

How wearable sensing can be used to monitor patient recovery following ACL reconstruction

(Technical Topic)

Exploring Competing Visions of a Personalized Healthcare Experience

(STS Topic)

A Thesis Prospectus

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By

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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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Introduction

Healthcare is constantly transforming. Conventional medicine originates from an empirical based approach that has gradually evolved towards mechanism-based treatments. The possibilities of the future of healthcare remain endless with new emerging diseases, countless breakthrough discoveries, massive technological advancements, and most notably, the progression towards personalized healthcare. With the emergence of a more personalized healthcare experience has also come the increased use of wearable technology. Wearable technologies are designed to track and collect data on the user's personalized health and exercise. In healthcare specifically, wearable technology includes health monitoring devices, therapeutic devices, and activity tracking devices. As a result, we have a large emerging market to utilize wearable technology to create a more personalized healthcare experience.

My technical project will study the use of wearable technology in the medical field to induce a data-driven, personalized medical experience for the patient. Specifically, it will study the ability of wearable sensors in detecting rehabilitation progress, the timing of return to sport, and precise and preemptive movement abnormalities in patients who have recently undergone ACL reconstruction surgery. Since current recovery methods have been standardized across all patients and involve subjective monitoring processes, our goal is to develop a data-driven way to detect movement and strength deficiencies between the operative and non-operative leg in order to reduce re-injury rates.

My STS topic will be coupled with my technical project beyond just the scope of wearable technology, but will still utilize the idea of personalization of medicine through data

analysis. I will analyze articulate visions for personalized medicine through a distinct sociotechnical imaginary that promises a future of technical solutions to complex problems by using a data-driven approach. This sociotechnical imaginary shall model personalized medicine as the self-evidently desirable future for healthcare. However, I will also contradict the advantage of personalized medicine by studying the ethical and social implications that could be faced.

Technical Topic

Anterior cruciate ligament (ACL) injuries are very common, especially in younger athletes with rates ranging from 6 to 32 injuries per 100,000 athlete exposures (Collins, 2013). When the ACL is torn, the knee becomes unstable, and the likely only option for recovery is a surgical reconstruction. There is evidence that patients recovering from ACL reconstruction surgery suffer from persistent muscle weakness and altered movement patterns that will ultimately lead to reduced activity levels, poorer quality of life and early onset osteoarthritis. Early detection of altered movement patterns and other neuromuscular deficits is paramount to optimize post-operative rehabilitation and to restore normal movement patterns.

There is currently little to no quantitative fact or data-driven method to determine when a patient is deemed 'fit' to return to activity, and current reinjury rate is between 20-30% (Grindem, 2016). Current methods for releasing patients to return to normal physical activity involve a visual examination of the patient's strength and movements and assumptions of the recovery timeline which has been standardized for all patients to be six to eight months provided by either the patient's surgical doctor or physical therapist. Our goal is to determine a more efficient, data-driven way to monitor and test ligament and tissue rehabilitation to prevent re-

injury. This will be through the use of continuous monitoring with sensors as opposed to current short term monitoring methods.

Multiple studies have been conducted in order to analyze the use of wearable technology in rehabilitation progress. One study conducted highlights the use of gyroscope inertial sensors in detecting knee power asymmetries of patients who are five months post ACL reconstruction. The study found that these sensors were about 80% accurate in recognizing knee power asymmetries (Pratt, 2018). An additional study conducted suggests that the proposed analysis was capable of detecting gait asymmetries early post-surgery and the improvement thereof at later time points supporting its utility for clinical evaluations (Beynon, 2018). This provides evidence for the use of this approach as a digital biomarker for rehabilitation progress with the end goal of enabling personalized rehabilitation protocols utilizing these sensors. Numerous additional studies have been conducted with similar results pushing for a more personalized, data-driven recovery process. Our study will differ in that we utilize the data we retrieve to implement machine learning in order to personalize the experience for each user and we will be determining the key features to extract that are most predictive of knee asymmetries.

To conduct our research, we will be testing twenty subjects in the UVA Kinesiology Lab weekly through the middle of December. Ten of the subjects will be non-operative, healthy patients, and ten of the patients will have undergone recent ACL reconstruction surgery. Each patient will be connected to two sensors: EMG and IMU. All patients will be asked to perform the same series of three activities while wearing the sensors. These activities will include walking, jumping, and leg resistance. Each technical team member will be conducting the trials (at least 2 members will be in the clinic a week). I will be conducting patient trials on Monday mornings along with another team member. We will be drawing comparisons using data analysis

and machine learning between the data collection from each leg of a subject and comparing post ACL reconstruction knee versus the healthy knee. The spring semester will be used to analyze the data and develop a recommendation for how to improve the current recovery methods through the use of these wearable sensors.

Our key goals and deliverables of our study are to identify the proper locations and types of wearable sensors to place on a patient's knee to collect accurate and valuable data, identify key features during analysis that can serve as indicators of a successful recovery following an ACL injury, and provide results to aid preventative techniques for healthy subjects and reduce the occurrence of a second tear.

STS Topic

It is no secret that medicine is constantly evolving. From early genome mapping to modern day medical technology, healthcare practices are constantly being revolutionized. Research efforts and business diversification have been two key driving forces of these movements, which has contributed to the new idea of 'precision public health,' also referred to as personalized medicine (Steffen, 2013). Advocates of precision medicine argue, "that adopting cutting-edge big data approaches will allow public health actors to precisely target populations who experience the highest burden of disease and mortality, creating more equitable health futures (Kenney, 2019)." My STS research will utilize multiple case studies to analyze two sides of this sociotechnical imaginary: the self-evidently desirable future of personalized medicine and the drawbacks including social and ethical concerns of promoting precision public health. By doing so, I hope to highlight the invaluable benefits precision medicine offers as the future of

healthcare, but also draw attention to the negative course that precision medicine could potentially take without transitional action.

Personalized medicine is driven by a large network of forces. It includes both individual and public engagement, health care professionals, end-users, large data sets, technological resources, integration into the healthcare system, and sustainable economic models. Additionally, personalized medicine relies on the collaboration of pharmaceutical and biotechnological industries with academic industries. Patient data is made available by industrial players from clinical trials to academic and scientific researchers for analysis of results and continued research. These results are then translated to industry partners for input into bioinformatic tools. Eventually, these research developments will have the end goal of implementation into the healthcare network (Agyeman, 2015). Thus, the success of this sociotechnical imaginary lies in the cooperation and coordination amongst a very large network, which is anything but simple.

To begin the analysis of the potential benefit of personalized medicine, let us narrow the scope to look at Herceptin, a recognizable success story for pharmacogenomics and precision health. Herceptin acts as a prototype for personalized medicine by serving as a guided missile for chemotherapy targeting breast cancer cells (HER2+). Typical methods of chemotherapy involve an aggressive attack of both healthy and cancerous cells, so this new method offers a medical fantasy with minimal collateral damage (Kenney, 2019). Herceptin lays a base for the imaginary of precision. Countless precision drugs with key success stories, like Herceptin, exist and continue to shape the future of medicine. Although, it must be mentioned that the glimmering hope of a cure for cancer obscures the reality that targeted chemotherapy methods, like Herceptin, still have underlying issues in clinical practice. The focus turns attention towards a moral imperative for drug research and development which seems to fully overwrite clinical

uncertainty (Kenney, 2019). Nonetheless, this type of precision medicine has potential to offer modern technology and humanitarian solutions to the highest priority public health issues.

With personalized medicine, it is now possible to expand beyond the scope of typical broad distinctions such as demographics and socio-economic factors, and dive into more specialized methods of classifying individuals. Melanie Swan studies the importance of the big data movement in driving the path towards precise medicine. ‘Big data’ refers to, “the collection of voluminous amounts (e.g., petabytes and exabytes) of a variety of unstructured and semi-structured data that is now possible, cheap, and occurring in most sectors of the economy (Swan, 2012).” From a macro perspective, large longitudinal datasets containing health related information become a public resource, and there is a greater worldwide ability to respond to outbreaks and other concerns. From a micro perspective, individual analysis provides the ability to study personal trends and develop viable suggestions for health issues and concerns (Swan, 2012). Hence, big data promises an exciting path for precise medicine and remains a driving factor for implementing this imaginary into a mainstream reality. It represents a sociotechnical phenomena with the powerful ability to transition into a world in which both human and data entities exist productively in mutual collaboration.

As with all emerging technologies and developments, wealth tends to be of high priority. Profit from business diversification and pharmaceutical developments remains a key driving force of this imaginary. Karoliina Snell studies two emerging framings for personalized medicine: innovation policy and data-driven medicine. Innovation policy represents the economic and commercial aspects and gains of personalized medicine, while data-driven relies on biomedical research and scientific breakthroughs to improve healthcare (Helen, 2019). Unfortunately, the last decade has been characterized by an overshadowing of scientific potential

with business potential as innovation policy tends to be of utmost priority. Assets such as researchers and research institutions in the category of medicine are now being classified as commercial power and potential economic gain ultimately defeating the focus on the end-user. Personalized medicine has a large emerging market of \$796.8 billion and suggests massive profit potential which raises concern that scientific research and development will be shaped based on greed rather than humanitarian good (“Personalized Medicine,” 2021).

The desire for profit suggests that this movement could exacerbate income-related inequalities in healthcare due to the less-than affordable nature of precision medicine. Thomas Ferkol and Paul Quinton study a notable example of rising income disparities with the case of a new precision drug for cystic fibrosis (CF) (Ferkol, 2015). CF has no cure, but past treatment methods have focused on downstreaming CF effects which have resulted in increased life expectancy. One precision drug currently on the market, ivacaftor, treats G551D which has the ability to change the clinical course of nearly 90% of all CF patients (Ferkol, 2015). However, it comes with a steep price tag of more than \$300,00 annually. Equally expensive is Orkambi which targets the delF508 mutation. Over the course of a patient’s life, it is expected that they would spend ten to fifteen million on this drug, which leaves its use in the hands of the nation’s wealthiest patients (Ferkol, 2015). Thus, we raise the painful questions: Does clinical effect justify exorbitant cost? Will precision medicine intensify the gap between rich and poor? Ivacaftor and Orkambi are only examples of possible financial trajectories that precision medicine could follow. Driving forces of this sociotechnical imaginary must direct themselves in a manner that compliments both the end-user and the producer while minimizing social damage.

With all in consideration, personalized medicine still remains at the forefront of the future of healthcare. The sociotechnical imaginary requires coordination between a large network of

end-users, researchers and scientists, academia, caregivers, technology, and socioeconomic players. All forces must work together to provide technoscientific progress in which research and development can bring humanitarian efficiency to a new world of medicine while combating related concerns.

Next Steps

TECHNICAL: During and after patient trials, our technical team must determine the following:

- Export data to a group database
- Standardize the process of cleaning data for all twenty and standardize the method for tagging patient trial video
- Clean, aggregate, and analyze data to compare operative and nonoperative legs movement patterns and muscle deficiency
- Work to find trends between ALL patients to provide a generalized result
- Determine key features that are most predictive of asymmetries (mean, range, min, max, amplitude, etc.)
- What techniques can be provided to reduce re-injury

STS:

- Go deeper into the sociotechnical actors that drives personalized medicine
 - Find more background on driving forces and constructing these visions-movements and critical actions taken to determine the future of personalized medicine
 - Two of the big driving forces of this imaginary are ongoing research efforts and business diversification. I want to specifically look into business diversification and tie it to the concerns-- study how the current driving forces could be on a path that exploits social, ethical and legal issues
- Expand on the topic of big data- it is crucial to the idea of personalized medicine so I want to study how it will change the healthcare system and actor relationships
- Continue to find specific cases of ethical and social concerns related to precision

medicine

- Find more literature that specifically addresses these concerns and related data
- Research more on how the driving forces can contribute to these concerns
- I would like to also study legal implications of personalized medicine including how this could have privacy and liability issues
- Tie it up all together with how the new transitions into personalized medicine will shape the healthcare system

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