Using the Patient Augmented Reality and Vibratory Array (PARVA) to Improve Patient Experience During In-office Laryngology Procedures

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Abstract

Over 10 million Americans suffer from laryngeal-specific conditions that are treatable through in-office procedures (IOPs) without the use of general anesthesia. While IOPs are safer and cheaper than procedures performed in the operating room (OR), patients can experience significant discomfort and pain during IOPs resulting in pursuing future procedures in the OR. Current literature demonstrates reduction in patient discomfort and anxiety through the use of vibrational stimulation and augmented reality (AR), but no studies have combined the two approaches. The Patient Augmented Reality and Vibratory Array (PARVA) combines these two elements, aiming to reduce patient discomfort and anxiety during laryngeal IOPs and reduce the IOP to OR procedure conversion rate. This would save patients time, money, and avoid the risks associated with general anesthesia. The vibratory array was designed to meet specifications related to wearability, anatomy, and comfort. An AR headset was selected based on durability, comfort, and its ability to be used in a clinical setting. Unstructured interviews were conducted with patients at the UVA ENT Clinic at Fontaine Research Park. Four of the five patients were extremely willing to try the device and thought it would help to distract them during their procedure. Validation of the PARVA will be carried out by the department of Otolaryngology at UVA through an IRB approved clinical study. The study will consist of four patient groups and will use the State-Trait Anxiety Inventory, visual pain analog scale, and heart rate variability as metrics of efficacy. Overall, based on literature and the unstructured interviews, the PARVA has the potential to help reduce the discomfort and anxiety felt by millions of patients who undergo laryngeal IOPs.

Keywords: In-office Procedures, Otolaryngology, Vibrational Stimulation, Augmented Reality, Patient Experience

Introduction

In-Office Laryngology Procedures

Laryngology is a medical subspecialty within the field of otolaryngology that treats diseases of the larynx, vocal cords, and trachea. These conditions include vocal fold tremor, vocal cord lesions, and respiratory papillomatosis, which collectively affect over 10 million Americans. Due to advances in technology and surgical techniques, procedures that treat these conditions, like vocal cord injection and laser ablation, can be performed safely as in-office procedures (IOPs) rather than under general anesthesia in the operating room (OR). The University of Virginia (UVA) alone performs over 300 of these IOPs each year with a waiting list of over 100 patients.[1–3]

While these IOPs are safe and effective, patients can experience significant discomfort due to the sensitive anatomic structures involved (Figure 1). A study assessing patient discomfort across various laryngology IOPs found that approximately 40% of patients reported moderate discomfort during endoscope placement, injection, and laser ablation. This study also found that greater than 10% of patients experienced severe discomfort during the procedure.[4] Patients are often so dissatisfied with their in-

office experience that they will elect to have any follow up procedures in the OR under general anesthesia.[5]

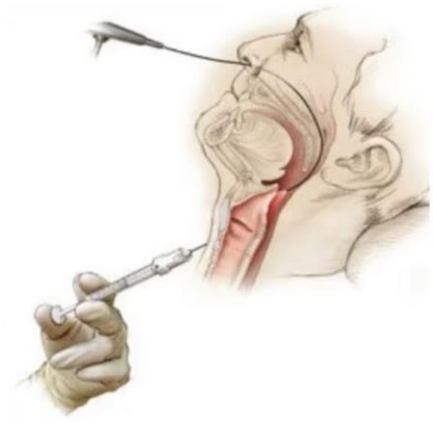

Figure 1: Endoscope and needle placement for vocal cord injection. The endoscope travels through the nasal passage into the larynx which can be uncomfortable for many patients. Several injections into the vocal folds from the front of the throat take place during these procedures.

IOPs have many advantages over OR procedures including decreased cost, duration, wait time, and improved safety. In the field of laryngology, the mean total charges for IOPs are $2,737, which is significantly less than the mean OR charge of $7,329 for the same procedures due to costs associated with staffing, OR time, and the administration of general anesthesia.[6] There are many risks associated with general anesthesia, especially for certain patient populations like those who are elderly, diabetic or have a history of heart disease, making IOPs safer than OR procedures.[7] Rare but serious risks of general anesthesia include myocardial infarction, stroke, pneumonia, and death.[8] Eliminating the need for general anesthesia also allows IOPS to be performed in less time and requires little to no recovery time. Shorter procedures also reduce patient wait time and allow physicians to treat more patients annually. Another important benefit of IOPs is that they offer increased patient autonomy, as patients are awake, aware of their surroundings, and able to communicate with their physician.

Our goal is to design a non-pharmacological method to reduce the pain and anxiety felt by patients during in-office procedures, improving their overall experience.

Vibration

Vibration is a non-pharmaceutical procedural pain management technique that has previously been investigated. The Gate Control Theory of pain developed by Mezlack and Wall in 1965 proposes that neural networks distributed along the dorsal horn of the spinal cord relieve pain in a specific location when a tactile stimulus is applied at the same location.[9] Vibration applied to areas surrounding the site of laryngology procedures may provide the necessary stimulation to reduce discomfort. This principle has been employed to reduce pain during other medical procedures like pediatric venipuncture. The Buzzy System is a small handheld device that vibrates on the skin to alleviate sharp pain associated with inserting an IV, taking a blood sample, receiving an injection, or accessing a port with a needle stick. This system has been found to be effective at reducing pain levels as measured using the Visual Analogue Scale (VAS), the Wong-Baker Scale (WBS) and the Numeric Rating Scale (NRS).[10] Vibration has also been used to reduce pain during facial injection with hyaluronic acid or botulinum toxin. In one study, 28 of 32 patients indicated that the vibration device applied adjacent to the injection site relieved the pain. A statistically significant difference was found between the NRS scores for the vibration and no-vibration injections ($p < 0.001$).[11]

Augmented Reality

Augmented reality (AR) is another tool that may be used to reduce patient discomfort during procedures. AR projects virtual elements into the user's field of view, whereas virtual reality (VR) completely immerses the user into a virtual environment. Currently at the Lucile Packard Children's Hospital at Stanford, the Childhood Anxiety Reduction Through Innovation and Technology (CHARIOT) team has found different ways to utilize VR and AR as tools to help distract children during painful or over-stimulating procedures. In a retrospective cohort study of this program, Certified Child Life Specialists found that 100% of the patients who were in the VR group were less

resistant to treatment pre- and post-operation than control groups.[12]

In 2005, a randomized control trial was performed to assess the efficacy of VR in modulating pain of children with burn injuries. It was found that the average pain scores (based on the Faces Scale), significantly decreased with the addition of VR ($p < 0.01$). [13]

More recently in 2020, a small case study was performed with three pediatric patients (ages 11 to 17) to assess the use of AR during otolaryngologic IOPs in reducing anxiety. At the conclusion of the study, the patients, their parents, and the otolaryngologists all recommended the use of AR based on their experiences.[14] For the purpose of this study, AR is utilized over VR to preserve the patient's ability to see and interact with their surroundings and medical professionals.

Project Aims

Drawing on the use of vibratory stimulation and augmented reality in clinical settings, this project set out to design, prototype, and validate a novel device composed of a wearable vibratory component used in conjunction with a pre-existing AR system. The Patient Augmented Reality and Vibratory Array (PARVA) aims to reduce patient discomfort during in-office laryngology procedures with the ultimate goal of reducing the conversion rate of procedures to the operating room, saving patients both time, money, and risks associated with general anesthesia.

Materials and Methods

Vibratory Device

The device uses two 6V 37mA DC vibration motors wired in parallel to four AA batteries, an on/off switch, and a 200Ω potentiometer. To enclose the motor, a two-piece case was designed in SolidWorks and 3D-printed with polylactic acid (PLA) on a Voxelab Aquila DIY FDM printer (Figure 2). The motor casing was then attached to a segment of ¼" Loc-Line® modular hose using a 2-part epoxy. To create a silicone cover around the motor casing, a custom two-part mold was designed and printed (Figure 3). The mold was designed to bolster the motor casing, allowing the surrounding space to be filled with Mold Max™ 30 silicone rubber. To join the two vibratory components, both segments of the modular hoses were covered with foam tubing and connected with a Loc-Line® Wye Connector.

Figure 2: CAD renderings of vibration motor casings. The motor casings are made up of two pieces joined together via a clasping mechanism. Wiring exits the case through a hole in the side.

Figure 3: CAD renderings of silicone molds. To secure the motor casing in the center of the mold, the modular hose segment is placed between the two components in a designated cavity and secured with nuts and bolts.

A control box containing the batteries, switch, and potentiometer was designed in Fusion AutoDesk360 and printed. To assemble the device, 3.5 feet of wire was run from the vibratory components to the control box and protected with a braided sleeving. The electronic components were soldered and secured in their respective sockets. Figure 4 shows the final prototype.

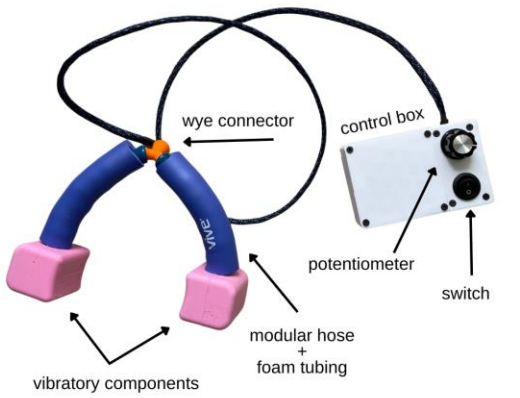

Figure 4: Labeled schematic of vibratory prototype. This is the final prototype that will be used in the patient study.

AR Experience

Stack3D is a simple stacking game developed with the Unity game engine using open-source code in the C# programming language (Figure 5). The game was configured using the Android software development kit in order to be compatible with the operating systems used in most AR devices. The application was then uploaded to the ThirdEye XR M2 glasses.

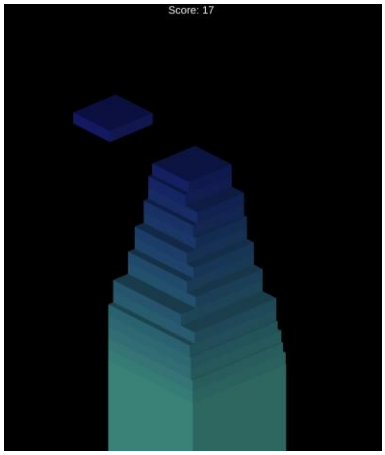

Figure 5: Stack3D. The game is played by clicking a button to drop a floating tile onto a stack. Any part of the tile that extends past the stack falls off, decreasing the area onto which the tiles can stack. The player loses the game by failing to stack the tile.

EKG Monitor

Polar H10 heart monitor, in conjunction with the EliteHRV smartphone application, was determined as the best fit for future clinical studies. The heart monitor is a chest strap, so it does not interfere with the procedural site and does not require multiple leads. Additionally, it is able to export raw data files that can be analyzed by the EliteHRV webapp for the computation of HRV values. One downside to the Polar H10 chest strap versus traditional ECG leads is that it may not be usable for patients with a very high BMI as it will not encircle the chest.

HRV Analysis

To quantify the efficacy of the study, heart rate variability (HRV) data will be collected using the Polar H10 heart monitor strap and analyzed with the EliteHRV application. The accuracy of the Polar H10 heart monitor strap in conjunction with the EliteHRV application has been validated in recent studies.[15] The ratio of the high and low frequencies of the HRV spectrum are commonly used to measure cardiac autonomic input; a decrease in this ratio indicates psychophysiological stress.[16] In this way, HRV will be used to determine relative pain levels. Studies have shown that pain reduces cardiac parasympathetic activity.[17] Therefore, the high frequency spectrum of HRV will be assessed using Chi-Squared Tests and paired t tests. A significant decrease ($p < 0.05$) in this frequency will demonstrate a reduction in pain.[18]

Clinical Study Design

The following IRB-approved study will be performed by the department of Otolaryngology at the University of Virginia. The protocol includes four randomly-selected groups of patients undergoing a laryngology IOP, (1) with standard of care (e.g. no distraction intervention), (2) with vibration only, (3) with AR only and (4) with both AR and vibration using the PARVA. During each patient's pre-operation appointment, they will be introduced to the technology (AR, vibratory array, or both) to gain familiarity with the device. On procedure day, each patient will wear the Polar H10, and HRV data collection will run before, during, and after the IOP. At the end of the procedure, each patient will also be asked to fill out the State Trait Anxiety Inventory on their overall surgical experience including elements of comfort, ease of use, anxiety, and pain. This is a validated survey that has been used in prior studies.[19] Pain will be rated using a visual analog scale. Following the procedure, the collected HRV data will be exported and run through the EliteHRV application to compute HRV specific values. At the end of the study, self-reported anxiety scores recorded post-procedure for all four groups will be evaluated using a Chi-Squared Test. Self-reported anxiety scores pre- and post-procedure will be evaluated within each of the four groups

using paired t-tests. The high frequency value of HRV recorded in each of the four groups will also be evaluated using a Chi-Squared Test. To evaluate the changes in high frequency values within the four groups pre- and post-procedure, paired t-tests will be performed. For each test performed, a p-value less than or equal to 0.05 will indicate a significant difference in level of anxiety and pain.[19]

Design Criteria

The vibratory device developed by the previous year's team consisted of a single vibrating component attached to the procedure chair via an articulating arm (Figure 7). Our team sought to improve this approach with three high-level design criteria: (1) The device should better target the relevant anatomy by delivering a greater degree of vibration to the superior laryngeal nerves on both sides of the neck, (2) the device should be customizable for different neck sizes in order to maintain contact with the neck throughout the procedure, and (3) the interface between the device and the patient's skin should be comfortable and easily cleaned.

Results

To increase the intensity of vibration, the team selected motors based on constraints specified in the decision matrix below, and a Pugh analysis indicated that 6V motors were optimal (Table 1). Additionally, based on feedback from advisors, the team found that the motors provided the most effective sensation when placed vertically on either side of the neck.

A narrow modular hose was used to provide both the rigidity and flexibility required to make the device wearable. The hose allows the device to expand to a maximum distance of about 5.5 inches, accommodating a range of neck sizes including the average male and female neck diameters of about 4.6 and 4.3 inches, respectively.[20] To further accommodate variability in patient size, sensitivity, and preference, the vibration intensity is adjustable with a rotating dial. The portion of the device that sits on the neck is lightweight, weighing only 9.2 ounces.

A silicone casing with a Shore A hardness of 30 was chosen as the interface between the vibratory components and the neck in order to prevent any abrasion or discomfort from the 3D-printed plastic. Once cured, the silicone was measured with a Shore A durometer to have an average hardness of 30.5. Additionally, the modular hose was covered in a foam tubing to prevent pinching of the patient's hair or skin. The device is easily wiped down with hospital-grade sanitizing wipes.

Results of Unstructured Interviews

On April 1, 2022 the capstone team went to the UVA ENT Clinic at Fontaine Research Park to conduct unstructured interviews with laryngology patients prior to undergoing their scheduled Botox injections for the treatment of spasmodic dysphonia, a condition that causes the vocal cords to contract involuntarily leading to difficulty speaking and breathing. Patients with spasmodic dysphonia will undergo trans-cervical Botox injections to their laryngeal muscles every 3 months to improve their speech and ability to communicate. A total of five patients were interviewed. The goal of the interviews was to gather information on how the patients felt about the use of the PARVA during future procedures. The team explained the project to each patient and asked a series of open-ended questions about their previous experiences with in-office procedures and their opinions on the vibratory device and AR experience. All patients were comfortable trying on our vibratory device to see how it felt.

	Evaluation Criteria				
Baseline	**Intensity**	**Size/Geometry**	**Heat Production**	**Noise**	**Score**
3V micro button	0	0	0	0	0
Alternatives					
3V micro	0	-1	0	0	**-1**
6V	1	-1	0	1	**4**
12V	1	-1	-1	-1	**-4**
12V double-head	1	-1	-1	-1	**-4**
Weight	3	1	4	2	

Table 1: Pugh Analysis of Motor Alternatives. The two highest-weighted criteria were that the motors do not produce heat after running for about 30 minutes and that the vibration intensity is greater than that of the baseline motor. The 6V motor received the highest score based on these evaluation criteria.

Four out of the five patients were extremely willing to try the device and said they would be willing to use it in their next procedure. None of the patients had an issue with the size or noise level of the vibratory device, or concerns about wearing an AR headset. Additionally, four patients believed the device would improve their experience and distract from the discomfort of the procedure. The only hesitation expressed by some patients was concern that the device could interfere with the physician's ability to perform the procedure. In discussion with the two UVA laryngologists and UVA otolaryngology residents, they did not anticipate this to be a problem. Electromyography (EMG) is used during some in-office procedures to identify the correct location for an injection into the appropriate laryngeal muscles. The vibratory device was tested during EMG use, and the EMG signal was unaffected by the vibration. The physicians and nurses in the clinic were also very receptive to the device and believed it would help improve patient experience. The one patient uninterested in using the device reported that they did not personally find significant discomfort in the procedure and as such the device was not needed.

Discussion

The team successfully developed a device that met the design constraints set out at the beginning of the project. Additionally, patients, nurses, and physicians felt the developed prototype would lead to an improved patient experience during awake in-office laryngology procedures.

Design Trade-offs

Although the Pugh analysis was useful in the selection of motors, the motor that delivered the appropriate intensity was larger than desired and had an asymmetrical geometry, making it more difficult to enclose. Because of the limitations of 3D printing certain geometries, the motor casing could not be cylindrical, as originally desired. Furthermore, the motors required a larger power supply. To prevent the wearable component from becoming too heavy, a separate battery housing was required. This, however, presented an opportunity to make a handheld control box, allowing the patient to adjust the vibration to their preferences.

Challenges

Last year's Capstone team used the ThirdEye XR M2 glasses when working on the PARVA. The limitations with the ThirdEye XR M2 glasses include its fragility (the headset was broken through normal use and had to be replaced), limited ability to accommodate different head sizes, and heaviness. In contrast, the NReal glasses are easily adjustable, light-weight, and compact due to the battery source being separate from the glasses themselves.

In the first iteration of the vibratory device, the noise from the motors was too loud to comfortably wear the device. It was determined that the noise was the result of the motor moving in the 3D printed case. To address this issue, silicone caulk was used to secure the motor in the case as well as to secure the case shut. After this adjustment the noise from the motors was greatly reduced.

Last year's Capstone team created a rectangular vibratory array with an outside shell composed of 3D-printed polymer. The sides of the device that were exposed to the neck had convex ridging to try and allow for more skin contact. The design of the model was not comfortable on skin contact due to the roughness of the polymer and did not fit properly on the neck due to its width and convex structuring. It could only be secured to the neck with the use of an additional device (Figure 6).

Figure 6: Device Comparison. Last year's vibratory prototype is on the left and the current prototype is on the right.

The first iteration of the vibratory device was designed with the motors oriented horizontally and a J-shaped silicone casing (Figure 7). It was determined that this design did not effectively target the superior laryngeal nerves and added unnecessary weight to the device.

The second iteration was designed with motors oriented vertically and a box-shaped silicone casing. This shape provided more targeted vibration, but did not fit the neck well, so the final iteration features a concave inner face (Figure 4). This also reduced the weight of the device.

Figure 7: First Iteration Vibratory Device. This shape was designed to fit the curvature of the neck, but did not deliver the vibration to the correct location on the neck.

Future Work

The next steps in the production and implementation of the PARVA mainly include the completion of the clinical study by the department of Otolaryngology at the University of Virginia with the use of the new vibratory device, Polar H10 heart monitor, the EliteHRV application, and the NReal Glasses. The gate control theory of pain and use of vibratory stimuli is not limited in use or potential effectiveness is not limited to any one anatomical location. Therefore, depending on the results of the study, it may prove beneficial to explore how the PARVA's use can be expanded to different medical specialties. Additionally, it would be ideal to have an array of different AR experiences for patients to choose from. AR experiences can include games (like the already developed Stacker game), short films, or calming scenery (like watching and listening to waves hitting the shore of a beach).

End Matter

Acknowledgments

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