the proper form. Throughout the inflation procedure the pressure was maintained between 0.5 and 1.5 psi. The system functioned properly. The balloon model was easily shapeable, could be punctured in a manner similar to an actual colon, and the pressure sensor allowed for a feedback system which signified perforation (Figure 12).

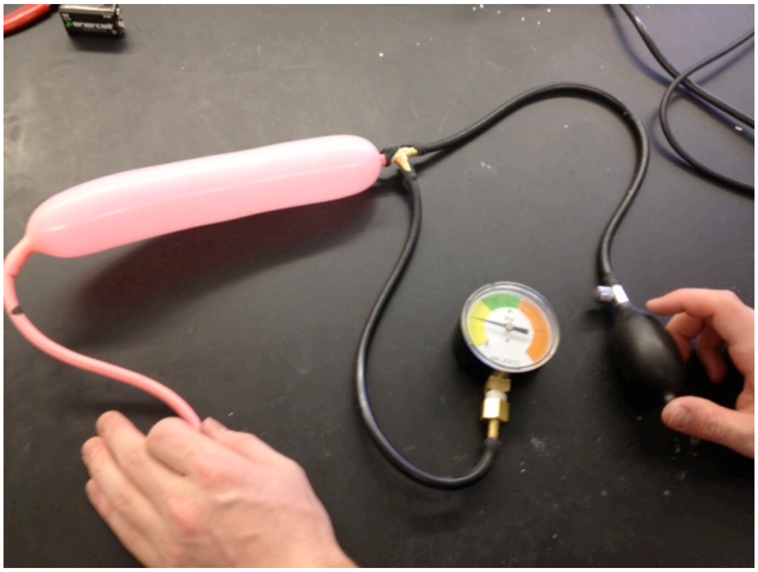


Figure 12: Pressurized Colon System

Torso

The torso was created using Reynolds FlexFoam-iT! 17 because of its durability, and flexibility, mimicking the feel of a human torso. By molding the foam around an existing torso model, the shape of the torso was created as accurately as possible. The foam retained shape very well, so that areas where incisions were made were indiscernible from areas where no incisions had been made. FlexFoam-iT! 17

was a cost-effective material which also was rigid enough to hold the spinal column, and colon guiding clips in place during the simulation (Figure 13).

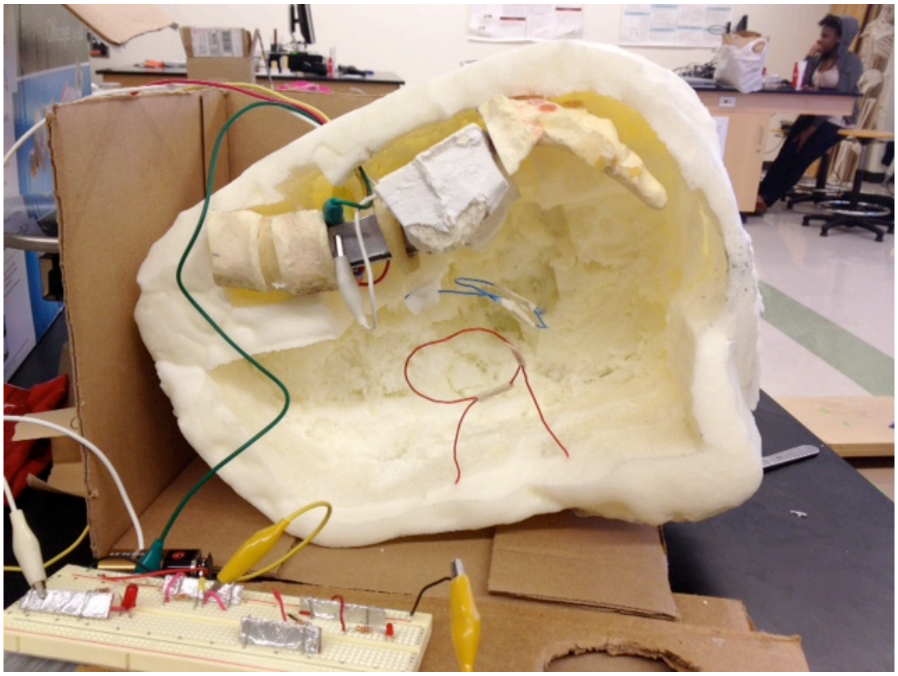


Figure 13: General Torso Model

Chapter 6 – Discussion

Polyurethane Foam

Polyurethane requires a blowing agent in order to set and harden correctly. The blowing agent is acquired through mixing when oxygen enters the sample's mix. A longer mix time will increase the amount of blowing agent in the sample and decrease the resulting density. As predicted, the longer mixing time of 30 seconds decreased the level of density in the samples. The lower density observed in the samples mixed for 30 seconds (as opposed to 10 seconds) was due to the increased the amount of blowing agent in the sample. The larger amount of blowing agent increased the distance of gap junctions in the molecular structure of the resulting foam thus decreasing the density by a substantial amount. The increase in density that was observed as the ratio of the polyisocyanate added to the mix increased can be explained by the fact that the isocyanate group has a larger molecular weight than the hydroxyl group (Fig. 8). All variations of PU fell short of the minimum desired density for the modeled lumbar and sacral bone (.12 g/cm^3) but the group presumes that since the tooling created for the model is of a lesser strength and density than the actual tooling used in the procedure, the lower density observed in the modeled lumbar and sacral bone will be suitable. A higher density of modeled lumbar and sacral bone would have result in the damage of the replicated tooling.

Sensor Feedback System

The electrical system for the sensors was designed so that the sensors would function independently of each other. This was ensured with the parallel placement of the LEDs. The operating tool functioned as the switch, which completed the circuit once it came in contact with the sensor. This set up ensured that contact with one sensor, did not result in the response of another.

Pressurized Colon Model

The balloon functioned as a representation of the colon that was easy to puncture. When the learners eventually perform a live AxiaLIF procedure it is imperative that the colon is not punctured. Such an error could potentially lead to infection and even death. By forming a circuit with the balloon, pump, and pressure gauge, the user will be made aware once the colon has been punctured, due to the reading on the pressure gauge. The balloon also is low cost and easily replaceable after each use.

Economic Influence

The AxiaLIF Spinal Fusion Simulation model is designed to be low cost and affordable for the targeted consumer. The target consumers of this product include hospitals and medical training sites. The budget presented to the project group to develop the model was $450 dollars and it is estimated that the cost for the product on the market will be in close range of that price. This device could potentially act to bring down health care costs, to the fact that the cost of training the procedure to surgeons will decrease.

Environmental Impact

The re-usability of our tools and model make it environmentally friendly ensure that there is little, if any, harmful waste resulting in the production or use of our product.

Social Influence

The AxiaLif procedure is a minimally invasive, quick procedure with a shorter recovery time. With our model, more physicians can practice the procedure, meaning that more AxiaLif procedures can be performed on patients. Making this procedure more available, more patients can experience its benefits of faster recovery, allowing them to carry on with their daily lives sooner.

Political Ramifications

This device would only have an effect in the markets and cultural of the United States and the European countries that perform the procedure. Back pain is one of the most common conditions in any population. It is currently the largest reported reason for sickness absence in the work force. The availability of this procedure that will result from the production of our device, will allow patients to return to work sooner.

Ethical Concern

The low cost our product will allow more physicians to be properly trained in the AxiaLif procedure. With this procedure being less invasive in comparison to alternative procedures, the operation and recovery time are both shortened. With over 85% of people over the age of 50 suffer from degenerative disc disease, the production of our device will grant patients with a good and satisfying life.

Health and Safety Issues

In addition to increasing the number of physicians trained in the procedure, the reusability and low cost (in comparison to the use of a live patient or cadaver) of the product will allow the surgeons and students to practice the procedure repeatedly, perfecting their technique. The colon and sensor feedback system will ensure that the surgeon is accustomed to avoiding potential errors that could prove to be fatal to the patient.

Manufacturability

The AxiaLIF Spinal Fusion Simulation Model can easily be reproduced for larger scale production. The mold for lower body was inexpensive and molded in as little as an hour. The polyurethane foam that was used for the spinal insert was also inexpensive. The actual shape of the vertebral disk is not as crucial as ensuring it has a uniform density, which is easily managed. The tools (with the exception of the few stainless steel parts) for the model were rapid prototyped from inexpensive ABS plastic and coated in epoxy and conductive paint.

Sustainability

The only element of the model that requires a source of power is the sensor feedback system which is powered by a single nine volt battery. The use and production of the product should have a negligible environmental effect in terms of renewable energy.

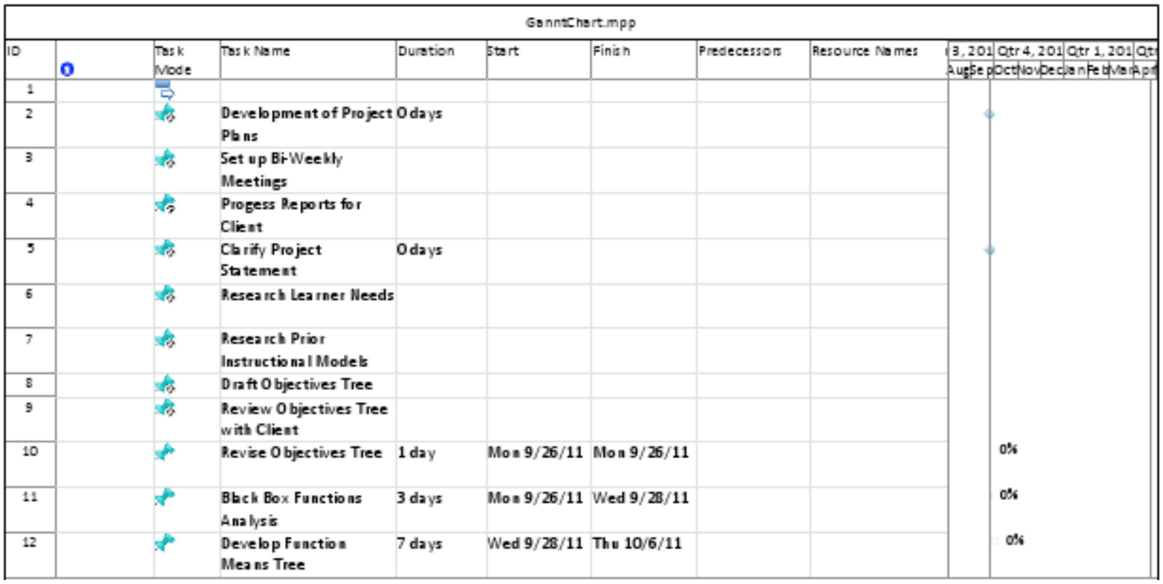
Chapter 7 – Final Design and Validation

This completed design included a cross-sectioned, semi-transparent variation of the lumbar and sacral spinal column held within a modeled torso. This model would be beneficial for a first time user or someone who wants to become familiar with the mechanics behind the surgery. The spinal column is comprised of the spinal discs ranging from the L4 to the S5 disc space. The vertebrate were shaped from a large block of PU with an adjusted ratio of hydroxyl to isocyanate group. This design contains metal sensors surrounding the working channel of the vertebrate for the AxiaLIF surgery. These metal sensors act in a similar manner to the board game Operation, where when touched by a surgical tool, they will act to complete the circuit and ignite a light. This light acts as a notification to the user that the angle of insertion of the tooling is incorrect and must be readjusted. The mean selected for the manifestation of the metal sensors was to present them as a series of coradial metal bars located in the L5 vertebrae and the L5-S1 intervertebral disc. The series of coradial metal sensors acts to show the exact incorrect direction of the trajectory that was performed. Each metal sensor is connected to a different light bulb indicating the degree of error.

The surgical tooling used in this model was modeled in SolidWorks 2011 and then constructed using a combination of rapid prototyped ABS plastic coated in epoxy and conductive paint, as well as stainless steel parts. Due to budget constraints this model does not incorporate the use of fluoroscopy. This design features a dual constant feedback aspect comprised of electrical and pressurized colon feedback systems. When the surgical simulation is over, the L5 to S1 fusion can be removed so the user can observe the completed surgery. New vertebral bones can be placed into the spinal gap and gelatin can be added to fill in the channel created in the simulation.

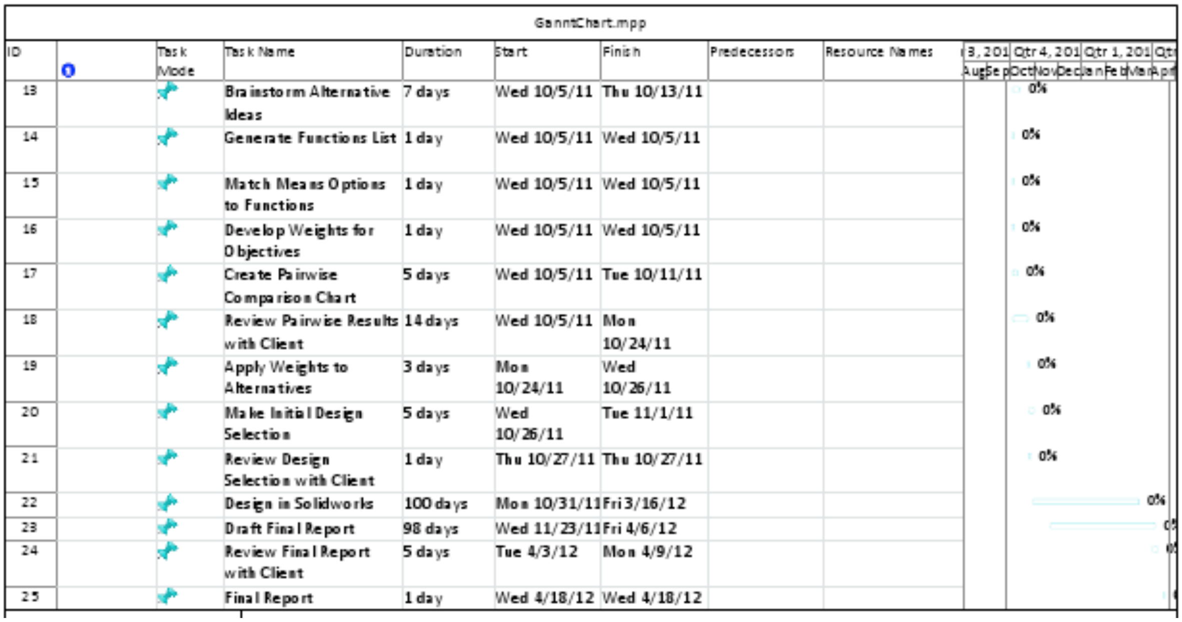
The AxiaLIF surgical model is effective. The model is safe, portable and instructional to an adequate degree. The model does not present a threat of danger as the focus of the learning exercise should be on the procedures being taught. Any lapse in safety could distract the learner from understanding how to complete the taught procedure correctly. Portability increases the value of the model as a stationary model is limited to few locations. The learner should be able to complete the exercise with the constructed model and acquire with a full understanding of what will be expected during surgery and how to properly run the procedure. The most vital portions of the model are realistic. The model allows learners to have foresight as to what the actual procedure will be like. The biomechanics of the vital material components in the model align with the actual biomechanics of an average patient. The model is also equipped with realistic bodily functions so the learner will be able to observe relationships between several different body parts throughout the duration of the procedure.

The model is manufacturable and scalable so the client can have the option of producing the model in mass quantities. The model provides instruction on the AxiaLIF surgery but it also includes the option of varying the fusion disk space (to the L4-L5 defect) and the types of degenerative disks present (patient specific). This allows for a larger group of learners to benefit from this model and this reduces the need for the design and manufacturing of additional models with a similar function. The model is reusable and cost effective. The model is also durable and can persist with light upkeep despite normal facility use. The project group organized project tasks and deadlines with the use of a Gantt chart (Figure 13). The project group recommends that any future work begins where the resulting research stopped. All unique aspects of the project and the organization of the project timeline are listed in the Gantt chart.



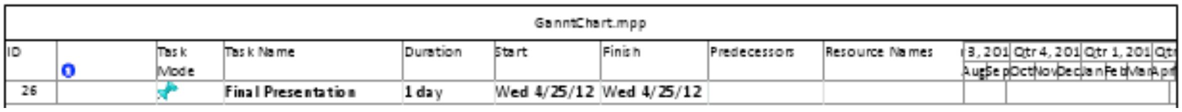
ID		Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names
1								
2			Development of Project Plans	0 days				
3			Set up Bi-Weekly Meetings					
4			Progess Reports for Client					
5			Clarify Project Statement	0 days				
6			Research Learner Needs					
7			Research Prior Instructional Models					
8			Draft Objectives Tree					
9			Review Objectives Tree with Client					
10			Revise Objectives Tree	1 day	Mon 9/26/11	Mon 9/26/11		
11			Black Box Functions Analysis	3 days	Mon 9/26/11	Wed 9/28/11		
12			Develop Function Means Tree	7 days	Wed 9/28/11	Thu 10/6/11		

Figure 14: Gantt Chart Including dates 09/01/11 – 09/28/11



ID		Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names
13			Brainstorm Alternative Ideas	7 days	Wed 10/5/11	Thu 10/13/11		
14			Generate Functions List	1 day	Wed 10/5/11	Wed 10/5/11		
15			Match Means Options to Functions	1 day	Wed 10/5/11	Wed 10/5/11		
16			Develop Weights for Objectives	1 day	Wed 10/5/11	Wed 10/5/11		
17			Create Pairwise Comparison Chart	5 days	Wed 10/5/11	Tue 10/11/11		
18			Review Pairwise Results with Client	14 days	Wed 10/5/11	Mon 10/24/11		
19			Apply Weights to Alternatives	3 days	Mon 10/24/11	Wed 10/26/11		
20			Make Initial Design Selection	5 days	Wed 10/26/11	Tue 11/1/11		
21			Review Design Selection with Client	1 day	Thu 10/27/11	Thu 10/27/11		
22			Design in Solidworks	100 days	Mon 10/31/11	Fri 3/16/12		
23			Draft Final Report	98 days	Wed 11/23/11	Fri 4/6/12		
24			Review Final Report with Client	5 days	Tue 4/3/12	Mon 4/9/12		
25			Final Report	1 day	Wed 4/18/12	Wed 4/18/12		

Figure 15: Gantt Chart Including dates 10/05/11 – 04/18/12



ID		Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names
26			Final Presentation	1 day	Wed 4/25/12	Wed 4/25/12		

Figure 16: Gantt Chart Including dates 04/25/12 – 04/25/12

Chapter 8 - Conclusions and Recommendations

The project group was successful in creating an effective simulation model of the AxiaLIF procedure. Several items are recommended to those who wish to further the research of this experiment. A model and tooling should be produced that are closer in accuracy to the weight and dimensions of the live patient and actual tooling. The model created through this research contains accurate proportion of strength of the tooling to the strength of our modeled bone, but the project group predicts that a more effective simulation on the human body would include not only an accurate ratio of specifications but accurate ones. A simulated fluoroscopy image should also be depicted during the simulation on a makeshift surgical monitor. Since fluoroscopy is used throughout the actual surgery, this would create an added sense of realism. Having a limited budget for the model definitely restricted the materials used and the biomimetic capacity of our model. A model that is more accurate than ours will require a larger amount of funding. The project group also recommends that future research groups delve into the educational aspect of the model to verify the effectiveness it has in teaching. Once these additional tests are conducted the model as a whole will be further verified by an adequate amount of data and should then be fit for mass production.

Executive Summary

Design for an Axial Lumbar Interbody Fusion Surgical Simulation

A. N. Daisley, M. Dupuy, J. Guttmann
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***Abstract*— The AxiaLIF procedure is performed on the lowest level of the lumbar spine, the L5-S1 disc space, which is accessed through a 2 cm surgical incision adjacent to the coccyx. Due to the minimally invasive nature of this procedure, there is reduced surgical trauma, less blood loss, shorter operative time, and most importantly, faster recovery. Roughly 1,600 AxiaLIF procedures have been performed in hospitals across the United States [1]; therefore, there are a limited number of physicians experienced in performing this procedure. Through the research conducted in the paper a biomimetic spinal anatomical model was created that can allow medical professionals to hone their skills performing the AxiaLIF surgery. The model includes the lower spine, highlighting spinal discs L3 through S5. The model also gives the learner feedback ensuring that the user does not cause any surgical complications. To ensure biomimetic capabilities, several materials were tested to see how their mechanical properties compared to those found in an actual patient; the most important biomechanical property being that of the sacral and lumbar bone, having a density of 0.120 g/cm^3.**

Introduction

The Axial Lumbar Interbody Fusion (AxiaLIF) procedure is an, alternative approach to traditional fusion procedures in the lumbar spine. This surgery, unlike previous fusion methods which required a ventral and / or dorsal approach method, is performed from an anterior approach along an axis perpendicular to the disc. The L5 to S1 disc space is accessed through a 2 cm percutaneous opening adjacent to the coccyx. The time of operation is under an hour, compared to the nearly 3 hours required in conventional fusion surgery. Due to the minimally invasive nature of this procedure, there is reduced surgical trauma, less blood loss, shorter operative time, and most importantly, faster recovery. With only about 1,600 AxiaLIF procedures completed in hospitals across the United States, there are a limited number of physicians experienced in performing this innovative method to spinal fusion [1].

In the field of medicine, mentorship and shadowing is the primary hands on teaching method, and until recently there was no better way to learn new skills and techniques, other than observing more experienced physicians. Advancement in the understanding of the human body and the adaptation of technology into the medical field has allowed for simulation training to rise as the preferred method of teaching medical procedures. Simulation is defined as the use of a model to practice a task, in place of performing the task on the actual item or person. An example of this is when medical students are taught how to suture; a common simulation method is to use a needle, thread, and a sliced orange peel to simulate a skin wound. The proposed project will create a spinal anatomical model that will instruct medical students, residents and other medical learners how to perform the new AxiaLIF spinal fusion surgery.

A. Statement of the Problem

The client originally requested that the MQP group design and create a surgical model of the AxiaLIF surgery. This surgery does not currently have an acceptable simulation but is modeled via performing the surgery on cadavers. Although this method allows the learner to perform the surgery on an anatomically correct model, cadavers are expensive and not a cost-effective solution. There is a need for a simulation of the AxiaLIF surgery because it is a novel procedure that requires extremely precise and accurate movements. Any surgery, as exact as this one, would require an enormous amount practice and understanding from the surgeon. The problem is that since a simulation for this surgical procedure does not exist, learners are subject to errors and complications in surgery with live patients. Simulating this procedure could follow a variety of different paths, ranging from creating a fully simulated human with correct physiological responses to modeling an extracted spinal column containing only the absolute necessary anatomy for the surgeon to practice.

B. Project Strategy

The goal is to use cost effective materials that are within 20% of the mechanical properties of the relevant structure in the body. Since the spinal components of the model are the focus of the surgery, it is vital that accurate to near accurate (within 20%, density: 0.0240 g/cm^3) mechanical dimensions are observed (spinal bone density: 0.120 g/cm^3 [4]). That being said, the density of the modeled lumbar and sacral bone should be between 0.0961 and 0.144 g/cm^3. The pedicle and facet joints of the spinal column are of a less concern given that the procedure is not focused on these components. The mock colon and soft tissue should reach the design requirement of having reflective properties in order to 'reset' the model after each use. There should also be a mechanism to alert the learner if the colon is punctured.

Design Analysis

Preliminary, Alternative Designs

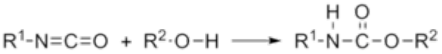
The preliminary design for our device composed of a model of the lower torso in which a replaceable spine incased in a transparent gel could be inserted into the lower back. The torso was intended to be made of a rubber, including a rubber flap on the back of the model covering the spinal insert while the learner attempted to perform surgery. Three other alternative designs were devised after meeting with our client. The first alternative design still incorporated the use of a spine insert; however, the entire model would be transparent. Another alternative design that was considered abandoned the use of a physical model completely and suggested a 3D force feedback virtual reality simulation.

Final Design and Verification

The final and preferred alternative design modeled the preliminary design; however this model incorporates the use of a feedback system. This feature of the model will alert the user when an undesired action in the surgery is made through the use of indicator lights. Metal sensors located in the L5 vertebrae and the L5-S1 intervertebral disc would notify the learner if they were entering the modeled sacral bone at an incorrect point/ angle when a surgical tool makes contact with it. The surgical instruments were modeled in SolidWorks 2011 and were constructed using a combination of rapid prototyped ABS plastic coated in epoxy and conductive paint, as well as prefabricated stainless steel parts. The tools were also painted with conductive paint so they could complete the sensor circuit. When the surgical simulation is over, the L5 to S1 fusion will be removed so the user can observe the completed surgery. New vertebral bones can be placed into the spinal gap and gelatin can be added to fill in the channel created in the simulation. The project group chose blended gelatin in a silicone shell to model the inter-vertebral disc (nucleus pulposus and annulus fibrosus respectively) and a blend of polyurethane to model the mechanics of the bone observed in the spinal column.

Results

Eight different variations of a polyurethane (PU) mix were tested; all having different proportions of the hydroxyl group to the isocyanate group or a different mix time varying from 10 to 30 seconds. The variations of PU that were mixed for 10 seconds (all groups labeled A) all displayed an end density higher than those that were mixed for 30 seconds. The average density of each mix (identified by the red data markers) increased as the ratio of the polyisocyanate added to the mix increased. All variations of PU that were created fell short of the minimum desired density for the modeled lumbar and sacral bone.



$$R^1\text{-}N{=}C{=}O + R^2\text{·}O\text{-}H \longrightarrow R^1\text{-}\overset{H}{N}\text{-}\overset{O}{\overset{\|}{C}}\text{-}O\text{-}R^2$$

Fig. 1: Generalized polyurethane reaction (note that the isocyanate group is shown first in the equation, followed by the hydroxyl group [3]).

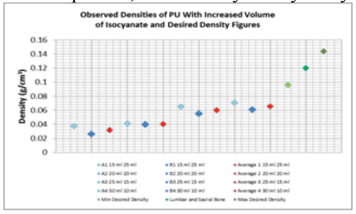


Fig. 2: Observed densities of PU blends (containing varying amounts of isocyanate and hydroxyl components) and the values of desired density.

Discussion

Polyurethane requires a blowing agent in order to set and harden correctly. The blowing agent is acquired through mixing when oxygen enters the sample's mix. A longer mix time will increase the amount of blowing agent in the sample and decrease the end density. As predicted, the longer mixing time of 30 seconds decreased the level of density in the samples. The increase in density that was observed as the ratio of the polyisocyanate added to the mix increased can be explained by the fact that the isocyanate group has a larger molecular weight than the hydroxyl group (Fig. 1). All variations of PU fell short of the minimum desired density for the modeled lumbar and sacral bone but the project group presumes that since the tooling created for the model is of a lesser strength and density than the actual tooling used in the procedure, the lower density observed in the modeled lumbar and sacral bone will be suitable.

Conclusions and Recommendations

Several items are recommended to those who wish to further the research of this experiment. A model and tooling should be produced that are closer in accuracy to the weight and dimensions of the live patient and actual tooling. The model created through this research contains accurate proportion of strength of the tooling to the strength of our modeled bone, but the project group predicts that a more effective simulation on the human body would include not only an accurate ratio of specifications but accurate ones. A simulated fluoroscopy image should also be depicted during the simulation on a makeshift surgical monitor. Since fluoroscopy is used throughout the actual surgery, this would create an added sense of realism. Having a limited budget for the model definitely restricted the materials used and the biomimetic capacity of our model. A model that is more accurate than ours will require a larger amount of funding. The project group also recommends that future research groups delve into the educational aspect of the model to verify the effectiveness it has in teaching. Once these additional tests are conducted the model as a whole will be further verified by an adequate amount of data and should then be fit for mass production.

Acknowledgments

The project group would like to thank Glenn Gaudette, Lisa Wall, W. Brian Sweeney M.D., Frederik A. Pennings M.D., and the UMASS Memorial Hospital Simulation Center.

References

[1] Aryan, H. E. et al. Percutaneous Axial Lumbar Interbody Fusion (AxiaLIF) of the L5-S1 Segment: Initial Clinical and Radiographic Experience. Minim Invasive Neurosurgery 2008; 51: 225-230

[2] Dym C. L., Little P., Engineering Design A Project-Based Introduction, Third Edition, John Wiley & Sons, 2009

[3] Seymour R. B., Kauffman G. B., Polyurethanes: A Class of Modern Versatile Materials. Chem. Ed. 69, 909 1992

[4] Unosso, E. (2010). Mechanical properties and spreading characteristics of bone cement for spinal applications. (Master's thesis, Lulea University of Technology)Retrieved from http://epubl.ltu.se/1402-1617/2010/115/index-en.html

References

Anastakis, Dimitri , Glenn Regehr, Richard Reznick, Michael Cusimano, John Murnaghan, Mitchell Brown, and Carl Hutchinson. "Assessment of Technical Skills Transfer From the Bench Training Model to the Human Model." *American Journal of Surgery* 177, no. 2 (1999): 167-170.

Aryan, H. E. et al. Percutaneous Axial Lumbar Interbody Fusion (AxiaLIF) of the L5-S1 Segment: Initial Clinical and Radiographic Experience. Minim Invasive Neurosurgery 2008; 51: 225-230

Bradley, Paul . "The History of Simulation in Medical Education and Possible Future Directions." *Medical Education* 40, no. 3 (2006): 254-262.

Bridges, M, and DL Diamond. "The Financial Impact of Teaching Surgical Residents in the Operating Room." *American Journal of Surgery* 177, no. 1 (1999): 28-32.

Datta, Rashmi, KK Upadhyay, and CN Jaideep. "Simulation and its Role in Medical Education." *Medical Journal Armed Forces India* 68, no. 2 (2012): 167-172.

Dym C. L., Little P., Engineering Design A Project-Based Introduction, Third Edition, John Wiley & Sons, 2009

Edmonds, CV, and D Sluis. *ENT Endoscopic Surgical Training Simulator*. Amsterdam: IOS Press, 1997.

"FemoraLineMan System | Practice CVC access using the femoral vein route | Simulab Corporation." Simulab Corporation: Medical Training Models and Surgical Simulators. http://www.simulab.com/product/ultrasound-trainers/femoralineman-system (accessed April 17, 2012).

"Lumbar Vertebrae - L3 to Sacrum." Sawbones. http://www.sawbones.com/products/product.aspx?2216 (accessed April 20, 2012).

Satava, Richard. "Assessing Surgery Skills Through Simulation ." *The Clinical Teacher* 3, no. 2 (2006): 107-111.

Seymour R. B., Kauffman G. B., Polyurethanes: A Class of Modern Versatile Materials. Chem. Ed. 69, 909 1992

Sutherland, Leanne, Philippa Middleton, and Adrian Anthony. "Surgical Simulation: A Systematic Review." *American Journal of Surgery* 243, no. 3 (2006): 291-300.

Unosso, E. (2010). Mechanical properties and spreading characteristics of bone cement for spinal applications. (Master's thesis, Lulea University of Technology)Retrieved from http://epubl.ltu.se/1402-1617/2010/115/index-en.html

"Virtual Reality as a medical training tool." Universiteit Twente. http://www.utwente.nl/ctw/opm/research/design_engineering/Virtual%20Reality/03_Virtual_Reality_as_a_medical_training_tool.doc/ (accessed April 16, 2012).