Development of a Distraction Elongation Measurement Device for Use in Surgical Jaw Distraction
(Technical Paper)

Precision Medicine and Machine Learning: Considerations Regarding Social Factors in Designing an Algorithm
(STS Paper)

A Thesis Prospectus Submitted to the

Faculty of the School of Engineering and Applied Science
University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements of the Degree
Bachelor of Science, School of Engineering

Rayaan Faruqi
Fall, 2020

Technical Project Team Members
Jillian Butler
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

Introduction

Facial recognition software more frequently inaccurately classifies people of color, misidentifying black people at a rate five to ten times higher than white people (“The Best Algorithms Still Struggle to Recognize Black Faces,” n.d.). Algorithmic bias is not limited to just facial recognition, however. An algorithm for selecting who is able to receive access to care management programs and extra healthcare services was found to routinely give preferential access to white Americans ahead of sicker black Americans, who needed the services more (“Finding Bias in Health Care AI Wins STAT Madness ‘Editors’ Pick’,” 2020). It is not that these algorithms were designed to be racist, but that in fact they had not been given sufficiently diverse datasets for learning. As machine learning and artificial intelligence (ML & AI) become healthcare tools, surgery and medicine must take into account more than just the clinical factors; despite the established dogmas of the medical field, it is also important to consider racial, societal, and socioeconomic factors in how a patient’s treatment plan will work for them. Many of today’s machine learning algorithms have been developed with the current *modus operandi* of medicine in mind, but a paradigm shift is being born within the intersection of machine learning and artificial intelligence in medicine. These algorithms designed without race, socioeconomic status, and other social factors can become prey to discriminatory modes of learning and processing. This is the problem that the proposed STS research paper seeks to address.

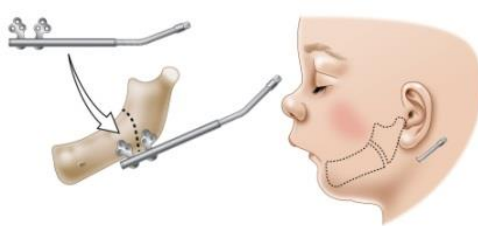
The proposed technical project involves developing a surgical device for use in pediatric mandibular jaw distraction. The research team, consisting of myself, Sarah Schroter, and Jillian Butler, will observe what factors are considered in surgery and medicine for treatment plans, as well as what factors are considered in design of a surgical device. In applying these considerations to the field of machine learning, it may be possible to arrive upon a set of factors that may be missing from traditional and even currently developing machine learning

algorithms for use in the clinical or medical device development setting. By considering these factors in the training, validation, and testing sets, the goal is to improve upon and even invoke a paradigm shift in the way that medicine is currently conducted. Over time, these considerations may help ensure that the intersection of ML and medicine is used equitably and effectively for as many people as possible.

Development of a Distraction Elongation Measurement Device for Use in Surgical Jaw Distraction

Micrognathia is a maxillomandibular deformity that appears in approximately 1 in 1500 births (*The Fetal Medicine Foundation*, n.d.). This condition occurs when the lower jaw is recessed and underdeveloped, a problem that degrades patient quality of life in a myriad of ways. A recessed jaw (micrognathia) can lead to problems such as sleep apnea, an obstructed airway, psychological toll due to cosmetic defect of the face, and more. Surgeons treat the recessed jaw by breaking the jaw bone in two and using a device called a jaw distractor to gradually separate the pieces, allowing for osteogenesis (the growth of new bone) to occur, as seen in **Figure 1** (Rachmiel & Shilo, 2015).

Figure 1



Jaw Distractor for Pediatric Use

Note: Jaw distractor for a child. Dotted line represents where the break in bone occurs. *Illustration created by Melbourne Royal Children's Hospital* (*Kids Health Information : Jaw Distraction Surgery (Mandibular Distraction)*, n.d.)

This is a months-long process that involves weekly X-rays and parents extending the distractor device from home with the use of a screwdriver rotating an internal activation rod within the device. The weekly scans provide clinicians with a qualitative sense of growth, evaluate treatment efficacy, and somewhat verify patient-parent compliance with the treatment plan. An issue that belies the treatment process is the inability to conveniently measure precisely how much the device has extended, and therefore how much longer the bone has become i.e. the *distraction length*. This standard treatment plan is not only expensive, but it fails to give parents and patients a real-time, quantitative indication as to how compliant they are with the doctor's orders. For these reasons, the research team is working on the development of a screwdriver-gyrometer combination that allows for the measurement of distraction length from within the home and without need for clinical specialists or excessively large and expensive machinery.

An initial stage of research is required to narrow the scope of the device design and solidify the mechanisms through which the device will work. After determining an exact mechanism for the device, CAD models of device iterations will be created in order to evaluate component synergy, material costs, and to visualize the form of the device as it is being prototyped. After this stage, the device will be given physical form and used with a wooden model of the distractor device in order to validate device design and evaluate measurements for accuracy and precision. Later stages of testing will utilize cadaver models to verify the efficacy of the final iterations of the device. The device and data that is collected through testing will be developed in cooperation with Dr. Jonathan Black at the UVA department of Plastic Surgery.

<u>Precision Medicine and the Machine Learning: Considerations Regarding Social Factors in Designing an Algorithm</u>

What are Machine Learning and Artificial Intelligence?

Machine learning (ML) and artificial intelligence (AI) have historically been relegated to the realm of science fiction, popularized by television programs, video games, and other media. Though ML and AI are currently unable to fully imitate a human being, the technology is advancing at an incredible rate. Machine learning algorithms, broadly speaking, use three types of learning: supervised, unsupervised, and reinforcement (Khan, 2020). In spite of their differences, all machine learning algorithms may be described as fundamentally using datasets to build a mathematical relationship between those datasets. These algorithms can produce powerful equations with vast numbers of factors in consideration, giving whoever is using them unique insight into nearly any situation. Artificial intelligence can be considered an evolution of machine learning; AI is effectively the use of a combination of machine learning techniques to produce an immensely complex algorithm that is able to make human-like decisions, evaluations, and predictions. ML and AI technology have the potential to vastly improve complicated fields such as medicine. Before the technology is applied freely, however, engineers and innovators must navigate issues that machine learning can exacerbate or create.

Potential Problems with Machine Learning

Though ML and AI can revolutionize the field of medicine, it is important to consider the role of clinicians and engineers in guiding the evolution of the technology and ensuring that it is able to reach all people fairly and equitably. As these models become more complex, a potential consequence is that the algorithm becomes so difficult to decipher that we no longer know *how* results are being computed. Trying to understand the model would in essence be attempting to decipher a black-box. This inability to validate and understand an algorithm has dangerous implications; what if a medical AI carries an unseen bias that causes it to perform worse for minority patients? What if an insurance algorithm disproportionately discriminates based on protected factors such as race, ethnicity, gender, or sexual orientation?

Machine learning algorithms have already demonstrated the ability to convey biases. For example, software designed to alert Nikon camera users of blinking subjects tends to "interpret Asians as always blinking" (Zou & Schiebinger, 2018). Commercial facial recognition systems misclassified gender at a rate of 0.8% for lighter-skinned men versus 35% for darker-skinned women (Buolamwini & Gebru, 2018). It is unlikely that the programs are specifically designed to be racist, but instead were given homogenous datasets that failed to train the models to classify and calculate output equitably. An undecipherable algorithm that also carries inherent biases is a disastrous prospect for medical and surgical fields. The question that must be answered then is this: how should machine learning and medicine's mutual growth and enmeshment be directed in order to ensure equitable, fair, and effective treatment for all demographics?

Applying Frameworks: Paradigm Shift and Co-Production in Precision Medicine

Thomas Kuhn's paradigm shift and Sheila Jasanoff's co-production theories will be used to explore and inform the question of how to ensure equitable development of precision medicine, a new paradigm within medicine, with machine learning. Kuhn defines the paradigm shift as a fundamental change from the status quo to a new mode of thinking entirely, analogous to how the view of the helium atom changes based upon considering it from a physical or chemical perspective (Kuhn, 1970). Jasanoff essentially describes co-production as a system in which two variables affect one another simultaneously, and in doing so define and build the system together (Jasanoff, 2004). Both Kuhn’s and Jasanoff’s frameworks have received some criticism.

Criticisms of Kuhn’s paradigm shift included suggestions that his conception of normal science is inherently false, that Kuhn fails to acknowledge and address the frequency with which revisions in “normal science” occur, and that his thesis of incommensurability between paradigms is vastly oversimplified (Dolby, 1971; Kordig, 1973; Toulmin, 1973). Jasanoff’s work has, to a lesser extent, also received criticism, mostly with regards to the vague parameters with which coproductionism is defined (Filipe et al., 2017; Fukushima, 2013). With these critical considerations in mind, the report will first apply the paradigm shift framework and secondly apply the co-production framework.

Kuhn’s framework will be applied to determine whether or not a paradigm shift is indeed happening within the medical field. The primary paradigm shift to examine is that of the shift from typical modes of medical practice to those of precision medicine, a paradigm in which patient-specific genomic and social factors are used to refine and individualize treatment for maximum efficacy, especially using machine learning techniques. In other words, precision medicine is the refinement of treatments to take into consideration more individual factors about the patient in order to construct the best treatment plan and prognoses possible (HealthITSecurity, 2018; *What Is the Difference between Precision Medicine and Personalized Medicine?*, n.d.).

Applying the co-production framework will specifically examine how machine learning and medicine are *currently* co-producing one another, and how future developments might be guided in order to co-produce a medical paradigm that offers fairness and equality to as many populations as possible. This application will also involve examining current machine learning methods, focusing on training and validation datasets that they generally use, and the use or non-use of social and racial parameters in modeling.

These frameworks will be utilized in concert with various STS research methods, as detailed in the following section.

Research Question and Methods

The question the report will attempt to address is: how should machine learning and medicine's mutual growth and enmeshment be directed in order to ensure equitable, fair, and effective treatment for all demographics?

Addressing this question will involve using the paradigm shift and coproduction frameworks, as mentioned above, and utilizing STS research methods, specifically discourse analysis, historical case studies, and interviews. Discourse analysis will involve exploring literature that deals with the problem of inclusion or disinclusion of social factors in algorithmic parameters, how machine learning is currently being implemented in medicine and other fields, and what direction ML/AI may take within medicine. For all discourse analysis, information will be organized according to which framework elements they explore and can broadly be divided into two sets: literature that deals with the present and future potential of ML, and literature about the ethical concerns.

The first set of papers examine machine learning's suitability for mathematically analyzing enormously complex relationships, and explore the potential use of ML and AI in driving a paradigm shift, performing surgery, analyzing patient health records, generating treatment plans, predicting prognoses for patients, and more (Adkins, 2017, p. 20; Bihorac et al., 2019; Ho et al., 2020; Khan, 2020). The second set of papers, which deals with ethical concerns behind ML, employ a series of ethical analyses to examine how a paradigm shift can be safely coproduced by ML and medicine. The papers specifically explore the use of ML and AI in medicine, discussing questions one must employ in evaluating machine learning algorithms, outlining important considerations on structural racism, and more (Basu et al., 2020; Binns, 2018; Robinson et al., 2020; Vollmer et al., 2018). In examining these papers and papers like them, the analysis will assess their common elements and differences in order to determine if and how a paradigm shift is occurring. These papers also explore problems in how machine learning is being integrated within medicine and other fields, and in some cases offer solutions or guideposts for equitable use. Both sets of papers will be used to determine what individual and global factors of patient-care must be closely monitored for equitable medicine.

Apart from the above discourse analysis, I will employ historical case studies and conduct three interviews. The historical case studies component will be used to delve into the intersection between ML/AI and social factors, and explore where certain factors were or were not included in computation. By analyzing the outcome of those scenarios, the report will elucidate how and why some social factors should be included or disincluded as parameters in a machine learning algorithm. These papers will be organized according to perceived impact of the outcome in those cases, perhaps corresponding to the inclusion/disinclusion of various social factors. For both the discourse and historical analysis, keywords for search include but are not limited to: ML, AI, machine learning, artificial intelligence, racism, bias, discrimination, adverse outcomes, algorithmic, etc.

The three interviews will be conducted with Dr. Yanjun Qi, Alexander Singh, and Rohit Rustagi. Dr. Qi is a machine learning professor at the University of Virginia with an interest in medical applications. Alexander Singh and Rohit Rustagi are the CEO and COO of a spinal technology company, respectively, and are familiar with the intersection of machine learning and medicine. Questions for the interviewees will involve what they believe regarding the potential impact of machine learning in the medical field, what may be important best practices in machine learning, and more.

Using these methods and resources, my report will ultimately attempt to create a set of guidelines and good practices for machine learning algorithms specifically for the use of ML/AI models within surgery and precision medicine.

Conclusion

The technical component of this portfolio will yield a device that is able to measure osteogenic elongation with a jaw distractor. The STS component will yield an analysis of the intersection between machine learning and medicine, hopefully providing a basis for guidelines and good practices when designing algorithms for medical use. With both the insights from creating a novel jaw distractor measurement system and insights derived from applying paradigm shift and co-production theory to the use of machine learning in medicine, it may be possible to deduce factors of treatment that escape typical design of medical tools and treatment plans. In discovering these factors and including them in the datasets that machine learning and artificial intelligence algorithms use to learn, medicine can move towards a more precision based mode of operation while being both fair and equitable.

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