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VISUAL FEEDBACK SYSTEM FOR OTOLARYNGOLOGY PROCEDURES

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ABSTRACT

The objective of this project was to design a visual feedback attachment for the Coblator II, tonsil and adenoid removal device. Currently, one device is used to perform both cauterization and ablation, controlled by two pedals outside of the field of view. A device is needed that distinguishes between the two functions visually within the field of view. This will be attached to the tray table that is used during the surgical procedure. It will feature two different colored lights, blue and yellow, and be disposable or have a special cover that is able to be replaced between each patient's procedure. In addition to this, there will be a slight delay between when the light is initially illuminated and the function begins, as an extra safety precaution.

Keywords: Otolaryngology, Infrared Proximity Sensors, Coblation II, Tonsillectomy, Adenoidectomy, Visual Feedback

1. INTRODUCTION

Tonsillectomies and adenoidectomies are very routine procedures with approximately 500,000 performed every year in the United States [1]. An otolaryngologist (Ears, Nose, and Throat, or ENT) doctor is the surgeon that typically performs this surgery, often being on children. A singular instrument is usually used that switches between performing ablations and cauterizations. The doctor is able to perform this switch via pedals controlled with the feet outside of the field of view. The current device being used to perform the surgical operations for the removal of the tonsil and adenoids (i.e. the Arthrocare ENT Coblator II surgical system), does not allow for clear distinction between the two functions. Coblation, which is the controlled cutting away of the tissue, and coagulation, cauterizing of the remaining tissue, are the two functions. Visually these two functions are distinguishable by the colors yellow and blue of the pedals, respectfully. However, the pedals are outside of the surgeon's visual field. It is imperative to differentiate between these functions because if there is a mistake made during the procedure it can be potentially fatal to the patient, as the carotid artery is within a close vicinity to the tonsils and adenoids, leaving no room for mistakes. If a surgeon intends on using the cauterizing function but instead presses the ablation pedal, the power of the ablation function can cut through several layers of tissue in a fractions of a second. The product proposed in this work is a visual feedback system, featuring corresponding yellow and blue lights to match each pedal that will differentiate between these two modes when the respective mode is activated, while also complying with FDA title 21 CRF 820.30 which regulates the procedure for designing medical devices to be sold in the United States [2].

There are currently some inefficient ways to ensure the safety of this routine procedure. The main method is for the surgeons to look at the pedals before pressing them and saying out loud which function they are about to press. This is a direct way of providing verification and safety, although this is a time consuming task that requires the surgeon to look away from the surgical field of view, and thus directing their attention away from the patient several times. Also, this increases the minutes used in the operating room which in return will increase the cost on the patient, especially if a mistake is made and more time is required to correct a mistake. The Coblator II emits an auditory signal associated with each function of the system. On the other hand the frequency of the two signals are quite similar to each other and often not relied upon. Previous studies were conducted in an attempt to solve this issue.

FIGURE 1: "BLATION BOUNCE" IMPLEMENTED ON COBLATION II PEDALS

Tactile sensation was also suggested as a discrimination factor. This was done by implementing the 'Blation Bounce,' shown in Figure 1 [3]. Upon implementation the method was found to be not ideal due to the change in feeling being too drastic. This is because surgeons often rely on their senses and muscle memory to perform surgeries. Especially for newer surgeons, an obstruction on the foot pedal would inhibit what they normally would feel or were taught to feel during a tonsillectomy procedure.

To be successful, a visual device would give visual feedback to the surgeons, without requiring them to shift their field of view away from the patient and current surgical area. Additionally, it would give feedback prior to the device activating, which would allow for a small-time frame for error correction in the instance that the surgeon had placed their foot on the opposite pedal than what was intended. We plan to implement a device that allows for visual distinction between functions, providing feedback prior to activation of the device, which in turn would allow for a very small-time frame for error correction. This device would add an additional safety precaution to the device and increase the safety of the patient during the operation. This device would be used in conjunction with the Coblator II, without the modification of the original device that would void warranties.

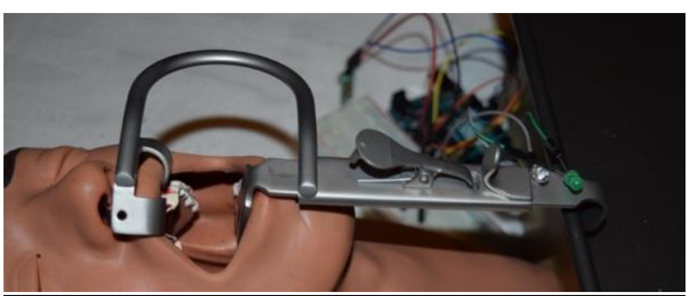

FIGURE 2: EXAMPLE OF MOUTH RETRACTOR PLACEMENT ON A MEDICAL MANNEQUIN

2. MATERIALS AND METHODS

The final product will consist of two small lightbulbs or LEDs located within the surgical field of view that will light up yellow when ablation is activated and blue when coagulation is activated. There is currently no other product on the market that performs the same functions as the intended product. A patent search was performed and there is no current patent on a product that performs these tasks.

A typical tonsillectomy procedure consists of the patient lying on their back with the surgeon oriented at the top of the patient's head. A surgical tray table hovers over the patient's chest. A mouth retractor is placed in the patients mouth to keep it open and then the other side is attached to the surgical tray (See Fig.2). The foot pedals to control the device are located on the ground next to the patient.

2.1 Design Concepts and Options

The initial design idea for the actuation of the visual indicators (that can be seen on the retractor in Fig.2) was to connect pressure sensors to the foot pedals that were then controlled by an outside Arduino code. Supportive plastic parts would connect a light to the mouth retractor. The code would wirelessly control the light by lighting up yellow when the ablation pedal is pressed and blue when the coagulation pedal is pressed. It was concluded that many devices and wires were passed under the retractor throughout the procedure and a light system might prove to be in the way of this. As an alternative to this problem, another design would feature a disposable light that clips on to the surgical tray. Disposability was determined to be important by nurses because if a non-disposable light component was to be placed on the surgical tray, there is a high chance that it would likely be unintentionally disposed of. Another design concept in Lieu of pressure sensors on the pedals was the use of magnetic switches. A magnetic strip would be attached to the surgeon's foot coverings, and magnetic sensors on the pedals would allow a slight anticipatory signal before the surgeon pressed the pedal so that there would be time for the doctor to adjust if a mistake was made. On the other hand, the shoe coverings would have to be an additional cost, and it would need to be wore by the surgeon, thus changing their pre-operatory routine.

The most feasible design concept was found in a low range infrared proximity sensor controlled by an Arduino circuit board. These sensors emit an infrared electromagnetic field. The sensors search for and detect changes in this field of view. A disturbance, such as a surgeon's foot, in the electromagnetic field is detected and reflected back to the sensor. The closer an object is to the sensors, the stronger the projected light is.

Another element to consider is the type of lighting system itself. It is important to ensure that the light would not be too bright or distracting for the surgeon. One option is a flashing light. The light would flash continuously as the foot was approaching the pedal, but prior to actually touching it. A continuous light is another option where the light would be continuous upon pressing of the pedal. Lastly, a “Stoplight System” could also be a feasible option. Light would blink as the foot approaches the pedal and then continuously shows when the surgeon has committed to that pedal. This allows for a delay in time before the surgeon actually presses the pedal to make any corrections if necessary.

3. RESULTS AND DISCUSSION

Visiting the operating room in which the ENTs and their team perform most of the tonsillectomy procedures as well as works closely with and trains residents proved to be useful in determining customer needs, specifications, and limitations. What has been determined from observations is that only the surgeon‘s foot comes in contact with the pedals and no one else is near it. Hence, proximity sensors would be the most beneficial to provide an intention signal for which pedal is to be pressed. Furthermore, cross or accidental communication would be minimal. Infrared proximity sensors are also ideal because of their high reliability and long lasting lifetime due to the lack of mechanical parts and physical contact.

In the present configuration, an Arduino transmitter and receiver were used. The transmitter is connected to the sensors on each on the foot pedals. The receiver then receives this signal and runs the stored code to determine which lightbulb is being activated. A prototype of this set up is shown in Figure 3. Figure 4 shows the structure referenced for the transmitter which was referenced from the Arduino website [4].

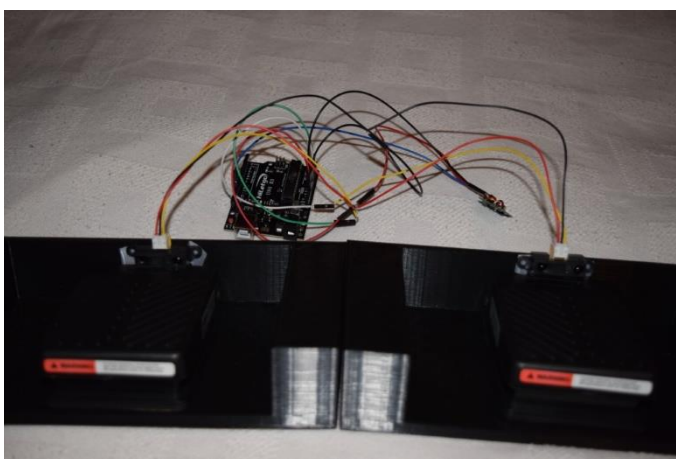

FIGURE 3: FINAL TRANSMITTOR END OF SYSTEM WITH FOOT PEDALS IN THE FOOT PEDAL BASE AND THE ARDUINO TRANSMITTER CIRCUIT BOARD

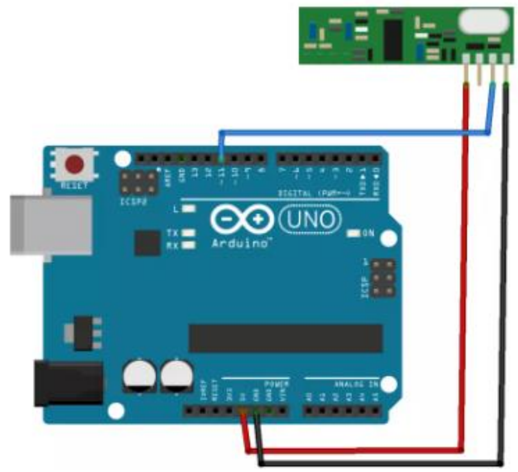

FIGURE 4: REFERENCED TRANSMITTER ARDUINO STRUCTURE

In Figure 2, the mannequin head is shown with the mouth retractor attached to the mouth and the surgical tray simultaneously. The light bulb size is shown and temporarily placed on the mouth retractor. Figure 5 depicts the receiver circuit. Figure 6 depicts the online receiver Arduino structure referenced.

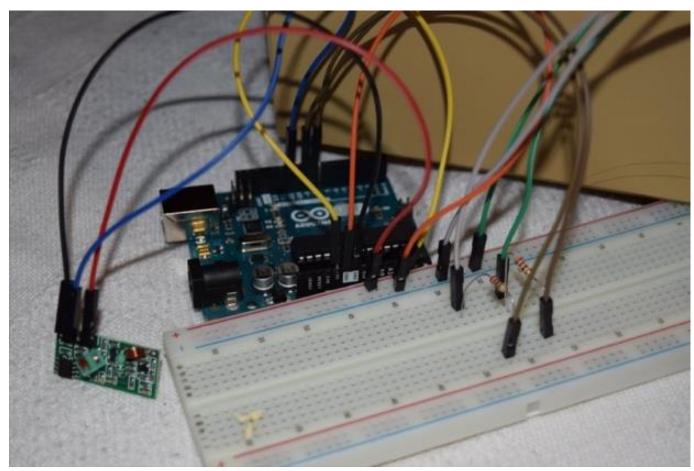

FIGURE 5: FINAL RECEIVER END OF SYSTEM

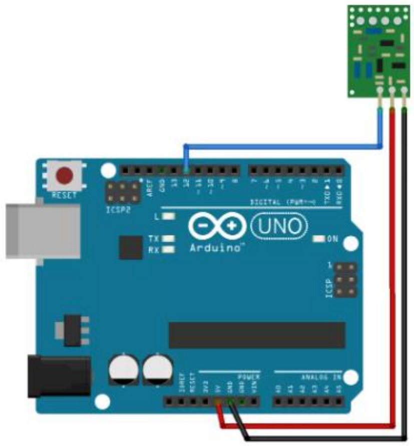

FIGURE 6: REFERENCED RECEIVER ARDUINO STRUCTURE

The surgical tray would be the most convenient location for the lighting system to be placed because it is within the field of view and yet not in the surgeon or nurse's way. Nurses expressed that if the product was reusable and attached to a tray, it could mistakenly be thrown away. A disposable lighting system would be best as it would not matter if it was accidentally disposed of post-surgery.

Associated risks with this system include a learning curve for the surgeons, system unreliability, and increased fire hazards. To ensure this does not happen, reliability must be the main priority. In addition to this, adding an electrical system with lightbulbs can increase the risk of a fire. Future testing will determine appropriate light bulb and battery sizes to decrease this risk, as well as confirm no flammable material is placed around the system.

The code being used to program the two lightbulbs is referenced from the Arduino website [4] for a lightbulb with a switch and it had been altered to add in a second light.

Sensors were then added in and the buttons were removed. After this, a second Arduino board was added for a transmitter and receiver end in order to make the sensors and lights wireless. The code for the sensors, transmitters and receivers was also referenced from the Arduino website [4].

The final version of code for the lights, proximity sensors, transmitter, and receiver combined are as follows:

Transmitter:

```
 else {
   white=0;
 //GREEN LED
 if (distance2 < triggerDistance2){
   green=1;
 else{
   green=0
 sendMessage(String(white) + "," + String(green));
 Serial.println(String(white) + "," + String(green));
   delay(10);
//Function for sending messege
void sendMessage(String message){
  const char *msg = message.c_str();
  driver.send((uint8_t *)msg, strlen(msg));
  driver.waitPacketSent();
```

Receiver:

```
#include <RH_ASK.h>
#include <SPI.h> // Not actually used but needed to compile
RH_ASK driver;
const int ledPin1 =  8;      // the number of the LED pin
const int ledPin2 =  9;      // the number of the LED pin
void setup()
  Serial.begin(9600); // Debugging only
   if (!driver.init())
         Serial.println("init failed");
  // initialize the LED pin as an output:
  pinMode(ledPin1, OUTPUT);
  pinMode(ledPin2, OUTPUT)
void loop()
    uint8_t buf[3];
    uint8_t buflen = sizeof(buf);
    if (driver.recv(buf, &buflen)) // Non-blocking
      bool white, green;
      char* s = (char *)buf;
      white = s[0] == '1';
      green = s[2] == '1';
      // Message with a good checksum received, dump it.
      //Serial.print(s[0]);
      Serial.print(s[0] == '1');// check if the pushbutton is pressed.
If it is, the buttonState is HIGH:
      Serial.println(s[2] == '1');
      if (white) {
        // turn LED on:
        digitalWrite(ledPin1, HIGH);
      } else {
        // turn LED off:
        digitalWrite(ledPin1, LOW);
       if (green) {
        // turn LED on:
        digitalWrite(ledPin2, HIGH);
      } else {
        // turn LED off:
        digitalWrite(ledPin2, LOW);
//String s = String((char*)buf);
```

This product may be able to provide a considerable business opportunity. About 500,000 tonsillectomy and adenoidectomy procedures occur each year in the United States. Ideally, each one of these procedures would use this product. If the method chosen is the proximity sensors, then the actual lightbulbs, the component attaching them to the tray, and the microprocessor would be the only parts disposed of between each procedure and would need to be purchased regularly. The motion sensors attached to the foot pedals would remain there between procedures and will be replaced, yearly. The total first cost including the cost of materials, facilities and payroll is about

$230.00 per work day. The disposable component will be replaced after each procedure. This will bypass any need for sterilization standards to be met as well as allow for a recurring revenue stream. Another possibility is expanding the market. Several surgical specialties use dual ablation and cautery instruments where this system would be useful. It might be useful in non-medical applications as well such as any vehicle with a gas pedal and brake pedal that may often be mistaken for each other on longer road trips, during times of fatigue, or to ease the minds of the elderly.

Based on the initial prototype, the product will be able to meet most initial specifications. The length of an average tonsillectomy procedure is approximately 30 minutes. At the same time an Arduino LED light bulb controlled by AA batteries can last approximately 1 Amp-hour. Even though this corresponds adequately to the disposable clip on element, custom circuit boards with customizable sizing will allow for a larger battery with a longer life which will increase the overall reliability specifications. Contributing to the reliability, the prototype was able to light up the correct, distinct color each time their corresponding sensor was triggered. The prototype, excluding the simulation set up, was able to be made with inexpensive materials including two Arduino boards ($21), two infrared proximity sensors ($10), Tx/Rx Communication ($10), 2 breadboards ($7), printer filament ($2 worth), 2 resistors ($0.05), 2 LED lights ($0.02), wires ($2.00), and batteries ($5.00). The total cost of materials for one Visual Feedback system is therefore, $57.07. Future designs of the clip-on element will ensure specifications regarding the system's ability to stay in place on the tray are met.

Future testing would be included in the next steps. The best analysis of effectiveness would be obtained through ENT surgeons' opinions by implementation of simulations and clinical trials. A tonsillectomy simulation setup has been developed in order to test the device in a real life scenario. Foot pedals, a mannequin head, a mouth retractor, and a surgical tray are part of the simulator. A 13 inch x 5 inch foot pedal base was designed in Creo and 3D printed. By having this simulation set up available, tests will be performed on the reliability of the system, light life, and straining to the eyes caused by the brightness. We will determine the maximum size of the lighting system that would allow for convenience in surgical setup but can still be visible. An exact replica of the surgical set up will be put together and local ENT surgeons will test out the new system and their first-hand opinions will be recorded and considered.

A provisional patent has been filed on for the Surgical Sensing System [5].

4. CONCLUSIONS

The goal of the ENT surgical visual signaling device is to provide safety and reassurance to surgeons. The next steps include creating a team that includes electrical and design engineers, creating smaller custom circuit boards, making the receiver end disposable, testing in a simulation set up as well as a clinical setting, filing for a full patent, and designing the aesthetics and disposable clip on element of the system.

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