Turning to Artificial Intelligence as a Diagnostic Device in Orthopedic Medicine

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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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Diagnostics in Orthopedic Medicine

Acute lateral ankle sprains are the most common injuries in both athletes and the general population. Around two million occur each year and they account for two billion dollars in healthcare spending (Waterman et al., 2010). Patients who suffer ankle sprains are likely to suffer from long term effects and may develop other conditions such as chronic ankle instability, a condition that limits their activities and causes pain. (Hunt & Griffith, 2020; Knupp et al., 2015; Ramírez, 2021). Ankle injuries, like many other injuries, can be treated with non-operative methods such as physical therapy and simply rest (McCriskin et al., 2015). However, in more severe cases when non-operative treatments fail, surgery can be done to repair the ankle (Hunt & Griffith, 2020). However, even with the billions of dollars spent on ankle injuries each year and the hundreds of thousands of lives affected by long term ankle instability, there is still a lack of a way to objectively assess the extent of instability and injury in order to provide each patient with the best course of treatment. The existing diagnostic stress tests, which assess the laxity of various ligaments in the ankle, lack robust reliability and validity because they are qualitative and depend on a physician's experience and subjectivity (Beynon et al., 2022).

The lack of objective testing is not limited to chronic ankle instability. It is estimated that the United States spends 600 billion to more than 1.9 trillion dollars on wasteful medical care spending (Speer et al., 2020). Furthermore, as many as 30% of surgeries performed in the United States are performed unnecessarily (Leape, 1989). Better diagnostic methods that rely less on a physician's expertise and subjectivity could reduce the wasted healthcare spending and prevent unnecessary surgeries.

The need for subjective decision making in orthopedic diagnoses is not for a lack of data and research. Numerous studies have been done to understand the different aspects that affect ankle instability including the initial tissue damage, the pain and impairments perceived and experienced by the patient, personal factors including demographics, and environmental factors (Hertel & Corbett, 2019). These studies have provided immense amounts of data, but systematic reviews, such as Guerra-Pinto et al., 2021, show a lack of reliability and consistency between studies. However, ankle pathologies, and many other orthopedic conditions, often have numerous possible causes, and other symptoms and factors such as patient weight and injury history can affect their ability to recover with or without surgery (Hertel & Corbett, 2019). Therefore, there is a need to understand the interactions between these factors and an efficient way to personalize a patient's treatment plan based on their specific condition and factors, in order to decrease treatment time, spending, and pain. Artificial intelligence is a technology that can combine vast amounts of data with patient specific factors to produce personalized treatment recommendations. This paper will examine the potential for artificial intelligence to become adopted in orthopedic medicine as a diagnostic device.

Artificial Intelligence as a Tool

The use of artificial intelligence (AI) is rapidly growing in our society across many domains, including the field of medicine. AI is the application of a complex computer algorithm to generate a useful output, with the goal of performing specific tasks at a level that matches or exceeds human performance (Lisacek-Kiosoglous et al., 2023; Myers et al., 2020). Applying AI to medicine can be used to quickly categorize and make sense of large amounts of data that can

improve patient diagnoses, treatments, and could cut annual US healthcare costs by $150 billion (Kalis et al., 2018; Lisacek-Kiosoglous et al., 2023). The increasingly large processing powers of AI give it the potential to transform health care by providing new and important insights from the vast amount of data acquired every day (FDA, 2023b).

There are many subfields under the umbrella of AI that are important to understand in order to fully see the potential of AI in medicine. Machine learning (ML) is the ability of an algorithm to learn and adapt to input data. In the context of healthcare, the computer is fed thousands of images with known outcomes, and it groups them together to detect patterns using an algorithm. Once the training process is complete the computer can provide the outcome based on the input data. Deep learning is a more comprehensive subset of ML, in which the algorithm uses artificial neural networks, similar to the networks in our brain. Like ML, human supervision is required for learning and modification, but deep learning algorithms can have a hundred fold or more degrees and layers of complexity to broaden its function. Deep learning and ML algorithms have been shown to be up to 98% accurate at fracture recognition, as well as high accuracy and specificity in other diagnostic image recognition capacities. The final subfield important to AI is natural language processing (NLP), which is the ability of the computer to comprehend human language. NLP algorithms could scan clinical medical records and make sense of physicians notes with incredible speed, then be able to sort and find patterns in the data from these records to aid diagnosis (Lisacek-Kiosoglous et al., 2023).

AI is already being applied to orthopedic medicine. Notable applications include identifying fractures from radiographic images, detecting scoliosis, robotic-assisted surgery, and detection of soft tissue abnormalities (Lisacek-Kiosoglous et al., 2023; Myers et al., 2020). In the case of chronic ankle instability, AI could be used to find patterns using ML/DL and NLP to find

patterns amongst existing research. It could use that data to process a patient's electronic medical records and determine whether a patient should or will need surgery, reducing unnecessary surgeries and decreasing time and money spent on treating the condition.

In the United States, the Federal Drug Administration oversees medical device regulation to ensure safety and effectiveness. Traditionally, medical devices are reviewed by the FDA through three main pathways: premarket clearance, De Novo, or premarket approval. In the 510(k) premarket clearance pathway, the device is deemed to be substantially equivalent, and thus as safe and effective, to an existing device. This is the most common pathway used for low to moderate risk medical devices (CDRH, 2023). AI software that is used to help inform diagnostic and treatment decisions falls under the category of Software as a Medical Device (SaMD), which is regulated under the same pathways as physical medical devices (IMDRF, 2014).

The existing infrastructure of the medical world exists in part to balance the many important values. Stakeholders in medical devices include, but are not limited to, healthcare practitioners, patients, professional and advocacy groups, government officials, risk managers, clinical engineers, maintenance personnel, trainers, and supervisors. The diversity in this stakeholder group goes to show how it can be difficult to satisfy the needs and values of each member of the group, thus posing barriers to novel technologies (Coulentianos et al., 2022). Additionally, there is a vital importance of a correct diagnosis, with diagnostic errors contributing to approximately 10% of patient death and 6 to 17% of adverse hospital events (Medicine et al., 2015). Patients go to doctors with the expectation of being treated properly, and it can be deadly when a mistake is made. Finally, there is a set of standards in place, the Health Insurance Portability and Accountability Act (HIPAA), which aim "that individuals' health

information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being" (Office for Civil Rights, 2008). While HIPAA rules don't specifically apply to medical devices, devices that transmit, receive or record health information must be HIPAA compliant (Mullin, 2019).

Infrastructure and the Adoption of Medical Technologies

Every year, nearly 3000 new medical devices are approved by the FDA, however most of these don't become widely adopted in healthcare (Dubin et al., 2021). Varabyova, et al. (2017) found in a review that the three key forces at play in determining when to adopt new innovations are organization, individualistic, and innovation-related characteristics. Groups involved in the adoption of medical technologies include doctors, patients, physical therapists, insurers, and healthcare administrators. For doctors, factors such as how accurate they believe the device is, whether it is as good as or better than other methods, efficiency, and ease of use may affect their decision to adopt the technology (Danesi et al., 2020). Healthcare providers may initially be wary of new devices because they are accustomed to doing things a certain way and have a duty to cause no harm to their patients. Additionally, current concerns over the application of AI to medicine include protecting patients' privacy, AI biasing, adversarial attacks, and the accuracy and reliability of such algorithms. Improving diagnostic technologies is essential to ensuring patients receive the proper care, however there are many processes, people, and institutions involved in the adoption of new medical technologies.

Using the properties of *infrastructure* as defined in Star's (1999) article *The Ethnography of Infrastructure*, we can explore the connection between technology and humans (Star, 1999). Star's framework describes the underlying concepts inherent in system design creation and how technological developments demonstrate these concepts (Star, 1999). One facet of infrastructure that can be applied to the introduction of new technology is *links with conventions of practice*, which describes how infrastructure is designed to fit in with existing conventions in its community, and in turn can lead to changes over time in those conventions. Another facet of infrastructure that will be used to analyze AI in medicine is that infrastructure is *built on an installed base*, which describes how infrastructure uses, expands or modifies existing infrastructure to improve it or fit a new need. The third facet I will be using to analyze this case is *embodiment of standards*, which describes how technology has qualities that allow it to fit into the existing system in a standardized fashion (Star, 1999).

Novel medical technologies tend to link with the existing practices in medicine. Danesi et. al (2020), argue that the introduction and use of medical technologies should be thought of as the adjustment and attachment needed to fit the new technology into the existing care infrastructure. They describe a new glucose monitoring system that will fit into the care infrastructure, thus linking with conventions of practice (Danesi et al., 2020). Fitting into the existing medical infrastructure is critical because of the size and effort that it takes to change such large systems. The least amount of change needed to integrate the technology, the higher the odds that the technology will be quickly adopted.

Additionally, medical devices must embody certain standards of the medical community including comfort, safety, and efficacy. Danesi et al., 2020 found that the new glucose monitoring device must fit ergonomically on the body and users must be able to trust the

information received from the device (Danesi et al., 2020). These needs show how the technology must embody certain standards we have as a society, that the devices are comfortable and provide accurate information. FDA regulation of medical devices also demonstrates how we ensure that the devices embody our standards of safety and efficacy. All medical devices that pose a certain level of risk must obtain some type of clearance or approval before they can be marketed (FDA, 2023a). In the case of artificial intelligence, since it is so new, we are still defining the standards we have, but different organizations such as the FDA are beginning to define the ways in which it is regulated and used (Hanson, 2023)

Finally, medical devices are constantly being improved upon, exhibiting the facet of Star's framework that technology is built on an installed base. In a case study on a cardiac telemonitoring technology by Nelly Oudshoorn (2008), we see how an existing technology, electrocardiograms, are used in combination with telemedicine technology as a new diagnostic tool (Oudshoorn, 2008), thus showing how medical technologies are built on an installed base. Similarly, AI came from improving and combining machine learning, deep learning, and natural language processing algorithms, and it continues to be improved for increasing accuracy and diversifying its uses.

Research Question and Methods

With the influx of new medical technologies, hospitals and doctors are constantly making choices about which new technologies they should start integrating into their practice. Artificial intelligence is a rapidly expanding technology being utilized across all fields, but with the immense power and capabilities comes ethical dilemmas and questions. In medicine especially,

there are many values at play. A logical question follows: What is the potential for artificial intelligence as a diagnostic device to become widely adopted in orthopedic medicine?

To investigate this question, I analyzed FDA and International Medical Device Regulators Forum (IMDRF) guidelines and regulations on Software as a Medical Device (SaMD) to understand AI in medicine from a regulatory point of view. Second, to understand researchers' and clinicians' perspectives on this topic, I conducted a focused review of research journals that explored applications of AI in orthopedic medicine. To select my articles, I started with Lisacek-Kiosoglous, et al. (2023), *Artificial Intelligence in Orthopaedic Surgery*, and examined the articles it cited to find two others that were exploring the use of AI for diagnostics in orthopedics. Finally, I analyzed the way AI is portrayed in the media to understand the general public's view on AI technologies and their potential in diagnostics.

I analyzed these sources using Star's infrastructure framework (Star, 1999) using thematic coding. I looked for mentions of how AI as a diagnostic technology links with conventions of practice, embodies societal standards, and is fixed in modular increments. I then used the results of these analyses to draw a conclusion on how AI in medicine exhibits the facets of infrastructure and provides a base for the adoption of AI in orthopedic medicine.

Results

Artificial intelligence is already being incorporated into medicine, and is thus far viewed as a tool that can improve accuracy and efficiency of diagnoses. Medicine is a well established institution with a complex and intertwining infrastructure, but regulatory bodies, clinicians, researchers, and the public all see the potential for AI to fit into this infrastructure. These groups agree that using AI as a medical device in orthopedic medicine links with existing conventions of

practice, embodies medical standards, and is added and fixed in modular increments. Thus, there is a great potential for artificial intelligence to be incorporated into existing diagnostic processes in orthopedic medicine.

Links With Conventions of Practice

One important aspect of the adoption of any medical device is that it links with conventions of practice. In an action plan developed by the FDA for AI and machine learning (ML) to be used as a medical device, the FDA (2023b, p. 1) stated that AI technologies,

> "have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day."

This statement from the FDA shows that they view AI as a solution to make sense of the large amounts of data generated daily from routine healthcare practices. This use of AI in combination with common healthcare practice, the collection of vast amounts of data, demonstrates Star's principle of linking with conventions of practice. In defining Software as a Medical Device, as opposed to software in a medical device, the International Medical Device Regulatory Forum (2013) states that the software may interface with other physical or software medical devices. This is evidence that regulatory bodies agree that software, and thus AI technologies, are able to link with the existing practices and devices in medicine. Both national and international medical device regulatory bodies see the potential for AI technologies to link with existing medical practices and devices. AI technologies have a greater potential to become used regularly as a diagnostic tool in orthopedic medicine because they fit into the existing medical infrastructure.

A similar sentiment is found when examining research articles written by doctors and researchers about the use of AI in orthopedic medicine. Myers, et al. (2020, p. 835), a group of

researchers and doctors specializing in total knee replacement, discuss how AI is currently used to make sense of the large amounts of data generated from wearable sensors and remote patient monitoring platforms during rehab post surgery, and that it,

> ”may enable predictions of which patients will struggle…help determine when patients can safely progress to the next level in their rehabilitation program”

This example shows one way that AI is already being used in orthopedic medicine by linking to existing smart devices and generating impactful results. In another article discussing the applications of AI in orthopedic surgery, Kurmis and Ianunzio, two orthopedic surgeons, provide a physician’s perspective as they discuss the value AI holds in the management of electronic medical records (EMRs). Kurmis and Ianunzio (2022, p. 7) ask,

> “With so much volumetric data available, how does a single clinician sort through and retrieve key elements critical for point-of-care decision making?”

Through this question, they indicate that EMRs provide a uniform platform of collecting patient data, and thus have led to massive amounts of data about each patient. Since AI relies on massive data sets, this evidence shows a potential avenue for AI to link with medical practices, helping healthcare workers without adding extra work.

When appealing to the broader public, it can be helpful to make new medical technologies feel familiar. In a public opinion article published by the Washington Post, Wen (2023) frames the use of AI under the context of a Type 2 diabetes diagnosis. She discusses how physicians have long been using patient demographics and histories to individualize treatment recommendations and that AI is “just one more tool to aid in clinical decision-making” (Wen et al., 2023). She emphasizes that patient-centered treatment has been a standard practice in

healthcare for some time, and AI will fit in well to help make these individualized treatment plans, thus demonstrating Star's principle of linking with conventions of practice.

Embodiment of Standards

In order to understand how AI fits into medical infrastructure, it is necessary to analyze how AI technologies embody the standards of medicine. Figure 1 shows a graphic contained in FDA guidelines for SaMD. This graphic illustrates how SaMD must embody the same standards of accuracy, reliability, and precision as physical medical devices. This stance shows how AI and other SaMD must embody the standards or efficacy and safety previously set forth in medicine to become approved.

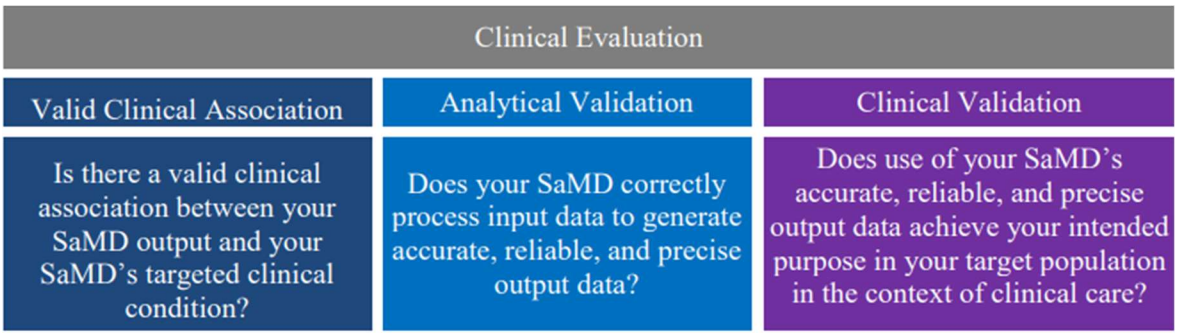

Figure 1. Clinical Evaluation Guidance for Food and Drug Administration Staff (Source: IMDRF, 2017)

Likewise, in their article on using AI in orthopedics, Kurmis and Ianunzio (2022, p. 5) state,

> "Prior to surgery, AI applications have already been employed to either improve the accuracy of, or reduce the time associated with critical diagnostic steps."

This indicates that existing AI technologies in medicine embody accuracy and efficiency standards of medical devices. Similarly, Kurmis and Ianunzio continue to cite (2022, p. 6) that several papers have reported AI precision in orthopedic uses and they,

> "described 'near-perfect' functionality with accuracies as high as 99.6%... Additionally, all … cited significant time-saving during this process".

This statement further supports that AI technologies currently used in orthopedic medicine embody the standards previously discussed in the paper. The image from a news article released by the NIH (Figure 2) shows how AI is being presented to the public as a human-like robot that is able to just point out the problem. This illustrates how the public views AI as an almost magical, science fiction technology that can perform better than humans, while still embodying the shape of a human. This image depicts how AI embodies society's standards of computer technology as evolving into human-like robots with superhuman capabilities. These statements and images support the arguments that AI technology embodies standards set forth by our regulators, researchers, and society and thus have a promising future in healthcare.

Figure 2. Image in NIH News Article depicting the use of AI in healthcare (Source: NIH, 2023)

Fixed in Modular Increments

The final facet of infrastructure that will be explored to understand AI's potential to become a commonly used orthopedic diagnostic tool is that it is fixed in modular increments. The Marketing Submission Recommendations by the FDA introduces a Predetermined Change Control Plan (PCCP) that allows the company to describe future modifications that may be made to the SaMD during the initial submission to reduce future need for PMA or 510(k) submissions. This plan, developed by the FDA, describes how they are planning ahead to allow for changes to software technologies and AI. This evidence shows that they are adapting their regulations

because of the expected regular changes to these technologies, thus embodying Star's concept of infrastructure that is fixed in modular increments.

Physicians and researchers also view artificial intelligence technologies in medicine as being added incrementally, as demonstrated by Lisacek-Kiosoglous et al. (2023) in Figure 3. This graphic shows how AI technologies are being incrementally incorporated into many different areas of orthopedic medicine ranging from detection and diagnosis of different pathologies to predicting patient specific outcomes. This shows that AI is modularly added to orthopedic medicine to fix specific deficits and issues, thus demonstrating the facet of infrastructure that it is fixed in modular increments.

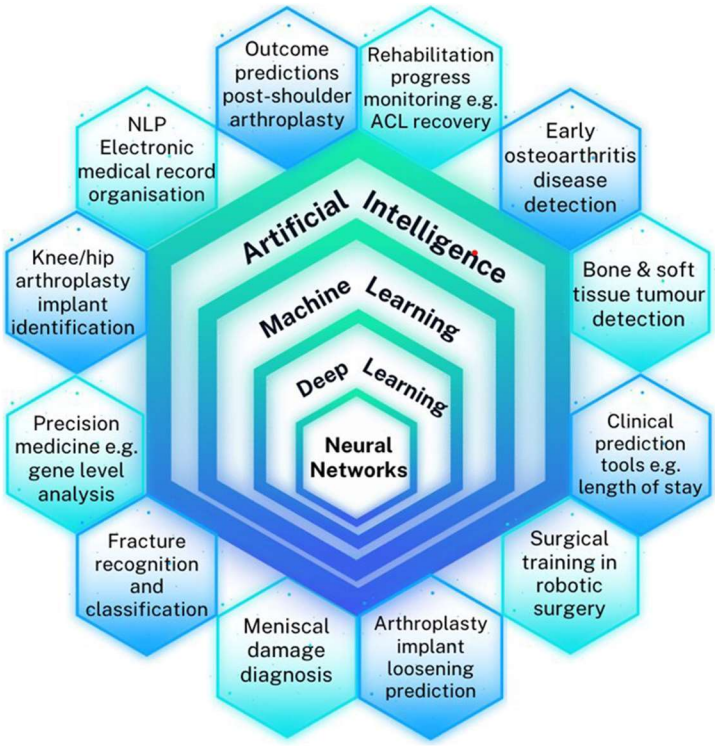

Figure 3. Applications of artificial intelligence in trauma and orthopedic and surgery. ACL, anterior cruciate ligament. (Source: Lisacek-Kiosoglous et al., 2023)

Discussion

The research done in this paper found resounding support for AI technologies to be integrated into the diagnostic process in orthopedic medicine. Integrating AI could have an enormous impact on the way orthopedic pathologies are diagnosed and treated, with the potential to greatly improve patient specific treatments. Many orthopedic ailments suffered by people both young and old are not as simple as seeing a bone fracture on an x-ray and putting a cast on it. NLP technology can be used to find patterns in how patients are describing their symptoms, and ML/DL can be used to combine these patterns with other diagnostic testing to determine the correct diagnosis and how other people in similar situations have responded to different treatments. As of 2022, there were 127 published papers on the incorporation of NLP to extract insights from electronic health records, with 72.5% originating in North America and the rest in Australia, Asia, the UK, and Europe (Hossain et al., 2023). Support for the use of AI was found in many areas of society throughout this paper, demonstrating how AI technology can fit into the existing medical infrastructure. These claims are further supported by a briefing issued in October 2023 by President Biden on the use of AI in which there is an emphasis on safety and security standards, as well as encouraging the responsible use of AI in healthcare and the development of life-saving drugs. Additionally, the report states that a new safety program will be established to mitigate harms from or unsafe healthcare practices involving AI (The White House, 2023).

While this paper focuses on the support for integrating AI technologies into medicine, it is limited in exploring current reservations about AI and its use in society as a whole. There is generally large support for expanding the use of AI technology in medicine, however other uses of AI have received a large pushback and sparked debates. Earlier this year, a class action

lawsuit was filed against multiple health insurance companies for using AI technology to wrongfully make claims. This lawsuit demonstrates the reservations many people have about the use of AI, especially when it can make decisions that can have a tangible negative impact on people's lives (Lopez & Pugh, 2024).

To improve on this work in the future, I would analyze the evidence in a quantitative manner that allowed more sources to be analyzed and to provide different perspectives on the use of AI in orthopedic medicine. This paper was limited in the number of sources used as evidence and a numerical analysis could show the broader picture. It would also be beneficial to look at the change over time in the perceptions of artificial intelligence, and to more closely examine the differences between stakeholder groups rather than the similarities.

Completing this research showed me the value of viewing technologies, especially in the medical field, under the lens of Star's *Infrastructure* framework. I will apply this research and findings to my future work as an engineer when I am developing new technologies. I understand the importance of viewing technology as infrastructure and I will be mindful to ensure that the technologies I am designing embody those facets. I also have learned the importance of looking at the technology from different perspectives rather than just mine as an engineer, and will apply this to my future work as a medical device engineer and researcher.

Conclusion

As AI technologies take on a greater role in our society, the benefits are debated and the ethics of its use are questioned. As with many revolutionary technologies, engineers are eager to incorporate AI into other technologies with the hopes of greatly improving existing technology. This change and innovation is essential for the continued improvement of medicine, however it's important to first acknowledge how the device fits into the greater infrastructures and powerful

institutions existing in medicine. Understanding how technology is infrastructure, and applying those principles to novel technologies, can help engineers develop useful and effective diagnostic technologies to better inform doctors and patients on medical diagnoses. My research found that AI easily fits into the medical infrastructure, and thus engineers should work to develop diagnostic technologies that harness AI to help physicians and improve patient care.

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