MAXILLO-MANDIBULAR DISTRACTION OSTEOGENESIS MEASUREMENT THE

RISING COST OF HEALTHCARE'S IMPACT ON AMERICAN AMBULANCES

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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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Many Americans view healthcare as a human right (Bailey, 2017, p.1). Quality healthcare can make an incredibly positive impact on an individual's life. Preventative medicine protects individuals from enduring the cost of illness, both financially and physically. However, not all disease-states can be prevented, especially those formed congenitally or by trauma. In the case of these disease states, such as any sort of medical emergency or birth defect, every American should have the ability to afford and receive quality medical treatment, without any hesitation due to the cost.

Congenital or trauma-induced deformities of the face, especially the mouth and jaw, are life-altering and can be life-threatening malformations (Navicent Health, 2019, p.1). Aside from visual aesthetics, the mouth and jaw serve as a passageway for airflow, food intake, and communication. Any alteration to their structure affects all three of these functions.

Maxillo-mandibular distraction osteogenesis (MDO) is a procedure that is used to treat and correct malformations of the face and jaw. The procedure involves breaking the malformed bones and slowly extending the fracture so that bone growth (osteogenesis) occurs, allowing the maxilla and mandible to properly reform. This procedure corrects the structure of these bones and their surrounding soft tissues, allowing them to reacclimate to their intended functions. Furthermore, this procedure typically makes the face more symmetrical and more aesthetically pleasing (AAOMS, 2013, p. 1). However, there is currently no way to measure how far the fracture has been extended in patients. This leads to imperfect asymmetry in the jaw, despite the initial malformity being corrected. If the jaw is not fully symmetrical, dental and respiratory issues can occur (Navicent Health, 2019, p. 1). In order to determine when to halt the fracture distraction, physicians require patients to come in for weekly x-rays and essentially 'eyeball' the x-rays. There is a need for a measurement device to determine how far the fracture has been distended so that physicians can ensure that both sides of the jaw will be as symmetrical as

possible.

The American healthcare system has become extremely business-oriented, with every procedure, device, and service coming with its own price tag. US healthcare expenses are rising, to the extreme where individuals have to prioritize their finances before their health (Bailey, 2017, p. 2). Typically this prioritizing of finances over care like preventative health leads to an increased need for emergency care. Americans have begun refusing ambulances and medical treatment while ill, due to the sheer cost of treatment. This business-minded ideology is actively harming the most vulnerable of Americans during the most vulnerable situations of their life.

In the 2020 fall semester American's use of emergency transportation services, ambulances, air ambulances, and paramedic services, has been researched via literature reviews. In spring 2021, the Charlottesville-Albemarle region ambulatory services will be investigated to determine the number of ambulances called versus the number of patients released from ambulance treatment and transport against medical advice. Understanding the full amount of potential patients for ambulance transports, patients treated and patients released, is essential in understanding the difference between the amount of patient's an ambulance is called for, and the number of patients who actually accept treatment. The relationship between ambulance costs and patient treatment volume is analyzed via the Social Construction of Technology (SCOT), with a focus on Technology and Social Relationships.

There is a clear need for an investigation in how rising insurance and healthcare costs affect American's usage of ambulances. There is also a clear need for the development of a device to determine the distraction length of a fracture in maxillo-mandibular distraction osteogenesis. While these topics seem unrelated, they both center around the need to improve current healthcare practices in the US.

Over the course of the fall 2020 semester, prototype designs for a distraction

measurement device have been developed and prior art and literature reviews have been performed. During the 2021 spring semester, a prototype design will be selected and research and development will continue.

MAXILLO-MANDIBULAR DISTRACTION OSTEOGENESIS MEASUREMENT

While MDO is an effective method to restructure jaw deformities, it lacks a way to be quantified. At present, there is no maxillomandibular distraction osteogenesis device in widespread use that measures and provides information on how far the fracture and the device itself have been extended. Obtaining this information is absolutely essential, as the manual extension of the distractor is performed at a patient's home without a surgeon present. A typical procedure consists of a surgeon creating the fracture while installing the distractor device, as shown in Figure 1, over the fraction and onto the bone. Each fracture plate will be installed on

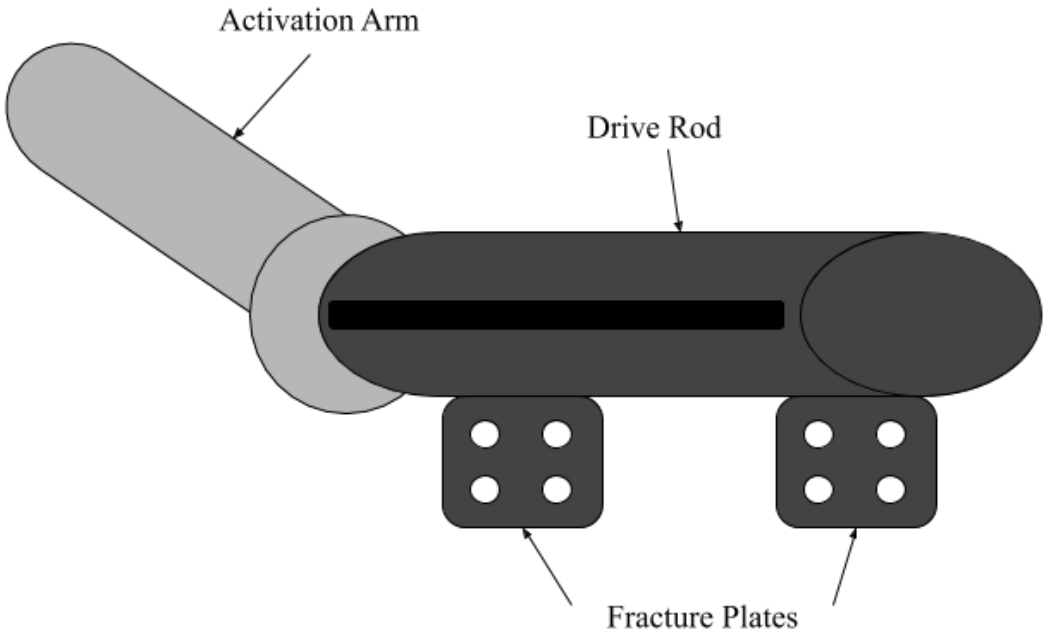

Figure 1: Distractor device. This figure visualizes the structure of the distractor device used in distraction osteogenesis. (Sarah Schroter, 2020).

opposite sides of the fracture and serve as the points where the device applies the extension

force. The patient will then be sent home and told to manually extend the distractor each day, by rotating the activation rod, for 2-3 weeks (AAOMS, 2013, p. 1). Once a week, the patient will go into their surgeon's office for x-rays to visualize the fracture and distractor device.

LACK OF MEASUREMENT INFORMATION

Currently, patients estimate how much they extend their distractor device with no understanding or sense of how far the device actually needs to be extended. Improper extension can lead to a delay in the procedure at best, and create a new bone malformation at worst (Master et al., 2010, p. 1565). Due to the unreliability of this extension method, patients must have x-rays taken every week to ensure proper bone growth and healing. According to Efunkoya et al. (2014), even with these x-ray images, doctors can only estimate how much osteogenesis has occurred ("Maxillomandibular distraction osteogenesis," p. 1788). By providing actual measurements of the bone extension, patients would not need to have x-rays taken every week and both patients and their physician would know how far the device and bone growth has been extended. Considering the fact that Master et al. (2010) found that there is an 11.4% incidence of nerve injury, an 8.8% incidence of an inappropriate distraction vector, and a 7.9% fusion error, there is plenty of room to improve the outcomes for patients ("Complications of mandibular distraction osteogenesis," pp. 1565-1566). The 8.8% incidence of having an inappropriate vector of bone growth alone is alarming. This issue would be diminished significantly by having physicians knowing how far extended the device was. This information would allow them to take corrective measures much earlier on in the process, creating less pain for the patient and an overall shorter recovery time.

SOLUTION OBJECTIVES

The specific aims of this measurement device include: creating reliable models and prototypes that are capable of quantifying the length of bone distraction via the incorporation of

a novel measurement device to the distraction process; validating the distraction elongation measurement via *in vitro* and cadaver models, utilizing calipers and ultrasound; and ensuring the durability of the device and its ability to withstand human physio-mechanical conditions for at least six months.

Should the proposed aims be achieved, the entire recovery process after the distractor device is placed in the patient will not be altered. The intent of the aims is not to change the function of the distractor device itself, as seen in Figure 1, but rather provide an output for the distractor device's extension via the separation between the two fracture plates. These aims would reduce in-patient time and the amount of radiation exposure for the patient. It also allows the patient to play more of an active role in their treatment by understanding how the device works when they use it due to the output of the extension measurement. In theory, it should also drastically increase the likelihood of a symmetric and successful outcome for the patient. Furthermore, it should allow physicians to determine if any soft tissue forces, such as the muscle forces from chewing and talking, have affected the bone growth vector.

The proposed approach to accomplish the objectives is to use a radio frequency identification (RFID) system to sense and communicate the distraction length. The base device will be left mechanically and functionally identical in order to retain its effectiveness in distracting the mandible, though an RFID-based system will be appended to the jaw distractor. By placing passive RFID tags to either anchor point of the jaw distraction set points, on the ramus and body of the mandible, it is possible to quantify change between the two initial points (Bouet & Dos Santos, 2008, pp. 2-3). Distance will be measured by quantifying the time delay between signals from two passive RFID tags located at the anchoring points of the jaw distractor and generating displacement by using the speed of the radio wave, and ultimately constructing a triangle between the two tags and the RFID reader. Like other RFID tags, the passive tags will

be powered by inductive coupling with the reader (Doug, 2020, p. 1).

In order to achieve the objective of this work, the design team personnel will have access to computer animated design (CAD) modeling software, the Stryker maxillo-mandibular distraction device, and the expertise of Dr. Jonathan Black. Depending on the COVID-19 pandemic the team may be granted access to the University of Virginia Hospital morgue, to perform cadaver trials, and the Stacy Hall laboratory, to perform 3D printing. The team personnel consist of Jillian Butler, Rayaan Faruqi, and Sarah Schroter (author), all fourth-year undergraduates studying biomedical engineering. Dr. Jonathan Black, M.D., of the University of Virginia's Medical School and Plastic and Maxillofacial Surgery, serves as the team's advisor. Upon completion of this work, the team will write a report, framed as a scholarly article, in the style of the New England Journal of Medicine.

THE RISING COST OF HEALTHCARE'S IMPACT ON AMERICAN AMBULANCES

Medical care costs, including health insurance, in the US continue to rise. "One-in-four Americans families" refuse preventative and emergency medical care due to the cost (Chin, 2017, p. 1). Many patients refuse to be treated by an ambulance and transported to the hospital out of fear of being burdened with debt for the foreseeable future (Chin, 2017, p. 2). This issue is compounded with the fact that the federal government "does not regulate ambulance fees for patients" (Bailey, 2017, p. 3). Without any federal regulation, ambulance patients are left to the mercy of the ambulance companies (O'Cathain et al., 2018, pp.1-2). If not a local volunteer group, these companies are typically for-profit, and are more concerned with their profit margins than overcharging the patient (Bailey, 2017, p. 1-10). The biggest concern with this issue is that physicians agree that patients needed to be transported by ambulance for the majority of ambulance transports (Jacob et al., 2008, p. 1).

The research question to be answered is: how does the increasing costs of healthcare and

health insurance affect the rate of ambulance transports in the US? This topic is significant, as it serves as an indicator of the overall wellbeing of the US (Meisel et al., 2011, pp. 1-2). If Americans cannot afford the cost of emergency care, it is highly unlikely they can afford the cost of day-to-day preventative care. Due to the current political climate, and given the fact that "health care has been a leading issue in the presidential campaign over the past year," it is likely that healthcare and insurance policies will be affected by the outcome of the election (Rovner, 2020, p. 2). As this research will be impacted by the course of the election, it's necessary to limit the scope of the investigation to policies put in place through February, 2021. The objective of this research is to determine if there is an indirect relationship between ambulance costs and the average number of patients who ride in ambulances annually. Another way to define this would be to determine the correlation between ambulance costs and the number of patient refusals for treatment. Essentially, the relationship between the number of people transported via ambulance and the price of an ambulance ride will be determined.

SOCIAL CONSTRUCTION OF AMBULANCE TRANSPORTS

A general (SCOT) approach will be taken (Bijker, Hughes, Pinch, 1987). This approach is useful due to the way it establishes and highlights all relevant social groups. While obviously, the patient is a relevant social group with regards to ambulances, there are a lot of other social groups involved including EMTs, paramedics, insurance agencies, and more as displayed in Figure 2, on page 8. It is important to determine all relevant stakeholders in this situation as it may shed light on why the relationship between ambulance costs and patient transport rates are the way that they are (Johnson, 2009, p. 1793). The Technology and Social Relationships model will be used to determine and define the relationships between all of these relevant social groups and the ambulance engineer (Baritaud & Carlson, 2020, p. 3). This model sets parameters on the research methodology, in that it focuses on how the end user, in this case the patient, uses the

ambulance technology to manage their relationship with their disease-state, finances, EMTs, bystanders, and insurance agency. It also focuses on how the patient uses the

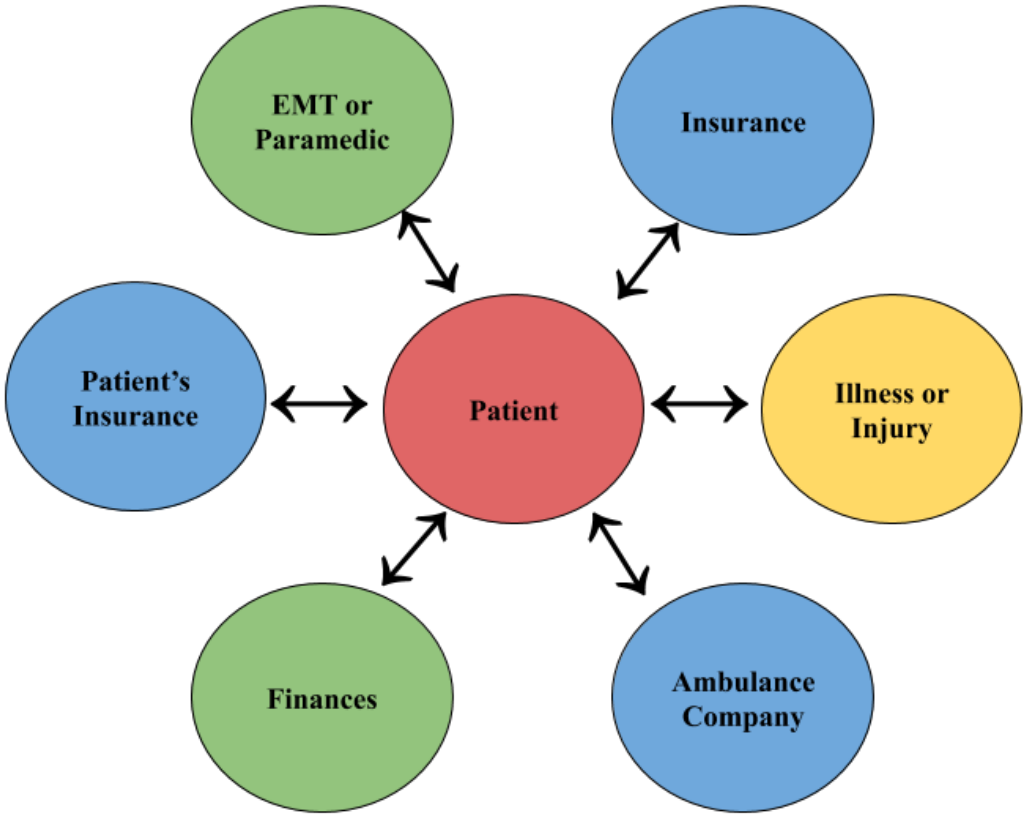

Figure 2: Technology and Social Relationship Model of an Ambulance's Patient. This figure shows the influence the technology and relevant social groups have on the end user, the patient. (Adapted by Sarah Schroter from Baritaud & Carlson, 2009, p.3).

emergency-response system to enhance their own experience. In this case 'enhance' refers to minimizing the cost of treatment or the amount of pain one is in. While the end user (the patient) may benefit from the ambulance treatment and transport, they may also incur the debt of the technological cost. So ultimately, although the patient may benefit from the technology, the emergency-response system benefits financially from the patient. Figure 2 is broken down into 4 categories based on color. The red color symbolizes the patient suffering an emergency, yellow symbolizing what the patient has no control over, the illness or injury, blue symbolizing the factors the patient would not know during the incident, and green as the factors that the patient

would, in theory, have knowledge of during the incident, assuming they're conscious.

When interacting with a patient, ambulance personnel, like EMTs and paramedics, are going to be looking out for the patient's best interest medically and will encourage the patient to receive medical treatment and be examined by hospital staff. Based on standard economics, the ambulance company that employs this personnel however is going to be looking to maximize their profits from the patient. The patient's insurance, however, is going to be looking to pay the smallest amount out to the ambulance company. Overall, insurance companies are focused on maintaining their own financial status and disregard the patient's. Ultimately this leaves the patient responsible for paying the difference between the ambulance company's cost and their insurance's coverage. According to Bailey (2017), this cost is known as "surprise billing" ("Ambulance trips can leave you with surprising — and very expensive — bills," p. 2). This forces the patient to have to weigh the cost of their illness or injury versus their personal finances when deciding to consent to ambulance treatment and transport.

An indirect relationship between ambulance costs and the number of patient transports is the anticipated outcome, simply based on the economic principle of supply and demand as shown in Figure 3 on page 10, with the green arrows indicating the rising costs of ambulances along with insurance and the red arrow indicating a decline in patients accepting ambulance assistance. The black arrows represent the cyclical nature of this relationship. If this is proven true, this makes an unfortunate statement about America's healthcare system, in that we treat an individual's health like a commodity that one may or may not be able to afford to purchase, instead of a god-given right. Of course, the hoped-for outcome is that there is no relationship between ambulance transport rates and the price of an ambulance ride, as this would indicate that Americans are not worried about any potential cost incurred and are solely focused on their wellbeing. This hoped-for outcome is far from the truth however, due to the negative impact

surprise billing has on patient's physical and mental wellbeing (Bailey, 2017, pp. 3-7).

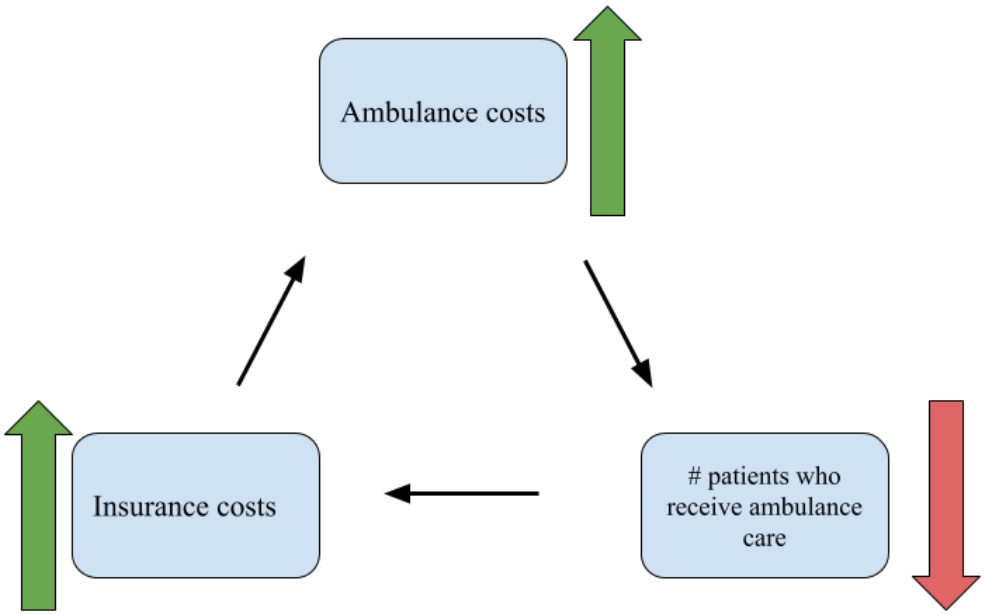

Figure 3: Price versus Quantity. This figure shows the expected indirect relationship between ambulance costs and patients treated and transported. (Sarah Schroter, 2020).

This research will culminate in a scholarly article that displays and analyzes the data found, as well as discusses the repercussions of that data. Ultimately, it will take into account the many factors that influence a patient's decision on whether or not to accept medical treatment via ambulance, including personal finances, their illness or injury, and their insurance provider.

WORKS CITED

AAOMS. (2013). *Clinical Paper*. 1–6. Retrieved from https://www.aaoms.org/docs/practice_resources/clinical_resources/distraction_osteogenesis.pdf

Bailey, M. (2017, November 20). Ambulance trips can leave you with surprising - and very expensive - bills. *The Washington Post*, 1–10.

Baritaud, C., & Carlson, B. (2020). *STS Frameworks* (p. 3).

(Navicent Health). (2019). *Bone Deformities*. Navicent Health. https://www.navicenthealth.org/oti/deformity-of-bone

Bijker, W., Hughes, T.P., Pinch, T.J. (1987). The social construction of technological systems. Cambridge, MA: MIT Press.

Bouet, M., & Dos Santos, A. L. (2008). RFID tags: positioning principles and localization techniques. *2008 1st IFIP Wireless Days, WD 2008*, 1–5. https://doi.org/10.1109/WD.2008.4812905

Chin, M. (Moneyish). (2017, June 7). 1 in 4 Americans refuse medical care because they can't afford it. *New York Post*, 1–2.

Doug. (2020). *Inductive coupling*. RFID Journal. https://www.rfidjournal.com/glossary/inductive-coupling

Efunkoya, A. A., Bamgbose, B. O., Adebola, R. A., Adeoye, J. B., & Akpasa, I. O. (2014). Maxillomandibular distraction osteogenesis. *Journal of Craniofacial Surgery*, *25*(5), 1787–1792. https://doi.org/10.1097/SCS.0000000000000907

Jacob, S. L., Jacoby, J., Heller, M., & Stoltzfus, J. (2008). Patient and physician perspectives on ambulance utilization. *Prehospital Emergency Care*, *12*(2), 176–181.

https://doi.org/10.1080/10903120701710058

Johnson, D. G. (2009). Social construction of technology. *Encyclopedia of Science, Technology, and Ethics*, 1791–1795.

Master, D. L., Hanson, P. R., & Gosain, A. K. (2010). Complications of mandibular distraction osteogenesis. *The Journal of Craniofacial Surgery*, *21*(5), 1565–1570. https://doi.org/10.1097/scs.0b013e3181ecc6e5

Meisel, Z. F., Pines, J. M., Polsky, D., Metlay, J. P., Neuman, M. D., & Branas, C. C. (2011). Variations in ambulance use in the United States: The role of health insurance. *Academic Emergency Medicine*, *18*(10), 1036–1044. https://doi.org/10.1111/j.1553-2712.2011.01163.x

O'Cathain, A., Jacques, R., Stone, T., & Turner, J. (2018). Why do ambulance services have different non-transport rates? A national cross sectional study. *PLoS ONE*, *13*(9), 1–20. https://doi.org/10.1371/journal.pone.0204508

Rovner, J. (KHN). (2020, January 29). No U.S. elections 2020: understanding what's at stake for health care. *Npr*, 1–19.