Improving Spine Surgical Care With Real-Time Objective Patient Tracking Using the Apple Watch

Study Protocol

NCT04379921

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1. PURPOSE OF THE STUDY

a. Brief Summary

For patients who undergo spine surgery or are experiencing back pain, mobilization is an important factor in long-term medical and psychological wellbeing. Unfortunately, there is currently no established objective method such that surgeons can track their patients' mobilization progress postoperatively. We hypothesize the ability of the patient to be able to track their own activity and discuss with their surgeon objective mobilization goals will not only help patients achieve empowerment in their own care but also improve their overall satisfaction and self-reported outcomes. The purpose of this study is to test our hypothesis using the most prevalent commercially available wearable technology, the Apple Watch.

b. Objectives

In this study, we will address the following questions:
1. Is it feasible for spine patients to wear the leading commercially available device (specifically, the Apple Watch) before and after spine surgery to assist with their spine care?
2. Do objective patient metrics (steps, distance traveled, max HR achieved) obtained from this commercially available device directly correlate with subjective patient reported outcome measures (PROMs) for spine surgery patients?
3. Do we see a significant change in objective outcome metrics before and after spine surgery?
4. Are patients more satisfied with their spine care as a result of using the Apple Watch in our practice?

c. Rationale for Research in Humans

The purpose of this study is to assess the efficacy of using a commercially available wearable activity monitor (the Apple Watch) in the postoperative care of patients undergoing spine surgery.

2. STUDY PROCEDURES

a. Procedures

This study protocol is similar in parts to previously approved protocol, "Accelerometers in spine surgery study," for which Dr. Desai (Co-PD on current proposal) is the PD.

All English-speaking adult patients (>=18 years old) who are undergoing elective spine surgery (excluding patients with spine trauma, tumors, or infection) for Cohort 1 or are undergoing any back treatment for Cohort 2 by neurosurgery attending physicians at Stanford (Dr. Corinna Zygourakis, Dr. Atman Desai, Dr. Anand Veeravagu, Dr. John Ratliff, Dr. Jon Park, Dr. Lawrence Shuer) will be eligible for participation in this study.

All participants in Cohort 1 and Cohort 2 will receive our standard of care.

In Cohort 1, percentage for random assignment to each group is 50%. Those are assigned to the "intervention" (i.e., the Apple Watch) will receive instructions on how to use the activity section within the Watch. The participants will either have their mobility data submitted via the previously approved app Neurocoach. The intervention group will wear the Apple watch 2-6 weeks pre-operatively as well as at least 6 months post-operatively (may continue to wear as long as 12 months). The control group will not. Patients in the interventional group receiving an Apple Watch may be asked to come in for a training and set-up visit at clinic. Parking passes will be provided for this visit.

All patients in Cohort 1 will be seen in follow-up clinic as per standard of care (4-6 weeks, 3 months, 6 months, and 12 months post-operatively). At each time point, all patients will complete standardized quality of life questionnaires (several of which are already incorporated in our postoperative clinic) and an additional study-specific questionnaire regarding satisfaction with their care and recovery.

In Cohort 2, all participants will receive an Apple Watch and instructions on how to use the activity section within the Watch. The participants will have their mobility data submitted via the previously approved app Neurocoach. Participants will wear the Apple Watch for 2-3 weeks. Participants will complete standardized quality of life questionnaires (several of which are already incorporated in our postoperative clinic) at the beginning and end of the 2-3 week study. This cohort will have their pain monitored daily using brief questionnaires.

b. Procedure Risks

Our protocol does not change the standard of care for any patient. It provides a supplementary intervention for half of our patients. The intervention is using a wearable activity monitor device (the Apple watch), which is a minimal risk.

c. Use of Deception in the Study

Deception will not be used.

d. Use of Audio and Video Recordings

Audio or video recording will not occur.

e. Alternative Procedures or Courses of Treatment

Standard of care will not be withheld. Our study does not involve alternative procedures or treatments.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

All patients will undergo standard of care for their spine surgery before, during, and after the study.

g. Study Endpoint(s)

For Cohort 1, the study endpoint will be 12 months postoperatively. Following enrollment during the pre-operative visit, we will see patients in clinic during their standard postoperative visits, at 4-6 weeks, 3 months, 6 months, and 12 months post operatively. All patients will complete the Stanford Spine quality of life questionnaires, as per the standard of care, at all postoperative visits. Patients with the Apple Watch will also fill out a paper questionnaire assessing satisfaction with the Apple Watch (all questions are included in attachment).

As participants reach the 12-month study period, we will conduct ongoing analysis of the data. If we observe clear statistically significant and clinically significant superiority in one group, the study will be terminated prior to the projected total participant population has been enrolled. If there are no such differences noted, the Cohort 1 will terminate after the all patients have had their 12-month postoperative visit, likely July 2023.

For Cohort 2, the study endpoint will be 2-3 weeks after enrollment and Apple Watch setup. If we observe clear statistically significant and clinically significant changes, the study will be terminated prior to the projected total participant population has been enrolled. If there are no such differences noted, the Cohort 2 will terminate after all patients have completed the study, likely August 2021.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

Our prior research protocol, "Accelerometers in spine surgery study," for which Dr. Desai (Co-PD on current proposal) is the PD, has informed the creation of the current protocol. In that study, we were used a low-cost accelerometer to objectively assess patient's mobility and function before and after elective cervical or lumbar surgery. It showed that recovery to baseline occurred for most by 8 weeks postoperatively.

General background

Spine surgery represents a significant portion of interventional procedures in the United States. There is an increasing rate of spine surgeries performed in the United States over the past 20 years[1,2], which has been driven – in large part – by an aging population.[3] This is expected to continue to increase, as the US Department of Health and Human Services projects the population age 65 and over to double from 49.2 million in 2016 to 98 million in 2060.[4] Spine degenerative pathologies and disability are highly prevalent, and represent a major economic burden; the annual cost of spine care in the US is estimated at $100 billion.[3,5] The postoperative management and rehabilitation of spine patients remains difficult and costly. Early postoperative mobilization of patients reduces complications, and is associated with improved survival, decreased length of

hospitalization, and improved psychological well-being.[6] Current methods for evaluating postoperative spine patients are limited as these mainly rely on self-reported quality of life and pain surveys, which are subjective outcome measures that may be heavily influenced by patient perception, psychological state, and other perioperative influences. Additionally, the breadth of patient reported outcome measures (PROMs) is extensive and unsustainable; for example, Guzman et al. (2016) recently evaluated 19,736 articles reporting on spine surgery, and found the use of 206 unique PROMs.[7]

Wearable activity monitors (WAMs)

Technological advances in recent years have resulted in novel wearable devices that interface with mobile phones and/or computers.[8] Such wearable devices, including smartwatches developed by Apple, Fitbit, and Samsung, incorporate sophisticated biosensors and wireless data communication that allow the wearer to monitor, access, and transmit information easily. Given the functionality and accessibility of such biosensors capable of wireless information exchange, these devices are poised to become vectors of innovative non-invasive monitoring solutions for effortless transmission of physiological data.[8] As these devices continue to propagate amongst the general public, they have the potential to provide health care providers with objective, data-driven information that can improve the quality of health care, clinical workflow, and positively influence clinical management.[9]

With advanced sensors on hand[10] (including an accelerometer, gyroscope, ECG, and heart monitor), and the ability to objectively measure patients' physical ability (via steps per day, distance walked, floors climbed, and calories burned), such technology could provide objective measures to supplement the subjective PROMs and provide physicians an improved ability to track postoperative mobility outcomes. The Apple Watch Series 4 obtained class II FDA clearance in 2018 for ECG monitoring and irregular heart rhythm notification. Studies have analyzed validity of the Apple Watch for activity metrics. Breteler et al. showed that participants gave favorable usability scores to the Apple Watch, and it had low variance compared to their reference standard Actigraph GT3X.[13] Veerabhadrappa et al. showed that compared to manual step count, the Apple Watch had an overall minimal under-estimation of step count, about 1 step mean-level difference.[14] Xie et al. have also demonstrated that compared to manual measurements, the mean error for heart rate, number of steps, and distance were minimal.[15] There are several WAMs available commercially; however, to widen the relevance of our study, we will be using the Apple Watch® (Apple Inc.), which is one of the most widely available wearable devices, and most recently was reported to have a global market share of 51 percent.[16]

WAMs in patients with spine disease

Few studies exist in the literature evaluating WAMs for spine patients, with small number of patients per study. In a case report using Fitbit, Phan and Mobbs showed that a patient who underwent minimally invasive lumbar fusion had initial decrease in step count and distance traveled but after 2 months post op, the patient improved in both categories.[11] This improvement was sustained at 12-month post op follow up (end point of study). In a prospective study of 30 patients undergoing spine surgery who were asked to wear Fitbits, Mobbs et al. showed improvement in steps taken and distance traveled at the 3-month post op visit. Participants also noted improvement in PROMs. Two patients did

not wear the device, and there were no comparison groups.[11] Interestingly, Mobbs et al. did not find a correlation between objective activity levels and subjective PROMS, although their study was limited by its small size.

Ours will be the first prospective, controlled clinical trial of a long-term outcome assessment of supplementing postoperative care of spine patients with commercially available WAMs.

1. Bernstein DN, Brodell D, Li Y, Rubery PT, Mesfin A. Impact of the Economic Downturn on Elective Lumbar Spine Surgery in the United States: A National Trend Analysis, 2003 to 2013. Global spine journal 2017;7:213-9.
2. Davis H. Increasing rates of cervical and lumbar spine surgery in the United States, 1979-1990. Spine 1994;19:1117-23; discussion 23-4.
3. O'Lynnger TM, Zuckerman SL, Morone PJ, Dewan MC, Vasquez-Castellanos RA, Cheng JS. Trends for Spine Surgery for the Elderly: Implications for Access to Healthcare in North America. Neurosurgery 2015;77 Suppl 4:S136-41.
4. 2017 Profile of Older Americans. 2017. (Accessed 05/31/2019, 2019, at https://acl.gov/sites/default/files/Aging%20and%20Disability%20in%20America/2017OlderAmericansProfile.pdf.)
5. Parker SL, Chotai S, Devin CJ, et al. Bending the Cost Curve-Establishing Value in Spine Surgery. Neurosurgery 2017;80:S61-s9.
6. Epstein NE. A review article on the benefits of early mobilization following spinal surgery and other medical/surgical procedures. Surgical neurology international 2014;5:S66-73.
7. Guzman JZ, Cutler HS, Connolly J, et al. Patient-Reported Outcome Instruments in Spine Surgery. Spine 2016;41:429-37.
8. Lu TC, Fu CM, Ma MH, Fang CC, Turner AM. Healthcare Applications of Smart Watches. A Systematic Review. Applied clinical informatics 2016;7:850-69.
9. Reeder B, David A. Health at hand: A systematic review of smart watch uses for health and wellness. Journal of Biomedical Informatics 2016;63:269-76.
10. Henriksen A, Haugen Mikalsen M, Woldaregay AZ, et al. Using Fitness Trackers and Smartwatches to Measure Physical Activity in Research: Analysis of Consumer Wrist-Worn Wearables. Journal of medical Internet research 2018;20:e110.
11. Mobbs RJ, Phan K, Maharaj M, Rao PJ. Physical Activity Measured with Accelerometer and Self-Rated Disability in Lumbar Spine Surgery: A Prospective Study. Global spine journal 2016;6:459-64.
12. Phan K, Mobbs RJ. Long-Term Objective Physical Activity Measurements using a Wireless Accelerometer Following Minimally Invasive Transforaminal Interbody Fusion Surgery. Asian spine journal 2016;10:366-9.
13. Breteler MJ, Janssen JH, Spiering W, Kalkman CJ, van Solinge WW, Dohmen DA. Measuring Free-Living Physical Activity with Three Commercially Available Activity Monitors for Telemonitoring Purposes: Validation Study. JMIR Form Res 2019; 24;3(2).
14. Veerabhadrappa P, Rhudy MB, Moran MD, Renninger MD, Dreisbach SB, Gift KM. Apple Watch Steps. J Gen Intern Med 2019; 34(1):14.

15. Xie J, Wen D, Liang L, Jia Y, Gao L, Lei J. Evaluating the Validity of Current Mainstream Wearable Devices in Fitness Tracking Under Various Physical Activities: Comparative Study. JMIR Mhealth Uhealth, 2018, 12;6(4).
16. Global Smartwatch Vendor Market Share by Region: Q4 2018. Strategy Analytics, 2019. (Accessed 06/01/2019, 2019, at https://www.strategyanalytics.com/access-services/devices/wearables/market-data/report-detail/global-smartwatch-vendor-market-share-by-region-q4-2018.)

b. Findings from Past Animal Experiments

Not applicable

4. PARTICIPANT POPULATION

a. Planned Enrollment

Cohort 1:
(I) around 200 patients total at Stanford Neuroscience Health Center and at Stanford Medicine Orthopaedic Spine Center
(II) around 200 patients total at Stanford Neuroscience Health Center and at Stanford Medicine Orthopaedic Spine Center (the cohort will not include participants from any other non-Stanford sites)

100 patients will be in the control arm - no Apple Watch or app; 100 patients will be in the intervention arm - will receive Apple Watch and will download app.

A few additional subjects may be enrolled so as not to delay the completion of the trial. Surgery for a subject may change to several weeks later or subjects may decide not to do surgery. The target in each cohort will remain at about 100 subjects.

Participants will be adults (greater than or equal to 18 years old) who will be undergoing elective spine surgery at Stanford University Hospital by a Stanford Neurosurgery or Orthopaedic Spine attending physician. The reason for using such participants is to be able to effectively assess long-term mobility and satisfaction outcomes of patients who have undergone spine surgery who will be using Apple Watch in addition to the standard of care.

Cohort 2:
(I) 15 patients total at Stanford Neuroscience Health Center
(II) 15 patients total at Stanford Neuroscience Health Center (the cohort will not include participants from any other sites)

Participants will be adults (greater than or equal to 18 years old) who are undergoing any back treatment by a Stanford Neurosurgery attending physician. The reason for using such participants is to be able to effectively assess short-term mobility and satisfaction outcomes of patients experiencing back pain who will be using Apple Watch in addition to the standard of care.

b. Age, Gender, and Ethnic Background

All participants will be adults (greater than or equal to 18 years old). There is no other specification in terms of gender or ethnic background.

c. Vulnerable Populations

Vulnerable subjects are not being selectively recruited for this study. Due to the study design, children and decisionally impaired individuals will be excluded from our study. It is possible that other types of vulnerable individuals would be included though not through targeting/solicitation (pregnant women, economically or educationally disadvantaged, homeless people, employees, and students). We will ensure that these individuals understand the voluntariness of the study and will assess that overall benefits outweigh risks of participation. All participants will be provided phone number and email address for the study coordinator whom they can contact at any point with any issues that may arise. If at any point the risks become greater and/or patients indicate no longer wanting to participate, we will take steps to ensure each individual's rights and welfare first and, if appropriate, discontinue their participation in the study. We will communicate with the IRB immediately about any issues that arise in regards to the vulnerable individuals.

d. Rationale for Exclusion of Certain Populations

Children are not included for several reasons. First, assessment of behavioral modification using WAM postoperatively in spine patients has not been studied via a trial in any population. We need to establish an understanding with an adult population first to better understand the full scope of risks and benefits before considering exposing children to the potential risks of this type of study. Second, a better assessment of commercially available WAMs use amongst children is needed to understand applicability of this research question to pediatric spine patients. Lastly, the neurosurgery faculty in this study operate primarily on adult patients, who have a much higher prevalence of spine disease than the pediatric population.

e. Stanford Populations

These populations are not being targeted by our study; however, it is possible that they will be recruited into the study if they meet eligibility criteria. We estimate that less than 10 percent of enrolled patients will be lab personnel, employees, and/or students.

f. Healthy Volunteers

All participants will have a spine pathology for which they will undergo surgery for Cohort 1 or back pain for which they will undergo standard treatment for Cohort 2. Healthy volunteers are not targeted for this study.

The primary risk to patients with their involvement in this study is an accidental privacy breach. As we describe in other sections, all data will be collected and stored on password-protected, encrypted computers. Apple will not have access to any of the patient specific health information. The patient's Apple Watch metrics (such as steps

traveled, HR, etc.) are all available on the iCloud for the patient only, not to Apple. We will ensure that only IRB-approved personnel have access to the patient-identifiable data.

g. Recruitment Details

Participants will be identified via referral from the treating surgeon in the Neurosurgery Department (Drs. Corinna Zygourakis, Atman Desai, Anand Veeravagu, Jon Park, Lawrence Shuer, and John Ratliff) or Orthopaedic Spine Department (Drs. Todd Alamin, Serena Hu, Kirkham Wood).

The patient will either be initially informed about the study by someone who is involved in the study and who he/she has a treating relationship with (e.g., in cases where patient is being treated by Dr. Zygourakis or Dr. Desai) OR the patient's physician will obtain approval from the patient to be contacted by the study team (e.g., in cases where the patient is being treated by another spine surgeon in our department).

Recruitment material will be distributed to treating physicians.

h. Eligibility Criteria

i. Inclusion Criteria

Cohort 1:
Adults (equal to or greater than 18 years old); scheduled to undergo elective spine surgery at Stanford University Hospital by a treating surgeon in the Neurosurgery Department (Drs. Corinna Zygourakis, Atman Desai, Anand Veeravagu, Jon Park, John Ratliff, and Lawrence Shuer) or Orthopaedic Spine Department (Drs. Todd Alamin, Serena Hu, Kirkham Wood); anticipated to have clinic follow up for a period of at least 12 months postoperatively.

Cohort 2:
Adults (equal to or greater than 18 years old); undergoing any back treatment at Stanford University by a treating surgeon in the Neurosurgery Department (Drs. Corinna Zygourakis, Atman Desai, Anand Veeravagu, Jon Park, John Ratliff, and Lawrence Shuer).

ii. Exclusion Criteria

For Cohort 1, we will exclude patients undergoing spine surgery for trauma, tumors, or infectious disease.

For Cohort 1 and Cohort 2, we will exclude patients who do not speak English because iPhone app, surveys and Apple Watch data is in English.

i. Screening Procedures

Screening for eligibility will be conducted in the clinic. Patients who are scheduled for pre-operative visits and meet inclusion criteria will be eligible for enrollment. Each patient's attending surgeon will give the referral to approach each patient for recruitment into the study.

j. Participation in Multiple Protocols

It is unlikely that patients will be involved in another research study, as there are no other prospective studies that are currently enrolling spine patients in the Stanford Neuroscience Health Center. We have contacted other spine faculty in the Neurosurgery Department and none have identified any trials that participants might be enrolled in during our study period. There are retrospective reviews which do not require patient enrollment.

k. Payments to Participants

Cohort 1:
If patients in the interventional group are asked to come for an extra clinic visit for training and setup, they will receive a parking pass for the visits.

For patients in the control group (100 patients), we will compensate their time for completing questionnaires (these patients will not be provided an Apple Watch during the study). At each visit during which questionnaires are completed, the participant will receive [redacted], for a possible total of [redacted] for the entirety of the study.

Cohort 2:
Patients will be given an Apple Watch and charging cable free of charge. This must be returned to Stanford at the end of the study period. If you are asked to come for an extra clinic visit for training and setup, you will receive a parking pass for the visits.

l. Costs to Participants

Not applicable.

m. Planned Duration of the Study

(i) Spring 2020: Obtain IRB approval for revised protocol; June 1, 2020 - May 31, 2023: Screen and enroll new patients;
(ii) Duration of active participation in study: approximately 12 months
(iii) June 1, 2020 - May 31, 2024: Continue collecting data, complete at least 6-month follow-up on all patients and perform interval analysis; June 1 - August 31, 2024: final data analysis.

5. RISKS

a. Potential Risks

i. Investigational devices

The device being used is a commercially available wearable technology (the Apple Watch); it has not been shown to have association with any significant risk to the user.

ii. Investigational drugs

Not applicable

iii. Commercially available drugs, biologics, reagents or chemicals

Not applicable

iv. Procedures

The study does not include any investigational procedures. For Cohort 1, patients will be using the Apple Watch daily for 2-6 weeks prior to their spine surgery and for 12 months following surgery. For Cohort 2, patients will be using the Apple Watch daily for 2-3 weeks. The entirety of the clinical care that patients will be outside the purview of this study.

v. Radioisotopes/radiation-producing machines

Not applicable

vi. Physical well-being

The Apple Watch has not been linked to any adverse physical health effects.

vii. Psychological well-being

The device will give patients feedback on their activity. This may have positive and motivating impact on patients; however, we acknowledge that it may also negative psychological effects. The degree of the latter risk is unknown and will be monitored throughout the trial, so that it may be addressed. At each time point, patients fill out the health-related quality of life questionnaires that address aspects of anxiety and depression, so we can assess whether the Apple Watch itself is having a detrimental effect on our patients.

viii. Economic well-being

Not applicable

ix. Social well-being

Not applicable

x. Overall evaluation of risk

Low

b. International Research Risk Procedures

Not applicable

c. Procedures to Minimize Risk

For Cohort 1, we will check in with patients throughout the study period in person (4-6 weeks, 3 months, 6 months, and 12 months post-operatively); these check-in meetings will include detecting any negative effects of the study on the patient. Any unexpected hazards will be reported to the IRB, and the patient will be removed from the study.

For Cohort 2, the study is only 2-3 weeks; however, participants will be able to contact study coordinator at any point to report any negative effects of the study on the patient.

Any unexpected hazards will be reported to the IRB, and the patient will be removed from the study.

The greatest risk to patients in this study will be confidentiality of identifiable information. All electronic devices (e.g., computers, hard drives, thumb drives, etc.) that contain identifiable patient information will meet Stanford School of Medicine security standards; additionally, the devices will be password-protected and encrypted. The patient's activity data will be downloaded to Stanford Research IT-approved Google Firebase storage. All data will be stored per approved Research IT / DRA protocol. No data will be shared with industry partner providing part of the funding.

d. Study Conclusion

For Cohort 1, as participants reach the 12-month study period, we will conduct ongoing analysis of the data. If we observe clear statistically significant and clinically significant superiority in one group, the study will be terminated prior to the projected total participant population has been enrolled. If there are no such differences noted, the study will terminate after the all patients have had their 12-month postoperative visit, likely June 2022. We do not expect adverse effects but will be able to identify them at postoperative visits (4-6 weeks, 3 months, 6 months, and 12 months post-operatively) and intervene if needed.

For Cohort 2, we will conduct ongoing analysis of the data. If we observe clear statistically significant and clinically significant changes, the study will be terminated prior to the projected total participant population has been enrolled. If there are no such differences noted, the Cohort 2 will terminate after all patients have completed the study, likely August 2021.

6. BENEFITS

We posit that patients with spine pathology who undergo surgery or are experiencing back pain will improve their physical activity level and feel more satisfied with their quality of life when wearable activity monitors are used to provide feedback on physical activity and when such data is used to initiate discussions about activity with their spine surgeon. Our hope is that using a commercially available device will make the results of our study applicable to future patients who may also have the Apple Watch (or other commercially available activity monitors).

7. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.