Prospectus

Quantifying Distractor Elongation in Maxillomandibular Distraction Osteogenesis
(Technical Topic)

Actor-Network Theory and the Roles of Caregivers and Doctors in Pediatric Mandibular Distraction Osteogenesis Patients
(STS Topic)

By

Jillian Butler

November 24, 2020

Technical Project Team Members: Rayaan Faruqi, Sarah Schroter

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.

Signed: ______________________________

Approved: ______________________________ Date ______________________

Ben Laugelli, Department of Engineering and Society

Approved: ______________________________ Date ______________________

Timothy Allen, Department of Biomedical Engineering

Sociotechnical Problem

Craniofacial anomalies are defined as deformities that affect a child's head and facial bones (*Craniofacial Anomalies | Boston Children's Hospital*, n.d.). These deformities occur in 2-3% of all babies, and 1 in 1600 newborns in the United States are born with a craniofacial anomaly, excluding cleft lip and palate (*Craniofacial Anomalies and Associated Birth Defects*, n.d.). Some abnormalities can occur in the mandible and cause severe problems if left untreated, such as micrognathia (undersized lower jaw) and retrognathia (malocclusion of the posterior mandible) (Brody-Camp & Winters, 2020). If there is concern about obstruction of the airway, most treatments consist of a procedure called distraction osteogenesis (DO). DO describes the growth of new bone through an osteotomy (intentional cutting or removal of bone) and the gradual separation of the two bony surfaces with a device called a distractor (Brody-Camp & Winters, 2020).

After the distractor is surgically placed, the device needs to be elongated in order for new bone to grow. Patients are typically too young to operate the distractor on their own, so parents or caregivers are responsible for turning the device to separate the bone. However, there is no way for parents to know how much they have turned the device, nor is there a way for doctors to know exactly how much the device has been elongated, even with weekly x-rays. In fact, there is an 8.8% incidence of an inappropriate distraction vector in mandibular DO patients, which could be attributed to improper elongation technique (Master et al., 2010; van Strijen et al., 2003). To address this technical deficiency within the distractor, we will install a technology that is coupled to the distractor in order to quantify its elongation.

As the project has progressed, it has become evident that there are various social actors that draw attention to the limitations posed by the technical project. The surgeons and caregivers of the patients are critical in the network established by the device, yet their roles and interactions can serve as potential adversaries to the success of the network. It is crucial that we understand these roles and relationships in order to prevent the failure of the distractor and therefore treatment of the patient's deformity.

To effectively allow for the quantification of distraction in pediatric mandibular DO patients, both technological and social factors must be considered. The following report will first outline the technical aspect of the project involving the implementation of the quantification device into the distractor. Then, the report will discuss the science, technology, and society (STS) framework of actor-network theory (ANT) along with Michael Callon's concept of translation to analyze the failure of a particular mandibular DO case to give insight into the maintenance and stability of the network.

Technical Problem

The use of DO in the craniofacial skeleton began in the 1990s, and its application has increased exponentially in the following years (Yu et al., 2004). In addition to craniofacial abnormalities, individuals may require DO if they show severe deficiency in either jaw or a narrow mandible that must be widened (*Distraction Osteogenesis*, 2017). DO can treat syndromic and nonsyndromic patients who present with craniofacial abnormalities, resulting in functional and/or cosmetic benefits.

The current approach to maxillomandibular DO includes a series of three phases after an osteotomy is performed and a distractor is placed. For placement, surgeons can use computer-aided design and computer aided manufacturing (CAD/CAM) to virtually plan surgical templates for distractor placement and progression. Specifically, CAD/CAM can be used to simulate operations and predict outcomes (Li et al., 2018). Immediately following the application of the distractor, the first phase is the latency period. This phase lasts anywhere from one to seven days and is followed by the activation phase, which involves activating the distractor (usually by parents/caregivers) by using a specialized screwdriver that turns the “activation arm” that is attached to the “activation rod”. Caregivers are usually advised to turn the screwdriver approximately one millimeter per day (usually in increments of 0.25 millimeters, four times per day). Once the activation phase is complete, the consolidation phase ensues. This phase is usually twice as long as the activation phase because the distractor remains in place for many weeks in order for the new primary bone to mineralize and mature (Yu et al., 2004). Doctors typically x-ray patients weekly to observe progression of the distraction and to modify or update treatment plans (Black, Jonathan, personal communication, September 28, 2020).

Throughout the period in which the distractor is implanted in the patient, there is no way for caregivers or physicians to quantify or verify how far the distractor has been lengthened. There have been cases of premature consolidation of distraction sites, which occurs when the new bone has hardened before the treatment has been completed (Chin & Toth, 1996; *Limb Lengthening*, n.d.). This phenomenon can be influenced by distraction rate, which caregivers cannot accurately know without a device that quantifies distractor elongation (Jauregui et al., 2016). This uncertainty makes it difficult for clinicians to verify patient-parent compliance, determine device efficiency, and compare CAD/CAM virtual surgeries against actual patient outcomes. In addition, having a device that can quantify bone lengthening can provide an additional diagnostic point that could be utilized to evaluate efficacy and deduce points of failure within the treatment plan. If this problem is not addressed, treatment of maxillomandibular deformities can be impeded and the time the device is implanted in the patient could be prolonged.

The goal of this project is to find the best design option, in terms of effectiveness and durability, to quantify distractor elongation in order to determine and verify patient-parent compliance and device efficiency. There are particular tasks the team will tackle: first, creating reliable models and prototypes for quantifying bone lengthening via attachment of a novel measurement device to the distractor; second, validating the precision and accuracy of the distractor elongation measurement *in vitro* and via cadaver models; third, validating measurement device durability and ensuring the ability to withstand human physio-mechanical conditions for the time the device remains implanted (around six months). We will test the first task by creating a wooden model of the jaw bone. Calipers and ultrasound will be utilized on the wooden model and on cadavers to quantify the success of the second task. Lastly, the device will be placed under normal and shear stress conditions to ensure the application of bodily forces does not impede device function. This analysis will dictate the best design option, which will be the most effective and durable for physicians, patients, and caregivers.

STS Problem

As pediatric orthopedic surgeons become more experienced with distraction procedures, the uses for mandibular DO have greatly expanded (Rhee & Buchman, 2003). However, as the application of mandibular DO broadens, it is imperative that we understand how to optimize caring for patients who undergo this procedure so that complications such as premature consolidation do not arise (Jauregui et al., 2016). One case of this complication was observed in a pediatric patient who underwent DO and consequently required additional surgery to mobilize the affected site and complete the distraction (Chin & Toth, 1996).

There are a multitude of factors that could be attributed to the failure of treatment for this patient, one of which is distraction rate, or the rate of elongation. When performing DO on a pediatric patient, especially in the craniofacial skeleton, special attention must be paid to the distraction rate. It has been found that increasing the rate of distraction can facilitate poor bone formation and severe soft tissue and nerve problems. Decreasing the rate of distraction can lead to premature consolidation (Natu et al., 2014). Currently, most caregivers are instructed to elongate the device one millimeter per day as that is the established optimal distraction rate. However, the majority of caregivers admit that they distract more rapidly than that (Hollier et al., 2006; Natu et al., 2014).

I argue that caregivers and surgeons can act as potential adversaries to the success of DO treatment due to a disconnect in their relationships with each other and a subsequent lack of knowledge and/or increase in stress about distractor elongation on the caregivers' ends. Parents reported feeling stress regarding lengthening the distractor, as there is significant effort required from parents to ensure proper care (Rhee & Buchman, 2003). Interestingly, the surgeons also recognized parental stress about proper distractor elongation, and even overestimated the stress relative to what parents actually reported (Zhang et al., 2018). This shows that there is a lack of confidence on both ends of the patient care team (doctor and caregiver) in regards to rate of distraction. By recognizing that the education of parents by surgeons and the overall execution of lengthening the distractor must go together, we can take the necessary measures to analyze this network to gain a greater understanding of the factors contributing to its vulnerability and failure.

In my analysis of the premature consolidation seen in a pediatric mandibular DO patient, I will utilize the STS concept of ANT to determine the roles and relationships between various human and non-human actors that contribute to the downfall of a network designed to accomplish a specific goal (Cressman, 2009). Furthermore, I will use Michael Callon's idea of translation, or the process that identifies actors and the potential for interactions between actors in order to form or maintain a network. To execute my analysis, I will utilize the treatment results obtained from the patient in the particular case mentioned above along with other data within the same and different studies to identify various actors in this network that make it vulnerable. Specifically, I will use data from a study that conducted a cross-sectional survey to evaluate parental and surgeon stressors and perceptions of DO in pediatric craniofacial patients (Zhang et al., 2018). This data will provide quantitative and qualitative insight into the factors contributing to the vulnerability of the network established by the device.

Conclusion

The technical report promises an addition to a distractor that allows both parents and physicians to accurately tell how far the distractor has been elongated. This will allow for improved patient-parent compliance, a better determination of device efficiency, and the ability to compare CAD/CAM virtual surgeries against actual patient outcomes. The STS report will analyze a case of premature consolidation to determine the relationships between various actors in the network created by the distractor device. Furthermore, Callon's concept of translation will be used to broaden our understanding of how the various interactions between critical groups such as parents and surgeons can lead to failure of the treatment plan for pediatric mandibular DO patients.

The device proposed in the technical paper will ultimately help to reduce the prevalence of complications caused by improper distraction rate in patients undergoing this procedure. The results of the STS report will provide insight in regards to identifying how and why the distractor network failed, and can help lead us to fix the social factors contributing to network failure.

Word Count: 1819

References

Black, Jonathan. (2020, September 28). Personal communication.

Brody-Camp, S., & Winters, R. (2020). Craniofacial distraction osteogenesis. In *StatPearls*. StatPearls Publishing. http://www.ncbi.nlm.nih.gov/books/NBK560915/

Chin, M., & Toth, B. A. (1996). Distraction osteogenesis in maxillofacial surgery using internal devices: Review of five cases. *Journal of Oral and Maxillofacial Surgery*, *54*(1), 45–53. https://doi.org/10.1016/S0278-2391(96)90303-1

Craniofacial anomalies | Boston Children's Hospital. (n.d.). Retrieved October 25, 2020, from https://www.childrenshospital.org/conditions-and-treatments/conditions/c/craniofacial-anomalies

Craniofacial anomalies and associated birth defects. (n.d.). World Health Organization. Retrieved October 29, 2020, from https://www.who.int/genomics/anomalies/en/Chapter02.pdf

Cressman, D. (2009). *A brief overview of actor-network theory: Punctualization, heterogeneous engineering & translation*. https://summit.sfu.ca/item/13593

Distraction osteogenesis. (2017). American Association of Oral and Maxillofacial Surgeons. https://www.aaoms.org/docs/practice_resources/clinical_resources/distraction_osteogenesis.pdf

Hollier, L. H. J., Higuera, S., Stal, S., & Taylor, T. D. (2006). Distraction rate and latency: Factors in the outcome of pediatric mandibular distraction. *Plastic and Reconstructive Surgery*, *117*(7), 2333–2336. https://doi.org/10.1097/01.prs.0000219354.16549.c9

Jauregui, J. J., Ventimiglia, A. V., Grieco, P. W., Frumberg, D. B., & Herzenberg, J. E. (2016). Regenerate bone stimulation following limb lengthening: A meta-analysis. *BMC*

Musculoskeletal Disorders, *17*. https://doi.org/10.1186/s12891-016-1259-5

Jenzer, A. C., & Schlam, M. (2020). Retrognathia. In *StatPearls*. StatPearls Publishing. http://www.ncbi.nlm.nih.gov/books/NBK538303/

Li, B., Sun, H., Zeng, F., Zhang, T., & Wang, X. (2018). Accuracy of a CAD/CAM surgical template for mandibular distraction: A preliminary study. *The British Journal of Oral & Maxillofacial Surgery*, *56*(9), 814–819. https://doi.org/10.1016/j.bjoms.2018.09.001

Limb lengthening: The process. (n.d.). International Center for Limb Lengthening. Retrieved October 12, 2020, from https://www.limblength.org/treatments/limb-lengthening-the-process/

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

Natu, S. S., Ali, I., Alam, S., Giri, K. Y., Agarwal, A., & Kulkarni, V. A. (2014). The biology of distraction osteogenesis for correction of mandibular and craniomaxillofacial defects: A review. *Dental Research Journal*, *11*(1), 16–26.

Rhee, S., & Buchman, S. (2003). Pediatric mandibular distraction osteogenesis: The present and the future. *The Journal of Craniofacial Surgery*, *14*, 803–808. https://doi.org/10.1097/00001665-200309000-00040

van Strijen, P. J., Breuning, K. H., Becking, A. G., Perdijk, F. B. T., & Tuinzing, D. B. (2003). Complications in bilateral mandibular distraction osteogenesis using internal devices. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology*, *96*(4), 392–397. https://doi.org/10.1016/S1079-2104(03)00472-4

Yu, J. C., Fearon, J., Havlik, R. J., Buchman, S. R., & Polley, J. W. (2004). distraction osteogenesis of the craniofacial skeleton. *Plastic and Reconstructive Surgery*, *114*(1), 1e. https://doi.org/10.1097/01.PRS.0000128965.52013.95

Zhang, R. S., Lin, L. O., Hoppe, I. C., Wes, A. M., Swanson, J. W., Bartlett, S. P., & Taylor, J. A. (2018). Evaluation of parental and surgeon stressors and perceptions of distraction osteogenesis in pediatric craniofacial patients: A cross-sectional survey study. *Child's Nervous System*, *34*(9), 1735–1743. https://doi.org/10.1007/s00381-018-3827-5