Virtual Reality Simulator for Carpal Tunnel Release Surgery

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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 ligament, 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 this procedure. To combat this problem, the previous design team created a simulator to allow surgeons to practice the surgery repeatedly, in as realistic of a setting as possible. The team interfaced a life-like hand model and the blade used in the procedure with a computer program that displayed images from the inside of the carpal tunnel and gave the operator realistic feedback while performing the mock surgery. In order to connect the hardware to the software, a Wii remote was used track distance that the blade had traveled inside the hand model. However, there were some downsides to using the Wii. Therefore, the client asked for improvement in the method of data transfer, the power supply, as well as the overall appearance of the simulator.

This team focused on these three main components and came up with a number of modifications: new data handling performed by an Arduino microcontroller that connects directly to the computer via a USB drive, new housing and circuitry for the LEDs, and finally a new locking mechanism to hold the LEDs. After testing and quantifying the improvements via a survey, it was found that these new components had an overall 10% improvement rating from the client. In compliance with our client's demands, a second simulator will be fabricated and sent to Johns Hopkins Hospital. Before this can be done, a printed circuit board must be purchased to replace the current breadboard, and the software must be modified to handle images smoother and to support a standalone application for both a Macintosh and a PC.

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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, which runs through this opening 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 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 United States [1]. Clearly, this ailment is not only extremely painful, but also seriously inhibiting to all those whom it affects.

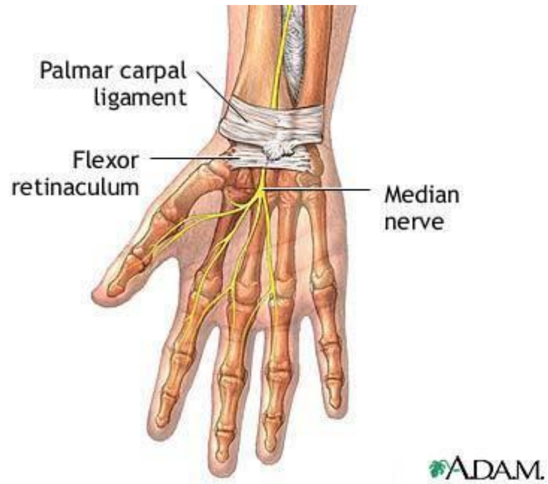

Figure 1: Representation of the Carpal Tunnel and the surrounding elements [2].

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 accidently 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 by having an accurate, realistic simulation.

Current Devices

Because of the high cost and limited availability of cadavers, there has been an increasing interest in development of affordable, reusable surgical simulators. Many systems are available that are meant to interface simulation devices with visual processing software for application to a specific surgical procedure. However, current instruments designed to help surgeons practice minimally invasive procedures are expensive, and some, such as the TrEndo and SIMENDO, do not provide a physical model with which to simulate the surgery (see Figures 2 and 3). Other programs, such as the ProMIS, integrate virtual and physical models to provide a more realistic experience (see Figure 4). However, here are no simulators specifically designed for carpal tunnel release surgery [4]. The team aimed to design a cost effective simulator for carpal tunnel release surgery that interfaced virtual images of the surgery with a physical model to provide accurate feedback and create a realistic experience for the user.

Figures 2-4: The TrEndo and SIMENDO surgical simulations (left and center) that incorporate the handheld instruments used to detect movement [5][6]. The ProMIS simulation (right) includes an anatomical model [7].

DESIGN CRITERIA

The client wanted a design that had a realistic size and weight, as well as similar tension when cutting the ligament. The simulator needed to look professional and be easy to set up and operate. Additionally, the external devices could not interfere with the surgical procedure, and the software/hardware interface needed to be integrated as well. The design needed to be durable enough for repeated use and provide accurate feedback within 1 mm of precision. Also, the design needed an improved power source since the Wii remote's batteries needed to be changed frequently. In addition, the current design warranted a different data transmission method, because the Bluetooth stack was difficult to operate and not PC-friendly.

The prototype should 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 entire 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 the tension felt when inserting the blade into the carpal tunnel and cutting the ligament as well as calculating the horizontal position and angular rotation of the blade attachment in the hand model. 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. A budget around $250 was given to use towards improvements upon the prototype that was provided.

Overview of Design Alternatives

The proposed design consists of three main parts: the Wii mote/infrared camera, 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 hand piece. 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 hand piece. However, the mechanism used must ensure that the lights always end up positioned in the correct spot. Lastly, additional measures will be taken to improve 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.

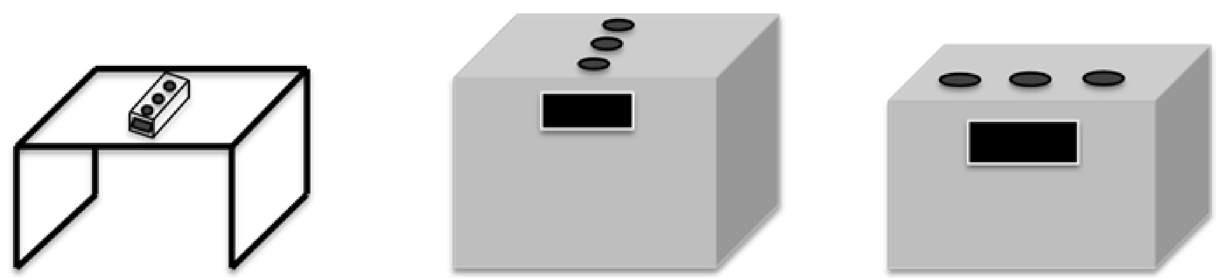

Figure 5: The three main designs for the Wii remote/IR sensor. From left to right: existing design, the hidden design, and the simplified circuit design.

For this component, three designs were considered (see Figure 5). 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 better enables it to communicate with the LEDs and with the computer program. The second design involves creating a control box 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 infrared 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 infrared 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 is to house the power cords of the external power source for the LEDs. Since a separate circuit is being created in the simplified circuit design, the control box will also house the one power source for both the LEDs and the circuit with the infrared 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 infrared device would be concealed in the control box, making them more polished designs. 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 synchronize 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 from 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. This simulator would be used repetitively in hospitals for training purposes, so 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 does not last through more than a couple simulations. The simplified 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 because 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 one and two 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 infrared 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

Another component of the 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 6. On the top of the hand piece, a ¼-inch hole would be drilled, allowing a screw to fit through and hold the LED mount in place. By securing the two parts together in a specific way, it can be designed to ensure proper orientation of the components relative to one another.

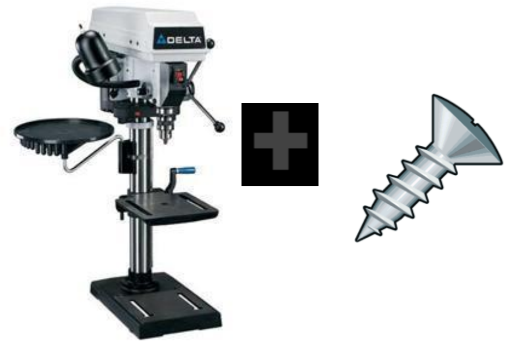

Figure 6: Design option 1: Drilling a hole and adding a screw mechanism [8][9].

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.

The final alternative design services the use of an internal lock system, as seen in Figure 7. For this, the team focused on two possible types: the expanding bolt and the Luer lock. For the expanding bolt, the system's 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.

Figure 7: Design option 3: using an internal lock system such as an expanding bold (left) or a Luer Lock system (right) [10][11].

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 many 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. Overall, 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 the LEDs being removable, they will be directly soldered onto the circuit board. 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.

FINAL DESIGN

Based on the design matrices, the three components chosen for the final design were the simplified circuit 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. All of these components were chosen to give the final product a finished, marketable appearance. However, for the finished product, a few modifications to the simplified circuit and the internal locking mechanism were made. The main goal for this semester was to provide the client with a polished product that can then be quickly reproduced and distributed to other hospitals. That way it can be used as a teaching device to train surgeons on the carpal tunnel release surgery.

Simplified Circuit

The simplified circuit is the main component to improve the user-computer interaction. Although the infrared camera in the Wii remote was very useful, the Wii itself had a plethora of extra parts that were not needed. The only part from the actual remote that was necessary was the camera itself. This piece was then removed, and instead connected to an Arduino Uno microcontroller (Figure 8). The Arduino, along with a logic converter and a crystal clock oscillator, is now responsible for all the data conversion that the Wii was previously handling (Figure 9). The data transfer could then be directly transmitted from the microcontroller to the computer through a USB cable. This provided many benefits. First, the Bluetooth aspect of the Wii remote could be bypassed altogether. The client had experienced difficulty maintaining the Bluetooth connection due to the simulator being in an environment surrounded by medical equipment and other interfering signals. Second, the simulation will no longer be limited to only Macintosh users. When using the Bluetooth, PC users are required to pay to download Bluetooth stacking capabilities that are incorporated into the Macintosh computers. This greatly reduced the number of users that this product could be used by. Now, the programs can be run regardless of the type of computer. In addition to direct data transfer, the USB provides enough power to run the Arduino as well as the infrared sensor. With this setup, batter power is no longer

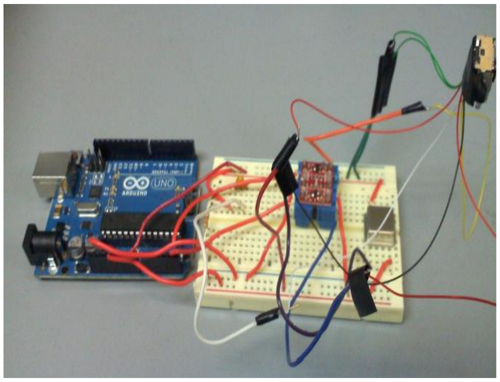

Figure 8: The Wii infrared sensor being operated and powered by the Arduino microcontroller.

necessary, which also proved to be problematic and costly to our client. With this design, buttons no longer needed to be fabricated for as originally planned. The USB cable allows the power and synchronizing functions to be directly controlled with the computer.

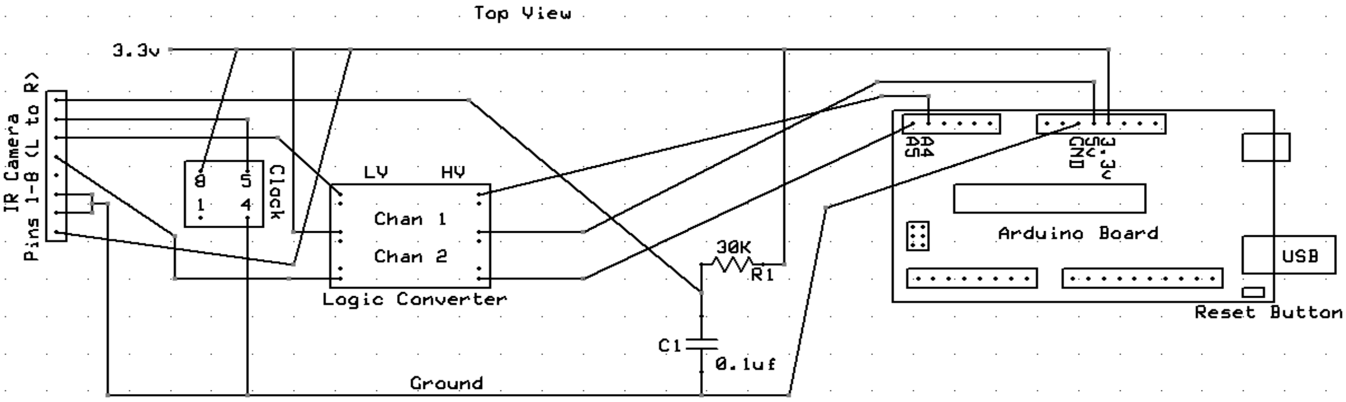

Figure 9: Schematic of the infrared camera generated on ExpressSCH.

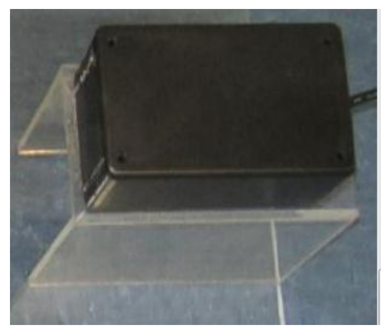

Figure 10: The new housing for the simplified circuit.

Another advantage of the simplified circuit was the ability to conceal the contents in a housing structure (Figure 10). This housing takes the place of the Wii remote shell and holds the infrared sensor and all the additional circuitry. In order to ensure that the camera can communicate with the LEDs, the front end of the circuit box was removed and replaced by a 2x2 inch square of infrared transparent material. Then, a smaller square was removed from the back to allow enough room for the USB cord to reach inside the housing with the lid firmly in place. Lastly, the whole circuit box was screwed into the top of the platform of the base to ensure that it remained in place. With a professional appearance being important, the new housing structure ensures that the device will not be seen as a toy or game due to the Wii involvement.

Locking Mechanism

In order to provide better security to the LED circuit, the team chose to take advantage of one of the hand piece's built-in features in order to lock in the LED housing made out of a polycarbonate rod. This rod was selected to fit snugly into the hand piece. By unscrewing the bottom half of the hand piece, a different internal screw was accessed. This screw was tightened onto a small piece of the polycarbonate rod, which was inserted into the inside compartment of the hand piece. Through this mechanism, the internal screw was used to firmly lock the rod into place before the bottom half of the hand piece was put back into place. By inserting the elbow piece with the switch button into the rod that was now screwed into place, a secure fit was accomplished. The fit was tight enough to ensure that the LED circuit would no longer undergo any unintentional rotation. This design provides more accuracy in calculating the distance, and ensures the operator, not loose equipment, produces any rotation picked up by the camera. Additionally, this design has a very professional appearance in that no external parts are showing (Figure 11).

Figure 11: The trigger and blade with the connected LED circuit.

LED Housing

The last component consists of some changes to the current LED circuit and its housing. In this design, the LEDs are firmly soldered directly onto the circuit board. By removing the sockets by which the LEDs were placed before, extra room extra room was created. This allowed the whole circuit board (LEDs included) to be able to fit within the housing. With the holes no longer necessary, the LED lights are now properly secured and can no longer fall loose and become lost. In order to accommodate for this change, the housing was switched to an acrylic plastic, which allows the infrared lights to emit through them. For a more professional appearance, the housing was painted black minus the small strip where the LEDs line up (Figure 11).

Ergonomics

Overall, the endoscopic carpal tunnel release surgery simulator incorporates many pieces of hardware in addition to multiple software programs. However, the individuals using this device will most likely have little to no background in electronics or computer science. Therefore, this device was designed to have a simple user-computer interaction. With the data handling now being handled by a USB cable, the synchronizing and Bluetooth operations are no longer necessary. The cable is simply inserted into the microcontroller while the other end is placed into the computer. With this design, the whole simulation can then be incorporated into its own standalone application where the user can simply click on an icon, select which computer type they are running the program (PC or Mac) and the appropriate software will automatically start running. 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. Because 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.

Testing

The goal in testing the prototype was to determine the optimal range of the LED detection by the infrared sensor, the accuracy of the device across this range, and its horizontal range orthogonal to the infrared detection. Overall, a range of maximal accuracy needed to be found to optimize the functionality of the device through the entire process of the simulated procedure.

Procedure for testing positioning accuracy:

1. The starting distances between the infrared sensor and the infrared LEDs were chosen at 20-55 cm (every 5 cm) and 55-70 cm (every 0.25 cm).
2. At each distance, the measurement given from the processing software was recorded.
3. Three repetitions were executed for each distance.
4. The average and standard deviation were calculated for each distance.
5. The average standard deviation across all distances was calculated.

By following the presented steps, the simulator was found to have a constant standard variation of 0.5 mm at all ranges from the IR sensor, which is better than the objective of achieving a variation of 1.0 mm (see Appendix D for the produced graph). Consequently, the optimal distance to be used could be anywhere from 20-70 cm because all distances in this range proved to have the same accuracy.

Procedure for testing horizontal range:

1. The starting distances between the infrared sensor and the infrared LEDs were chosen at 20, 30,40,50,60, and 70 cm.
2. The LEDs were placed at each distance and then moved perpendicularly to the line of action of the infrared sensor.
3. The horizontal distance at which the processing software indicated the LEDs were out of range was recorded.
4. At each distance, the viewing angle was determined based on the recorded horizontal distance (as seen in Figure 12).

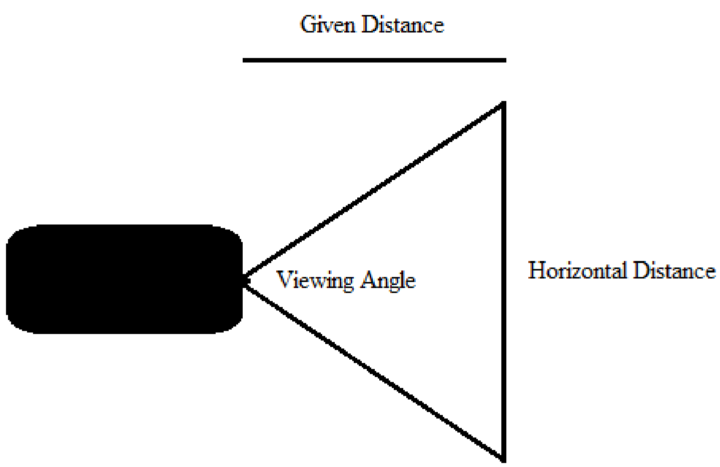

Figure 12: Diagram representing the testing procedure for horizontal range.

By testing for the horizontal range, the viewing angles at given distances from the IR sensor proved to increase as the distances did. Table 3 shows the horizontal distances and viewing angles at each test given distance.

Given Distance from IR Sensor (cm)	Detectable Horizontal Range (cm)	Viewing Angle (degrees)
20	8	22.62
30	14	26.26
40	20	28.08
50	26	29.14
60	34	31.64
70	42	33.40

Table 3: Testing horizontal range – Ranges and Viewing Angles

The last performed test was qualitative. Surgeon Ben Mandel, M.D., studied the prototype and compared it to the previous version from last semester by taking a survey (Appendix E). The criteria were professional appearance, realistic and useful training tool, smooth visual transitions, intuitive and easy to use, and realistic haptics. According to Dr. Mandel, the new device was found to improve in each category, except the visual transitions. He found them to be at least as good as last semester, but still would like to see more improvement. This could easily be handled by continued streamlining of the software code. With more streamline images, the improvement would be even more significant as the client is very excited about the USB connection allowing for program usage on multiple computer types—which was previously a great restriction. Overall, Dr. Mandel concluded that the design was 10% better than the previous version.

SEMESTER SUMMARY

For an overview of the semester accomplishments and completion dates, a timeline can be found in Appendix B. The team was able to complete all of the necessary tasks, albeit a bit behind schedule in a few regards. The fabrication was delayed due to the design shift from one power source powering both the LEDs and the camera circuit to a 6V power supply for the LEDs and USB/ microcontroller use for the camera. There were also complications with the assembly of a functioning circuit to connect the camera to the microcontroller.

The total budget and expenditures can be found in Appendix C, but after the initial budget ($100) was reassessed due to a change in emphasis on what our client wanted out of the project. The more appropriate budget of $275 for costs (excluding the endoscope and hand replica) was approved, and the team was able to stay reasonably close to the budget with an expenditure of $278. The completion date of the first simulator was on time, with a second one on the way. The team also spent approximately 534 hours on the project altogether.

FUTURE WORK

As part of the plan with the design of this simulator, the client had asked for two functional simulators to be completed: one for the UW Hospital and another to be sent to Johns Hopkins University Hospital for beta testing. For this plan to be completed, there are a few different areas of future work. In one regard, a plan has been make to fabricate another simulator almost identical to the one that has already been completed. Since the team already has the design functional and looking much more professional, a few additional parts need to be ordered in order to complete the second simulator. However, in another regard, a few changes will be made for the benefit of both simulators.

The first is to take the circuit design from the breadboard and solder the proper components onto a printed circuit board. Each simulator requires one set of circuit boards (one for the LEDs and another for the camera). The schematics for these have already been drawn up, but they still have to be submitted to ExpressPCB to be manufactured. The design of the circuit boards has taken into account the proper function of the circuits and the dimensions of our project box/ LED housing respectively, where the circuitry will be held. These will enhance the professional appearance of the simulator and prevent accidental mishandling of the camera, microcontroller, and LEDs.

Another change to the physical components will be to find another IR camera that still has the same functionality as the PixArt camera taken from the Wii remote. Further research should be done in order to find a camera that can track at least three LEDs up to a distance of 70cm. The main benefit of this change will be to steer away from dependence on the Wii remote as the source of the camera. The design will be much easier to replicate and more than likely cheaper if an alternative camera can be found, instead of desoldering one from a Wiimote for every future simulator.

From the survey of Dr. Ben Mandel, the client and a surgeon who is very familiar with the Endoscopic Carpal Tunnel Release procedure, the team has found a few areas of improvement. In order to make the simulation as accurate as possible, the transitioning of the images displayed when the LEDs are moved needs to be as smooth as possible. Currently, they are a bit disjointed and choppy. This most likely comes from removing the Wii remote components, which did a majority of the data handling. Now that the team has removed those, the code for the program will need to be fine-tuned to make the image processing more fluid.

Finally, the goal is to make this instructional instrument as user-friendly as possible. One user suggestion was to add calibration memory in the program, so that the user does not have to calibrate the distance of the LEDs on the start of every simulation. This would improve the overall ease of use of the simulation and would work nicely with the fixed distance of the hand from the camera created by the base. One hindrance of the prototype was that due to the Bluetooth stacking, the simulation could only be run on a Macintosh computer. A step has already been taken in the right direction by integrating the two computer platforms (Macintosh and PC) by changing the Bluetooth data transfer to USB. The last step to opening the door to both types of operating systems is to create an application that can be saved on a Flash drive or CD and installed on either computer. The application will contain all of the files necessary to run the simulation on either platform. Once installed, the simulation can be run without any additional software programs. With these changes, the simulator will be a very efficient instructional tool for Carpal Tunnel Release surgery and has the potential to save hospitals thousands of dollars on overpriced devices that perform the same tasks. It will also improve the quality and skill level of surgeons and residents performing this common operation.

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APPENDIX

Appendix A: Product Design Specifications

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 $250 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.

Appendix B: Semester Schedule/Timeline

Tasks	September				October				November				December	
	9	16	23	30	7	4	21	28	4	11	18	25	2	9
Research		✔	✔	✔	✔				✔	✔				
Brainstorming				✔	✔					✔				
PDS			✔											✔
Prototype Design						✔	✔	✔		✔		✔	✔	
Prototype Fabrication										✔	✔	✔	✔	✔
Testing														✔
Meeting with Client	✔		✔											✔
Team Meeting	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Presentation							✔							✔
Written Reports							✔							✔
Peer/Self Evaluations							✔							✔

Table A1: Semester Schedule/Timeline. Colored coding indicates the projected timeline at the beginning of the semester. The check marks indicate when each task was completed.

Appendix C: Expenses

FOR THE SEMESTER	
Item	Price
Arduino Board	$36.92
Printed Circuit Boards (x4)	$82.00
IR Material	$17.00
Project Box	$4.21
Base Material	$47.36
USB Cord	$31.64
Circuit Components (x3)	$24.11
Polycarbonate Rod	$5.00
Button Switches (4)	$3.90
LEDs	$11.56
Acrylic Tubing	$14.75
Total	$278.45

Table A2: Total expenses spent by the team throughout the semester. The PCBs have not been ordered, however projected costs have been included.

Cost Per Simulator	
Item	Price
Base Material	$47.36
Hand Model	$300.00
Trigger/Blade	$500.00
LEDs (x3)	$6.93
Acrylic Tubing	$4.92
Button Switch	$0.98
Printed Circuit Board	$20.50
Infrared Sensor	$40.00
USB Cord	$31.64
Circuit Components	$8.04
Arduino Board	$36.92
IR Material	$17.00
AC Converter	$22.66
Elbow Piece	
Project Box	$4.21
Total	$1,041.16

Table A3: Total expected costs per simulator. The Printed Circuit Board still have to be completed, as well as an additional elbow piece.

Appendix D: Testing Results

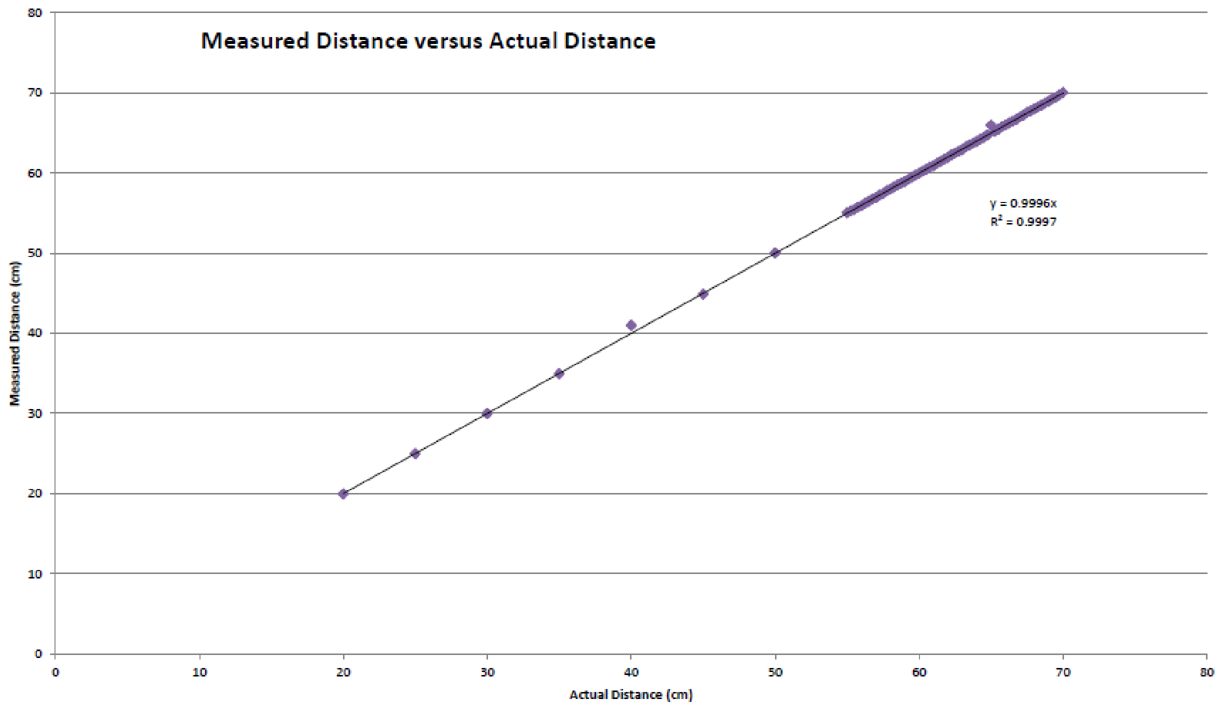

Figure A1: Graph showing the measured distance with the simulation in comparison to an actual measured distance.

Appendix E: Survey

Carpal Tunnel Release Surgery Simulator Survey

December 2011

What is your position at the hospital?

How many times have you performed the carpal tunnel release surgery? *Please circle one.*

0 1 to 5 6 to 9 10+

Please rate the following statements by circling 1-5, 1 meaning strongly disagree and 5 meaning strongly agree.

	Previous version (if applicable)	Current version
The image display is an accurate representation of the endoscopic camera view.	1 2 3 4 5	1 2 3 4 5
The design is professional in overall appearance.	1 2 3 4 5	1 2 3 4 5
The design is a useful tool to train doctors and residents how to perform the surgery.	1 2 3 4 5	1 2 3 4 5
The simulator is intuitive and easy to use.	1 2 3 4 5	1 2 3 4 5
The program is easy to use (set-up, user interface).	1 2 3 4 5	1 2 3 4 5
The weight of the simulator endoscope is accurate relative to actual operating equipment.	1 2 3 4 5	1 2 3 4 5
The sensation of cutting the simulator ligament is comparable to that of the actual surgery.	1 2 3 4 5	1 2 3 4 5

What is the most challenging aspect of the set-up and/or operation of the simulator?

Overall, how comparable is the simulator to the actual surgery?

Comments:

Figure A2: The survey that was given to Dr. Ben Mandel to test the overall design of the simulator.