RE-DESIGNING THE NASAL CANNULA FOR FACIAL SURGERY

THE DIFFERENCE IN THE PERCEPTION OF DRUGS AND ANESTHESIA

A Thesis Prospectus
In STS 4500
Presented to
The Faculty of the
School of Engineering and Applied Science
University of Virginia
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Biomedical Engineering

By
Michael Epps

November 1, 2022

Technical Project Team Members:
Kareem Hassan
William Sande

On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

ADVISORS

Catherine D. Baritaud, Department of Engineering and Society

Dr. Samuel Oyer, Associate Professor, Department of Otolaryngology- Head and Neck Surgery

Medical avoidance is a phenomenon where a person willingly delays or completely avoids obtaining health care at the cost of their own well-being. Medical avoidance can lead to a simple issue becoming worse if the person ignores it, making it more difficult to fix later on. The reasons a person may practice medical avoidance are slightly different person to person, with the most common reasons in first world countries being cost and fear. Finding ways to reduce either of these barriers would make people more likely to get the medical help that they need as soon as possible. The technical project and the STS project will each tackle ways to lower medical avoidance by focusing on the physical and mental aspects of the problem respectively.

The technical project and tightly coupled STS research project proposed in this prospectus directly address the issue of medical avoidance. The objective of the technical project is to create an adaptor for the dual nasal cannula that will allow it to be placed in the mouth to removing it from the surgical field, making surgeries cheaper and faster. Tightly coupled, my STS research will focus on the differences of societies current perception of over-the-counter drug usage and anesthesia in surgery, in order to identify where the fear may be originating from. The technical project will be recorded in a technical report, and the STS project will be recorded in a scholarly article. The technical project will be carried out during the Fall 2022 and Spring 2023 semesters, while the STS project will be done concurrently with the STS 4600 class. Figure 1 below shows how the technical work will be carried out throughout the two semesters. A working prototype design of the adaptor is planned for completion by the end of the Fall 2022 semester, with the Spring 2023 semester being used for patenting and gaining UVA Institutional Review Board (IRB) approval in order to conduct a study testing the efficacy of the adaptor under facial plastic surgeon Dr. Samuel Oyer as the Principal Investigator of the study.

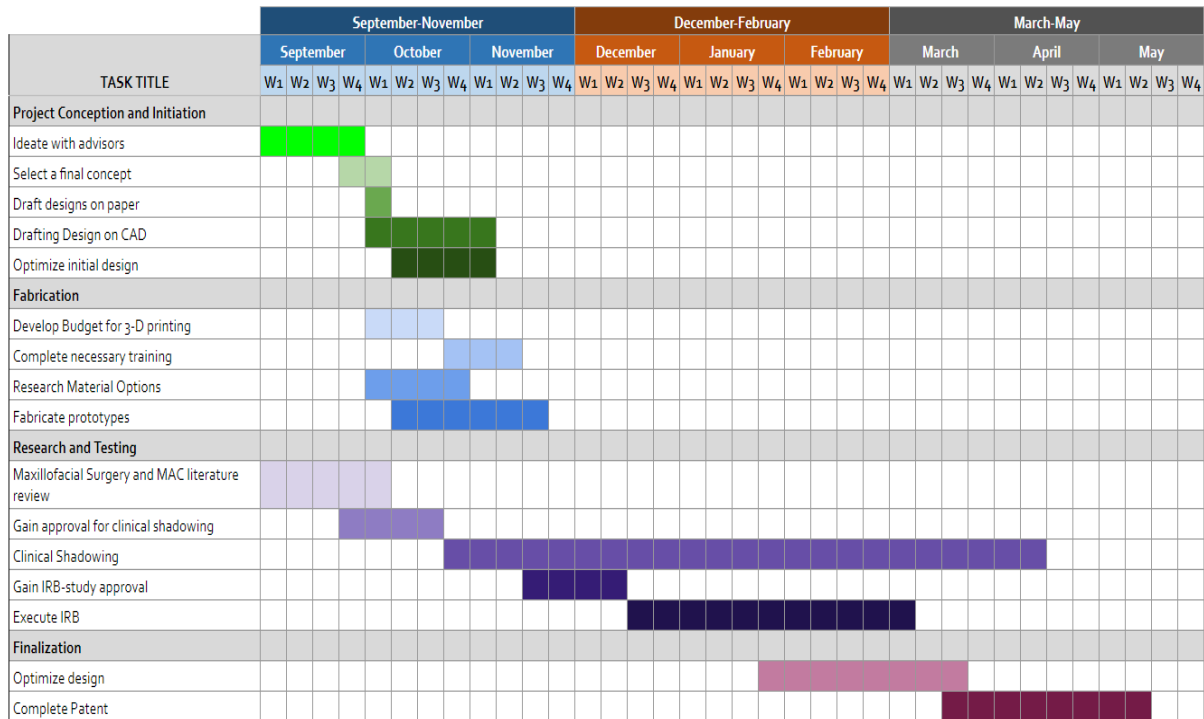| TASK TITLE	September-November												December-February												March-May											
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Figure 1: Gantt Chart for the technical project. This figure visualizes the expected timeline for the deliverables for the technical report (Michael 2022).

RE-DESIGNING THE NASAL CANNULA FOR FACIAL SURGERY

Facial plastic surgery reconstructs or reshapes structures of the face such as the nose, lips, and cheeks after an injury i.e., dog bites, skin cancer resection, or to change features present from birth. In 2021, a total of 1.4 million facial plastic surgery procedures were performed (Kugler & Reconstructiv, n.d.). In order to see the entire face and provide the best outcome, these surgeries are often performed under monitored anesthesia care (MAC), also known as conscious sedation, rather than general anesthesia. MAC allows for the patient to be partially sedated, making them unaware of their surroundings, while still breathing on their own. This prevents having to perform an endotracheal intubation, or placement of a breathing tube, to perform the surgery (Bitar et al., 2003; Taub et al., 2010). Using MAC is cheaper and faster than general anesthesia, and also avoids the risks associated with general anesthesia and endotracheal

intubation such as injury to teeth, lips and gums, bleeding, and aspiration of gastric contents

leading to pneumonia (Bitar et al., 2003; Jaisani et al., 2015; Taub et al., 2010). Because of these

reasons, MAC is the first choice for surgical anesthesia in 10-30% of all surgical procedures.

Under MAC, the patient's oxygen supply and end-tidal carbon dioxide still require monitoring,

and this is done via a nasal cannula. The nasal cannula obstructs the facial surgical field, making

some facial plastic surgeries harder to complete or sometimes impossible under MAC. MAC is

preferable to general anesthesia, when possible, because it leads to a quicker overall surgery

time, is cheaper to do compare to general anesthesia, and reduces the risk of complication that

comes with using less anesthetic drugs, especially in younger patients and patients with

significant comorbidities (Prathigudupu et al., 2018).

Currently, MAC is performed with a dual nasal cannula containing two channels: one

which delivers oxygen to the sedated patient and another which returns carbon dioxide for monitoring of ventilation by an anesthesiologist. A picture of a dual nasal cannula being used on a patient is shown in Figure 2. In the trauma setting, some patients have significant disruption of their nasal anatomy preventing the use of the standard nasal cannula to deliver oxygen. Usage of a nasal cannula may also dry the nasal mucosa, leading to epistaxis (nosebleed) (Diamond, 2014; Tabassom & Cho, 2022). During facial plastic

Figure 2: Picture of a dual nasal cannula being used on a patient ("Dual Nasal Cannula," n.d.).

surgery specifically, the use of a nasal cannula obstructs the surgical field, specifically the upper

lip, the nose and the cheeks. Thus, there is a need for a device to monitor oxygen and carbon

dioxide designed specifically for facial plastic surgery.

CURRENT UVA HOSPITAL WORKAROUND

The current solution used by the UVA Department of Otolaryngology – Head & Neck Surgery (OHNS) during cases under MAC is to place the nasal cannula in the mouth to maintain surgical access to the face. However, since patients are partially awake, they will frequently bite on the nasal cannula compressing the tubing or spit it out because of discomfort. Frequent repositioning of the cannula is often required during the operation to optimize oxygen flow and carbon dioxide detection. This interferes with surgical efficiency prolonging length of sedation, increasing the cost of the surgery (mean cost of operating room time is about $35 per minute), and risks contaminating the sterile surgical field leading to postoperative infections (Childers & Maggard-Gibbons, 2018).

The standard nasal cannula is not designed to be placed in the mouth. The tubing for the standard nasal cannula includes two thin, flexible prongs and tubing that trail over the chin or lower lip when placed into the mouth. Previously patented designs for transoral administration of oxygen and monitoring of carbon dioxide through the mouth include designs similar to an oropharyngeal airway (OPA). However, OPAs displace the resting local anatomy of the jawline and lips which complicates the surgery (Shantha & Wieden, 2021). Other designs are seated over the lips as opposed to being entirely intraoral, again obstructing access to the surgical field. Alternate device designs that succeeded in covering no part of the face were composed of small parts causing an unacceptable choking hazard for patients under any form of anesthesia (Diorio, 2008).

THE PROPOSED NEW SOLUTION

To resolve these issues, the objective of this project is to create a device that is an oral adaptor for the dual-channel nasal cannula allowing the cannula to be placed into the mouth. The main goals for the device will be to: 1) protect the prongs making them incompressible, 2) be comfortable for placement into the mouth decreasing a patient's desire to spit out the device, and 3) remain minimally obstructive or distortive to the soft tissues of the face. Adapting a dual-channel nasal cannula will be accomplished by designing an adaptor with two grooves on the lateral surface that follow the curve of the oral cavity. The tubing of the oxygen and carbon dioxide lines of a dual-channel nasal cannula will be placed inside these external grooves, preventing compression by the tongue. To accommodate this, a frontal flange will have two holes just large enough to accept the tubing of the nasal cannula. The adaptor will rest onto the surface of the tongue with the tongue gathered beneath the archway to prevent potential airway obstruction. The frontal flange will be curved to rest against the teeth behind the lips, giving complete access to the face.

Previous designs did not resolve the issue of obstruction, utilized small parts that were choking hazards, and were typically only compatible with single-channel nasal cannulas. Improving on these designs, the adaptor will minimize obstruction, make use of a single-part design to reduce the chance of a small piece detaching and obstructing the airway resulting in an emergency situation, and will be able to accept both single- and dual-channel nasal cannulas, improving applicability to a variety of user settings. Through its innovative design, this adaptor will enable a greater range of facial plastic surgeries to be performed under MAC. This increased use of MAC reduces the time patients spend under sedation, decreasing the likelihood of

associated complications that comes with using multiple medications and improve the efficiency of surgical centers, while reducing costs for both healthcare professionals and patients (*General Anesthesia and Monitored Anesthesia Care for Oral and Maxillofacial Surgery and Dental Services - Medical Clinical Policy Bulletins | Aetna*, n.d.). If the proposed design were to save even one minute of surgery time during MAC cases, this could potentially save $77 to $221 million per year.

The prototypes will be 3D printed out of Polylactic acid (PLA) material until a final design can be agreed upon. As this project has no research grant or funding, we are currently using the free 3D printers provided by the UVA libraries, but have plans to move to a higher performance printer when the design of the adaptor and a choice of what material to use are done. In order to get funding to move to a better printer and try different materials, we are applying to design competitions to win prize money. The project is made up of seven total members: three senior BME undergraduate students, Michael Epps (me), Kareem Hassan, and William Sande; a fourth-year student in the UVA School of Medicine, Andrew Zaninovich; two otolaryngology residents at UVA, Claudia Gutierrez and Rachel Jonas; and leading the project is Dr. Samuel Oyer, Associate Professor, Department of Otolaryngology- Head and Neck Surgery.

We hope to be able to design and produce a functional prototype. The UVA OHNS department has given confirmation that following UVA IRB approval, a study testing the efficacy of the adaptor could be conducted under facial plastic surgeon Dr. Samuel Oyer as the Principal Investigator of the study. If the study results are determined to be successful, the team would like to patent the design. In a technical report, we will explain our technical project and show the data behind the study conducted.

THE DIFFERENCE IN THE PERCEPTION OF DRUGS AND ANESTHESIA

Major medical procedures are events that can affect someone for the rest of their lives. Not only can the surgery itself be long and take hours, but the recovery time can last for days or weeks, and the quality of life of the patient will change for the better or worse afterwards. This makes surgery procedures a big decision to make, which can cause anxiety in patients. In recent years, anxiety has been a major reason for patients avoiding medical care. These anxieties can come from different sources, and the two most common in first world countries are cost or fear of complications. During the recent COVID-19 pandemic, Mark É. Czeisler found that about 41% of the population had reported to having delayed or avoided any medical care, with 12% avoiding emergency care and 32% avoiding routine care, and the primary reasoning being concerns about COVID-19 (Czeisler, 2020). While a pandemic can be seen as an extenuating circumstance, there are still other factors that can affect the anxiety of getting medical care. In a study done by Kyle T. Smith a few years before the COVID-19 pandemic, he found that 45% of the participants would delay or avoid medical care due to the cost, even though many of them were insured (Smith et al., 2018).

Fear of anesthesia is another major reason for medical care avoidance. This fear of the anesthesia can sometimes be greater than the fear of the actual surgery itself. In a study done by ME Ruhaiyem, it was found that the top three causes of their fears were the fear of postoperative pain, intraoperative awareness, and being sleepy postoperatively, with that representing about 77%, 74% and 70% respectively. Patients were found to be less fearful factors like needles in the operative theater, revealing personal issues under general anesthesia, and of not waking up after surgery, with those coming in at 48%, 55%, and 56% respectively (Ruhaiyem et al., 2016). The fear of dying from the anesthesia is tied to the severity of the surgery, with the fear of death

increasing as the severity increased (Burkle et al., 2014).   This is all despite of the fact that

morality caused by anesthesia has declined a significant amount in the last few decades. Dr

Daniel Bainbridge looked at studies that had more than 21.4 million anesthetic administrations

given to patients undergoing general anesthesia for surgery. From those studies, the morality

rate fell from 357 per million before the 1970s, to 52 per million in the 1970s and 80s, to 34 per

million in the 1990s and 2000s (Bainbridge et al., 2012). Understanding why there is still a fear

of anesthesia despite these improvements can help increase the amount of people who go get the

medical care they need.

  While the idea of anesthesia being used for surgeries can cause anxiety and fear, the

general perception of over-the-counter drugs in society is completely different. Prescription

drugs are used by a lot of people, with prescriptions for generic ibuprofen and naproxen

exceeding 500 million in 2003 and 2004. In a study done by C. Mel Wilcox, it was found that

54% of users were not aware of the potential side effects of these drugs, and that 18% of users

had previously experienced side effects but still continued to use them (Wilcox et al., n.d.).

Users of these drugs use them without worrying about the consequences that may come. There

are many possible factors that could lead to this, such as cost, speed, convenience (Blenkinsopp

& Bradley, 1996). Understanding why the perception in prescription and over-the-counter drugs

is so different from anesthesia could help researchers find ways to reduce the anxieties that

anesthesia brings.

IDENTIFYING THE FACTORS THAT CAUSE FEAR

In a scholarly article, a comparison will be made on the perception of over-the-counter drugs and the perception of anesthesia in surgery in order to find factors that may cause medical care avoidance. This will be done via the Actor Network Theory (ANT) framework, which was originally developed in the early 1980s by Michel Callon, Bruno Latour and John Law (Cresswell et al., 2010). An example of this network when applied to over-the-counter drugs can be seen in Figure 3 on page 11. ANT is a way of viewing technology in a network that is made up of human and non-human actants, and by finding the differences in the actants we can understand how the social view surrounding the technology differs. Over-the-counter drugs and anesthesia have a lot of the same actants in their networks, which helps with the comparison between the networks. Since networks are built by their actant elements, an understanding of an actant can lead to changes that affect the network. A network connection between actants is not always a positive relationship, which means that altering the way one actant is interacting can negatively or positively affect the entire network web.
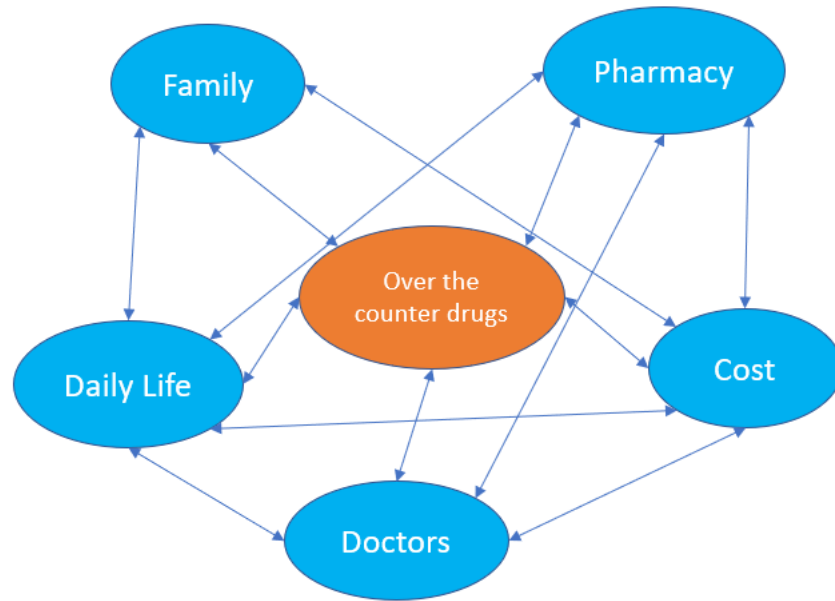
Figure 3: Over-the-counter drug ANT model. This figure shows various groups that affect the perception of over-the-counter drugs (Adapted by Michael (2022) from Cresswell, 2010).

The ANT framework has a lot of interconnecting parts, as such, it will be very important to ensure that each actant is correctly defined in how they interact. This will be accomplished by first using the Technology and Social Relations STS framework. This framework looks at how different groups that interact with the user of the technology can be positively or negatively affected, with the technology being either over-the-counter drugs or anesthesia during surgery. An example of what this framework looks like can be seen in Figure 4 on page 12. The Technology and Social Relations STS framework is similar to ANT, but there are no connections between the groups themselves, the relevant actants are only tied to the user. The factors that cause the differences in the perception of similar technologies can be found by looking at how the relationship with each group connected to the technology is changed when using it. Starting the analysis from a simpler STS framework will make it easier to understand each group and will

make the differences in the connections between groups easier to see when using to the more complex ANT framework.
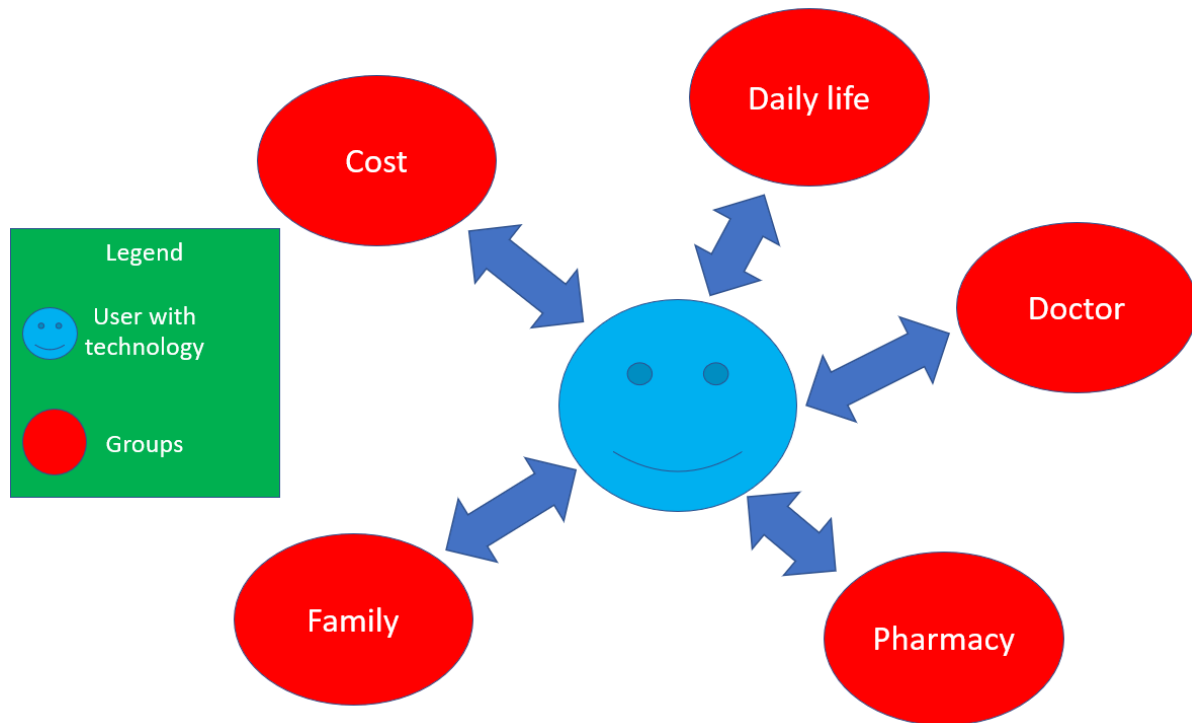

Figure 4: Technology and Social Relation model. This figure shows how the network will be organized to not have any connections between groups in order to correctly define how each group behaves (Adapted by Michael (2022) from Carlson, 2009)

The STS research project will be recorded in the form of a scholarly article that examines the perception of over-the-counter drugs when compared with the perception of anesthesia used during surgery. The anticipated outcome of the scholarly article is to identify the factors that cause the differences in the perception between the two situations. By identifying these factors, steps can then be taken to create a plan to change the way the networks interact, in order to make the perception of anesthesia more positive, which will result in less people being afraid and more people being more willing to get the surgeries they need.

IMPROVING ANESTHESIA CARE

Lowering the chance a person will practice medical avoidance will lead a healthier overall population, and making surgeries more appealing to patients is an important way to increase the likelihood that someone will go to receive the medical care they need. Solutions to medical avoidance can focus on the issue physically or mentally. By making an adaptor for the nasal cannula, facial plastic surgeries become easier for surgeons to perform, and increase the number of surgeries that can be performed under MAC instead of general anesthesia. Removing the need for general anesthesia not only lowers the cost and risks for the patient, but may also lower any anxieties that may arise from surgeons not using medical devices as they were intended. By looking at the perception of anesthesia compared to over-the-counter drugs, the factors that cause the differences in how society views them can be found to improve the view on anesthesia. With the technical report looking at physical methods to reduce medical avoidance, and the STS scholarly article looking at the mental factors that cause medical avoidance, the overall goal of this paper is to find ways to get people to be more willing to get surgeries done, leading to a healthier society.

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