



CENTER FOR DISRUPTIVE
MUSCULOSKELETAL INNOVATIONS

A validation study using gait analysis to test accuracy
of wearable sensor data in post surgical patients

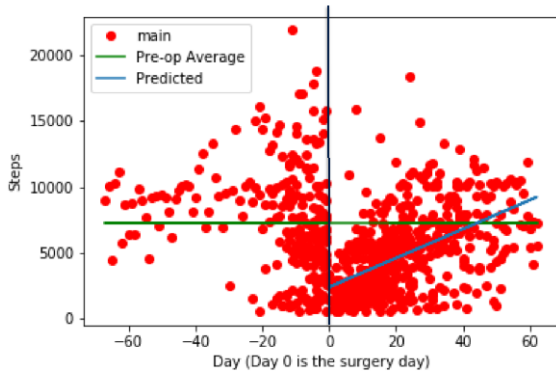
Stefano Bini, MD. PI
UCSF

WWW.NSFCDMI.ORG

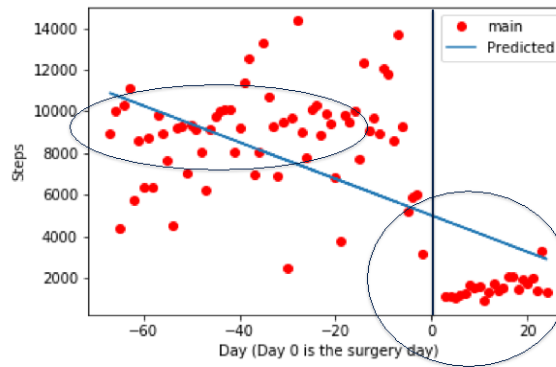
- In our prior study we have demonstrated that sensor data can accurately predict PRO outcomes
 - Trends in some individual data points correlate with 6 week PRO outcomes
 - Machine Learning algorithms can accurately cluster patients based on combinations of features collected from sensors
 - 2 week data correlates with 6 week PROs
 - Different data sets predict different PROs
 - EHR data not helpful

Individual Patient steps vs time

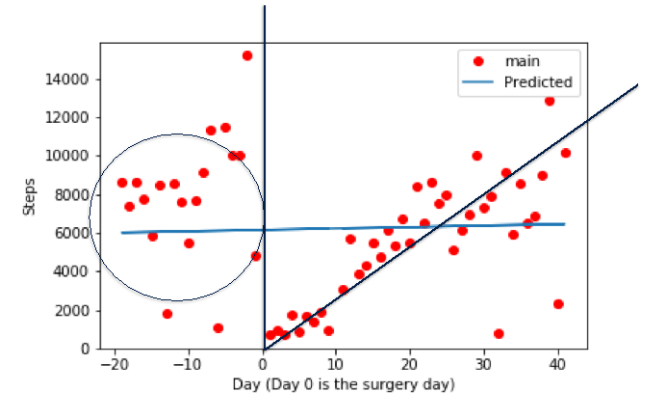
All data points
(Value of multiple data points to see trends)



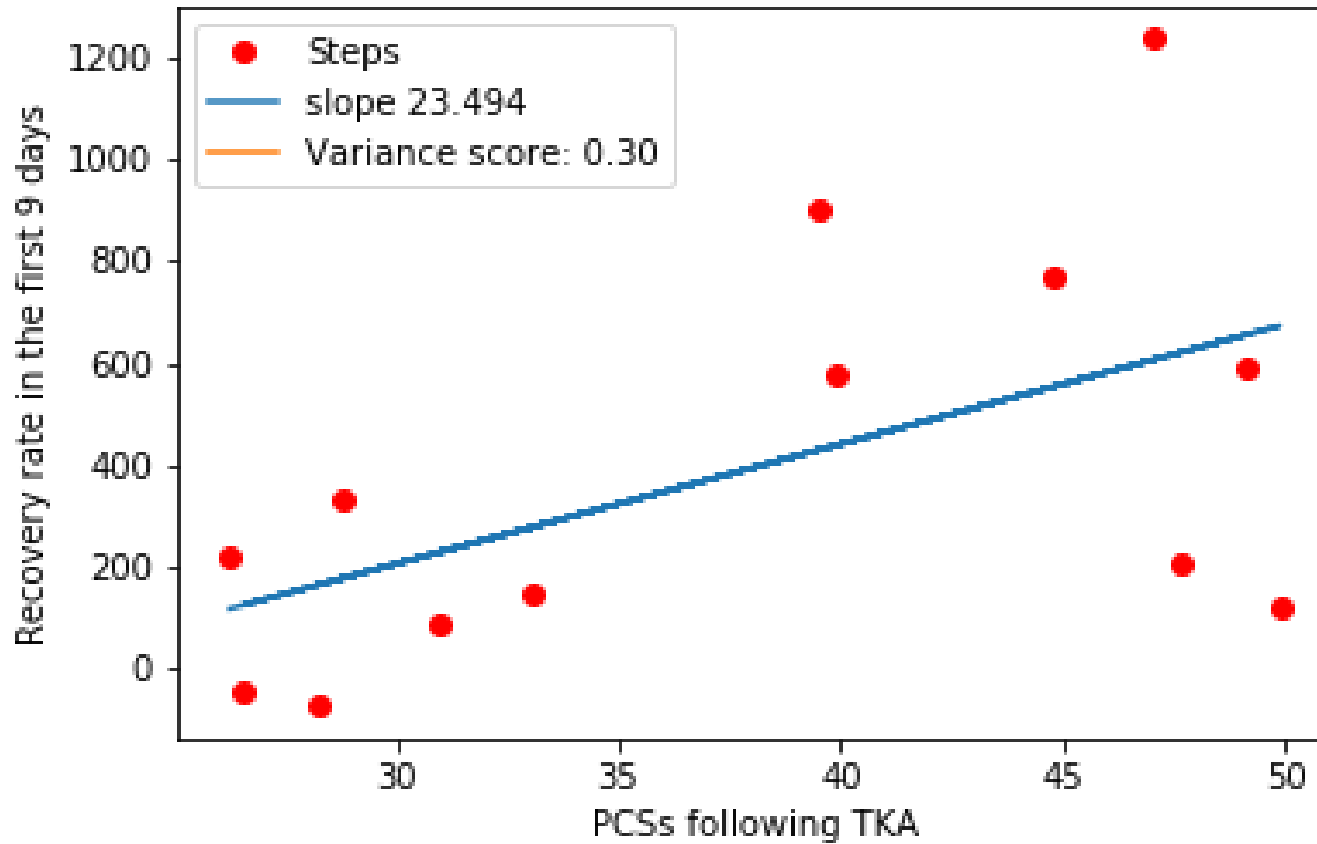
Very engaged pre-op (wide range)
did poorly post-op



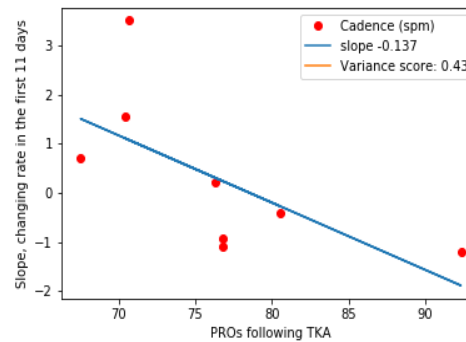
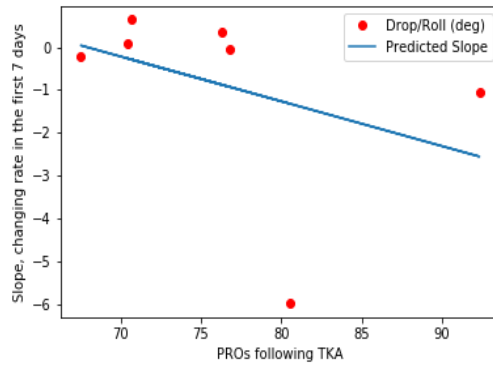
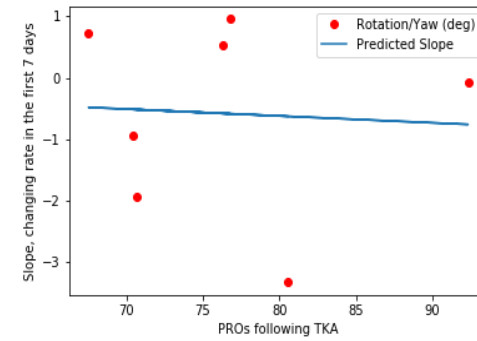
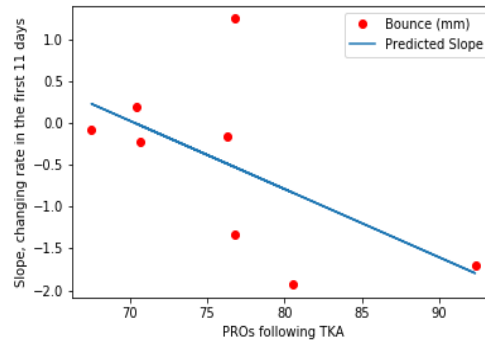
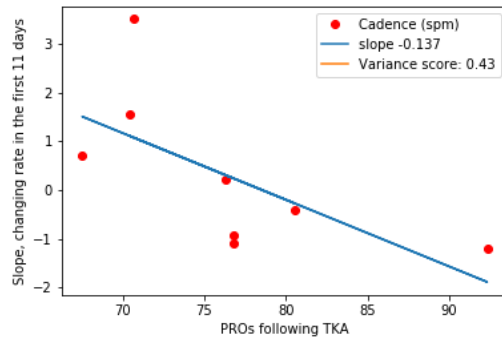
Patient doing well, still improving at 40 days,
linear improvement



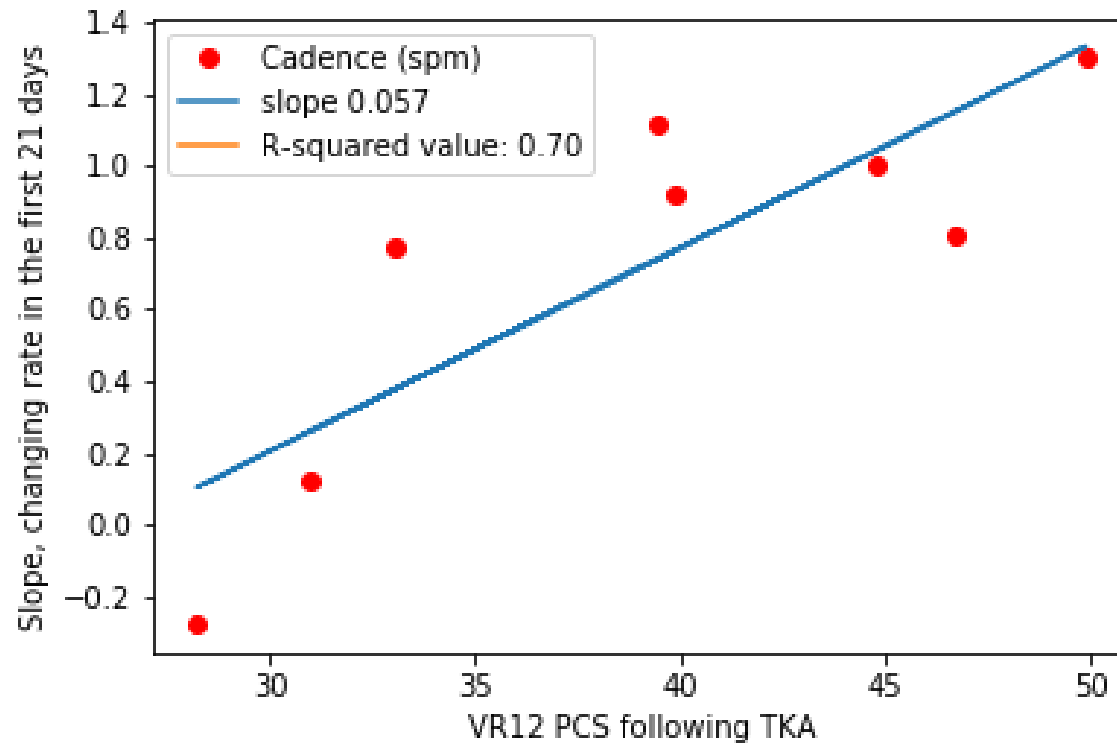
Steps vs. VR-12 PCS



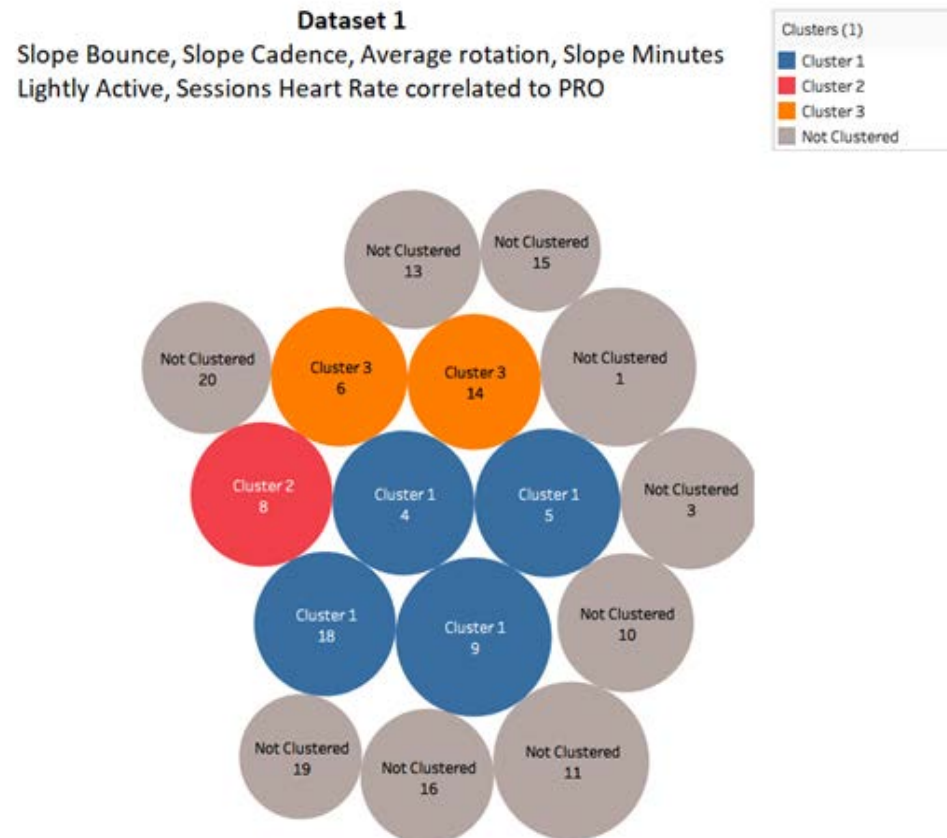
Plot of linear regression of some data points' R^2



Cadence vs. VR12 PCS



Machine Learning: K-means analysis clustering



Patient clustering and PRO (HOOS/KOOS)

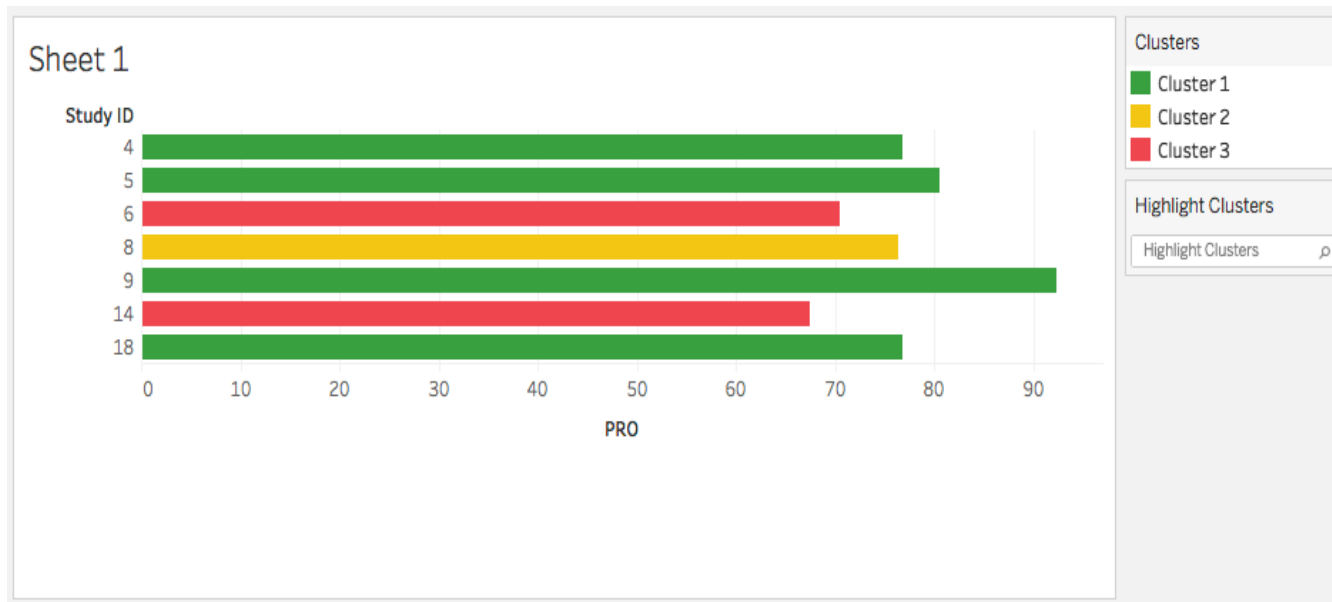
Sum of Slope Bounce (mm)

Sum of Slope Cadence (spm)

Sum of Average Rotation/Yaw (deg)

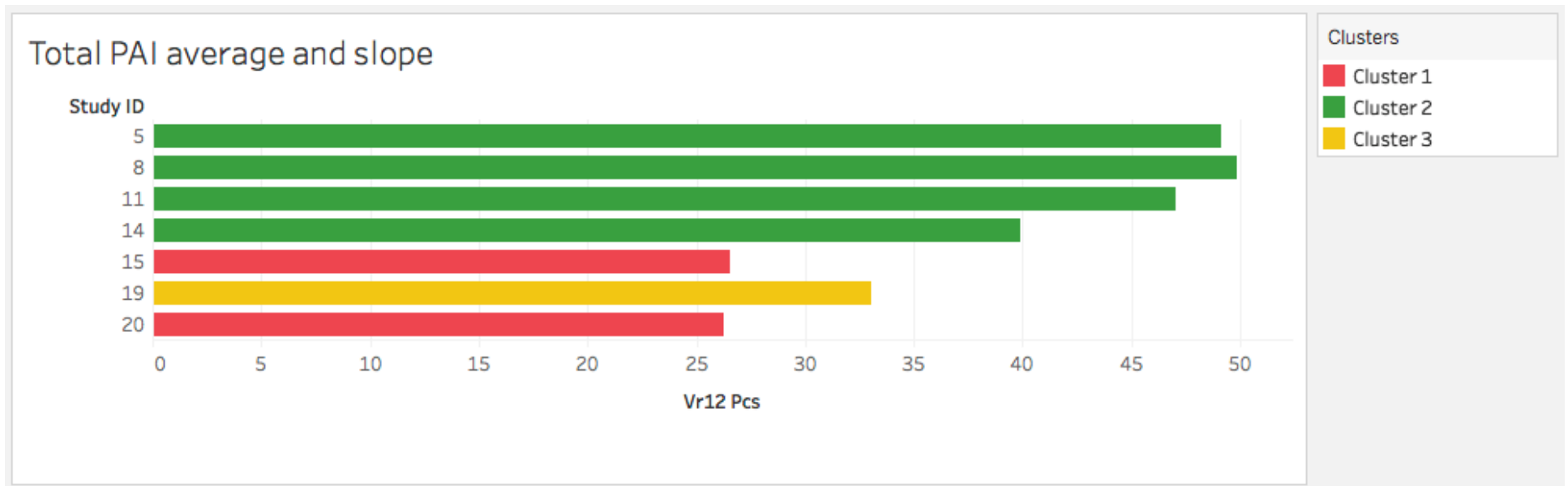
Sum of Slope Minutes Lightly Active

Sum of sessions HeartRate



PAI vs VR12 PCS

(measure of overall metabolic output)



Background: accuracy study

- The accuracy and consistency of sensors to detect motion in post surgical patients has not been validated
- Reproducibility of data is important when comparing intra-subject results in the clinical setting
 - And for creating normative data sets

Project Aims

- Aims:
 - Perform a Pilot Study to compare the accuracy of a number of standard, OTC sensors to data collected from a state of the art gait analysis lab.
- Hypothesis
 - OTC sensors can provide a measurable assessment of gait and function that is internally consistent and shows proportional inter-subject variability when compared to the gait lab data.

Original Methods

- Recruit 25 patients, 3 months s/p TKA and collect PRO data (VR-12, KOOS).
- Identify a number of OTC wearables based on 2017 CDMI funded study
- Collect data from sensors and simultaneously kinematic data (10 camera Vicon System) and force plate data (3 AMTI force platforms)
- Compare Gait Lab and sensor data to each other and also PRO data and age matched controls (existing data)



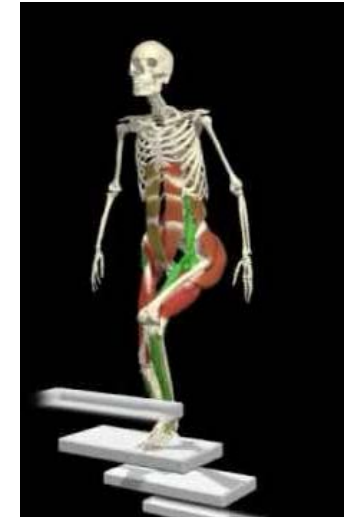
Updated Methods- sensors and data

- Recruit 25 patients, 4 weeks s/p TKA and collect sensor data
- Select OTC wearables based on 2017 CDMI study
 - LUMO
 - FITBIT
 - Under Armour HOVR shoes
- Collect data from sensors, kinematic data (10 camera Vicon System), force plate data (3 AMTI force platforms), and EKG
- Compare Gait Lab and sensor data



Updated Methods – Testing protocol

- Self Selected Walk Speed test
- 30 sec Sit to Stand Task
- Stair Ascent and Descent Trial
- Treadmill level, incline and decline walking (speed: 1.3 M/s)
- Timed Get Up and Go Test
- 40 meter walk test
- Stair climbing test
- Heart Rate and Calories Burned Analysis
 - Certified exercise physiologist



Milestones

- Submitted IRB
- Completed predicate study
- Updated study design details based on results of prior study

- Delays
 - IRB
 - CRC
 - Prior Study data completion

- Timeline: depending on when we get the IRB, we can probably recruit patients and run them through over the summer without too much delay

- *Patient compliance:* we saw a clear difference in our prior study. In this controlled environment, patients will be supervised and therefore will wear the devices.
- *Which signal?* We will use those with the highest R^2 in the prior study or those we think are better suited to that which we can test in the lab
- *Is the N large enough?* We expect that 25 patients with complete data sets will be sufficient to show consistency across patients. This study is not looking to prove correlation (though we will look).
- *Cross Specialty Applicability:* This method will be applicable to any surgical patient or even rehab patient. However, we have learned that not all sensor data correlates with all PROs so for each PRO and procedure a validation study would be needed