Title: A) Does a web-based pre-habilitation protocol favorably impact 90 day clinical results following TKA as measured by patient reported outcome reports and wearable sensor data?
B) Does data collected through wearable sensors predict patient reported outcomes data following total knee arthroplasty?

University: University of California, San Francisco	
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Need and Industrial Relevance:
Decreasing the cost of care while improving the quality of care through digitally enabled technology is a major aim of the digital health movement. Within the area of orthopedics, improving patient outcomes by focusing on upstream patient optimization has been shown to decrease complication rates. Further, monitoring quality through the collection of Patient Reported Outcomes (PROs) has become a cornerstone of the move towards value purchasing by payers. However, collecting PROs either at the POC or at home has been quite challenging as few patients have the desire to answer numerous questions.

In this study we aim to address both opportunities by collecting data both passively and actively through a sensor worn by patients before and after surgery and by using apps to support patient pre-operative rehabilitation and postoperative recovery. To this data set we couple our existing PRO data collection database collected by the UCSF department of orthopedics. These three data sets (1) PRO data collected actively, 2) our passively collected sensor data and 3) data collected through iPhone apps) will provide insight in two particular areas of interest: A) what impact on post-operative outcome does a course of pre-habilitation have on patient's activity level after surgery, and B) how accurately does passively collected sensor data correlate with PRO scores? Our hypothesis is that patients undergoing pre-habilitation would register a lower Length of Stay and higher overall satisfaction with their hospital stay than non-pre-habilitated patients. In the context of bundled payments, such a correlation could be easily turned into a risk mitigation tool for hospitals and providers keen on improving quality and lowering costs. Further, if it can be shown that a combination of data points gleaned passively through sensors or wearable devices would correlate with and be predictive of PROs, there would be a large market opportunity for implant manufacturers, providers and insurers alike. For example, sensors build into implants could passively collect outcomes data that currently patients are unlikely to provide, and wearable devices could be engineered to specifically focus on data collection and feedback loops to help patients recover quicker or identify patients who need greater attention. There are many more potential applications.

Project Aims (including Hypotheses): The study to answer both questions would involve recruiting a single group of patients, half of whom would undergo a pre-habilitation intervention delivered over the web through an iOs device and the other half of whom would receive routine care. All patients would be asked to wear a Fitbit sensor or similar device. For study A) we would compare results between the intervention and the non-intervention group, for study B) we would use the data collected from all patients and compare them to the standard PRO data they submit to look for a correlation. For study B, no control group is necessary.

A) Intervention: numerous apps exist that provide either video based or avatar based programs that patients can use to drive self-directed exercise. These can be coupled to or integrated into a platform

such as CaptureProof or HealthLoop to provide a feedback loop between patients and mid-level providers.

B) For both A & B projects we would be collecting sensor data passively. Generally, this data comes down to steps, distance, speed, sleep, temperature, respiratory rate, heart rate and blood pressure. There are two primary sensors types we would look to use: the typical wrist bracelet such as a Fitbit and some more novel products such as rings, socks or chest bands. Using these physiologic parameters and the GPS driven data collected by these devices, a great deal can be inferred about metabolic activity. As patient reported outcomes are, fundamentally, an attempt to objectively quantify the return of function following surgery, we believe that an as yet unknown combination of these raw variables will have a strong correlation with PRO scores.

C) During the course of discovery of the full capabilities of these devices and the iPhone to which they are connected, it is entirely possible that we may have access to more data points. We may identify apps that create feedback loops to patients or that collect data points such as food intake that might also impact our findings or the design of the study.

Methods:

- 40 patients in need of a unilateral total hip replacement would be recruited to participate in the pilot study (total hip patients tend to be younger and recover quicker). Patients will all be treated for unilateral hip pain through a posterior surgical approach. They will be 70 years of age or younger, be digitally competent (have an email account and know how to use an app on a smart phone) and own an iPhone. All patients will be enrolled in HealthLoop (healthloop.com) a patient management platform. A dedicated research "loop" will be designed to instruct and manage patients with respect to their responsibilities throughout the research project (example: reminders to wear the sensors).
- 40 patients would be asked to complete PRO outcomes (VR12, WOMAC, HOOS, and VAS scores) one month before surgery, at one month after surgery, and at 3 months and 6 months following surgery.
- Patient collected sensor data vs. PROs: At the one-month pre-op visit, patients would be assigned one or more (depending on funding) tracking devices. Ideally, we would use a Fitbit that tracks both heart rate (example: FitBit charge HR -$129.00 USD + T&S) or a potentially more accurate ring sensor ($250) with a longer batter life. Patients would be asked to wear the tracking device 24/7 while awake for the time periods noted above to obtain accurate data.
- Impact of Pre-Hab on patient activity: as part of a nested study, 20 patients would be randomized to undergo a PT supervised pre-habilitation program designed by our PT department and delivered virtually using CaptureProof.com as the app (an asynchronous video platform). Randomization will occur through a sealed envelope protocol. 20 patients would act as controls for the pre-hab study.
- Data would be uploaded by patients through their iPhone using Apple Health Kit. Data would be shared by patients with the research team. Further data collection would include demographic parameters, hospital length of stay, and patient satisfaction scores.
- Aggregate data would be sent for statistical analysis to answer the following questions:
    - Does pre-habilitation impact any of the variables being tested (Length of stay, patient satisfaction, speed of rehabilitation, actual physiologic parameters collected by the sensor
    - Do any of the variables collected through the sensors predict or correlate with any of the PRO results?
    - Statistical analysis will be designed and performed through the biostatistics department of UCSF.

Milestones:

- Q4 2016
    - Statistical model designed
    - Obtain IRB approval
    - Write and prepare recruitment materials
    - Identify final sensors to be used and platform through which to collect the data
- Q1 2017
    - Establish patient management protocols
    - Create HealthLoop and CaptureProof protocols

- Begin patient recruitment in Jan 2017 (40 patients will take approximately 6 months to recruit)
- Q3 2017
  - Complete recruitment
  - Early data available
- Q1 2018
  - Data collection completed
  - Data analysis completed
- Q2 2018
  - Final publication

Deliverables (must include):
Quarterly presentation updates:

- *December 2016 – conference call*
- *Spring 2017 – Spring Symposium @ UT (conference call option for non-UT teams)*
- *June 2017 – conference call*
- *September 2017 – Fall Symposium @ UCSF (conference call option for non-UCSF teams)*

Final written report including results - October 31, 2017
*Specific work product (e.*g. protocols, material, device, database)

General Budget Outline:

Personnel	$	15,000
Supplies	$	12,000
Specimens	$	4,000
Imaging	$	5,000
Total Direct	$	36,000
Indirects (10%)	$	3,600
Total	$	39,600

Start Date:
(Example: Sometime *after* October 1, 2016)

End Date:
(Example: End *on or before* September 30, 2017)

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by Friday, September 9th.