A validation study using gait analysis to test the accuracy of wearable sensor data in postsurgical patients

University: UCSF	
PI and Co-PI name(s): Stefano Bini, MD	**Proposed Budget:** **(includes 10% indirect costs)**: **$40,000**
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Need and Industrial Relevance:

- Industry, providers and payers **need** objective, quantifiable measures of clinical outcomes to effectively participate in Value Based Care and APMs. Subjective PRO data and generalized population level outcomes data is not sufficiently granular or accurate to assume risk.
- Sensor data (patient generated or embedded) is a promising solution. However, we **need** validated models of passive, individual level, objective data collection to move forward with these tools.
- Industry further needs objective, rapid cycle-time data collection to inform and expedite product development and services optimization.

Project Aims (including Hypotheses):

- We aim to partner with the Human Performance Lab to test the accuracy and reproducibility of the signal obtained from patient worn sensors ("wearables") during commonly performed activities 3 months following surgery when compared to a gold standard gait analysis lab data.
- We hypothesize that in combination with our earlier study, we will be able to identify 1) the optimal combination of data points (which data points, how many of them and over what time frame-prior study) and 2) the most accurate and reproducible way to collect those data points (proposed study) that will provide an accurate picture of an individual's clinical outcome that is predictive of standardized PRO results.

Methods:

- Recruit 25 patients scheduled for unilateral primary total knee arthroplasty to undergo standardized evaluations in the gait lab while wearing a number of sensors (most likely Mio, Fitbit, Lumo and possibly others including smartwear) (see addendum 2).
- These exercises include standardized tests such as chair rising, walking, stair climbing and stair descent.
- The Gait Analysis data will be compared to that of healthy age matched controls previously tested in the lab in a 2:1 ratio.
- A thorough statistical evaluation will be performed including analytical algorithms used in "big data" (SVM neural networks used as supervised classification algorithms whose goal is to generalize each of the classes under evaluation to identify data accuracy and reproducibility,

trends and associations -Cloudmedx) to identify patterns and associations amongst this very large set of variables.

Milestones:

- Obtain IRB Approval, sensor selection and acquisition – Dec 30, 2017 (reality)
- Finish Pilot Experiments – Jan 30, 2017
- Patient Recruitment – April 30th
- Finish Collecting all data – July 31, 2018
- Finish Data analysis – August 31, 2018

Deliverables (must include):

Quarterly presentation updates:

- *December 2017 – conference call*
- *Spring 2018 – Spring Symposium @ UT (conference call option for non-UT teams)*
- *June 2018 – conference call*
- *September 2018 – Fall Symposium @ UCSF (conference call option for non-UCSF teams)*

Final written report including results – November 2, 2018

Specific work product:

- Data analysis and research abstracts delineating results of the two pilot experiments
- Identification of a theoretical protocol for passive data acquisition through wearable sensor technology for the measurement and quantification of patient outcomes following surgery.
- Such data could result in the development of a new, purpose specific sensor designed to track and monitor clinical outcomes following total joint arthroplasty and subsequent longitudinal research designed to test the hypothesis.

General Budget Outline:

- The budget for this project will be broken down mostly in terms of per patient cost for data acquisition in the Gait Lab.

Item	cost	Total (N=25)
Data Collection	450	11,250
Post Processing	450	11,250
Sensors (N=6)	250	1,500
Data Analysis	8,000	8,000
Research Personnel	4,000	4,000
Total Direct		36,000

Start Date:
October 15th, 2017

End Date:
August 31st, 2018

Addendum 1.

Stefano A Bini, MD (PI), Professor Department of Orthopaedic Surgery
Anthony Luke MD, Director UCSF Primary Care Sports Medicine and Benioff Distinguished Professor in Sports Medicine, Director, Human Performance Lab
Richard Souza PT, PhD; Vice Chair for Research and Program Director Rehabilitation Science UCSF
Brooke Schultz, MS; Lab Manager UCSF Human Performance Center
Kaitlin Vitek Formaker, Research Coordinator Arthroplasty Division UCSF
A Pitcher MD, UCSF Orthopaedic Resident
I Bendich MD, UCSF Orthopaedic Resident
K Hwang MD, UCSF Orthopaedic Resident
E Kamara MD, UCSF Orthopaedic Fellow
J Patterson MD UCSF Orthopaedic Resident

Addendum 2. Gait analysis protocol.

See below for the gait analysis protocol. Each patient will simultaneously wear a set of 6 sensors that will collect individual data sets for each patient which will be compared to their PRO data at that point in their recovery and the gait lab data, thus creating a total of 3 data sets for later analysis for each of the 25 patients. We will know which exact sensors to work with once we analyze fully the data acquired in 2016 project.

Motion Analysis – Acquisition: All testing will be performed in the Human Performance Center at UCSF. Kinematic data will be collected at 250Hz using a passive 10-camera system (VICON MX, Oxford Metrics, UK) and ground reaction force data recorded at 1000 Hz from three AMTI force platforms (AMTI, Watertown, MA). Anatomical landmarks (AL) used to create segment ends of the trunk, pelvis and lower extremities will be defined using 14 mm retro-reflective markers placed on the suprasternal notch, C_7 and L_5S_1 joints as well as bilateral on the acromion processes, iliac crests, ASIS, greater trochanters, lateral and medial femoral condyles, lateral and medial malleoli, 5^{th} and 1^{st} metatarsal heads. Rigid thermoplastic shells affixed with four markers will be attached to an elastic underwrap surrounding the thigh and shank. Both shank and thigh shells will be placed posterolaterally and overwrapped to minimize movement. Subjects will wear appropriately sized athletic shoes and non-restrictive clothing. Rigid triads of markers will be securely attached to the heel counter of the subject's shoes. The hip joint centers will be determined using a functional method previously described in the literature. Data will be recorded during dynamic motion as the subject balances on one leg while moving the contralateral leg through hip flexion-extension, hip abduction-adduction, followed by full leg circumduction [a][k]. Visual 3D software (C-Motion, Germantown, MD) will be used to calculate the pivot point of the leg indicating the estimated hip joint center. Each subject will perform several practice trials to become comfortable with the procedures. A total of 10 usable trials will be collected for each activity: (1) regular walk at self-selected speed (SSW). For SSW trials, speed will be measured by 2 photoelectric beams placed 3.9 m apart. Subjects will practice until a constant velocity is achieved and the subject is positioned appropriately to hit the center of appropriate force plate by the test limb without targeting. Trials in which the walking speed varied no more than 5% of the self-selected speed will be used. (2) Sit-to-stand task (STS). For STS trials, subjects will be seated on an armless, backless chair with one foot on each force platform. Chair height will be standardized amongst all participants. Subjects will be asked to hold their arms across their chest to standardize arm position, and prevent the upper extremities from blocking markers during the collection. Subjects will be asked to rise from the chair at a self-selected pace. (3) Stair ascent (StA) and descent (StD). A staircase with four steps will be placed longitudinally along the walkway with two force platforms embedded in the floor and first step. Subjects will be required to be able to ascend and descend the stairs with reciprocal foot placement and without the use of handrails to complete this task [84]. Trials will be

collected with each foot leading in both directions making a total of four different test conditions. (4) Treadmill incline (TI) and decline (TD) walking at a speed of 1.3 m/s; the average adult walking speed.

Motion Analysis – Processing: Marker trajectories and ground reaction force data will be low-pass filtered (Butterworth 4th order, phase lag) at 6 and 50 Hz respectively using Visual 3D (C-Motion, Germantown, MD). Three-dimensional joint kinematics will be calculated using rigid body analysis and Euler angles and referenced to the coordinate system from a standing calibration taken prior to motion trials. Joint moments will be derived from inverse dynamics using standard equations. All joint moments will be normalized to subject's body weight and height.

For SSW, knee kinematic and kinetic variables will be compared during the gait cycle - peak moments in all 3 planes during first (initial contact to zero-crossing of anterior-posterior ground reaction force) and second (zero crossing of A-P ground reaction force to toe off) halves of stance; knee adduction impulse during the two halves of stance; knee kinematics at initial contact, peak knee flexion during loading response, peak knee extension during mid-stance, knee flexion excursion (knee angular motion from initial contact to peak knee flexion) , knee extension excursion (knee angular motion from peak knee flexion to peak knee extension) and peak adduction angle during stance. Walking speed will also be compared between the groups. For STS task -The start and end will be determined by the change in vertical displacement of the pelvis in the vertical direction. When the motion of the pelvis is initiated in the vertical direction, the start of stand will be marked, and when the motion stops, the end of stand will be marked. Pelvis will be chosen to avoid using a data point that may be limb dependent, due to asymmetries in this population. For STS, StA and StD, peak knee kinematic and kinetic variables in all planes will be compared between groups. For TI and TD walking tasks, similar knee kinematic variables for prior walking trials will be accessed but due to restrictions from treadmill walking, kinetics will not be measured. Temporal spatial parameters; cadence, speed, percent single support, percent double support, and stride length, will be evaluated instead.

Functional Assessment: Performance measures are required to obtain a complete picture of the impact of knee osteoarthritis. Also, performance measures have been shown to be more responsive compared to self-report measures in people with knee OA who undergo TKA. Most commonly used measures are Timed Up and Go, Six Minute Walk Test and Stair Climbing Test .

Timed Up and Go test (TUG): The TUG requires a subject to rise from a chair, walk 3 m at free speed, turn and come back to sit down. Patients will be instructed to walk as quickly as they feel safe and comfortable. The use of the arms of the chair will be permitted to stand up and sit down. A stopwatch will be used to measure the time to complete the TUG within the nearest one hundredth of a second. The TUG is widely used to measure mobility in older adults with excellent test-retest reliability (Intraclass Correlation Coefficient [ICC] = 0.97) The duration of the test is recorded .

Six Minute Walk Test (6MWT): Subjects will be instructed to cover as much distance as possible during the 6-minute time frame. Standardized encouragement—"You are doing well," "Keep up the good work"—will be provided at 60-second intervals. The outcome is the distance walked in 6 minutes. Validity, reliability and responsiveness of the test have been reported in subjects with knee OA and knee TKA.

Stair Climbing Test (SCT): The SCT measure assesses the time it takes a subject to ascend and descend a flight of twelve 18-cm–high steps with a depth of 28 cm. Subjects will be asked to complete the test as quickly as they feel safe and comfortable; and 1 handrail will be allowed if required, although participants

will be encouraged to use just their legs for stair negotiation. Time to negotiate the stairs will be measured to the nearest one hundredth of a second with a stopwatch. Rejeski et al found that a similar stair climb task had an excellent test-retest reliability coefficient of 0.9.

For both the TUG and SCT, a practice trial will be completed; and the mean of 2 subsequent trials will be used for analysis. Assistive devices will be allowed only if the patient feels unsafe or is unable to complete the test without a cane or walker. The incidence of use of assistive devices for all performance tests will be recorded. The use of handrail during the SCT will be recorded.