REDESIGNING THE NASAL CANNULA FOR FACIAL PLASTICS SURGERY

MEDICAL MISTRUST AND DEVICE DESIGN

A Thesis Prospectus
In STS 4500
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Bachelor of Science in Biomedical Engineering

By
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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.

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Facial plastic surgery reconstructs or reshapes structures of the face such as the nose, lips, and cheeks after an injury e.g. dog bite, skin cancer resection, or to change features present from birth. In 2021, a total of 1.4 million facial plastic surgery procedures were performed ("2020 Plastic Surgery Statistics Report," 2020). 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 (Bitar et al., 2003; Taub et al., 2010). MAC allows for the patient to be 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. Using MAC 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). However, under MAC oxygen supply and end-tidal carbon dioxide monitoring is still required via a nasal cannula (Bitar et al., 2003; Taub et al., 2010). MAC is preferable to general anesthesia when possible because of reduced risk of complication, especially in younger patients and patients with significant comorbidities (Bitar et al., 2003; Prathigudupu et al., 2018; Taub et al., 2010). Despite this, in both surgical cases utilizing general anesthesia and MAC, patients experience significant preoperative anxiety (Celik & Edipoglu, 2018; Shafer et al., 1996). During facial plastic surgery specifically, the use of a nasal cannula obstructs the surgical field. Thus, there is a need for a device to monitor oxygen and carbon dioxide designed specifically for facial plastic surgery.

To address these needs, the technical project will design and prototype a plastic oropharyngeal airway (oral airway, OPA) to address this technical need and the tightly coupled STS research project will investigate and establish the relationship between patients, physicians, patient fear of anesthesia, and medical mistrust in the wake of the COVID-19 pandemic. This work will be completed during the Fall 2022 and Spring 2023 semesters over the course of 28 weeks.

DESIGN OF THE NASAL CANNULA-ADAPTING (MODIFIED) ORAL AIRWAY

In order to meet the technical specifications of this project, the standard OPA design will be modified such that it accepts the tubing of a dual-channel nasal cannula without reducing air flow through the tubing, is stable within the mouth to minimize patient discomfort and adjustments by the surgeon, minimally distorts or distends the soft tissues of the face which may be critical areas of interest during a surgery, is easily insertable, and must be comfortable enough for a semi-conscious patient to use for potentially multiple hours at a time.

As seen in Figure 1 below, various simple modifications can be done in order to

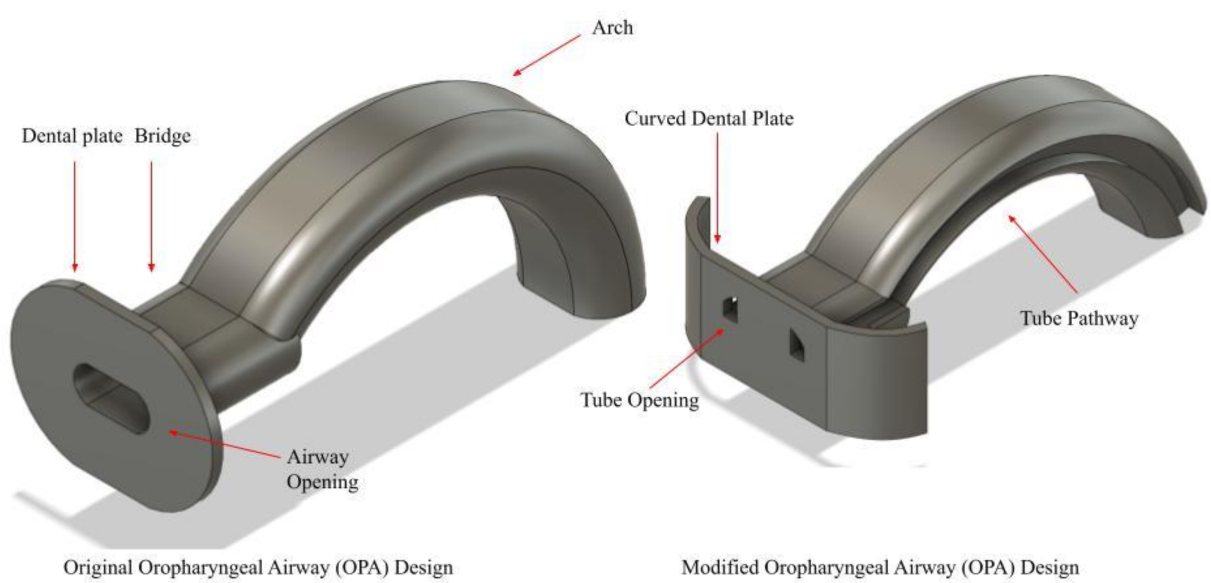

Figure 1: Comparison between the original and modified OPA. Representation of original OPA consisting of dental plate, bridge, airway opening, and arch and modified OPA consisting of curve dental plate, tube opening, and tube pathway. (Sande, 2022)

improve the design of the original OPA for use in facial plastic surgeries. First, the dental plate height will be reduced significantly. With the original OPA, the dental plate rests exterior to the lips. This is not feasible during a facial plastic surgery as it obstructs potential areas of interest to the plastic surgeon, therefore with the modified OPA the dental plate must rest interior to the lips, such that if the patient were to bite down, their teeth would rest just behind the dental plate, on top of the bridge. A curve to the dental plate will be added to rest against the curve of the teeth to provide greater stability. Additionally, the airway opening can be altered to the tube opening design to better accommodate the nasal cannula tubing. This change leads to the second major feature: the center of the arch no longer must be hollow, therefore the modified OPA will have a solid arch with two side channels to accommodate the nasal cannula tubing. This will guide the tubing to the rear of the mouth so that it cannot be blocked by any soft tissues within the mouth. The third change also relates to the arch as it can be shortened and thinned significantly. Typical OPAs are designed such that the arch is long enough to extend from the rear of the bridge to end within the patient's throat. This is important as OPAs may be used with general anesthesia where airway collapse is common (Eastwood et al., 2002; Hillman et al., 2003). Since the modified OPA will be used with MAC, the threat of airway collapse is eliminated as a patient is given a low enough dosage of sedative such that they maintain control of their airway (Bitar et al., 2003; Taub et al., 2010). Shortening the arch is beneficial as the gag reflex is less likely to be triggered with a shorter airway, improving patient comfort, and increasing the likelihood of successful insertion for the duration of the surgery.

When implemented, this device will make MAC a significantly more attractive option for use during facial plastic surgeries as the primary barrier regarding the placement and securing of the nasal cannula will have been alleviated. This is ideal as MAC maintains many benefits over general anesthesia, both from a medicinal perspective with shorter, smoother recovery periods and from a patient mental wellbeing perspective where it is associated with lower preoperative anxiety (Fung et al., 2005; Kindler et al., 2000; Taub et al., 2010). Given that 1.4 million facial plastic surgery procedures were performed in 2021 alone, this has the potential to be a low-cost, easy-to-use option which will significantly improve patient experiences ("2020 Plastic Surgery Statistics Report," 2020).

The development of the modified OPA will be completed over the course of the 2022-2023 academic year with the support and assistance of Samuel Oyer, an associate professor of facial plastic and reconstructive surgery in the Department of Otolaryngology - Head and Neck Surgery (OHNS) at the University of Virginia Medical School (UVAMS), Claudia Gutierrez, a resident physician in the OHNS at the UVAMS, with additional advice and support from Rachel Jonas, a resident physician in the OHNS at the UVAMS, and Andrew Zaninovich, a 4th-year medical student at the UVAMS. The technical team will consist of William Sande, Michael Epps, and Kareem Hassan, each of whom is a 4th-year undergraduate student studying biomedical engineering (BME) at the University of Virginia School of Engineering and Applied Science. During the aforementioned time period, this product will be designed using rapid prototyping techniques and an iterative design process where modifications will be made to 3D-printed prototypes modeled and modified in AutoDesk Fusion 360. The final product from this project will be a biosafe medical device capable of being used within an operating room to assist in facial plastics surgery. This project will be documented in a technical report.

THE RELATIONSHIP BETWEEN PATIENTS, PHYSICIANS, FEAR OF ANESTHESIA, AND MEDICAL MISTRUST POST-COVID-19

Patients rely on the medical system and medical professionals for potentially life-saving care and yet, particularly in ethnic minority groups, many Americans report high levels of medical mistrust (Thompson et al., 2021). Both medical mistrust and research into the topic have grown significantly in recent years, but common metrics between studies remain lacking, muddying the available data (Benkert et al., 2019; Williamson & Bigman, 2018). Medical mistrust can contribute to preoperative anxiety where a patient expects to receive anesthesia; fear of the unknown is seen as a primary contributing factor to this anxiety and fear of being harmed by a doctor during an operation is significantly less common in medical professionals as compared to patients (Kindler et al., 2000; Shafer et al., 1996). During the COVID-19 pandemic, despite rapid advances in life-saving measures such as the invention, adoption, and mass production of safe mRNA vaccines, less than 70% of the United States population has received the complete primary series of vaccinations, and less than 50% have received the first booster dose, representing a nationwide issue with medical mistrust (CDC, 2020).

Often, medical mistrust is primarily examined in ethnic minority communities where both historic and continuing forms of discrimination create rifts between community members and the medical professionals who wish to serve them. A common example is that of the Tuskegee Syphilis Study, where over a 40-year period beginning in 1932, the US Public Health Service subjected black men to experiments involving syphilis without their knowledge or consent, despite a treatment in the form of penicillin being readily available, simply to study the long-term effects of the disease on the body (Jaiswal & Halkitis, 2019). In addition to this, underutilization of health services is associated with increased medical mistrust (LaVeist et al., 2009). This creates a feedback loop where previous acts of discrimination by medical professionals and institutions contribute an initial feeling of mistrust from various communities resulting in those communities being less likely to make use of health services, contributing to underutilization, which in turn contributes to medical mistrust, widening the rift between medical professionals and patients.

Beyond historic acts of discrimination contributing to mistrust, modern medicine is faced with vaccine skepticism. This movement beginning in the early 2000s can attribute much of its growth to online communities spreading misinformation and propaganda regarding vaccines, treating complex medical topics as something that can simply be taught over the Internet by untrained laypeople (Hussain et al., 2018). In this instance, there was no precipitating event of concrete harm done by the medical community in regards to vaccines. The origin can instead be attributed to Andrew Wakefield, a medical professional who published a fraudulent study stating that he had found evidence showing that the MMR vaccine predisposed children to developing autism (Rao & Andrade, 2011). Vaccines were previously viewed as a lifesaving technology, something which led to the eradication of polio, and yet, the technology as it was viewed by the public changed rapidly because of Andrew Wakefield.

IDENTIFYING SOLUTIONS TO MEDICAL MISTRUST

As a result of these complications to the patient-medical professional relationship, many efforts have been made to identify a method by which medical mistrust can be overcome. As described by Jessica Jaiswal, a researcher at the Department of Health Science at the University of Alabama:

> Looking ahead, it is becoming increasingly clear that medical mistrust must be addressed at multiple levels of society, including government, policy, and health care systems, among others. Often framed as a direct consequence of slavery and the Tuskegee Syphilis Study, we must endeavor to broaden our understanding of medical mistrust, and shift our emphasis to its ongoing, rather than solely historical, nature. This requires a shift in perspective- rather than viewing medical mistrust as a cultural or population characteristic, medical mistrust is a phenomenon that can be meaningfully addressed by researchers and clinicians (Jaiswal & Halkitis, 2019, p. 83).

Jaiswal describes active participation on the part of clinicians and researchers but does not include engineers, the people who design medical devices. This is a critical gap in analysis as medical devices represent a large portion of unease people feel toward medicine. For example, potentially up to 30% of young adults and 50% of adolescents exhibit a phobia of needles, one of the most commonly used medical devices (McLenon & Rogers, 2019). In patients who are about to undergo surgery, some of the most common and greatest concerns are found with curiosity regarding the function and efficacy of the anesthetic, but the lack of knowledge contributes to a fear of the unknown and preoperative anxiety (Celik & Edipoglu, 2018; Kindler et al., 2000).

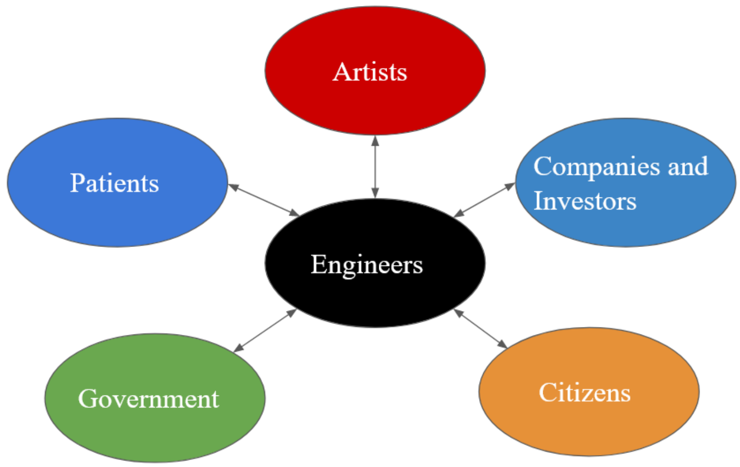

Figure 2: Medical mistrust SCOT model. The engineer represents a mediator between interest groups with multiple interests, which at times conflict, intending to produce the best possible outcomes for all parties involved (Sande, 2022)

As seen in Figure 2 above, this relationship the engineer has as a medical device designer is one where they attempt to balance the interests of multiple groups, who at times compete for the resources of the engineer. In the social construction of technology model, the engineer creates a technology which is shaped by the listed interest groups and, in turn, each of those interest groups exhibit interpretive flexibility upon the technology produced by the engineer where it becomes something different to each actor involved. For example, when the engineer produces a medical device, they may view it as a simple machine performing a function, but to a company or an investor, this device instead represents a business opportunity or potential profits, and because of this view, companies or investors may pressure an engineer to change the device to maximize what it represents to them. From the perspective of a patient, a medical device may represent something life saving or terrifying. This representation effectively changes what the device is to those who perceive it as such. Patients place a great degree of trust in both physicians and engineers and so medical devices become incredibly significant to them, either becoming something critical to their lifestyle or something of great fear, as is seen with the fear that patients often experience before a surgery where the unknown mechanisms of the method of anesthesia weigh on their mind, and contribute to their anxiety (Celik & Edipoglu, 2018). SCOT theory was developed by Bijker, Hughes, and Pinch in 1987 (Bijker et al., 1987).

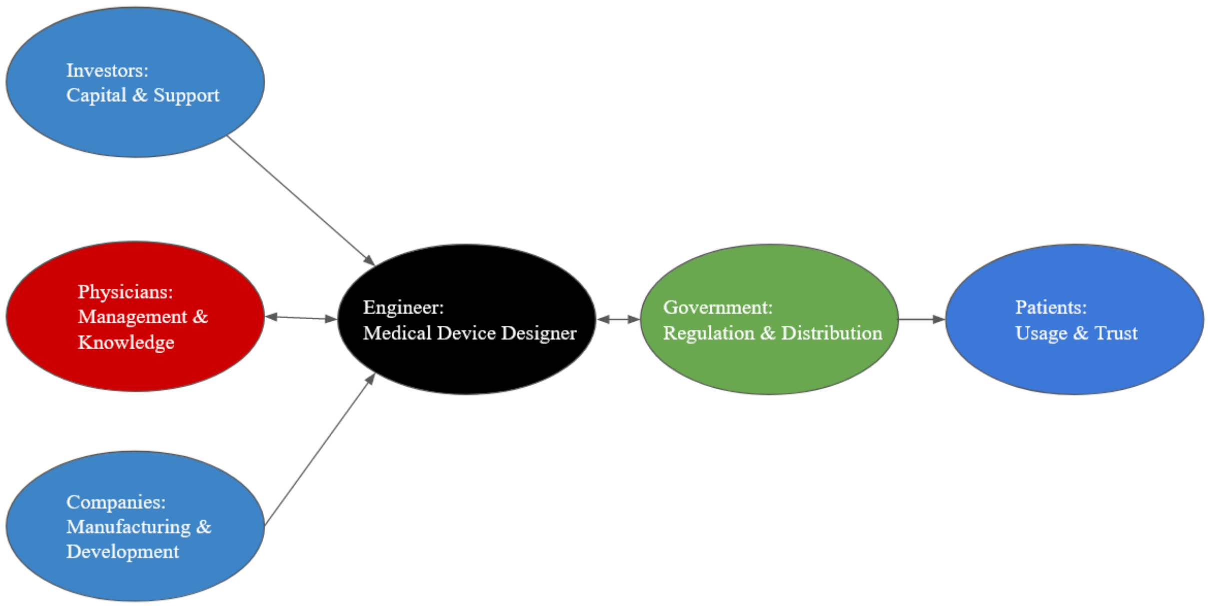

Figure 3: Alternative model for the current transfer of medical devices. Note the only two-way exchange is between engineers and physicians and between engineers and the government

Figure 3 shown above describes an alternate view of the current model for the transfer of medical devices. In this conception, the engineer is affected by many outside pressures but is only able to have an effective line of two-way communication with physicians who often work alongside engineers in the development of these medical devices and government agencies in the form of regulatory bodies who control whether or not a device can make it to market. Companies and investors often set demands to which an engineer must conform and patients are often unable to relay feedback directly to engineers. This is critical as patients are the most affected by medical devices yet are the least able to affect change regarding the design and production of these devices, contributing to a fear of the unknown and medical mistrust (Benkert et al., 2019; Celik & Edipoglu, 2018; Jaiswal & Halkitis, 2019; Kindler et al., 2000; Shafer et al., 1996).

Changes in medical device design specifically done to alleviate fear and reduce anxiety in patients currently have little available research. One example is altering the design of robots for usage in pediatric contexts and being particularly cognizant of the patient population encountered (Mott et al., 2021). One application of SCOT to medical mistrust and specifically needle phobia can be seen with the clinical application of cognitive behavioral therapy where a psychiatrist may begin to desensitize the patient to needles by having them look at images of needles. This represents a standard of care in specific forms of needle phobia (Jenkins, 2014). SCOT is utilized in this instance because the psychiatrist is exploiting the interpretive flexibility of an artifact to change how a patient perceives it and in doing so, changes the function and role of the artifact within the perspective of the patient, demonstrating a proof of concept for the ability to alter the individual perception of a device which previously caused fear via the interpretive flexibility inherent to the artifact.

This STS research project will be a scholarly article detailing the relationship between the introduction of medical devices to patients, historic medical mistrust, and preoperative anxiety. The paper will demonstrate how the alien nature of devices contribute to a continuing rift between patients and medical professionals. Through the SCOT analysis, the paper intends to demonstrate that changes in the form of medical devices can positively contribute to their adoption by patients in order to reduce preoperative anxiety by utilizing the interpretive flexibility of technology to establish a positive interpretation of these devices in patients' minds.

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