Virtual Reality Simulator for Carpal Tunnel Release Surgery

November 1st, 2011

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ABSTRACT

Carpal tunnel release surgery is the cutting of the carpal transverse ligament to relieve pressure on the median nerve at the base of the hand. It is a minor, minimally invasive procedure that requires only local anesthesia and pain medication. As for all surgeries, medical students and surgeons must practice this surgery to guarantee precision during the live procedure. When cutting the carpal tunnel, surgeons must be careful not to cause more damage by accidentally cutting the median nerve or other surrounding nerves and tendons. To avoid this error, along with other common mistakes, surgeons and residents practice the surgery on cadavers. However, cadavers are costly and after the surgery is performed once, the cadaver cannot be used again for the practice of this surgery. To combat this problem, the previous design team created a simulator that would allow surgeons to repeatedly practice the surgery in as realistic a setting as possible. The team interfaced a life-like hand model and the blade used in the procedure with a computer program to display images inside the hand and wrist and give the operator realistic feedback while performing the mock surgery. This team is now working on improving the system by adding different scenarios that might occur during surgery and adding to the range of motion of the camera, as well as repackaging the prototype to look more professional. The improvements for this semester will be focused on three different areas: the housing and technology of the Wii remote, which is used to calculated the distance the blade is inserted into the hand model, the connection between the LED circuit and the trigger, as well as some additional modifications to the LEDs themselves and their housing.

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INTRODUCTION

Background and Motivation

The carpal tunnel is a narrow space at the base of the wrist where the carpal ligament surrounds the median nerve that run through this open area to reach the hand (see Figure 1). The median nerve allows for feeling and movement of the hand. When the hand is overused, the joints and ligaments can all become inflamed which can result in increased pressure on the median nerve. This pressure results in the pain, numbness and tingling sensations known as carpal tunnel syndrome. It affects over 8 million Americans and is the most common work-related injury. According to the U.S. Department of Labor, carpal tunnel syndrome results in the most missed days due to work-related injury; on average, it requires 31 days of sick leave. Additionally, worker's compensation for carpal tunnel syndrome costs over $20 billion annually in the U.S [1]. Clearly, this ailment is not only extremely painful, but also seriously inhibiting to all those whom it affects.

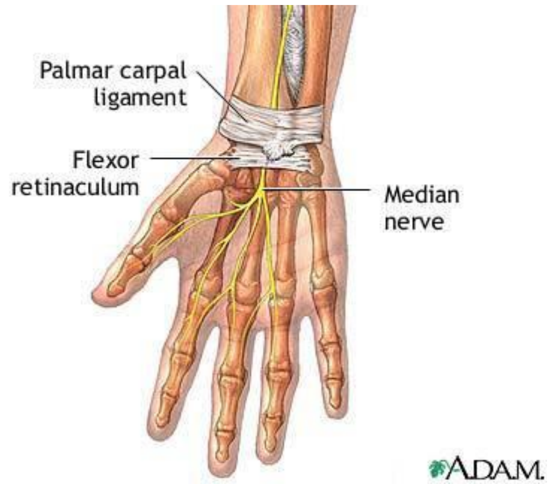

Figure 1: Representation of the Carpal Tunnel and the surrounding elements [2].

Current Treatments

Carpal tunnel syndrome can be treated by carpal tunnel release surgery, during which a surgeon makes an incision at the base of the hand and inserts a small blade to cut the transverse carpal ligament. This relieves pressure on the median nerve and allows the hand to heal normally. About 465,000 Americans get this surgery each year [3]. This basic yet common surgery requires the surgeon to be extremely accurate so he or she avoids cutting nerves or tendons while cutting the carpal ligament. Currently, the only method available to practice this surgery is on cadavers, which are very expensive and not reusable. A simulator would not only provide a more cost-effective, reusable alternative, but also provide feedback on the trainee's performance to ensure precision.

DESIGN CRITERIA

The design of the simulator needs to be safe, durable, have a professional appearance, and be as accurate to the actual surgery as possible. No cords should interfere with the execution of the simulated procedure.

First off, the device needs to be safe for the medical personnel and durable in that the components should be able to last through repeated usage without needing to be replaced. No component should create any danger for the user or damage any of the other connected parts of the design. This includes all blades, wires, and any other additional components that could potentially lead to harm. It must also be durable enough to last at least five years. Every component must also remain functional throughout the whole simulated procedure, especially those that require power, in order to ensure that it does not malfunction in the middle of the procedure. This could lead to incorrect feedback being provided to the user.

Most importantly, the design must have a professional appearance, and be as accurate to the actual surgery as possible. Since this device will be marketed as an important training tool, each component must have a professional appearance and accurately represent the visual and physical characteristics of the actual surgery. This includes calculating the horizontal position and angular rotation of the blade and trigger in the hand model, as well as the tension felt when inserting the blade into the carpal tunnel and cutting the ligament. The total weight/feel of the endoscope and trigger should remain close to the surgical setup. Ultimately, the device should be designed so that it could potentially be mass-produced. The budget is around $100 to use towards the prototype that was provided.

OVERVIEW OF DESIGN ALTERNATIVES

The proposed design consists of three main parts: the Wii remote, the mounting of the LEDs onto the trigger, and the housing for the LEDs. The Wii remote is responsible for calculating the location/distance of the blade in the hand model and communicating this information with the computer software in order to display the correct image to the user. Eventually, the Wii remote will also be used to calculate rotational movement in addition to the translational distance. It is able to do this by triangulation using three LED lights connected to the trigger. In order to provide the most accurate distance, the LED lights should not be allowed to rotate unintentionally. In order to accomplish this, the circuit board containing the LEDs must be securely fastened to the trigger. However, the mechanism used must ensure that the lights always end up positioned in the correct spot. Lastly, additional measures will be taken to optimize the housing responsible for containing the LEDS, and to ensure everything has a professional and marketable finish.

Wii Remote Designs

The Wii remote functions as an infrared (IR) receiver and Bluetooth communicator with the computer program. The functionality of the receiver is crucial to the simulator because without it, the program and simulation will not run. Another goal in the design of this component was to transition from the prototype stage into a more finished, commercialized product stage.

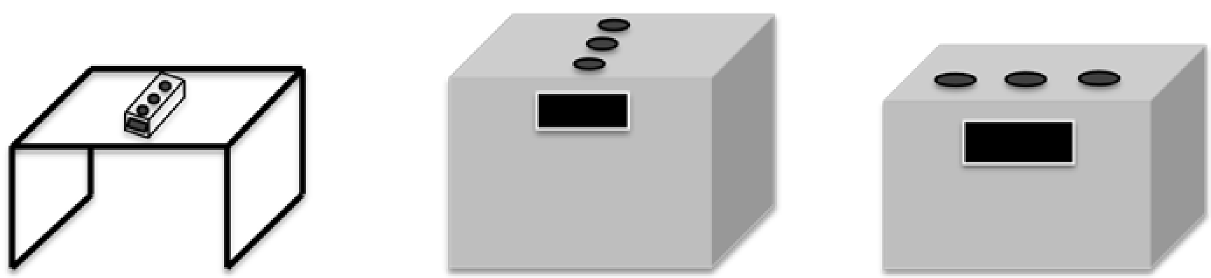

Figure 2: The three main designs for the Wii remote/IR sensor. From left to right: existing design, the hidden design, and the simplified circuit design.

For this component, three designs were considered (see Figure 2). The first was the existing design, which consisted of the remote held in place with Velcro on a raised acrylic platform. Having the Wii remote on a raised platform enables it to communicate with the LEDs and also with the computer program. The second design involves creating a control box, in which to attach and hide the remote instead of it resting on top of a raised platform. By fabricating a section of the control box out of IR transparent material the LEDs, Wii remote, and computer will all still be able to communicate with each other. The third and final design would be to create a simplified circuit that has an IR receiver inside the control box and its own specialized buttons, which would be located on top of the control box. Another design element for the control box in the second and third designs is to house the power cords of the external power source for the LEDs. Also, for the third design, since a separate circuit is being created, the control box will also house the one power source for both the LEDs and the circuit with the IR sensor. This would greatly improve the issues with dying batteries that present with the current prototype.

Evaluation of Wii Remote Design Alternatives

In order to properly assess the effectiveness of each design, a design matrix was created. Five main areas of focus were weighted for the design of the simulator. As one of the goals of the project for this semester, professional appearance was considered the most important. In order of descending weight, the categories were professional appearance, durability, ease of use, ease of fabrication, and cost (see Table 1).

Table 1: Design matrix for the Wii remote, which consists of the as is, hidden, and simplified circuit designs.

Criteria	Weight	As Is	Hidden	Simplified Circuit
Professional Appearance	40	20	32	36
Durability	20	12	12	14
Ease of Use	15	11	11	14
Ease of Fabrication	15	15	12	11
Cost	10	10	9	9
Total	**100**	**68**	**76**	**84**

The most heavily weighted item in the design matrix was the professional appearance of the design since it was important to the client to make the simulator look as much like a manufactured product as possible. The existing design received the poorest marks in this category simply because it is a prototype with the remote attached by Velcro to the raised platform. The hidden design and simplified circuit design scored well in this category mainly because the IR device would be concealed in the control box, giving them a much more polished design. However, the hidden design did score slightly lower because holes would have to be drilled on the top of the control box in the precise locations of the Wii buttons in order to still be able to turn the device on and off and sync it with the LEDs and computer. With the simplified circuit, all of the buttons on the Wii remote would be taken out, and the functions of power, synchronizing, and resetting would be designated to three distinct buttons. The hidden and simplified circuit designs would also incorporate taking the simulator for the prototype stage to the finish product stage by concealing the Wii remote or circuit from view and by having all of the power cords originating from one central location.

The durability was the next highest in weight. Since the goal for this simulator is to be used repetitively in hospitals for training purposes, it needs to last a long time. For this category, the existing design and the hidden design scored lower than the simplified circuit because the Wii remote constantly runs out of batteries and will not last through more than a couple simulations. The simpliftied circuit design addresses this issue by having its own external AC power source. For this reason, it scored higher than the other two designs.

The ease of use and fabrication were weighted equally because if this simulator is to be widely used in hospitals, it must be easy to set up and operate while still able to be mass-produced. For ease of use, the existing design and the hidden design scored the same due to the fact that the buttons for operating the Wii remote in conjunction with the computer software is not always intuitive. Enabling the Bluetooth capabilities is done by holding the number 1 and 2 buttons. This flaw is addressed in the simplified circuit design by fabricating a circuit that will still achieve the same functions as the Wii remote but will be simpler and more straightforward. However, in order to make this functionality possible, there is a fair amount of fabrication. The simplified circuit must be created, tested, and modified in order to still perform the same tasks as the Wii remote. In addition, the modification to enable an external power source must be done. For these reasons, the simplified circuit scored the lowest in ease of fabrication. The existing design scored perfect because nothing needs to be fabricated. The hidden design scored just above the simplified circuit because the control box needs to be fabricated and modified for the Wii remote buttons.

The final design criterion was the overall cost. While this is an important factor to consider, all of the designs have very little or no cost involved with them. The only expenses for the hidden and simplified circuit designs would be the purchase of IR transparent material and the acrylic for the control box, and for the simplified circuit only, the material for the circuit. The existing design has no cost associated with it, since all of the materials have been purchased already.

LED Mounting Designs

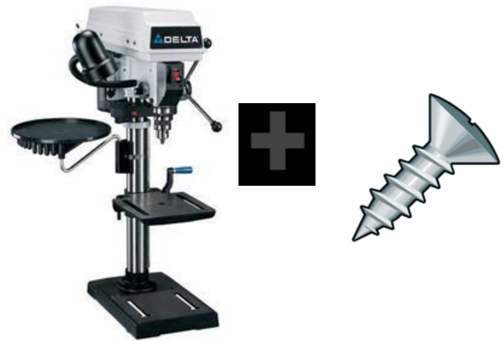

Figure 3: Design option 1: Drilling a hole and adding a screw mechanism [4][5].

Another component of th overall design is the attachment of the trigger housing and the LED mount. The first option uses a screw concept and a drill, as seen in Figure 3. On the top of the rear of the trigger housing, a ¼ inch hole would be drilled, allowing a screw to fit through and hold the LED mount in place. In addition to this idea securing the two parts together in an effective way, it would also allow for the correct orientation of the components relative to one another.

The second design employs either plastic or metallic clips. These clips would be external to the device, with the male piece on the trigger housing and the female piece on the LED mount. Once again, this concept would allow for a secure attachment and correct orientation between the two components of the device.

Figure 4: Design option 3: using an internal lock system such as an expanding bold (left) or a Luer Lock system (right) [6][7].

The final alternative design services the use of an internal lock system, as seen in Figure 4. For this, there are two possible types: the expanding bolt and the Luer lock.

For the expanding bolt, the systems own casing holds it in place. As the bolt is tightened, the casing expands and would create a force in all directions on the inside of the trigger housing, holding the LED mount in place. The Luer lock works similar to a lock and key. The LED mount would be forced to enter the trigger housing in one orientation, and then when it is turned ninety degrees, it locks in place. Once more, both of these systems would attach the two components securely and in the correct orientation.

Evaluation of LED Mounting Design Alternative

In assessing the three design alternatives for the trigger housing/LED mount attachment, five main criteria were used: professional appearance, durability, ease of use, ease of fabrication, and cost. As seen in the design matrix contained in Table 2, the plastic/metallic clip idea performed well in the ease of fabrication category, but did not do well in the professional appearance due to it adding a lot of external pieces to the device. For this reason, it was clearly not the best fit solution to this part of the design. The drilling/screw concept and internal lock system perform very similarly across the board. However, due to the internal lock system being completely contained within the trigger housing, it does better in professional appearance. And all in all, it leads to the internal lock system deeming itself the best fit design for this component of the project.

Table 2: Design matrix for the trigger/LED connection including the Drilling/Screw mechanism, Clips mechanism, and Internal Lock mechanism as the possible designs.

Criteria	Weight	Drilling/Screw	Clips	Internal Lock
Professional Appearance	40	35	15	40
Durability	20	18	10	18
Ease of Use	15	14	13	14
Ease of Fabrication	15	5	8	8
Cost	10	9	9	7
Total	**100**	**81**	**55**	**87**

LED Mount

The LEDs and their respective mount are also going to be slightly changed. Instead of three domed infrared-emitting LEDs, three flat ones will be used to limit the size of the circuit board and its housing. In addition, the housing will be infrared-transparent. Because of this, no holes will need to be made to allow for the transmission of the infrared light, creating a more packaged and finished appearance to this part of the device. Furthermore, the circuit board and housing will be shortened to minimize the clumsiness of the device, since the mount does come perpendicularly off the trigger housing. Finally, the power cord exit site will also be changed. The cord will exit parallel to the trigger ho using and the LED mount attachment. This will give the user a much better feel with the device, since before it came off the end of the LED mount, creating a greater inconvenience to the user.

FINAL DESIGN

Based on the design matrices, the three components chosen for the final design are the simplified circuit that will be used to replace the current Wii remote, an internal lock mechanism in order to attach the LED circuit onto the trigger, as well as some additional changes to the LEDs to improve their overall appearance (see Figure 5). With the internal lock system and the changes being made to the LEDs, additional research and testing will have to be done before a conclusion can be made as to exactly which apparatus will be utilized to accomplish the goals for the final design. All of these components were chosen to give the final product a finished, marketable appearance. The main goal for this semester is to provide the client with a polished product that can then be quickly reproduced and distributed to other hospitals and used as a teaching device to train doctors on the carpal tunnel release surgery.

The simplified circuit is the main component to improve the user-computer interaction. All of the additional buttons, electrical components, and special features provided by the Wii remote that are not necessary for this procedure will be removed. These will then be replaced by only two or three buttons labeled with the direct action that they will be responsible for carrying out. By increasing the intuitiveness of this step, it will create an easier and better experience for the user when running the program. Another advantage seen with this device falls in its contents being concealed in some sort of housing in comparison to the openly exposed Wii remote. This will ensure that the device is not seen as a toy or a game due to the Wii involvement. Instead, it will add onto the professional appearance of the overall design.

Depending on further research, a specific internal locking mechanism will then chosen and incorporated into the design to provide stabilization for the LED connection to the trigger. This would ensure that the LEDs will not be allowed to undergo any unintentional rotation and thus lead to greater accuracy in calculating the distance and rotation of the actual blade/trigger in the hand throughout the simulation. This design also has a very professional appearance in that no external parts would be showing. The LED circuit would simply slide into the compartment and lock into place.

The last component consists of some changes to the current LED circuit and its housing. Right now, the prototype consists of three dome shaped LED lights and the PVC tubing used to hold the circuit. These LEDs stick out of holes drilled into the housing and are very loosely fitting and can easily fall out and become lost. In addition, the current PVC tubing is a lot larger than it has to be, and the paint is peeling off giving it a worn look. Some of the current ideas to improve this situation is to use flat, rectangular shaped LED lights on a smaller circuit board. With the extra room, alterations could then be made to the housing material. Instead of the PVC piping, an infrared transparent material could be used. No holes in the housing would then be necessary because the signal from the LED lights would no longer be blocked. The shape of the housing could also be altered to take advantage of the flat LED lights. Instead of a cylindrical shape, which takes up a lot more room than necessary for the square circuit, a smaller more compact shape could be fabricated. Another option would be to move all of the LED lights closer together so that the circuit would not have to stick out so far from the trigger. However, the optimal distances would have to be tested before a conclusion could be made. A final design alteration would be switching the location of the power source. Instead of the cord running through the entire length of the housing and coming out on the opposite end, the cord would instead insert into the end nearest to where the circuit connects to the trigger. With this configuration, the cords would then be less out of the way. Also, in the actual surgery, the cord from the endoscope would be coming out of the trigger at this location. So placing the cord here would be almost identical to what the doctor would see in the operating room.

Figure 5: The different components making up the final design: the simplified circuit, internal locking mechanism and additional options for the LEDs and the housing [8][9].

Ergonomics

With the current prototype, only a knowledgeable user would know how to correctly operate the Wii remote in tandem with the computer software interface due to a number of unintuitive button sequences. This does not create a good user–computer interaction. This would not be an issue with the simplified circuit design. With this design, the buttons needed to run the program would not have to directly come from the Wii remote, instead, they could be drastically cut down to two or three buttons with clear labels describing the actual function of the button. This advantage to redesigning a new circuit would increase the ergonomics of the user-computer interaction and provide a clear, easy to operate teaching tool.

Ethical Considerations

The main ethical consideration for this project is that no user should be harmed while using this surgery simulator. This device was designed to be as similar to the actual surgical procedure as possible, meaning that real equipment and blades are used. Since this product is just used as a practice tool, it potentially is available for everyone to use—whether trained on how to use the equipment properly or not. Although a plastic cap currently covers the blade, it can easily become uncovered while the blade is inside the hand model. This could potentially be dangerous for the user and for the hand model itself. Further measures should be taken to design additional safety features to protect the user from harm.

Future Work

For the rest of the semester, the main focus will be in outfitting the trigger piece with a luer lock and fabricating the housing for the LEDs, the control box for the simplified circuit and power supply, and the circuit itself. These fabrications will hinge upon further research into internal locking mechanisms, infrared sensor technology, infrared transparent materials, and circuit design. Once this research is completed, the components will be fabricated. The simulation software must also be tested and modified, but this will be done with the help of the program author Mason Jelling. Testing all of the fabricated components with the software will be necessary to ensure the entire simulator is functional. Once the testing is completed, the simulator will be taken to the UW Hospital where surgeons will run through the simulation and give feedback on their experience. The goal is to have the simulator operational and looking like a finished, marketable product by the end of the semester.

Fabrication Process

Since all of the components in this simulator are specific and custom to this particular device, they components must all be fabricated and not purchased. Only the raw materials will be purchased. The fabrication of the luer lock in the trigger piece will start with the creation of a SolidWorks® file. The same will be done for the LED housing. Both components will be designed to incorporate the luer lock. The housing will also be constructed from a suitable IR transparent material. Once the housing is complete, the trigger piece and LED housing will be taken to the machine shop to be modified with the luer lock inside. The control box must also be fabricated along with the circuit and IR receiver. Professor Tom Yen will aid in the fabrication of the circuit, IR sensor, and power supply. After making a circuit and the corresponding button and IR receiver attachments, a SolidWorks® file will be created for the fabrication of the control box. Following the completion of all of the components, they will be tested in the following manners.

Testing

There will be two waves of testing before the simulator will be finished individual component testing and all of the components put together and tested with the simulator software. The main focus of the tests will be in the circuit. Since there will be multiple different functionality aspects to this circuit, (Bluetooth communication, button response, and external power supply) it will need to be tested thoroughly to ensure it works perfectly. The Bioinstrumentation lab will be useful for taking apart the Wii remote to see exactly how it works and how we can expect the circuit to work as well. Professor Yen will be aiding in the exploration of the Wii remote and circuit assembly and testing. With the help of Professor Yen and further research into circuits, it will become clearer exactly how to test each aspect of the circuit to make sure the simulator will run properly.

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APPENDIX

Virtual Reality Simulator: Product Design Specifications
September 20, 2011
Client: Professor Robert Radwin
Team: Ashley Mulchrone, Spencer Strand, Katie Jeffris, and Patrick Hopkins
Advisor: Professor Tom Yen

Problem Statement

All surgeons, no matter what experience level, require practice in order to achieve positive outcomes when going into surgery. Currently, carpal tunnel syndrome release surgery is only performed on cadavers or live patients. As the cost of cadavers is quite expensive, especially for this simple of a surgery, a better practice method is in need. An ideal substitution would be an anatomically accurate simulator with realistic haptics. In previous semesters, a simulator was designed by interfacing a life-like hand model with computer software to display images of the inside of the hand and wrist to create the most realistic experience possible. The goal is to further this prototype by adding in special case scenarios that could possibly occur during a real surgery, in addition to furthering the current capability of the range of motion of the camera.

Design Requirements

1. Physical and Operational Characteristics
    a. *Performance requirements*: The simulation should be as life like as possible to the actual surgery. The force feedback provided by the hand model should replicate the forces experienced by the surgeon, and should increase when the blade is deployed. The endoscope images should represent the depth and angle experienced by the surgical tool, and should create a smooth transition.
    b. *Safety*: The simulation should not cause any harm to the surgeon or any of the connected devices.
    c. *Accuracy and reliability*: Signaling device should detect position within 1 mm. The tracking system should maintain accuracy of position throughout multiple simulations. The force feedback mechanism should provide a consistent amount of force in each simulation.
    d. *Life in service*: Simulator needs to withstand at least 5 years as a training tool.
    e. *Operating Environment*: The device will be used in standard conditions. It will not need to be sterilized.
    f. *Ergonomics*: All forces and components should replicate those felt when performing the actual surgery. The external circuit should also be positioned so that it does not interfere with the surgical technique.
    g. *Size*: Hand model should be life size and the incision site should be 5 mm proximal of the distal wrist crease. The carpal tunnel should be 1 cm in diameter.

The transverse carpal ligament should be 5 mm thick. The ligament corrugations are 1 mm in height and thickness with 1 mm of spacing between consecutive corrugations.

h. *Weight*: Should be able to be disassembled and easily transported.
i. *Material*: Hand material has to have mechanical properties similar to carpal tunnel tissue. The force feedback mechanism should be compatible with the silicone material used in the hand model.

2. Product Characteristics
   a. *Quantity:* Ideally, two working prototypes are easy with easy manufacturability for the future.
   b. *Target Product Cost:* Around $100 for the remaining parts for the first prototype, in addition to cost needed to replicate the model.

3. Miscellaneous:
   a. *Standard and Specifications:* No specific standards because the prototype is only used in simulation as a training tool and not in actual surgery.
   b. *Customer:* The device will be used to train other surgeons to practice the endoscopic carpal tunnel release procedure. The tracking system will be incorporated with a virtual environment created by the client in Adobe Director.
   c. *Patient-Related Concerns:* None, the prototype will not be used on patients.
   d. *Competition:* A current device involving minimally invasive surgeries called TrEndo. It creates a physical connection between the tacking element and the surgical device, however, has not been applied to carpal tunnel surgery.