Undergraduate Thesis Prospectus

An Actuated Robotic Model of the Lewis Rat Hindlimb

(technical research project in Biomedical Engineering)

Redefining Care: Competing Forces Shaping the Future of Medical AI

(sociotechnical research project)

by

Jeremiah Druckenmiller

November 8, 2024

technical project collaborators*:*

Maximus Cresti
Brandon Lawrence

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.

Jeremiah Druckenmiller

Technical advisor: Shawn D. Russell, Department of Orthopedic Surgery

STS advisor: Peter Norton, Department of Engineering and Society

General Research Problem

How can models and automation improve patient care?

Advanced modeling and automation techniques have the potential to greatly improve the accuracy and efficiency of medical diagnoses, treatment plans, patient monitoring, and more. Biomimetic models can replicate key aspects of human physiology without relying on live animal models, thereby eliminating ethical concerns, reducing variability issues, and avoiding the procedural and financial burdens associated with animal testing. Some examples include organ-on-a-chip, which replicates human organ functions on a small scale to improve drug testing accuracy, and robotic animal surrogates, which simulate anatomical movements for biomechanical and neurological studies, enhancing research precision and reproducibility (Bhatia & Ingber, 2014; Kamm & Bashir, 2014).

These technologies have become especially appealing to healthcare entities with large financial motives due to the substantial savings they offer. The global healthcare automation market is projected to grow significantly, reaching $88.9 billion by 2027 (Grand View Research, 2020). Machine learning algorithms, in particular, have already proven effective in areas like diagnostics and data sorting. AI-based predictive models can reduce medical errors and improve outcomes by identifying patient risk factors and providing data-driven insights (Topol, 2019). Such models could be instrumental in addressing diagnostic errors, which currently affect 12 million U.S. adults each year (Singh et al., 2018). These technologies have the potential to bridge critical gaps in underserved communities; however, without careful oversight, could exacerbate disparities due to flaws in development. To evaluate whether automation improves patient care, quality care must be defined; Is it state-of-the-art diagnosis and treatment of distinct medical conditions or is it care for the whole person?

An Actuated Robotic Model of the Lewis Rat Hindlimb

How can neural control strategies for restoring normal gait following a volumetric muscle loss injury be rapidly developed and accurately tested?

A robotic model of a Lewis rat's hindlimbs will substantiate evidence gathered using the Dr. Russell's current computational models through its interaction with the physical world, while enabling rapid injury simulation and testing. We aim to accurately replicate both anatomical movement patterns and force exertion while allowing for easily customizable injury simulations. Therapeutic methods extrapolated from the model will be applied to treat wounded warriors recovering from VML injuries. I will work alongside fellow biomedical engineering students Maximus Cresti and Brandon Lawrence, under the guidance of Dr. Shawn Russell and Hudson Burke (GRA).

Current state of the art in VML injury simulation and testing, combines in vivo models, computational simulations, and advanced measurement techniques to better understand and develop treatments. Most commonly, animal models, specifically rats, are used. A standardized approach involves creating a 6mm biopsy punch defect in the tibialis anterior muscle (Corona et al., 2022). Computational models have also been developed to simulate various processes related to VML injuries. For example, Dr. Russell uses an open-source movement analysis tool—which simulates hindlimb gait in Lewis Rats—to investigate the impact of the injury on gait and explore potential therapeutic interventions. Agent-based models (ABMs) have also emerged as powerful tools focused specifically on the cellular mechanisms driving the regeneration response in VML injuries, predicting tissue remodeling patterns (Ceresa et al., 2021). In addition to computational models, wireless, noninvasive nanomembrane systems have been developed for real-time, continuous monitoring of VML injuries. These measurement systems integrate skinwearable printed sensors and electronics to measure the electrophysiology of the muscle during active movement (Kim et al., 2021). Researchers are increasingly shifting away from animal models due to the high financial and time costs, as well as ethical concerns, associated with inducing severe injuries in live subjects. Our solution aligns with this trend, offering a viable and innovative alternative for VML study.

We will design the hindlimb structure in CAD based on anatomical data, focusing on maintaining the general biology—such as length, size, and connection points—while making purposeful simplifications that prioritize functional movement over precise natural replication. Components will be manufactured using 3D printing and CNC machining techniques. Key equipment includes actuators that will function as synthetic muscles, ground reaction force sensors, and joint angle (positional) sensors to enable responsive self-correction and ensure motion accuracy. The model will integrate an onboard microcontroller and power source, supporting extended testing and durability.

Success in this project will yield ankle and foot joints that mimic a rat's natural gait, verified through motion capture analysis. The next step would be to integrate our model with another capstone team's knee and hip joints. Ultimately, the now comprehensive leg model, will pair with a neural network capable of adapting its gait in response to simulated injuries, mimicking the adaptive learning process seen in rats and even humans. In doing so, this project equips researchers with a critical tool to bring future regenerative therapeutics closer to clinical implementation, especially for complex injuries seen in polytrauma patients.

Redefining Care: Competing Forces Shaping the Future of Medical AI

In the US, how are medical professionals, hospitals, insurance companies, patient advocates and MedTech companies competing to draw the line between the legitimate and the illegitimate applications of medical AI?

Introduction

Your next medical consult could be with an algorithm. AI is enhancing diagnostics, patient care, and operational efficiency, while saving the medical industry billions (Snowflake, 2024). Algorithms can even handle more complex tasks like needle insertion and surgical procedures (Knudsen, Ghaffar, & Hung, 2024). The rapid adoption of AI throughout the industry has sparked a crucial competition between participants. Improvements in the accuracy and efficiency of care are counterbalanced by concerns about bias, patient safety, and the potential for over-reliance on technology (Parikh, Teeple, & Navathe, 2019; Naik et al., 2022). Boundaries drawn during this early phase will shape the ethical, legal, and clinical frameworks that will govern AI's future in healthcare.

Relevant Research:

There are fundamental differences between the way human clinicians and AI algorithms make conclusions. Clinicians rely on ecological rationality, using targeted cues and expertise to make decisions with limited but relevant information. AI systems debound the clinical decision-making process, using all available information, even if it's not optimal or relevant. Debounding allows AI models to rely on irrational “shortcut” features learned from training data, mathematically improving accuracy but lacking clinical validity (Tikhomirov et al., 2024). This mismatch makes it harder to anticipate AI errors or detect biases. Bias detection and mitigation is essential for fair and generalizable AI technology (Mittermaier, Raza, & Kvedar, 2023). These systems can amplify biases in training data, exacerbating existing inequalities in socioeconomic status, race, gender, and more, particularly disadvantaging marginalized populations with less accurate predictions or underestimated care needs (Obermeyer et al., 2019; Spector-Bagdady et al., 2022; McCradden et al., 2022).

Participants

Doctors like Danton Char of Stanford warn that the tension between profit motives and effective healthcare in the US could lead to ethical conflicts based upon the clashing priorities of algorithm designers and clinicians (Webster, 2020; Ward, 2019). Abraham Verghese, Vice Chair for the Theory and Practice of Medicine at Stanford, cites the “greater financial incentive for relying on technology, testing, processes, and efficiency” as the driving force that is “eviscerating” the foundation of the physician-patient relationship. Physicians are "losing contact" as they engage with the "intermediary" of electronic systems. He cautions that viewing patients “through a screen” risks the omission of essential context, and subtleties that elevate the quality of care. Physicians, unlike AI, are not limited to only processing data and can perceive details—a patient’s body language, tone of voice, or the worn “outline of a cigarette packet” in a pocket—revealing risks often absent from patient records (Verghese, 2016). These nuances enrich the standard of care and are exceptionally difficult for AI to interpret.

Trade associations such as the American Hospital Association (AHA) advocate for AI tools, citing their ability to improve health outcomes with "timely and precise interventions," reducing costs, and increasing productivity at multiple stages of care. To successfully adopt AI in healthcare, the AHA advises patients and clinicians take a proactive approach: patients should engage with AI regularly, especially through tools like health chatbots, while clinicians should use AI to augment clinical decision-making (AHA, 2023). Another of these associations, AdvaMed, contends that AI should continue to be regulated as any other medical device, pointing out that the FDA's "25 years of experience reviewing and authorizing AI/ML-enabled medical devices" has created a stable framework that supports innovation without compromising safety. Shifting AI into a separate regulatory category risks a disruption and "stifling innovation and reducing patient access" (AdvaMed, 2023). This perspective overlooks the evolving nature of AI, especially machine learning models, which, unlike traditional devices, may require ongoing updates to maintain their relevance and accuracy—posing challenges to a one-time approval model.

As AI empowered tools are increasing in popularity the FDA and its Canadian and UK counterparts are emphasizing the need for regulation, advising developers to use training data representative of the intended patient populations to fight biases (FDA, 2021). According to the National Conference of State Legislatures, at least six states introduced legislation aimed at regulating AI in healthcare during the 2024 legislative session (NCSL, 2024). Colorado legislation mandates that insurers test their big data systems, including "external consumer data and information sources, algorithms, and predictive models," to ensure they do not unfairly discriminate against consumers based on race, sex, disability, or sexual orientation (Colorado DORA, 2021). A bill backed by the California Medical Association aims to ensure algorithms, AI, and other software are applied "fairly and equitably." Initially, the bill included a requirement for licensed physicians to oversee AI-based decisions to "approve, modify, or deny requests by providers," but this clause was later removed (California State Senate, 2024).

President Biden's recent Executive Order on AI emphasizes the need for “privacy-preserving techniques” to protect personal health data and mandates “standards and best practices for detecting AI-generated content and authenticating official content,” which can enhance transparency and trust in AI-driven healthcare tools. Additionally, it calls for the Department of Health and Human Services to “establish a safety program to receive reports of—and act to remedy—harms or unsafe healthcare practices involving AI,” ensuring that tools are continually monitored for safety and effectiveness (White House, 2023). While these standards are not immediately enforceable on the private sector, they can influence the broader regulatory landscape, especially as agencies begin to develop specific policies and guidelines in line with the EO.

Industry leaders with decades of development experience are now addressing the regulatory landscape. Peter Shen, Head of Digital & Automation at Siemens Medical Solutions, recently testified before the Senate, emphasizing that a “continuation of flexibility in the approval process” is crucial, warning that a “one-size-fits-all approach could seriously inhibit [AI’s] potential.” For large, financially driven institutions, a more flexible regulatory approach could accelerate adoption by reducing costs tied to lengthy approval processes. Siemens pledges to self-regulate by “openly communicat[ing] insights into underlying technology,” “carefully compil[ing] training and test datasets” for traceability, and eliminating biases, aiming to create systems that are “ethically acceptable and beneficial to humankind and society” (Shen, 2024). While this approach may be feasible for public-facing corporations, it raises concerns with smaller, less visible startups. Nonetheless, early-stage health-tech companies developing AI solutions continue to push boundaries, with biotech venture investments nearing 2021’s record totals (Gormley, 2024).

References

AdvaMed. (2023). *Artificial intelligence in medtech overview.* https://www.advamed.org/member-center/resource-library/artificial-intelligence-in-medtech/

American Hospital Association. (2023). *Artificial intelligence and care delivery: Market insights.* https://www.aha.org/center/emerging-issues/market-insights/ai/ai-care-delivery

Bhatia, S. N., & Ingber, D. E. (2014). Microfluidic organs-on-chips. *Nature Biotechnology, 32*, 760–772.

California State Senate. (2024, March 8). *Hearing on artificial intelligence in healthcare*. California Senate Committee on Health. Digital Democracy. https://digitaldemocracy.calmatters.org

Ceresa, C. C., Knox, C. J., Diaz-Pinto, A., Ballotta, V., Karande, P., & Roux, B. M. (2021). Agent-based model provides insight into the mechanisms behind volumetric muscle loss injury and regeneration. *PLoS Computational Biology*, *17*.

Colorado Department of Regulatory Agencies, Division of Insurance. (2021, July 6). *SB21-169: Protecting consumers from unfair discrimination in insurance practices.* Colorado Department of Regulatory Agencies. https://doi.colorado.gov/for-consumers/sb21-169-protecting-consumers-from-unfair-discrimination-in-insurance-practices

Corona, B. T., Greising, S. M., Garg, K., Ward, C. L., & Walters, T. J. (2022). Retrospective characterization of a rat model of volumetric muscle loss. *BMC Musculoskeletal Disorders*, *23*, 1-13.

David L. Morris. (2023, August 30). How technology is speeding the shift to value-based care. *Medical Economics*.

FDA (2021, Oct.) Good Machine Learning Practice for Medical Device Development: Guiding Principles. www.fda.gov/medical-devices/software-medical-device-samd/good-machine--learning-practice-medical-device-development-guiding-principles

Gormley, B. (2024, Sept. 26). Venture Mega-Rounds Return to Biotech. *Wall Street Journal*.

Kamm, R. D., & Bashir, R. (2014). Creating living cellular machines. *Proceedings of the National Academy of Sciences, 111*, 1869–1870.

Kim, H., Kwon, Y. T., Zhu, C., Wu, F., Kwon, S., Yeo, W. H., & Choo, H. J. (2021). Real-Time Functional Assay of Volumetric Muscle Loss Injured Mouse Masseter Muscles via Nanomembrane Electronics. *Advanced Science*, *8*, 21-37.

Knudsen, J. E., Ghaffar, U., Ma, R., and Hung, A. J. (2024). Clinical applications of artificial intelligence in robotic surgery. *Journal of Robotic Surgery*, *18*, 102.

McCradden, M. D., Anderson, J. A., A. Stephenson, E., Drysdale, E., Erdman, L., Goldenberg, A., and Zlotnik, R. (2022). A Research Ethics Framework for the Clinical Translation of Healthcare Machine Learning. *The American Journal of Bioethics*, *22*, 8–22.

Mittermaier, M., Raza, M. M., and Kvedar, J. C. (2023). Bias in AI-based models for medical applications: Challenges and mitigation strategies. *npj Digital Medicine*, *6*, 113.

Naik, N., Hameed, B. M. Z., Shetty, D. K., Swain, D., Shah, M., Paul, R., Aggarwal, K., Ibrahim, S., Patil, V., Smriti, K., Shetty, S., Rai, B. P., Chlosta, P., & Somani, B. K. (2022). Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility? *Frontiers in Surgery*, *9*.

National Conference of State Legislatures. (2024). *Artificial intelligence 2024 legislation. https://www.ncsl.org/technology-and-communication/artificial-intelligence-2024-legislation*

Obermeyer, Z., Powers, B., Vogeli, C., and Mullainathan, S. (2019). Dissecting racial bias in an algorithm used to manage the health of populations. *Science*, *366*, 447-453.

Parikh, R. B., Teeple, S., and Navathe, A. S. (2019, Dec.). Addressing Bias in Artificial Intelligence in Health Care. *JAMA*, *322*, 2377–2378.

Singh, H., Meyer, A. N., & Thomas, E. J. (2018). The frequency of diagnostic errors in outpatient care: Estimations from three large observational studies involving U.S. adult populations. *BMJ Quality & Safety, 23*, 727-731.

Snowflake (2024). Data Trends 2024 Healthcare and Life-Sciences. www.snowflake.com/wp-content/uploads/2024/04/Data-Trends-2024-Healthcare-and-Life-Sciences.pdf

Spector-Bagdady, K., Rahimzadeh, V., Jaffe, K., and Moreno, J. (2022). Promoting Ethical Deployment of Artificial Intelligence and Machine Learning in Healthcare. *The American Journal of Bioethics*, *22*, 4-7.

Tikhomirov, L., Semmler, C., McCradden, M., Searston, R., Ghassemi, M., and Oakden-Rayner, L. (2024). Medical artificial intelligence for clinicians: The lost cognitive perspective. *The Lancet Digital Health*, *6*, 589-594.

Topol, E. (2019). *Deep medicine: How artificial intelligence can make healthcare human again*.

Verghese, A. (2016). The Importance Of Being. *Health Affairs*, *35*, 1924–1927.

Ward, L. (2019, Oct. 14). The Ethical Dilemmas AI Poses for Health Care. *The Wall Street Journal*.

Webster, P. (2020, April). Virtual health care in the era of COVID-19. *The Lancet*, *395*, 1180–1181.

The White House. (2023, October 30). *FACT SHEET: President Biden issues executive order on safe, secure, and trustworthy artificial intelligence.* https://www.whitehouse.gov/briefing-room/statements-releases