Improving Patient Experience During In-Office Procedures Using PARVA - Patient Augmented Reality Vibratory Array

By:

Rehan Chaudhry, Undergraduate Department of Biomedical Engineering
Tucker Cullen, Undergraduate Department of Biomedical Engineering
Sarah Glatz, Undergraduate Department of Biomedical Engineering
Chaeyeon Kim, Undergraduate Department of Biomedical Engineering

Advisors:

Logan McColl, B.S., M.D./M.B.A. Candidate, School of Medicine & Darden School of Business
Claudia Gutierrez, M.D., M.S., Resident, Department of Otolaryngology
James Daniero, M.D., M.S., Department of Otolaryngology

Word Count: 4559
Number of Figures: 7
Number of Tables: 1
Number of Equations: 0
Number of Supplements: 2
Number of References: 37

Improving Patient Experience During In-Office Procedures Using PARVA - Patient Augmented Reality Vibratory Array

Rehan Chaudhry[a,1], Tucker Cullen[a,2], Sarah Glatz[a,3], Chaeyeon Kim[a,4], Logan McColl[b], Dr. Claudia Gutierrez M.D.[b], Dr. James Daniero M.D.[b]

[a] Biomedical Engineering Undergraduate at the University of Virginia
[b] Department of Otolaryngology at UVA Health System
[1] rc3ve@virginia.edu
[2] stc7mg@virginia.edu
[3] sg2hf@virginia.edu
[4] ck3vc@virginia.edu

Abstract

In recent years the prevalence of in-office procedures (IOPs) has been increasing steadily across medical specialties. During IOPs, patients are kept awake and only local anesthetic is used. There remains a need for an effective non-pharmacological intervention to reduce patient discomfort, stress, and anxiety during these IOPs. We have developed a two-pronged solution to meet this need: a device that combines augmented reality (AR) immersion and vibratory stimulation to distract patients undergoing uncomfortable and stressful awake procedures. The augmented reality component consists of two simple one-button games that can be played by patients via an AR headset. The vibratory component is a hands-free, adjustable device that can be positioned directly on patients' skin near the procedure site to provide vibratory distraction. The AR and vibratory components are integrated together via bluetooth, enabling the games to provide haptic feedback. The device was designed with a focus on otolaryngology IOPs, but can be easily modified to work with IOPs in other medical specialties, greatly expanding the scope and impact of this device. Future work includes conducting a patient study on the device in the University of Virginia Medical Center otolaryngology clinic.

Keywords: In-Office Procedures, Augmented Reality, Gate Control, Otolaryngology, Patient Experience, Cost-Effective Care, Haptic Feedback, Vibratory

---

Introduction

Significance

As health care costs in the US have continued to rise,[1–3] one cost-effective evolution in care has been the proliferation of in-office procedures (IOPs) and surgeries across medical and surgical specialties.[4–6] Unlike procedures conducted in an operating room, patients are kept awake throughout IOPs and only local anesthetic is used. The benefits of IOPs to medical professionals include higher procedural volume, decreased cost, and improved patient safety and outcomes through avoidance of general anesthesia. Benefits to patients receiving IOPs include decreased cost, decreased time needed for treatment, ability to drive home the day of the procedure, and improved patient safety. For

example, in Otolaryngology−Head & Neck Surgery (OHNS), the mean total charges for office-based procedures is $2,737.17, while the same procedures cost $7,329.69 on average if conducted in the operating room (OR).[7] A barrier to the further proliferation and adoption of IOPs is the lack of non-pharmacological interventions to improve patient anxiety, stress, discomfort, and perception of pain during these procedures. The focus of the proposed project is to improve patient experience during IOPs using a novel, non-pharmacologic device which will improve patient care and capture a growing market for a currently unmet clinical need.

While the outcome of this project has needed applications across specialities, we focused on OHNS IOPs while developing the device. IOPs have become increasingly common within OHNS and across all of it's subspecialties. For example, within Laryngology (voice and swallowing specialists) IOPs are increasing in frequency when treating conditions such as vocal fold paralysis, respiratory papillomatosis, and pre-cancerous vocal cord lesions. These conditions collectively affect over 10 million Americans, and treatment often involves repeat procedures.[8–10] At UVA alone, over 300 otolaryngology IOPs are carried out every year with many additional procedures needed, as evidenced by a waiting list that routinely exceeds 100 patients.

Two of the most common OHNS IOPs are vocal fold injection (VFI) and laser ablation. In VFI, an endoscope is placed through a patient's nose into their throat, and is used to visualize and guide a direct injection given through the neck and into the vocal cords (Figure 1).[11]

In laser ablation, an endoscope is used in a similar way, but this time to guide the removal of precancerous lesions and other growths on the vocal cords using a potassium-titanyl-phosphate (KTP) laser.[12] Patients are kept completely awake and coherent during both procedures (only local anesthetic is provided). While these procedures are generally straightforward for the attending laryngologist, they can be anxiety-inducing and painful for the patient, which sometimes leads to failed procedures (needing to abort the procedure due to patient discomfort) or other unfavorable outcomes. When studying patient discomfort across various otolaryngology IOPs, Young et al. found that ~40% of patients reported moderate discomfort during endoscope placement, injection itself, and laser ablation itself.[4] They also found that >10% of patients reported *severe* discomfort during injection itself. Patient discomfort is also correlated with increased procedure times, a higher likelihood that multiple approaches will be needed, and a greater likelihood that the procedure will have to be rescheduled in the OR. The goal of the device developed throughout the course of this project is to reduce the severity of patient discomfort and thereby further advance the proliferation and usage of IOPs.

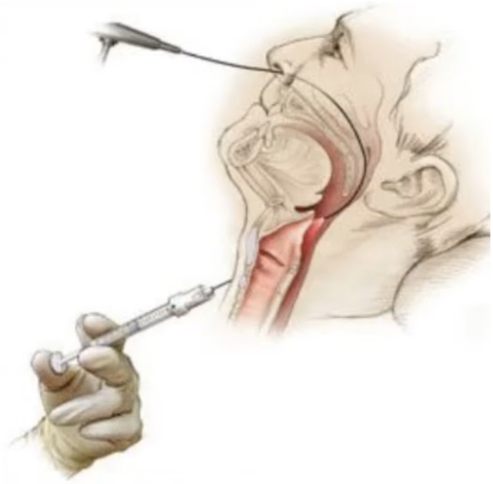

Figure 1. Diagram of endoscope & needle placement during vocal fold injection

A common ONHS IOP. Patients are only given local anesthetic.

Innovation

The Gate Control Theory of Pain asserts that the central nervous system can only process a limited number of stimuli at one time (Figure 2). It postulates that non-painful stimuli such as vibration, which activate non-nociceptive sensory neurons, can interfere with signals from pain receptors, thereby inhibiting or lessening the transmission of painful stimuli.[13–15] This has been shown to have clinical utility for painful injections and other IOPs as evidenced by reduced perception of pain during procedures when low-frequency vibration is administered.[16–18] Some medical devices, such as Buzzy®, employ this theory to reduce pain during vaccine injections and other minimally invasive procedures.[19] However this theory has yet to be applied to in-office OHNS procedures such as vocal fold injection.

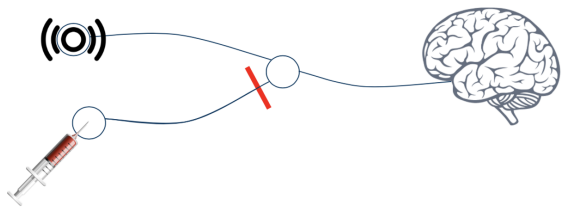

Figure 2. Gate Control Theory of Pain

The nervous system can only process a limited number of stimuli at once. Activating non-nociceptive sensory neurons using non-painful stimuli such as vibration can block or lessen the transmission of painful stimuli.

In addition to vibrotactile sensation, another mechanism to improve patient experience is virtual distraction. The virtual simulation model that a patient experiences and interacts with serves to give a feeling of an alternate reality. As attention is increasingly focused on that reality, perceived pain decreases.[20–22] The most common approach studied has been the use of virtual reality (VR) by patients either before[23–25] or during[26–29] procedures. Uniformly these studies have shown decreased patient anxiety, decreased stress, improved comfort, and/or decreased perception of pain.

Augmented reality (AR) is a variation of VR, in which the user of an AR system always experiences their own reality in real-time with augmentation in the form of displays, information, or other visual effects provided through a headset connected to bluetooth. This is in contrast to VR, in which the visual environment of the user is completely synthetic and thus the user is separated from reality.[30] Compared with VR, there has been less investigation of AR use by patients, however the literature shows the same efficacy[31–33] and head-to-head studies have shown no significant difference between them.[34] For IOPs, AR headsets hold specific, clear advantages over VR headsets; namely, they are cheaper, use faster/easier to program software, allow for greater patient interaction and instruction, and are significantly smaller in overall size and facial footprint. The smaller sizes of AR headsets yield specific benefits for medical procedures in which access to facial structures, such as the oral cavity and airway, are needed. Despite the advantages of AR over VR in head and neck region procedures, there are very few studies investigating any type of AR use in otolaryngology and there are no studies investigating AR use by patients before and/or during otolaryngology procedures.[35] Furthermore, the combination of vibratory stimulation paired with augmented reality immersion for patient care has not been explored in any field.

Project Aims

This project set out to create a two-pronged approach for sensory distraction in order to improve patient experience. By combining the knowledge gained from prior vibratory distraction and augmented reality approaches, this project draws on the Gate Control Theory of Pain in maximizing non-painful sensory stimuli to improve patient experience within OHNS

IOPs. The project consisted of two primary aims. The first aim was to develop a multisensory device to reduce patient perception of pain and improve overall patient experience during awake in-office procedures of the head and neck. This aim consisted of the more specific sub-objectives of (1) developing a modular wearable device prototype that delivers vibroacoustic stimulation in the range of 180-250 Hz to the head and neck and has a battery life of minimum 45 minutes,[5] (2) developing a custom visual augmented reality experience compatible with an existing augmented reality headset to reduce patient anxiety, stress, discomfort, and perception of pain relative to patients without any distractory technology, and (3) minimize patient's head movement during IOPs. Once these two individual components were complete the final goal was to integrate the wearable vibratory device prototype with the custom visual augmented reality experience using Bluetooth connectivity that enables device communication up to 1 meter, yielding a multisensory device. The design process for this device is the primary focus of this technical report.

The second aim of the project was to test the feasibility of using the vibratory device, the augmented reality software, and the integrated multisensory device in a controlled patient study. While this part of the project was not accomplished due to restrictions regarding COVID-19, a plan for the patient study was submitted to the IRB. This study will explore patient experience in a randomized controlled pilot study evaluating patient anxiety, stress, discomfort, and perceived pain during awake in-office procedures at the UVA Otolaryngology Clinic. Those aforementioned factors will be measured through the use of continuous heart rate monitoring (a clinically validated metric of pain, discomfort, and anxiety) and the administration of validated standardized patient-reported surveys (specifically, State-Trait Anxiety Inventory [STAI] and Visual Analog Scale [VAS] scores). The study will also evaluate physician satisfaction when using the device on enrolled patients using Likert-scale survey questions to assess ease of use, and assess impact of set-up time and take-down time. The plan for this study is discussed in the Opportunities for Future Development section.

Materials and Methods

Materials

Vibrostimulatory Device

There are three major components to the vibrostimulatory device: a 3D printed casing, internal circuitry, and an articulating arm. The casing is printed using polylactic acid (PLA) filament. The device is run using an ESP32 microprocessor, which is capable of making Bluetooth and Wi-Fi connections. This allows for control of the vibratory component remotely and integration of the vibration with the AR games. Small 3V vibratory motors were utilized as they have a favorable size profile and vibrate at 200hz, which is within the range of frequencies shown to be most effective in reducing pain (180-250 Hz).[36] To power the device, lithium ion batteries were selected as they are energy dense and integrate easily with the ESP32 development board. A Suptig Jaws Flex Clamp Mount was used for the articulating arm and a GoPro mount was used to attach the arm to the 3D printed casing. An itemized list of components is located in Supplemental Table 1.

AR Headset

Although the AR headset market is currently dominated by Microsoft's Hololens and the Magic Leap One, these headsets focus more on experience rather than functionality. They feature higher quality screens and better color

		Design Factors						
		sterilizability	adaptability	ease of use	affordability	patient comfort	closeness	
Approaches	articulating arm	5	5	5	5	5	4	**22**
	stick-on unit	5	5	5	5	4	5	**21.9**
	necklace	5	4	5	5	4	4	**20.5**
	vibroacoustic headphones	4	4	4	3	5	3	**17.4**
	pillow	3	2	5	4	5	2	**15.6**
		1	0.9	0.8	0.7	0.6	0.5	

row scoring (5 = highest)
column weighting (1=highest priority)

Table 1. Decision Matrix

There are 6 different design aspects in the columns. These aspects were ranked by all of our advisors who are MDs and score range of 0.5 to 1 was used for calculation purposes. 1 as the highest priority which is sterilizability and 0.5 as the lowest priority which is closeness to the injection site.

There are 5 approaches in the rows for what we could model our device after when creating the initial prototype. These rows were given a number 1 to 5, 5 being the highest.

The sum of these numbers (Approaches × Design Factors) to these aspects for each device model helped us to create our initial prototype. Two design ideas that had the highest totals were: a device with stick-on unit and an adjustable arm.

quality, but they are also much larger and heavier. For these reasons, ThirdEye Gen's X2 was selected as the headset of choice because it was designed specifically with functionality, including medical procedures, in mind. The X2 is also an Android based system which allows for relatively easier set up of a development environment using Android Studio. Additionally, the X2 also features onboard Unity support, enabling animations and games made with the Unity game engine to easily be tested and deployed to the X2. This makes the X2 a user-friendly device that simplifies the steps of prototyping by removing the complicated development processes that other headsets require. This was necessary for development of AR games and integration of haptic feedback in this project since time was limited and the team had few developers working on the project.

Methods

Vibrostimulatory Device Modelling and Building

The encasement for the vibrostimulatory circuit was designed in AutoDesk Fusion360. 3D files of circuit components were downloaded from the websites from which they were ordered, allowing us to directly fit the components into the CAD model prior to printing. All iterations of the encasement were printed in polylactic acid (PLA) using a MakerBot Replicator at Clemons Library's Robertson Media Center at the University of Virginia. Circuitry was assembled using tools at the Fabrication Laboratory at the School of Architecture.

AR Game & Software Development

The games for the AR headset were created using the C# programming language and the Unity game engine. The Unity game engine was chosen due to the ThirdEye X2's compatibility with this engine which would allow for easy development and deployment of the subsequent game.

Results

Design Constraints

With the help of clinician advisors, 6 factors were identified to help guide the design of the vibratory device. The most important factors were sterilizability and the ability of the device to be modified for other IOPs (outside of Otolaryngology). Other factors included ease of use, affordability, patient comfort, and proximity to the injection site. After the creation of a variety of early conceptual designs, a Pugh analysis was conducted in order to rank each design based on these six factors. The results of this analysis can be seen in Table 1. The design which scored the highest was the "articulating arm" concept; subsequently, it was developed into a functioning prototype.

Vibratory Device

Electrical Design

The circuit components required for the haptic simulation device included a breadboard, wires, ESP32 microcontroller, vibratory motors, and batteries. The initial circuit featured 2 motors connected in parallel to the power and ground pins on the ESP32 microcontroller. However, the vibration from the initial circuit was not strong enough to induce enough sensory stimulation and also did not feature a switch, draining the battery quickly and leaving operators/developers with limited control over the circuit. The next iteration was modified with two extra motors (for a total of four), which allowed for stronger vibration, and a button that allowed for the circuit to be switched on or off. The problem with this circuit design was that the button had to be pressed down constantly to connect the circuit and power the motors. To fix this issue, the button was replaced with a switch in the third iteration of the vibratory prototype, which for a stable switch design of "on" or "off" without constant pressure (Figure 3).

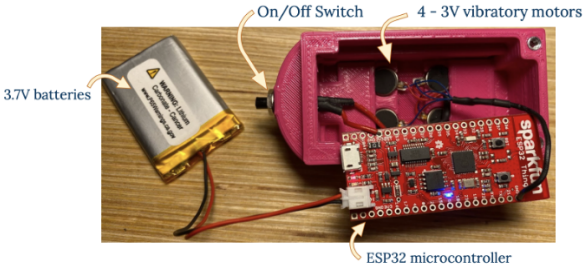

Figure 3. Final Haptic Circuit

The final circuit contains an ESP32 microcontroller, four vibratory motors in parallel circuits, a switch, and a lithium battery.

Case Design

Throughout the design process, the 3D printed case underwent modifications to improve its overall functionality. Three iterations of the case were developed to incorporate improvements in each subsequent version. The first iteration had slots to hold two motors and featured a flat contact surface (Figure 4a). Following assembly, it was discovered that the vibration supplied by two motors was not sufficient during the subsequent testing. The flat surface of the encasement was also not ideal for its intended use, since the flat surface would have a very limited area of contact with the patient's neck (as well as many other body surfaces) and the square edges were uncomfortable. In the second

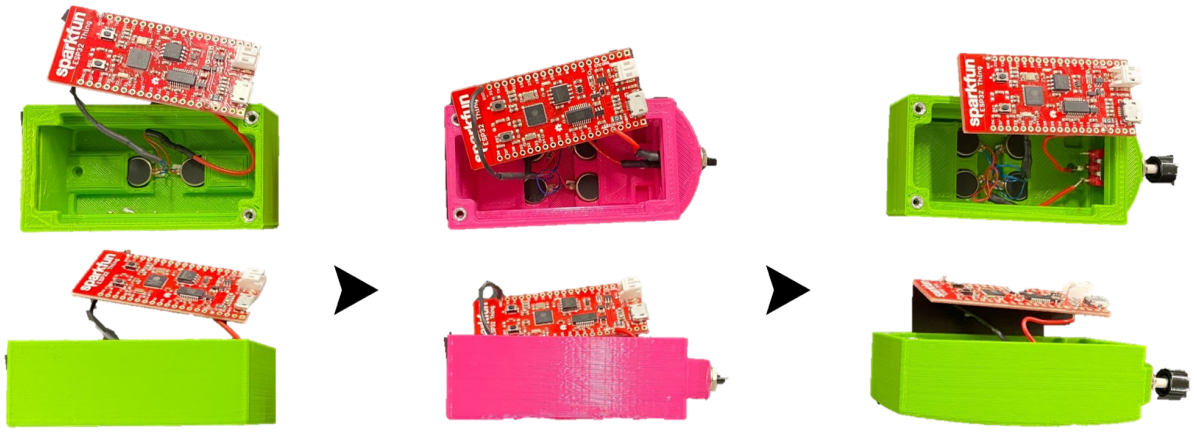

Figure 4a. Prototype Assembly (v1.0)

Features two vibratory motors and contact surface that is a flat, rectangular shape.

Figure 4b. Prototype Assembly (v2.0)

Features four vibratory motors, a push-hold button, and a concave contact surface on the bottom.

Figure 4c. Prototype Assembly (v3.0)

Features four vibrator motors, a clicker switch, and a convex contact surface for more comfortability.

version, the number of motors was increased from two to four. This increased the amount of stimulation transmitted through the case. Additionally, the contact surface was made concave instead of flat, with the intention of increasing the area of contact with the patient's neck by modelling the curvature to the approximate curvature of a human model neck. This change in concavity proved difficult to 3D print, leaving the contact surface of the box much thinner than desired. In the final iteration, the curvature of the contact surface of the case was made convex, with the intention of improving patient comfort by reducing contact with square edges and also allowing for the device to be more applicable in other uses beyond just head and neck surgery.

Prototype Assembly and Mount Selection

After each design, the circuit was assembled and inserted into the 3D printed case. This allowed for the intensity of vibration to be tested as well as testing the fit of the circuit components within their respective slots. Figure 4a-c shows the progression of prototype assembly.

While PLA is a sturdy 3D printing material, threads printed in PLA for repeated screw insertion often do not exhibit much longevity. The lid of the case, which has the GoPro-like attachment, was designed to be screwed onto the rest of the box. With the potential need for battery changes and disassembly, metal screw threads were utilized to ensure that the threads would not deteriorate with repeated use. M3 tapered heat-set inserts for plastic were inserted into the screw slots on the box using a soldering iron, allowing for repeated assembly and disassembly of the case.

Once it was decided that the articulating arm was the preferred approach for the vibratory component, various out-of-the box options for the clamp and mount were explored. The clamp, which would connect the arm to the patient's chair, needed to be strong enough to support the weight of the case and circuit as well as the potential force that the patient would apply to the arm when the case is being pressed against their neck. A GoPro-style attachment was added to the lid of the case, as it was decided that this type of attachment would be easy to incorporate with already existing arms. The 9 inch Suptig Jaws Flex Clamp Mount was purchased from Amazon and used to secure the vibratory component to the chair while also allowing for precision placement via the articulating arm. The final mounted vibratory prototype can be seen in Figure 5.

Figure 5. Prototype on a GoPro Attachment in a Hospital Setting

The final vibratory device is placed on an articulating arm, which is clipped to the ENT examination chair.

AR Game

The AR games were designed to keep the patient constantly engaged and focused so that they will be distracted throughout the procedure, but not so much so that they are overwhelmed and/or unable to follow physician instruction. To accomplish this, games similar to very popular and simple mobile applications were developed One of the games created is called "Flappy Butterfly", shown in Figure 6, which is similar to the popular iOS game called "Flappy Bird". This game features a one-button control

mechanism, and simple controls so that people of all ages can use the device. Additionally, we chose this game because it requires consistent interaction from the user. This interaction, paired with haptic feedback from the vibratory device, provides the proper sensory stimulation we had planned for.

Figure 6. Flappy Butterfly
In this game, the player clicks the button to flap the butterfly's wings to make it fly up. The butterfly will slowly fall if no clicking happens. The goal is to navigate the butterfly through the hedges.

In addition to "Flappy Butterfly", we developed a similar game called "Stacker", shown in Figure 7, which was created with the same goals in mind. It also features very simple controls, calming aesthetics, and requires consistent interaction from the user.

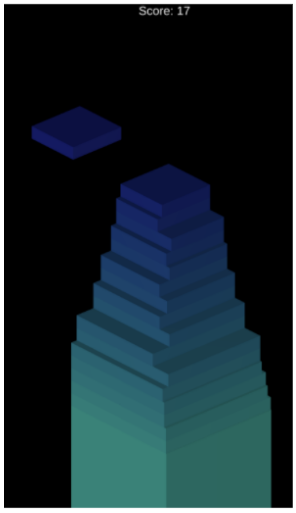

Figure 7. Stacker
In this game, blocks fly in from the left and right corners one at a time, and the user tries to click the button when the moving block is perfectly lined up with the block on top of the stack. This causes the block to get added to the stack, and any part of the block overhanging the stack gets cut off and falls down. The goal is to stack the blocks as high as possible before the top block becomes so small that the user completely misses when trying to set the moving block, causing the game to end. The black background shown here is transparent when viewed through the AR headset, so the blocks appear as if they are floating in space.

Flappy Butterfly Code Architecture

The Flappy Butterfly game uses the Unity game engine to build its user interface. The characters and animation are controlled with C# scripts which were also built using the Unity development environment. There are many script classes that the game contains, the most important ones being `GameManager`, `PlayerController`, `HedgeObstacleLogic`, `ScoreText`, `BluetoothManager`, `BackgroundManager`. The `PlayerController` is the class which manages the butterfly's control. This includes responding to when the user clicks a button by adjusting the butterfly's velocity, as well as controlling the animation for the butterfly. The `HedgeObstacleLogic` and `BackgroundManager` are similar in the sense that they control the horizontal translation of the hedges and the background. The difference between the two classes is that the `HedgeObstacleLogic` class randomizes the vertical position of the hedges and also responds to collisions when the player and the hedge collide with each other. The `ScoreText` class simply keeps track of the score and makes sure to display and hide the score above the player when appropriate. Lastly, the `BluetoothManager` class is where the communication between the vibration device and AR headset occurs, which will be discussed in detail later.

Stacker Code Architecture

The overall graphical user interface (GUI) of the Stacker game was configured using Unity's scene builder. The backend of the game consists of a collection of C# scripts. The scripts contain four main classes: `GameManager`, `CubeSpawner`, `MovingCube`, and `ScoreText`. The `GameManager` class provides the high level controls of the game. When the user presses the button, the `GameManager` responds by stopping the current cube and spawning a new one by calling the `SpawnCube()` method on an instance of the `CubeSpawner` class. This method spawns a new cube in the correct position and assigns its direction of travel (either X or Z direction). The

name “cube” in our scripts refers to an individual block that is being stacked (even though sometimes they do not take the shape of a perfect cube).

The `MovingCube` class takes care of properly modifying the attributes of each cube such as color, size, speed, etc. The `MovingCube` class stores these attributes in private variables, and can change the attributes of new cubes based on previous ones (for example, the color of each new cube is set to a shade slightly different then the last cube to create an aesthetically pleasing and calming color gradient). When the `GameManager` tells the current cube to stop after a button press; it does so by calling the `Stop()` method in `MovingCube`. This method sets the moving speed to 0, and also takes care of slicing off any part of the cube that overhangs the stacked cube below it. Finally, the `ScoreText` class keeps track of the player's current score and displays it above the stack.

Haptic Feedback

To enhance patients’ immersion while using the device, a simple communication system between the vibration device and the AR headset was developed to enable haptic feedback. The haptic feedback would serve to increase or decrease the strength of the vibration that the patient experiences for a brief moment. This communication system is built off of Bluetooth 5.0, which exists on the ESP32 microcontroller as well as the ThirdEye X2. When the user interacts with the game, for example when the button is pressed, then the AR headset sends data to the vibration device. This data is a number: either 0, 1, or 2. Once the data is retrieved by the device, it can interpret the number to determine change that should occur in the vibration pattern. A “0” is interpreted by the device to decrease the vibration strength, a “1” is for increasing the strength slightly, and a “2” represents maximum strength increase. All changes to the vibration strength last for exactly 300 milliseconds, and then the strength is returned to default. This maximizes the immersion and distraction through variable sensory stimulation, and it also prevents patients from getting used to one constant level of vibration.

Clinician Feedback on the Prototypes

Although a patient study was unable to be run this year (as hoped), feedback and testing by the three project advisors in UVA’s OHNS department was able to be obtained. These advisors are: Dr. James Daniero (an attending Otolaryngologist, specialized in Laryngology, who conducts hundreds of IOPs every year), Dr. Claudia Guitieerez (a UVA Otolaryngology resident), and Logan McColl (a current UVA Medical School and Darden student, and incoming Otolaryngology resident). These advisors shared similar sentiments about our designs. Specifically, they all appreciated the articulating arm positioning system, the convex surface design, and the simple gameplay. They also shared views on a few suggestions for improving the device: (1) while four vibratory motors are better than two, they still don’t output quite a strong enough vibration, so different motors will likely be needed; (2) multiple articulating arm length options and mounts may be needed, as not all procedure rooms are set up the same way; and (3) The games should be made even slower/easier. With regard to the games specifically, the advisors noted that unlike traditional games, our games do not need to be overly challenging to keep the user engaged. Instead, having the patient constantly lose and restart a game during the procedure may be counterproductive to reducing their anxiety levels and more linear gameplay may be desirable. They also suggested creating an augmented reality “scene” option for patients that don’t want to play an interactive game, but still want to be immersed in a virtual world.

Discussion

Challenges

Given the virtual nature of this past academic year and the restrictions put in place due the COVID-19 pandemic, this project faced numerous unique challenges that slowed progress and required creative work-arounds. This is in addition to standard challenges faced in any design project.

COVID-19 and Access to Components and Fabrication Facilities

A significant amount of time in the fall was spent determining where to access the necessarily prototyping tools. Access to maker-spaces traditionally used by biomedical engineering students - such as Stacy Hall - was extremely limited, forcing us to seek out facilities in other university departments. The best 3D printing option we found for standard PLA printing was at the Robertson Media Center (RMC) in Clemons Library. However the facility did not allow for us to complete prints on our own. We instead had to send STL files to the RMC staff who would conduct the prints for us. While the finished prints received were high-quality, the turnaround time was 1-2 weeks per print which slowed down the time between each iteration significantly.

For print post-processing and circuit building, multiple departments were contacted and eventually access was obtained to the School of Architecture's Fabrication Lab. Their lab provided us with soldering stations and various other tools for putting the finishing touches on our prototypes, allowing for completion of the designs without access to BME resources.

Scope of Understanding

It was initially planned for the project team to spend a few weeks shadowing otolaryngologists in the clinic to gain a first-hand understanding of the IOPs that are conducted. In the fall semester, the project team underwent all of the training and paperwork necessary to shadow UVA physicians. However, a subsequent COVID-19 outbreak in the UVA ENT department prevented any observers, including the project team, from entering the clinic. Instead, the team was limited to watching videos of the procedures in order to gain as much understanding as possible.

Vibrostimulation Device

One of the main pandemic related challenges with vibratory device development was the lack of in-person meetings. Some of the project team members were not living in Charlottesville, so different components were shipped to different team members. Some team members then had to drive long distances for the team to meet as a full group and combine all the individually developed components together. Another more traditional technical problem with the vibratory device was the tradeoff between device weight/size and vibratory strength. Small vibratory motors were utilized in order to keep the device size down. However, it necessitated an increase in the number of motors used in later iterations to generate enough vibration strength. Future iterations of the device will likely need to employ even stronger motors to achieve the desired strength.

Headset

The ThirdEye Gen X2 AR headset was chosen for the project due to its low profile and weight. However, ThirdEye Gen is a relatively new company and some parts of the X2 headset still need ironing out. While the X2 was advertised as one-size-fits-all, once it was received it was

soon discovered it was much too small for some of our team members. To be too small for one-in-four people in the project team brings concerns regarding limited patients being able to test the device, as many patients may not be able to wear the headset due to it's small head circumference. Furthermore, the X2 was also advertised to be the only drop-proof industrial grade AR headset on the market. However, it broke easily when trying to get it to fit on a team member's head. This prevented the team from getting full feedback on theAR games since the headset needed to be sent back to ThirdEye for repairs.

Opportunities for Future Development

Patient Study

A proposal was submitted to the IRB outlining the plan for a patient study. The study will consist of patients all undergoing the same procedure, but split into four treatment groups: combination AR and vibratory component, AR only, vibratory component only, and no intervention (control group). The study aims to quantify the success of the device in reducing patient pain, stress, and anxiety. Patients will be asked to fill out validated, standardized forms to assess their pain and anxiety experienced during the procedure. For pain, patients will self-report their perceived pain level during the procedure using the Visual Analog Scale (VAS).[37] Patients will be provided with a 10cm line and asked to indicate their pain level along the line somewhere between 0 (no pain at all) and 10 (worst pain imaginable). The location on the line will then be measured in centimeters and converted into a score out of 10. For anxiety, patients will also be asked to report their anxiety levels using the State Trait Anxiety Inventory (STAI). A single lead ECG will also be placed on the patient to measure the change in heart rate during the procedure, which is a biological indicator for anxiety, discomfort, and perceived pain.

Application to other IOPs:

While the focus was on Otolaryngology procedures when designing this device, the principles behind it have broad applications to many other areas of medicine. In-office procedures are becoming significantly more common across medical subspecialities: from dermatology to gastroenterology to gynecology.[4–6] Subsequently, this device would likely be applicable to other types of IOPs out-of-the-box, and could be easily modified to fit even more procedures still. For example, the augmented reality games could become more or less immersive depending on the type of procedure, patient population, and pain levels experienced. Furthermore, the vibratory component could be repositioned to stimulate whatever part of the body is being operated on and could, in future iterations, have different shapes and vibratory strengths to further expand its scope. In this way, the PARVA could be expanded to reach a massive market and ease patient discomfort across a wide variety of IOPs.

Acknowledgements

The project team would like to thank its advisors Dr. James Daniero, Dr. Claudia Gutierrez, and Logan McColl, for providing help and advice constantly on the project. We would also like to thank all the staff of both the Fabrication Lab (FabLab) at the UVA School of Architecture and the Robertson Media Center; we would not have been able to complete the project if it weren't for their help and access to their tools and materials. Furthermore, we would like to thank all the staff of the Biomedical Engineering Department and Department of Otolaryngology for making the project an educational and enjoyable experience.

Works Cited

1. McCarthy, M. US health-care system faces cost and insurance crises. *The Lancet* **362**, 375 (2003).
2. Rice, T. *et al.* United States of America: health system review. *Health Syst Transit* 15, 1–431 (2013).
3. Hoffer, E. P. The American Health Care System Is Broken. Part 7: How Can We Fix It? *Am J Med* 132, 1381–1385 (2019).
4. Young, V. N., Smith, L. J., Sulica, L., Krishna, P. & Rosen, C. A. Patient tolerance of awake, in-office laryngeal procedures: A Multi-Institutional Perspective. *The Laryngoscope* 122, 315–321 (2012).
5. Saini, A. T., Citardi, M. J., Yao, W. C. & Luong, A. U. Office-Based Sinus Surgery. *Otolaryngologic Clinics of North America* 52, 473–483 (2019).
6. Shah, P. D. Patient Safety and Quality for Office-Based Procedures in Otolaryngology. *Otolaryngol Clin North Am* 52, 89–102 (2019).
7. Prickett, K. K., Wise, S. K. & DelGaudio, J. M. Cost analysis of office-based and operating room procedures in rhinology. *Int Forum Allergy Rhinol* 2, 207–211 (2012).
8. Recurrent Respiratory Papillomatosis. *NORD (National Organization for Rare Disorders)* https://rarediseases.org/rare-diseases/recurrent-respiratory-papillomatosis/.
9. Idiopathic Subglottic Stenosis. *NORD (National Organization for Rare Disorders)* https://rarediseases.org/rare-diseases/idiopathic-subglottic-stenosis/.
10. Ahmad, S., Muzamil, A. & Lateef, M. A Study of incidence and etiopathology of vocal cord paralysis. *Indian J Otolaryngol Head Neck Surg* 54, 294–296 (2002).
11. Mallur, P. S. & Rosen, C. A. Vocal Fold Injection: Review of Indications, Techniques, and Materials for Augmentation. *Clin Exp Otorhinolaryngol* 3, 177–182 (2010).
12. Zeitels, S. M. *et al.* Office-Based 532-nm Pulsed KTP Laser Treatment of Glottal

Papillomatosis and Dysplasia. *Ann Otol Rhinol Laryngol* 115, 679–685 (2006).

13. Braz, J., Solorzano, C., Wang, X. & Basbaum, A. I. Transmitting pain and itch messages: A contemporary view of the spinal cord circuits that generate Gate Control. *Neuron* 82, 522–536 (2014).
14. Treede, R.-D. Gain control mechanisms in the nociceptive system. *Pain* 157, 1199–1204 (2016).
15. Zhang, Y. *et al.* Timing Mechanisms Underlying Gate Control by Feedforward Inhibition. *Neuron* 99, 941-955.e4 (2018).
16. Smith, K. C., Comite, S. L., Balasubramanian, S., Carver, A. & Liu, J. F. Vibration anesthesia: a noninvasive method of reducing discomfort prior to dermatologic procedures. *Dermatol Online J* 10, 1 (2004).
17. Mally, P., Czyz, C. N., Chan, N. J. & Wulc, A. E. Vibration anesthesia for the reduction of pain with facial dermal filler injections. *Aesthetic Plast Surg* 38, 413–418 (2014).
18. Sharma, P., Czyz, C. N. & Wulc, A. E. Investigating the efficacy of vibration anesthesia to reduce pain from cosmetic botulinum toxin injections. *Aesthet Surg J* 31, 966–971 (2011).
19. Industry Leader in Drug Free Pain Relief. Home of Buzzy & VibraCool. *Buzzy®* https://buzzyhelps.com/.
20. Legrain, V. *et al.* A neurocognitive model of attention to pain: behavioral and neuroimaging evidence. *Pain* 144, 230–232 (2009).
21. Sil, S. *et al.* The effects of coping style on virtual reality enhanced videogame distraction in children undergoing cold pressor pain. *J Behav Med* 37, 156–165 (2014).
22. Melzack, R. Pain: past, present and future. *Can J Exp Psychol* 47, 615–629 (1993).
23. Hendricks, T. M., Gutierrez, C. N., Stulak, J. M., Dearani, J. A. & Miller, J. D. The Use of Virtual Reality to Reduce Preoperative Anxiety in First-Time Sternotomy Patients: A Randomized Controlled Pilot Trial. *Mayo Clin Proc* 95, 1148–1157 (2020).
24. Eijlers, R. *et al.* Virtual reality exposure before elective day care surgery to reduce anxiety and pain in children: A randomised controlled trial. *Eur J Anaesthesiol* 36,

728–737 (2019).

25. Bekelis, K., Calnan, D., Simmons, N., MacKenzie, T. A. & Kakoulides, G. Effect of an Immersive Preoperative Virtual Reality Experience on Patient Reported Outcomes: A Randomized Controlled Trial. *Ann Surg* 265, 1068–1073 (2017).
26. Gold, J. I. & Mahrer, N. E. Is Virtual Reality Ready for Prime Time in the Medical Space? A Randomized Control Trial of Pediatric Virtual Reality for Acute Procedural Pain Management. *J Pediatr Psychol* 43, 266–275 (2018).
27. Hoxhallari, E. *et al.* Virtual Reality Improves the Patient Experience during Wide-Awake Local Anesthesia No Tourniquet Hand Surgery: A Single-Blind, Randomized, Prospective Study. *Plast Reconstr Surg* 144, 408–414 (2019).
28. Chan, E. *et al.* Virtual Reality for Pediatric Needle Procedural Pain: Two Randomized Clinical Trials. *J Pediatr* 209, 160-167.e4 (2019).
29. Frey, D. P. *et al.* Virtual Reality Analgesia in Labor: The VRAIL Pilot Study-A Preliminary Randomized Controlled Trial Suggesting Benefit of Immersive Virtual Reality Analgesia in Unmedicated Laboring Women. *Anesth Analg* 128, e93–e96 (2019).
30. Azuma, R. *et al.* Recent Advances in Augmented Reality. *IEEE Comput. Graph. Appl.* 21, 34–47 (2001).
31. Mott, J. *et al.* The efficacy of an augmented virtual reality system to alleviate pain in children undergoing burns dressing changes: a randomised controlled trial. *Burns* 34, 803–808 (2008).
32. Morris, L. D., Louw, Q. A. & Grimmer-Somers, K. The effectiveness of virtual reality on reducing pain and anxiety in burn injury patients: a systematic review. *Clin J Pain* 25, 815–826 (2009).
33. Eijlers, R. *et al.* Systematic Review and Meta-analysis of Virtual Reality in Pediatrics: Effects on Pain and Anxiety. *Anesth Analg* 129, 1344–1353 (2019).
34. Yeh, S.-C., Li, Y.-Y., Zhou, C., Chiu, P.-H. & Chen, J.-W. Effects of Virtual Reality and Augmented Reality on Induced Anxiety. *IEEE Trans Neural Syst Rehabil Eng* 26, 1345–1352 (2018).
35. Wong, K., Yee, H. M., Xavier, B. A. &

Grillone, G. A. Applications of Augmented Reality in Otolaryngology: A Systematic Review. *Otolaryngol Head Neck Surg* 159, 956–967 (2018).

36. Manfredi, L. R. *et al.* The Effect of Surface Wave Propagation on Neural Responses to Vibration in Primate Glabrous Skin. *PLOS ONE* 7, e31203 (2012).
37. Delgado, D. A. *et al.* Validation of Digital Visual Analog Scale Pain Scoring With a Traditional Paper-based Visual Analog Scale in Adults. *J Am Acad Orthop Surg Glob Res Rev* 2, (2018).

Supplemental Material

Supplemental Figure 1. Buzzy®

Buzzy combines cold numbing and vibration to reduce sensation experienced during vaccination.

Item	Unit Cost	Quantity	Total Cost
Vibratory Component			
Vibration Motor Disks (12000 rpm)	$14.99	1	$14.99
Vibration Motor Disks (11000 rpm)	$1.95	5	$9.75
ESP32 Microprocessor	$21.95	3	$65.85
LiPo Battery (850 mAH)	$9.95	1	$9.95
LiPo Battery (1 AH)	$9.95	1	$9.95
LiPo Battery (400 mAh)	$4.95	1	$4.95
Coin Battery	$5.99	1	$5.99
Coin Battery Holder	$1.25	4	$5.00
Bone Conduction Transducer	$8.95	6	$53.70
USB Micro-B	$4.95	1	$4.95
5V Wall Adapter	$3.95	1	$3.95
Female Headers	$1.50	12	$18.00
Male Headers	$1.50	12	$18.00
Breadboard	$4.95	1	$4.95
Breadboard Wires	$1.95	1	$1.95
Resistors	$5.99	1	$5.99
Solder	$1.95	1	$1.95
Red Wire	$2.95	1	$2.95
Black Wire	$2.95	1	$2.95
White Wire	$2.95	1	$2.95
PLA Printing Filament	$22.99	1	$22.99
Suptig Jaws Flex Clamp	$16.99	1	$16.99
Tapered Heat Set Inserts	$13.20	1	$13.20
Steel Hex-Drive Screws	$5.51	1	$5.51
Push Button Switch	$7.70	1	$7.70
Vibratory Device Subtotal			$315.11
AR Headset			
ThirdEye X2 (+ Shipping, Tax)			$2,535.00
Services			
Free use of equipment in A-School Fab-Lab and Stacy Hall			$0.00
TOTAL			**$2,850.11**

Supplementary Table 1. Component Breakdown / Budget Sheet
Every component ordered for this project is included in the breakdown above.