An Accessible Virtual Reality Model of Surgical Microscopy for Microsurgical Practice

Haochen Wang[1*], Samuel S. Neuman[1*], Sahand C. Eftekari[2], Zeeda H. Nkana[2], Ellen C. Shaffrey[3], and Samuel O. Poore[3] ✉

[1]Department of Biomedical Engineering, Univeristy of Wisconsin-Madison, Madison, WI, USA
[2]School of Medicine and Public Health, Univeristy of Wisconsin-Madison, Madison, WI, USA
[3]Department of Surgery, Division of Plastic Surgery, University of Wisconsin-Madison, Madison, WI, USA
[*]H.W. and S.S.N contributed equally to this work.

Access to realistic training modules and equipment plays a large role in the global need for microsurgery procedures. Many surgeons surveyed around the globe report a lack of equipment and lack of training exposure as a barrier to incorporating microsurgical procedures in their practice, and many students experienced reduced training hours in the OR during the COVID-19 pandemic. In this study, we present a novel approach for microsurgical training and procedures utilizing multiple webcams to create a realistic stereoscopic view of the surgical specimen. Using Unity software and an Oculus VR headset, the images are streamed over a local server and displayed in the 3D virtual reality space with the capacity for digital zoom. Following calibration and proof-of-concept testing with a trained medical student, this design will undergo rigorous testing on the latency and clarity of the of the images. Medical trainees of various stages will be asked to provide numerical rating on various aspects of the design according to the SMaRT scale, and statistical analysis will show how stage of training confers certain benefits and challenges with the use of this design relevant to replacement of commercial microscopes.

Microsurgery | Surgical Education | Virtual Reality

Correspondence: ***poore@surgery.wisc.edu***

Introduction

Microsurgery, or the performance of surgery under a microscope, has been an integral part of surgical residency curricula since the 1960s. Anastamosis, or the surgical joining of blood vessels, can be used to join vessels of 1mm diameter. Microsurgery is thus one of the most technically demanding surgical techniques; recommended training includes a 40 week course on the basics of the technique, and three months of integration into a resident's practice is considered the minimum to achieve proficiency (1). Previous work has shown standardized eight-week courses in residency improve time-to-completion and latency in trials of anastamosis in animal models (2, 3).

Significant barriers to microsurgical practice exist for surgeons operating in communities with limited technical resources. A survey conducted in Latin American found that orthopedic surgeons in high-income countries were up to 45% more likely to perform free-flap sugeries than orthopedic surgeons in middle-income countries, and only 44% of orthopedic surgeons had received formal training in soft tissue surgery in all nations surveyed (4). A survey in African nations found that 84% of microsurgeons agreed that there is a current shortage of surgical expertise in their region, and 81% agreed that the lack of instruments and resources is a hindrance (5).

Cost-effective solutions to current global limitations in microsurgical training are urgently needed (6, 7). Popular surgical microscopes can exceed $100k USD; when this cost is distributed to the patient, the use of a microscope adds during surgery adds a minimum of $2k USD to the cost of the procedure (8). The costs associated with surgical microscope use are higher outside of the US and Europe (9). For the training microsurgeon, access to commercial microscopes is further limited by their portability, size, and durability (10). This became apparent during the COVID-19 pandemic when surgical residents had limited hands-on operative hours and were limited to virtual instructional modes (11, 12).

While numerous devices have been proposed to fill the need for an affordable model of the surgical microscope, no self-contained devices exist that can accurately mimic the experience of the microscope. Stereotactic vision is an ubiquitous feature of modern surgical microscopes (10) and allows the user to perceive three dimensions in their field of view in a manner similar to unassisted human vision. Cameras integrated into smartphones allow for digital zoom and livestreaming of the acquired image, and because of their popularity, smartphones are an attractive option for microscopic vision. Previous work involving the use of smartphones has been successful as an alternative to commercial microscopes; standardized trials of anastamoses performed by surgical residents using a suspended smartphone camera found no difference in operation times or ALI scores when compared to a commercial microscope (13). Virtual Reality provides users with an immersive three-dimensional field of view and can allow for the perception of stereotactic vision when the two eyes are presented different images. Previous work has found success in streaming images taken through the objectives of a commercial microscope to a VR headset (14), though this design encountered significant delays in the projection of the image to the user.

In this study, we propose a simple model for microsurgical practice that is comparable to commercial surgical microscopes while maintaining accessibility. Our design utilizes two Logitech webcams in an array with fixed horizontal disparity and angles of projections. The webcams are connected to a laptop computer via hardwire connection. Within Unity software, basic manipulations are made to position the two images in 3D virtual space before the images are streamed through a local server to an Oculus VR headset. The user is able to visualize the surgical specimen on the field with optimal ergonomics through a stable local connection with minimal lag.

Results

The Proposed Design.

The proposed model of the surgical microscope achieves stereoscopic vision via the use of two Logitech webcams (hereafter referred to as cameras, which is to distinguish the web camera hardware from the webcam objects in Unity software) with disparate perspectives. The cameras are held in place by a 3D printed fixture such that their horizontal disparity and angle of projection are constant, 63mm and a variable angle θ °, respectively to match the interpupillary distance and viewing angle of human eyes (Fig. 1).

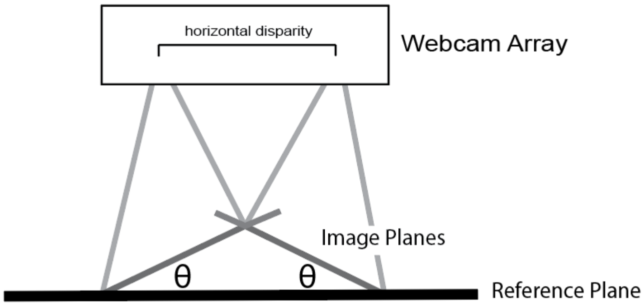

Fig. 1. The geometry of the camera array. Two cameras are fixed within the 3D printed array such that they are located at a fixed horizontal disparity and angled downwards at an angle θ relative to the norm of the reference plane. Two respective image planes are acquired, each inclined at angle θ from the reference plane. The discrepancies in the two image planes allow for the perception of stereoscopic vision for the user.

The design process can be broken into two separate phases (Fig. 2A). The first phase involved proof-of-concept software development for the acquisition, transmission and projection of separate visual channels. An iPhone was used to acquire a single image through a mirror array; the geometry of this mirror array was comparable to the final design of the camera array and included a 63 mm horizontal disparity between the two hemispheres in the recorded video. After streaming the video to a computer through wired connection, two hemispheres of this single video were spliced into separate visual channels in the software developed with Unity, and each channel was displayed individually on the computer screen.

The final design achieved during phase 2 of development can be divided into three aspects (Fig. 2A and B). First, the Logitech cameras acquire two separate images that are used for stereoscopic vision. The two images acquired by the cameras are then sent to the VR headset through from wireless connection on a Raspberry Pi single board computer. The VR headset runs a software developed with Unity (v. 2020.3.14f1, San Francisco, CA) using $C\#$ Code. Two camera objects are declared in the software. In the second aspect of the design, after instantiation of the cameras, the code allows Unity to toggle the current image input source to set the input source to the two external cameras based on the IP address provided by Raspberry Pi. If the cameras are connected via wired connection, this can be done by pressing a button on the user interface. For each declaration of the camera instance, the code allows for mapping of a second button on the user interface that serves as an on/off switch for the image input. This is achieved by a punctuated mechanism as the image build is turned off when the texture associated with the camera object is set to null and the texture is then reassigned to a non-null value with valid hardware index; this turns the camera on when selected by the user. Third, in order to display the images in the VR system, two canvas objects were declared in Unity to display each image separately, thus forming two visual channels. The two objects filled by the camera inputs also are declared in Unity software (hereinafter referred as left and right subcams so as to not confuse the objects with the Logitech camera hardware). The specified parameters of left and right subcams in Unity determine the content and orientation of the images being displayed by the Oculus Quest 2 VR Headset (Meta, Irvine, CA). Each subcam focuses on one of the image planes (Fig. 1), and the two images are displayed to each corresponding eye of the user. Direct output of dedicated visual channel forms the stereoscopic vision that is needed for microsurgery practice. The source code can be found in Supp. Note 1.

Modifications to the images are necessary for the perception of the field of view. First, in Unity, the left and right images are separately mapped to the 3D canvas vector space. Their exact position will be calibrated to match the distance between human pupils with no vertical offset. Because the size of the images are exported by the cameras with the minimum aspect ratio, modifications to the size of the image will be applied such that the size of the image is meaningful to the user. This capability of the design allows for 'digital zoom' of the images, or an artificial magnification of the images to resolve finer details of the specimen. The two images are then placed on the canvas with spatial camera setup such that their position is always in front of the eyes of the user and fixed in the 3D space when the user moves. The canvas is rendered in Unity software and displayed by the subcams. The textures are oriented on the canvas such that the broader visual context of the user can be seen in their peripheral vision.

Similar to a commercial surgical microscope, this device can achieve magnified stereoscopic vision with minimal and negligible latency due to wireless streaming. Based on preliminary testing of the final design, an average framerate of 30 fps was measured. Over long-duration testing, the framerate never fell below 15 fps, proving the device is capable of providing real-time, usable video feed at framerate that does not hinder user experience (15). The device is portable and requires minimal setup, making it optimal for use by medical students, surgery residents, and attending physicians with limited access to commercial surgical microscopes. The device is also affordable when compared to current commercial microscopes (Table 1) (10).

Because user experience is one of the most important aspects outlined in the design specifications (Supp. Note 2), we aimed to qualitatively characterize the usability of the device

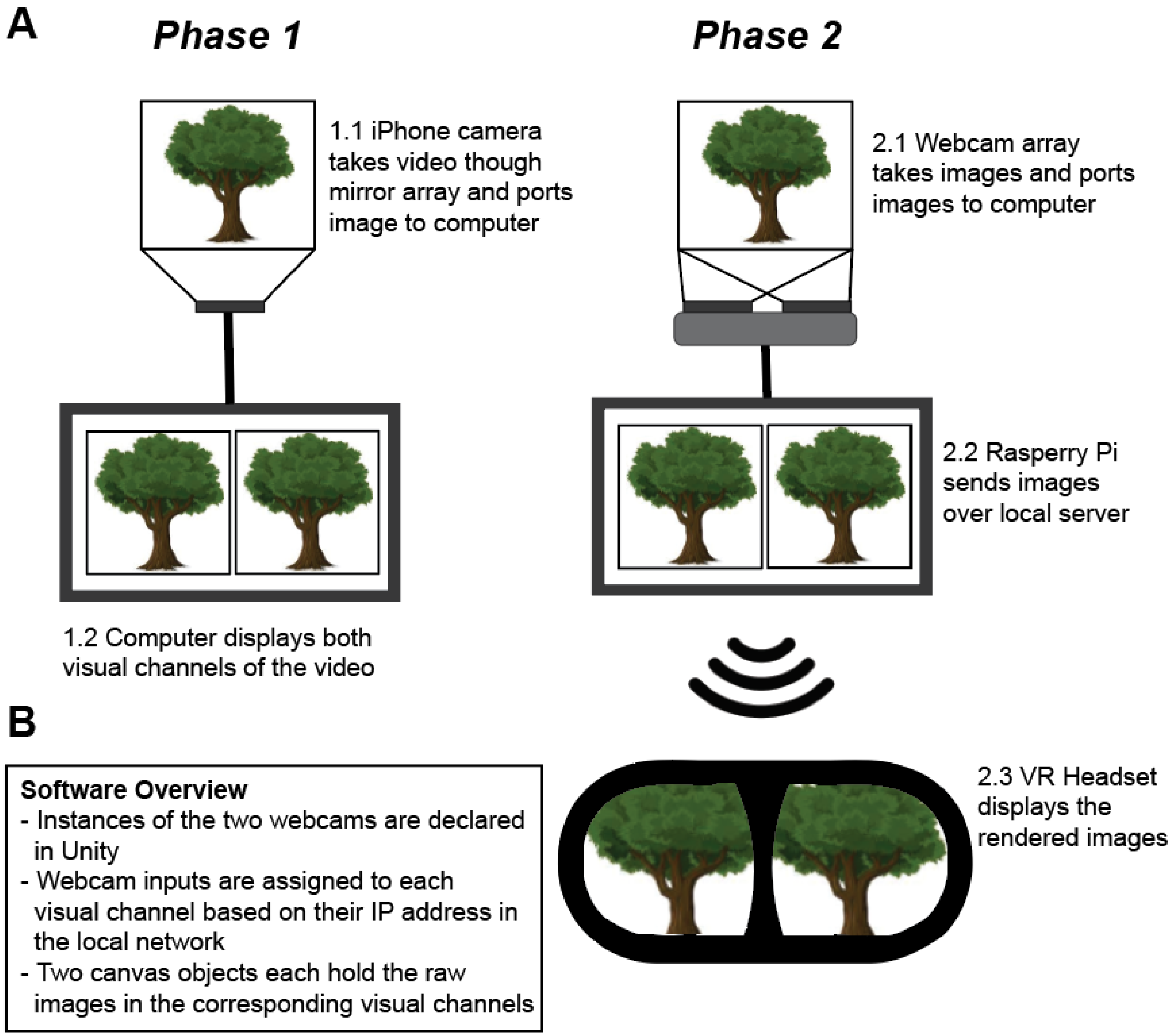

Fig. 2. Schematic of the VR Microsurgery Model. A. The development of the final design can be divided into two phases. During the first phase of video acquisition, a simple setup was created to develop the software. During this phase, an iPhone captured the video through a mirror array, and the video was spliced and presented on a computer screen. Once this framework was established, during phase 2 of video display, the two-camera apparatus was implemented to record two separate visual channels. The video inputs were sent via Raspberry Pi through a local server to the user's VR headset. B. The overview of the software used for the final design in phase 2. First, the two cameras were recognized in Unity software with two separate instances of cameras. The cameras were then assigned to each of the left and right visual channels based on their IP address in the local network. Finally, the two canvas objects were declared, and each canvas held the corresponding video relayed by the camera objects.

Table 1. Itemized expenses associated with design construction

Item	Quantity	Unit Price ($USD)
Logitech C920 Webcams	2	100
3D Printed Chassis	1	53
Oculus Quest 2	1	320
Raspberry Pi 4b	1	130
Phone Boom Arm	1	30
Total		733

with a trained medical student. In general, the design was usable, and a series of sutures were able to be completed (Fig. 3). Minor adjustments to the camera angles helped correct for horizontal disparities between the two images. Though, several aspects of the design complicated the user experience. In general, the software build in Oculus was stable, though minor fluctuations in video quality occurred. Additionally, the autofocus feature of the cameras often corrupted the view of the surgical field. With these two factors, subjective user experience could be noticeably distinguished from the experience of a surgical microscope, though the relative success of this version of the design offers promise for its utilization as a training modality.

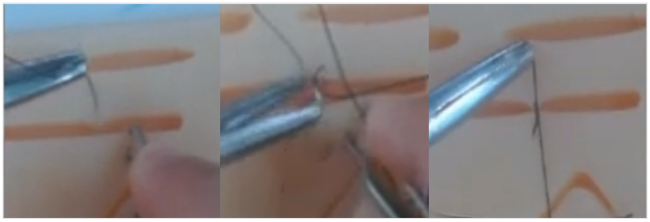

Fig. 3. Example suture completed using the VR microscope system. From left to right, the needle is inserted into the cut, pulled though the other end, and the knot is tied to complete the suture. The pace of work was noticeably slower and more labored when compared to operating under a commercial surgical microscope, and some inaccuracies resulted from misalignment of the two images and unregulated autofocus features of the cameras.

Discussion

Limitations and Considerations of the Current Design.

Because this design relies on fixed calibration parameters, any adjustments made to the focal distance, camera angles, or size of surgical specimen may create misalignment of the images in the 3D canvas. Further work is needed to account for changes in focal distance and focus of the cameras, and a temporary solution can be applied for testing that disables the autofocus of the cameras. The development of software to allow for image stabilization and automatic adjustments to the positions and cropping of the two video canvases in the 3D VR space may also resolve these issues. Additionally, the cameras used in this design provide a 90 °field of view, which creates distortion near the edges of the cameras' fields of view through spherical aberration. Future iterations of the design may require software to modify the images to overcome these inaccuracies, such as adapting Logi Tune, a software developed by Logitech that can achieve some of the desired features, to the Linux system on Raspberry Pi.

While this design represents great progress in an accessible model of a surgical microscope, the design relies on existing hardware and infrastructure. The Raspberry Pi operates near its functional limit during the streaming of the two images, which may limit the lifetime of use of the device. More advanced hardware may be needed in future iterations of the device. Further, the design in its current iteration is prone to obsolescence due to the frequent package updates pushed by Unity, which acted as a major complicating factor during the development of this design. A stable source code library would need to be maintained for long-term use of this device. Further, our device relies on the ability of the surgeon to provide a laptop computer, Oculus VR headset, and stable internet connection, all of which may not be guaranteed for plastic surgeons around the world (16). When successful, the advantages conferred by the utilization of this device include the ability to remotely stream surgeries, which may help increase exposure when in-person training is not possible (11, 12).

Data obtained from testing is intended to quantify image quality and latency as well as the useful of the device of inexperienced and experienced surgeons. Implicit in our comparison is the assumption that the skills acquired through training on commercial microscopes is translatable to our VR system. It is possible that these surgeons experience more difficulty while using this device; *post hoc* interpretations of this data will require their responses on the exit survey of user experience.

Progress in Unity Project Development.

The current version of Unity project uses WebSocket protocol to set up wireless communication between the sender device (Raspberry Pi) and the receiver device (Oculus Quest 2). However, compatibility issues arose in current builds in Unity after a major update, and the communication between Oculus and Raspberry Pi was not resolved until succeeding Unity updates were published. Future efforts shall involve the utilization of packages such as "WebSocket-Sharp" (to enable WebSocket protocol to run in $C\#$) and other native Unity functions such as "Unity Render Streaming" (to utilize new streaming protocols for the project) to develop software that maintains functionality upon frequent updates from Unity.

Conclusion.

The goal of this stage of the design process was to refine the final prototype before extensive testing of the device. Ultimately, the design concept should be able to fulfill three use cases - as a training system for inexperienced microsurgeons to gain new skills, as a training system for experienced microsurgeons wishing to maintain skills, and as a substitute for commercial surgical microscopes in hospitals with limited resources. Some of the most important goals achieved with this iteration of the design include a significant cost reduction when compared to commercial microscopes, a compact design concept that is portable and easy to set up, stereoscopic vision that allows for depth perception, the ability for students to practice from any location, a stabling housing for the cameras, improved image quality, and minimization of blind spots in the image. Among the goals not maximally achieved in this current iteration, minimal conceptual modifications to the prototype are needed. The largest limitations like in the hardware configurations of the prototype. In all, this design can find good company as part of a larger trend in VR simulations of the technical aspects of various skilled professions and may find other applications outside of the medical field.

Methods

Preliminary Testing and Calibration.

Preliminary testing on the current design was performed with the help of an experienced medical student. The student performed multiple sutures on a practice suturing pad (Fig. 4). This allowed for calibration of the camera angles and the collection of various qualitative aspects of the design, including efficiency, accuracy, and comfort. In addition, data on the time delay of streaming and frame rate were acquired. Time delay in streaming was defined as the time interval between the events of the user's operation and the display of the events on the VR headset. The VR training system was set to record a stop watch displayed on a laptop screen. The video record function in Oculus was used to record the displays of two visual channels in the 3D space and stopwatch simultaneously.

Randomly choosing five timestamps in the recorded video, the difference in the time between the true and streamed images was be measured and reported as the average as time delay as a result of wireless streaming.

Fig. 4. The setup used for preliminary testing of the VR system. A trained medical student wore the VR headset and performed multiple sutures on a practice suturing pad guided exclusively by the images acquired by the cameras. The images were streamed through a private Wifi server. The focal length and camera angles were easily calibrated to achieve an optimal configuration.

Evaluation of the VR System as a Replacement for Commercial Microscopes.

To evaluate the potential for this VR system as a replacement for commercial surgical microscopes, suturing abilities will be compared in three different regimes (Fig. 5A). Participants will be recruited from a pool of attending plastic surgeons trained in microsurgery (n>12) with informed consent and asked to complete three trials in random order. All trials will consist of three sutures performed on a practice suture pad. The three trials include sutures performed without any assistance, sutures performed using a commercial surgical microscope, and sutures performed with the VR system. Participants will be asked to complete an exit survey about the overall user experience, including their efficiency, technique, and respect for tissue as defined by the SMaRT scale (17); multivariate regression analysis will be used to weigh and compare the scores in each category.

Evaluation of the VR System as a Microsurgery Training Tool.

To evaluate the VR system as a potential training tool, suturing abilities will be compared with students that trained using a commercial surgical microscope (Fig. 5B). Participants will be recruited from medical schools (n>10) with informed consent and asked to take a background survey on their current level of experience in microsurgical training. The participants will be randomly assigned to one of two groups regardless of their level of experience. In the first group, the participants will undergo a standardized 40 hour training course using the VR system (1). In the second group, the participants will undergo the same standardized course but with a commercial surgical microscope. 30 days after completion of the training course, participants will be asked to perform microsurgical procedures using a commercial microscope. Each participant will perform two sets of three trials; the first set will be performed on larger blood vessels requiring 8 stitches, and the second set will be performed on smaller blood vessels requiring 5 stitches. The time spent on the task will be recorded for each trial of microsurgery practice. Student's T-test will be used to find if there is is a statistical difference in the time to complete the procedures for familiar and unfamiliar groups.

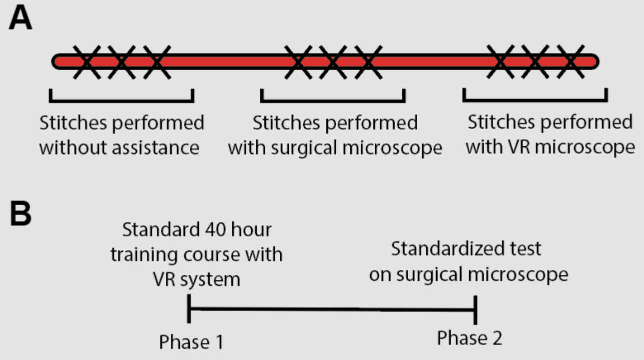

Fig. 5. Testing of the design concept will occur in two rounds. A. Methods intended to evaluate the potential for the VR system as a replacement for commercial surgical microscopes. The VR system will be compared against surgical microscope-assisted and unassisted suturing by the performance of three sutures on a practice suture pad by groups of trained attending plastic surgeons. The order in which each trial is completed will be randomized. B. Methods intended to evaluate the VR system as a training tool for untrained medical students. Medical student participants will undergo a standardized 40 hour training course on either the VR system or a commercial microscope and will then be asked to perform a standardized test on a surgical microscope. This test will involve anastomosis procedures on a preserved chicken breast.

ACKNOWLEDGEMENTS

We would like to thank Dr. Block for his insight and advice on this project, Alexander Vazquez for his help in the conception of the design, Dr. Puccinelli for coordinating BME Design, and the UW Makerspace.

Bibliography

1. Vinagre, G., Villa, J. and Amillo, S. Microsurgery training: does it improve surgical skills? *Journal of Hand and Microsurgery*, 9:047–048, 2017.
2. Di Cataldo, A., Li Destri, G., Trombatore, G., Papillo, B., Racalbuto, A., and Puleo, S. Usefulness of microsurgery in the training of the general surgeon. *Microsurgery*, 18:446–448, 1998.
3. Ko, J.W., Lorzano, A., and Mirarchi, A.J. Effectiveness of a microvascular surgery training curriculum for orthopaedic surgery residents. *Journal of Bone and Joint Surgery*, 97:950–955, 2015.
4. MacKechnie, M.C., Flores, M.J., Giordano, V., Terry, M.J., Garuz, M., Lee, N., Rojas, L.G., MacKechnie, M.A., Bidolegui, F., Brown, K., and Quintero, J.E. Management of soft-tissue coverage of open tibia fractures in Latin America: Techniques, timing, and resources. *Injury*, 53:1422–1429, 2022.
5. Banda, C.H., Georgios, P., Narushima, M., Ishiura, R., Fujita, M., and Goran, J. A comparison of using a smartphone versus a surgical microscope for microsurgical anastomosis in a non-living model. *Journal of Plastic, Reconstructive, and Aesthetic Surgery*, 20:19–26, 2019.
6. Wilkinson, E., Aruparayil, N., Gnanaraj, N., Brown, J., and Jayne, D. Barriers to training in laparoscopic surgery in low- and middle-income countries: A systematic review. *Tropical Doctor*, 51:408–414, 2021.
7. Nguyen, H.N., Chen, J., Nguyen, T.V., Le, D.T., Nguyen, T.S., and Jeng, S.F. Training the Trainers in Microsurgery: A Success Story from Vietnam's Hanoi National Hospital of Odonto-stomatology. *Plastic and Reconstructive Surgery - Global Open*, 22:e3637, 2021.
8. Zhang, Y., Zhang, M., Lin, M., Gephart, M.H., Veeravagu, A., Ratliff, J., and Li, G. Costs

and Complications Associated With Resection of Supratentorial Tumors With and Without the Operative Microscope in the United States. *World Neurosurgery*, 138:e607–e619, 2020.

9. Shrime, M.G., Dare, A., Alkire, B.C., and Meara, J.G. A global country-level comparison of the financial burden of surgery. *World Neurosurgery*, 103:1453–1461, 2016.
10. Ma, L., and Fei, B. Comprehensive review of surgical microscopes: technology development and medical applications. *Journal of Biomedical Optics*, 26:010901, 2021.
11. Higgins, C.G., Thomson, S.E., Baker, J., Honeyman, C., Kearns, M., Roberts, J., and Tay, S. COVID-19 lockdown and beyond: Home practice solutions for developing microsurgical skills. *Journal of Plastic, Reconstructive Aesthetic Surgery*, 74:407–447, 2021.
12. Oltean, M., Nistor, A., Hellstrom, M., Axelsson, M., Yagi, S., Kobayashi, E., Ballestin, A., Akelina, Y., and Nemeth, N. Microsurgery training during COVID-19 pandemic: Practical recommendations from the International Society for Experimental Microsurgery and International Microsurgery Simulation Society. *Microsurgery*, 41:398–400, 2021.
13. Jianmongkol, S., Vinitpairot, C., Thitiworakarn, N., and Wattanakamolchai, S. A comparison of using a smartphone versus a surgical microscope for microsurgical anastomosis in a non-living model. *Archives of Plastic Surgery*, 49:121–126, 2022.
14. Ho, D.K. Using smartphone-delivered stereoscopic vision in microsurgery: a feasibility study. *Eye (London)*, 33:953–956, 2019.
15. Haines, R.F. and Chuang, S.L. A study of video frame rate on the perception of compressed dynamic imagery. *Space and Earth Science Data Compression Workshop*, 3191:75, 2002.
16. Koch, H., Dabernig, J., Allert, S., Puchinger, M., and Scharnagl, E. Wearable technology for global surgical teleproctoring. *Annals of Plastic Surgery*, 49(5):470–471, 2002.
17. Satterwhite, T., Son, J., Echo, A., Spurling, T., Paro, J., Gurtner, G., Chang, J., and Lee, G.K. The stanford microsurgery and resident training (smart) scale: validation of an on-line global rating scale for technical assessment. *Annals of Plastic surgery*, 72:s84–s88, 2014.

Supplementary Note 1: Source Code for Webcam Address Declaration and Start/Stop

```
using System.Collections;
using System.Collections.Generic;
using TMPro;
using UnityEngine;
using UnityEngine.UI;

public class CameraScript : MonoBehaviour {
// Start is called before the first frame update
public static int currentCamIndex = 1;
WebCamTexture tex;
public RawImage display;
public TextMeshProUGUI startStopText;
int cameraRequestedWidthRes = 1920;
int cameraRequestedHeightRes = 1080;

public void SwapCamClicked() }
if (WebCamTexture.devices.Length > 0) {
currentCamIndex += 1;
currentCamIndex %= WebCamTexture.devices.Length;
if(tex != null) {
StopWebcam();
StartStopCamClicked();
} } }

public void StartStopCamClicked() {
if (tex != null) {
StopWebcam();
startStopText.text = "Start Camera";
}

else {
WebCamDevice device = WebCamTexture.devices[currentCamIndex];
tex = new WebCamTexture(device.name, cameraRequestedWidthRes, cameraRequestedHeightRes);
display.texture = tex;
tex.Play();
startStopText.text = "Stop Camera";
} }

public void StopWebcam() {
display.texture = null;
tex.Stop();
tex = null;
}

void OnEnable() {
StartStopCamClicked();
currentCamIndex += 1;
currentCamIndex %= WebCamTexture.devices.Length; } }
```

Supplementary Note 2: Product Design Specifications (PDS)

Title: iPhone Virtual Reality Training Model for Microsurgical Practice.
Samuel Neuman, Alexander Vazquez, Haochen Wang
September 23th, 2022

Function: This training model will make microsurgical training less expensive and more accessible to a wide range of users. It eliminates the need for an expensive surgical microscope by replacing it with a smartphone. The prototype will utilize the zoom functionality of the smartphone for the surgeon to clearly see sutures and tissues up close. By using a smartphone, it is also possible to stream the training to Zoom or a similar platform so training can occur virtually. The design will minimize lag time between the recording phone and projecting device for simultaneous view of both the trainee and observers, while increasing spatial awareness and depth perception via binocular live video.

Client requirements: Must allow for depth perception with regard to where the trainee's hands are in relation to the work site. Must create an image with high enough zoom and resolution to see sutures (0.070 mm in diameter) clearly [1] Must remain inexpensive so it is widely accessible to training surgeons. Must produce a streaming resolution of at least 10.2 megapixels. Must have a frame rate of at least 24 frames per second. Must have a stream delay of no more than 0.5 seconds. Should utilize full magnification power of the smartphone.
Design requirements:

1. Physical and Operational Characteristics
    a.Performance requirements:
        i.The device must be able to provide a clear image of the subject in a clinical environment. The device must be able to handle daily use and must be able to handle a load of at least 400g, the weight of the heaviest available smartphones.
    b.Safety:
        i.The device should be out of the way of the surgeon to prevent interference during practice and contact with hazardous material encountered during the simulated surgery. The device also needs to be able to be sterilized in an efficient manner before and after each use.
    c. Accuracy and Reliability:
        i.The device should be able to consistently maintain a magnification of 2x and the displayed magnification should be accurate with repeated trials. The device should display an accurate and clear image of the surgery area with minimal latency.
    d. Life in Service: .The device should withstand continued use over the duration of the training process, the longest of which can last up to 12 hours. The device should be able to withstand this use everyday over its lifespan, as many different trainees may use the device.
    e. Shelf Life:
        i.The device should be stored in normal interior conditions for an indefinite amount of time. This means that the device should not be made out of materials that degrade over a short period of time (6 months, the duration of one semester) in absence of normal use. With continued use, the team would expect the smartphone being the limiting factor for the whole design. Thus, the final deliverable should have at least one year of lifespan, which matches the lithium battery warranty provided by Apple. [2]
    f. Operating Environment:
        i.The product will most likely be used in a domestic or indoor environment, so the device will not be exposed to extreme conditions.
        ii.0-35 ° C operating temperature, - 20-45 ° C nonoperating temperature, 5-95% non-condensing, relative humidity (the specification of iPhone 8, and more restriction may be applied as other hardware is introduced to the final deliverable) [3] .
        iii.The person who will use this will be the trainee, which is the person who is practicing surgery using the iphone, and the trainer(s) who is/are watching the trainee on the headset.
        iv.Potential splash of food dye, blood, in vitro tissues, etc. [4]
        v.Components that are exposed to the operation station shall not be malfunctioned upon such splash.
        vi.Potential scratches from the surgical equipment, such as tweezers or needles.
        vii.The final deliverable should at least endure accidental damage from the aforementioned scenarios, while maintaining the resolution to recognize the suture
    g. Ergonomics:
        i.The product can involve delicate technology, such as smart phones and laptops, so the same restrictions of force that cause those devices not to be damaged or break apply here.
        ii.For the iPhone 8, do not submerge in water greater than 1 meter and for longer than 30 minutes. [3]
    h. Size:

i.Should be able to be set up in an indoor living space (i.e. 10 x 10 sqft, approximately 3 x 3 meters)

i. Weight:

i.Optimum weight: < 10lbs (approximately 4.5 kg). Must be easily transportable

j. Materials:

i.No restrictions on material mechanics.

ii.Cannot be toxic upon skin contact or inhalation.

iii.Shall have minimal degradation resistance, such as from sunlight.

k. Aesthetics, Appearance, and Finish:

i.The color of the product should be dull so that it doesn't distract from the microsurgical practice it is intended for. The shape and form should be adjustable so that each user/consumer can place it into alternate positions to get a better and more comfortable practice for themselves. The texture of the finish should be flat and soft in order for it to be comfortable for the user and in order for it to not be a distraction.

ii.Should simulate the working condition of an operation room with microscopes

iii.Must not interfere with the operation and training performance of the user

2. Production Characteristics

a. Quantity:

i.Tens of Thousands of units will be needed so that this can replace all current expensive training mechanisms for microsurgical practice for medical residents.

b. Target Product Cost:

i.The target cost of the product is undetermined thus far until clients discuss but it will need to allow for an iPhone, a stand, and any attachment that is necessary to put over the camera to replicate microsurgery practice as best as possible. There are existing products whose costs are at least $100,000 [5] which is drastically greater than the target cost. The prototype is a cheap alternative for medical students to use for remote training, using materials that are commonly owned.

3. Miscellaneous

c. Standards and Specifications:

i.ISO 10936-1:2017: Specifies the requirements for microscopes used during surgical procedures, so the team must adhere to these specifications when creating a design. However, since this prototype will be used for practice purposes, the requirements many not all apply [6]

ii.Code of Federal Regulations Title 21, Volume 8, Sec. 882.4525 Microsurgical instrument [7]: The final deliverable will fall into the Class I medical device category, which is exempt from the premarket notification procedures 510(k).

iii.Code of Federal Regulations Title 21, Volume 8, Sec. 878.4700 Surgical microscope and accessories [8]: The final deliverable, under definition of this section, will be a Class I device. However, since the recording device in this design will be a DC powered smartphone, no more actions shall be made upon this regulation

d. Customer:

i.The customer would prefer the delay of relaying the image to the headset to be minimized for enhance practicing technique (less than 0.5 s).

ii.The quality of the camera while zooming should be clear enough to clearly see the material being worked upon. 2x zoom using an iPhone 11 Pro was tested to be the most practical. The requirement is that the trainee is able to see the suture, which is 0.070 mm [1].

iii.The camera should be able to show the depth of the workspace in order to help determine the distance between the instruments being utilized and the suture on the workbench. This may require the use of two lenses to allow for a binocular view.

iv.The device should be comfortable to wear for extended periods of time.

e. User-related concerns:

i.As this is a device used for practice, there will be no requirements for patient confidentiality.

ii.Sterilization should not be an issue with regard to the camera setup. However, it may be practical to clean the headset with a wipe between uses.

iii.The design should be able to receive accommodations for users with visual impairments.

f. Competition:

i.Augmented Reality (Mixed Reality) The Microsoft Hololens is a very complex device which allows for similar types of practice. However, the Hololens is much less accessible and much more expensive. This will be an alternative that is possible to use from many different remote locations. Meanwhile, mixed reality provided by Hololens is rather redundant for the purpose of the clients. [9]

ii. Exoscopic Platforms: Zeiss, Olympus and Mitaka are well known medical device providers for exoscopes, featuring high definition images of the field with 8x to 30x magnifying capability. However, the price varies from 0.2 to 1.5 million dollars, resulting in limited access for trainees from less developed regions [5].

References

[1] B. M. A. A; “The surgical suture,” Aesthetic surgery journal, Apr-2019. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/30869751/. [Accessed: 18-Sep-2022].

[2] Apple, “iPhone battery and performance,” Apple Support, 24-Sep-2021. [Online]. Available: https://support.apple.com/en-us/HT208387. [Accessed: 19-Sep-2022].

[3] Apple, “iPhone 8 - Technical Specifications,” Official Apple Support, 25-Mar-2021. [Online]. Available: https://support.apple.com/kb/sp767?locale=en$_US.[Accessed:22-Sep-2022]$.

[4] “Dr. Sam POORE and team featured ON BTN LiveBIG Wisconsin,” Department of Surgery, 13-Jul-2020. [Online]. Available: https://www.surgery.wisc.edu/2020/07/13/dr-sam-poore-and-team-featured-on-btn-livebig-wisconsin/. [Accessed: 20-Sep-2022].

[5] D. J. Langer, T. G. White, M. Schulder, J. A. Boockvar, M. Labib, and M. T. Lawton, “Advances in INTRAOPERATIVE Optics: A brief review of Current Exoscope platforms,” Operative Neurosurgery, vol. 19, no. 1, pp. 84–93, 2019.

[6] “ISO 10936-1:2017,” ISO, 26-Jul-2017. [Online]. Available: https://www.iso.org/standard/69819.html. [Accessed: 18-Sep-2022].

[7] CFR - Code of Federal Regulations Title 21 Sec. 882.4525, vol. 8. 2020.

[8] CFR - Code of Federal Regulations Title 21 Sec. 878.4700, vol. 8. 2020.

[9] “Microsoft mixed reality – Healthcare,” Microsoft Mixed Reality – Healthcare. [Online]. Available: https://www.microsoft.com/en-us/hololens/industry-healthcare. [Accessed: 17-Sep-2022].