VR Headset for Endoscopy and Microsurgery

Product Design Specifications

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Function:

Dr. Azem Ahmed from the neurosurgery department of the University of Wisconsin - Madison School of Medicine and Public Health presented this team with the task to improve surgeon visualization during endoscopic procedures. Endoscopic surgeries have become increasingly prevalent in the operating room along with the visualization techniques used to perform them [2]. Traditionally, large monitors have been used to display the images from the surgical tools (endoscopic view), however, these are bulky and do not provide as immersive of an experience for the surgeon as other methods do. This problem has been partially addressed by using virtual reality (VR) headsets. One major limitation of these, however, is that they do not allow the surgeon to see anything outside of the endoscopic view. This is a problem as the surgeon will have to remove the headset everytime he or she has to change instruments, or perform an action requiring a clear line of sight (environmental view). This team's goal is to create a VR headset that would allow the surgeon to transition from the endoscopic view to the environmental view without the use of the surgeon's hands, all the while presenting a continuous, non-interfering, and immersive experience for the surgeon.

Client Requirements:

- Create a more immersive view for performing endoscopy.
    - Endoscopic surgery is currently performed with the use of large display monitors stationed above the head of the patient. The monitors occupy a small field of view for the surgeon and result in a suboptimal and potentially distracting means of viewing the procedure.
    - The client would like a wide field of view display that allows for fewer distractions. The more immersive viewing experience will make anatomical visualization easier and facilitate more effective endoscopy.
- Maintain smooth workflow of endoscopic procedures in operating room.
    - The client must be able to conduct surgery unobstructed by the new display platform. Any kind of immersive display must allow for an easily accessible environmental view.

Cords or accessories to the display must not hinder movements of the surgeon or others in the operating room.

- Create an ergonomic platform for the surgeon using a new interface.
    - The surgeon will be using the display for long periods of time. The display must therefore be comfortable to wear and intuitive to interact with.

Design Requirements:

1. **Physical and Operational Characteristics**

a. *Performance requirements:*

The designed VR headset must comfortably sit upon the surgeon's head for the duration of an endoscopic surgery, which averages about 10 to 12 hours according to Dr. Ahmed. Moreover, the VR headset should produce minimal additional strain on the surgeon aside from inevitable operating pains [3]. In terms of technical performance, the headset must reliably deliver 1080p, standard HD display to the user throughout the course of an endoscopic surgery. This display must be a continuous feed from the endoscopic camera communicated through hardwire or bluetooth. Any source of video lag could be detrimental to the surgery. Additionally, the VR headset should be able to effectively switch from the endoscopic view to the environmental view through hands-free command at various times during the course of the operation.

b. *Safety:*

There are two main safety requirements for the device. The first concerns the surgeon and the second concerns the patient. Since the duration of the surgeries being conducted are so long, the headset has to be comfortable and ergonomically friendly enough so that the surgeon doesn't fatigue. If the surgeon is not performing to the highest level possible, the health of the patient is at risk. Additionally, the device has to provide a continuous and clear, immersive experience for the surgeon otherwise the health of the patient is once again at risk. The most frequent major complication of endonasal skull base surgery (the kind performed by Dr. Ahmed) is a cerebrospinal fluid (CSF) leak [5]. This results from accidental tissue damage. Any lag or deficiency in visualization by the surgeon will increase the risk of CSF leaks and other complications.

c. *Accuracy and Reliability:*

The VR headset must administer a reliable communicative feed between the endoscopic camera and the display. For seamless streaming, the laging latency should not exceed 30 ms between the video input and output [4].

d. *Life in Service:*

The device must function with perfect accuracy during all operations with a projected lifespan of five years based on technological trends and development of VR technology. It must also withstand regular use without deformation or breakdown due to standard sterilization procedures.

e. *Shelf Life:*

The device must be able to be stored in a stable environment without having contamination issues involving sterilization. Along with sterilization, batteries must be self-contained with no issues involving the spilling of harmful contaminants.

f. Operating Environment:

The device will be initially used in neurosurgical operating rooms. These operating rooms are dark environments with focused light on the patient. The OR contains both sterile and non-sterile fields that must be maintained through proper workflows. A variable number of monitors are in the OR which may be utilized for external displays of the endoscopy view.

g. Ergonomics:

The VR headset will be worn for 10-12 hours during surgery and must fit comfortably on the surgeon's head with optimal comfort. The VR headset must also be balanced very well and fit snugly to the head to avoid any tipping or movement of the device during regular use. Along with a comfortable fit, the design must not cause any strain or pain in the head, neck, or spinal regions due to sustained use. The design must focus on easing the view of detailed information pertinent to the procedure that will minimize strain on the body. Within the design, any cords or wires used must be contained and controlled to ensure no entanglement between body parts and cords occurs.

h. Size:

The current oculars used by surgeons cover the eyes and part of the front of the face. This is comparable to current VR headsets which vary in size and are approximately 225x185x140mm. These dimensions will serve as a general baseline for the sizing of our VR headset.

i. Weight:

The weight of the top six major VR headsets range in weight from around 453 grams to 610 grams. The average of these is 501 grams [6]. As of now the oculars used by neurologists now range from about 453 grams to 906 grams.

j. Materials:

The base of the VR headset will be the main material needed since the plan is to modify an existing product. In addition to the headset, cameras will be needed to view the operating room during surgery. The headset could end up being connected to the endoscopic tower via bluetooth but if not we will need to acquire an HDMI cable or USB cable to connect the headset. Depending on what headset is chosen, the design would require the separate purchase of a smartphone to display surgery.

k. Aesthetics, Appearance, and Finish:

The headset will be set on the face of the operator and should fit comfortably for long surgeries. It will have appropriate weight distribution and have small cords connected to the back of the headset. The outside of the headset itself will most likely be unmodified and look similar to the factory versions of the product.

2. Production Characteristics

a. Quantity:

For this project, only one prototype will be constructed. The one prototype will prove whether it will be necessary to continue production and whether it would be feasible to create more on a larger scale for mass distribution. If the prototype excels while being used in a surgical setting, creation of more could be reality and will be pursued.

b. Target Product Cost:

This product is seeking to compete with current television display screens that are approximately forty inches if not larger. The televisions like what Dr. Ahmed is using likely are priced at approximately $500 and may be even more expensive. Therefore, we are seeking to make a product that costs approximately $500. This price point also fits the higher-level virtual reality devices on the market right now. This price would likely involve the entire assembly along with software expenses and any other incurred costs. Though this may increase throughout the development of the device.

3. Miscellaneous

a. *Standards and Specifications:*

VR headsets of display monitors for surgical procedures fall under the Class I Medical Device FDA regulation [1]. Currently, the FDA sets the requirement of going through the 510(k) acceptance process for all new medical devices that are seeking to be offered in the future medical device market. These applications must be sent at least 90 days before individuals intend to market a device and go through a very thorough investigation.

b. Customer:

The client, Dr. Azam Ahmed mentioned that he would prefer focusing on VR devices over other technologies such as AR. He also communicated that he would prefer if the device can be wireless so that there is not tangling of cords that can occur. Additionally, Dr. Azam iterated that this product cannot stall as a lag in video timing or quality would be detrimental to his patients health. Last, Dr. Ahmed has warned that lighter and lighter designs would be best as they will decrease the strain put on surgeons during these extensive procedures.

c. User-related concerns:

The client's main concern for the device is maintaining a smooth workflow. While the immersive view allows for more effective endoscopy, a potential side effect may be preventing environmental views or adding obstacles to the surgeon or team. Our solution must be cognizant of the activity in the OR as well as the motions required of the surgeon during operation. This may be accomplished by offering a product with a seamless transition between endoscopic and environmental views, and potentially through the addition of voice commands by allowing the surgeon to change views without the need to move his hands.

d. Competition:

Currently, the client uses a large monitor to display the output by the endoscope, similar to that created by Synaptive Medical. This technology presents a wide image that capable of ideal image quality, but lacks the immersiveness of a VR headset and required the surgeon to crane their neck to one side and away from the patient during procedures. Other competing technologies include all VR headsets currently on the market that could be adapted to be used in the OR. Many of these existing products appeal to a

recreational audience, and are not adapted to the OR desipite their use of bluetooth, 360° POV angles, and sleek designs. Similarly, AR is another type of competing technology applicable to endoscopic procedures.

Works Cited:

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