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Brief communication

Changes in prospectively collected longitudinal patient-generated health data are associated with short-term patient-reported outcomes after total joint arthroplasty: a pilot study

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ABSTRACT

Data from wearable technology may correlate with patient-reported outcome measures (PROMs). The objective of this prospective pilot study of 22 total joint arthroplasty patients was to determine if sensor-generated data are predictive of short-term PROMs in total joint arthroplasty. Data on "average daily step count" and "average daily minutes active" were generated by the provided wearable sensor preoperatively and up to 6 weeks postoperatively. PROMs were collected preoperatively and at 6 weeks postoperatively. Changes in PROMs were calculated as "Δ". Linear regression of the sensor data and PROMs generated R^2 values. Changes in the average daily step count from preop to 6-week postop strongly associated with changes in Veterans Rand 12 Physical Component Score ($R^2 = 0.4532$) from preop to 6 weeks. Changes in average daily minutes active from preop to 6-weeks postop were strongly associated with ΔHOOS/KOOS ($R^2 = 0.4858$).

Introduction

Total joint arthroplasty (TJA) is among the most successful procedures in orthopedic surgery [1]. Although 10-year survivorship of TJA exceeds 95%, up to 3% of patients may have complications within the first 30 days after the operation, requiring readmission [2]. As a result, there is a growing interest in modalities that are able to identify at-risk individuals and monitor patients after discharge from the hospital to ensure they are progressing safely and appropriately.

Potential predictors of TJA postoperative outcomes have previously been studied and include preoperative expectations, preoperative pain and function, mental health, patient demographics, and baseline health [3]. Frequently, these variables are measured using one of many validated patient-reported outcome measures (PROMs), which, moving forward, may have financial implications for providers when reimbursement is linked to them [4].

Commercial grade wearable sensors have been used to collect patient-generated health data (PGHD) to monitor arthroplasty patients postoperatively. These sensors have been shown to be accurate in monitoring the physical activity of patients after arthroplasty [5]. Toogood et al [6] used an ankle accelerometer to quantify the postoperative activity level in patients who underwent total hip arthroplasty (THA). Crizer et al [7] used a mobile step-tracking application to correlate step count to scores from the Lower Extremity Functional Scale (LEFS), a PROM. They found that step counts weakly correlate with LEFS in patients who are undergoing arthroplasty up to 12 weeks after the operation.

The objective of this prospective pilot study was to determine if perioperative PGHD such as daily step count (DSC) and activity level measures are associated with early postoperative PROMs. Specifically, we prospectively collected preoperative, 2-week, and 6-week DSC and daily minutes active (DMA) data using a wearable sensor in patients who are undergoing TJA and evaluated how well these data points correlated with the Veterans Rand 12 (VR-12) outcome score, the Knee Injury and Osteoarthritis Outcome Score

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(KOOS), and the Hip Disability and Osteoarthritis Score (HOOS) at 6 weeks postoperatively. We further measured how effectively early data could correlate with the final (6 weeks) clinical outcomes. We hypothesized that preoperative DSC and DMA will be associated with 6-week postoperative PROMs.

Material and methods

Study overview

Twenty-two patients scheduled to undergo TJA (13 THA and 9 total knee arthroplasty [TKA]) at a single institution were prospectively enrolled. Inclusion criteria were primary TKA and THA. Exclusion criteria were revision surgery or chronic pain history. The patients were given a Fitbit Flex (Fitbit Corp, San Francisco, CA) wrist-based wearable activity tracker that measured DSC and DMA. Patients were asked to wear the tracker starting 4 weeks before their operation and up to 2 months after the operation. Training and support were provided regarding the use and maintenance of the device. HOOS, KOOS, and VR-12 surveys were administered preoperatively and at 6 weeks after operation. Data were collected and stored in a deidentified fashion.

Institutional review board approval was obtained before initiation of the study.

Data collection and analysis

Preoperative baseline levels of “average daily step count” (aDSC) and “average daily minutes active” (aDMA) were determined for each patient by averaging daily data from all preoperative days the patient wore the sensor. Postoperatively, we calculated the aDSC and aDMA values at 2 weeks and 6 weeks as the average of all values collected on postoperative days 11 through 17 and days 39 through 45, respectively. Data from days that showed both zero steps taken and 0 minutes active were excluded on the assumption that the sensor was not worn. Changes in daily step count (ΔDSC) or daily minutes active (ΔDMA) were determined at 2 weeks and 6 weeks after operation by subtracting the previously calculated averages from preoperative averaged values. PROM changes from baseline were determined by subtracting 6-week results from preoperative results and are reported as ΔPROM (ΔHOOS/KOOS, ΔVR-12 Mental Component Score (MCS), and ΔVR-12 Physical Component Score (PCS)). Linear regression R^2 values were used to determine if changes in PGHD were associated with changes in patient-reported outcomes. Given that R^2 values, or the “goodness of fit” of a model, tend to be between 0.2 and 0.4 in clinical studies, we define a strong association as $R^2 > 0.4$ [8]. Statistics were performed using Microsoft Excel (Microsoft, Seattle, Washington).

Results

Twenty-two patients scheduled for TJA (13 THA and 9 TKA) were enrolled. Complete data were available for 17 patients (10 THA and 7 TKA) at 2 weeks postoperatively and for 13 patients (7 THA and 6 TKA) at 6 weeks postoperatively. The attrition of compliance was due to either loss of the device or patient decision not to wear the device. Preoperative baseline demographics, VR-12 and HOOS/KOOS scores, step count, and minutes active daily can be found in Table 1. The preoperative, 6-week postoperative, and change in PROM values between preoperative and 6-week postoperative VR-12 and HOOS/KOOS scores were not statistically significantly different between patients compliant with sensor use and those who were noncompliant.

With respect to DSC, the preoperative aDSC was weakly associated with ΔPROM values ($R^2 = 0.1735$, 0.0023, and 0.2278 for ΔHOOS/KOOS, ΔVR-12 MCS, and ΔVR-12 PCS, respectively) in this cohort. Postoperatively, the aDSC at 6 weeks was weakly associated with 6-week PROMs ($R^2 < 0.03$). Although the 2-week ΔDSC was weakly associated with ΔVR-12 PCS ($R^2 = 0.2183$), the 6-week ΔDSC was strongly associated with ΔVR-12 PCS ($R^2 = 0.4532$).

With respect to the DMA measure, the preoperative aDMA was weakly associated with ΔPROM values ($R^2 = 0.2899$, 0.1462, and 0.2446 for ΔHOOS/KOOS, ΔVR-12 MCS, and ΔVR-12 PCS, respectively). Postoperatively, the aDMA at 6 weeks was weakly associated with 6-week PROMs ($R^2 < 0.07$). ΔDMA from preop to 2-weeks postop was weakly associated with all 6-week PROMs ($R^2 < 0.03$). ΔDMA from preop to 6-weeks postop was strongly associated with ΔHOOS/KOOS ($R^2 = 0.4858$).

Table 1
Baseline demographic, activity tracker, and PROM data.

	Overall	THA	TKA
Demographics			
Percent procedure (%THA, %TKA)	22	13/22 (59.09%)	9/22 (40.91%)
Age	63 (6.46)	64 (6.51)	62 (6.53)
BMI	28.51 (6.26)	25.84 (4.38)	32.37 (6.77)
ASA grade	1.86 (0.56)	1.69 (0.63)	2.11 (0.35)
Sex M:F	7:15	6:7	1:8
Preoperative activity tracker data			
Mean step count (SD)	6089 (2990)	6031 (3265)	6175 (2737)
Mean minutes active (SD)	202 (84)	185 (83)	228 (86)
Mean resting heart rate (SD)	89.2 (14.1)	84.6 (13.9)	96.3 (12.1)
Preoperative patient-reported outcome			
VR-12 MCS	49.97 (9.22)	49.43 (10.10)	50.74 (8.31)
VR-12 PCS	32.14 (8.14)	32.73 (8.83)	31.29 (7.45)
HOOS		51.58 (13.0)	
KOOS			47.42 (12.3)

ASA, American Society of Anesthesiologists grade; BMI, body mass index; SD, standard deviation.

Discussion

In this study, we correlate wrist-based PGHD, including DMA and DSC, to short-term postoperative PROM data in patients who are undergoing arthroplasty. We found that comparing longitudinal variation in both sensor data and PROM data provided the greatest insight. The relevant findings of this study are that an increase in the postoperative aDSC at 6 weeks compared with preoperative levels is strongly associated with a ΔVR-12 PCS postoperatively and that an increase in 6-week ΔDMA is strongly associated with ΔHOOS/KOOS scores.

We did not find preoperative, 2-week, or 6-week aDMA values or 6-week aDSC values to be strongly associated with 6-week PROMs. This is similar to the finding of Crizer et al [7] who found 6-week activity level, as measured by steps on a mobile phone–based platform, and LEFS to have only a weak correlation of 0.18 for THA and 0.29 for TKA. Similarly, Luna et al [9] studied short-term PROMs compared with objective physical performance at 20 days postoperatively and found no correlation between the 2. Brandes et al [10] looked at data collected in a longer timeframe and also failed to find a relationship between increased activity and PROMs. In that study, step counts at 1 year postoperatively were compared with Knee Society Score and SF-12 scores in patients who underwent TKA, and a strong correlation was not identified. Our results, in conjunction with the existing, albeit limited, literature suggest that 6-week PROMs are only weakly associated with absolute step count and daily activity measures as collected from a wrist-based wearable consumer-grade device.

Conversely, we did find stronger relationships when comparing the overall ΔDSC and ΔDMA from before surgery to 6 weeks after surgery with the overall change in the physical function–focused PROMs, specifically ΔVR-12 PCS and ΔHOOS/KOOS. Our results suggest that changes, rather than absolute values, in patient steps and activity from preoperative levels to 6 weeks postoperatively may serve as more accurate objective surrogates for improvements in 6-week clinical outcomes. These findings suggest tracking changes in activity of patients may provide a potential objective measure to identify patients who may not be progressing appropriately in the short-term postoperative period.

One of the main limitations of this study is the relatively small sample size. This was because of it being designed as a pilot study and the limited funding available. However, as there is sparse published prospectively collected data on this topic, it was not possible for us to effectively calculate an appropriate cohort size for further study without first performing a pilot. Furthermore, we acknowledge that only 77% of patients had complete data available at 2-week follow-up and 59% at 6-week follow-up. This was due to noncompliance with the use of the wearable devices issued and will need to be considered to calculate the cohort size in future studies. Although we did not explore reasons for attrition in compliance, we did find that the use of wrist-based devices was higher than that of belt-based sensors. Furthermore, given some patients may wear watches and the type of sensors we used may not replace a wristwatch, further sensor-based research may need to use wristwatch-type wearable technology. Moreover, although our sensor compliance was relatively poor, we did not find differences in PROM outcomes between patients who were compliant and those who were noncompliant with sensor use.

Despite this, our results are among the first in the domain of PGHD to draw attention to the fact that absolute values generated by wearable sensors may not be as predictive of clinical outcomes as a documented change over time of the same values. Furthermore, the strongest data relationships we documented in this group of patients who are undergoing joint replacement occurred when we compared the change over time in sensor data (ΔDSC and ΔDMA) with the change in a patient's clinical status from before surgery to the 6-week follow-up (ΔPROMs). Larger studies are needed to investigate the purpose of using PGHD to predict PROMs in surgical patients. The data presented in this study and others will help us better understand sample size and which sensor data values are most likely to predict outcomes.

Conclusions

Changes from preoperative levels to 6-week postoperative levels in "DSC" and "DMA" data collected with a commercial grade wearable sensor are strongly associated with improvements in patient-reported outcome values (ΔHOOS/KOOS and ΔVR-12 PCS) collected over the same time period in patients who are undergoing TJA. In this study, absolute sensor values were weakly associated with PROM values after TJA. Our results suggest that research on the use of sensors to quantify outcomes after total joint surgery will need to focus on comparing longitudinal data if it is to be predictive of clinical results.

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References

[1] Ethgen O, Bruyère O, Richy F, Dardennes C, Reginster JY. Health-related quality of life in total hip and total knee arthroplasty: a qualitative and systematic review of the literature. J Bone Joint Surg Am 2004;86(5):963.
[2] Avram V, Petruccelli D, Winemaker M, de Beer J. Total joint arthroplasty readmission rates and reasons for 30-day hospital readmission. J Arthroplasty 2014;29(3):465.
[3] Fortin PR, Clarke AE, Joseph L, et al. Outcomes of total hip and knee replacement: preoperative functional status predicts outcomes at six months after surgery. Arthritis Rheum 1999;42(8):1722.
[4] Black N. Patient reported outcome measures could help transform healthcare. BMJ 2013;346:f167.
[5] Battenberg AK, Donohoe S, Robertson N, Schmalzried TP. The accuracy of personal activity monitoring devices. Semin Arthroplasty 2017;28:71.
[6] Toogood P, Abdel MP, Spear JA, et al. The monitoring of activity at home after total hip arthroplasty. Bone Joint J 2016;98(11):1450.
[7] Crizer MP, Kazarian GS, Fleischman AN, et al. Stepping toward objective outcomes: a prospective analysis of step count after total joint arthroplasty. J Arthroplasty 2017;32(9):S162.
[8] Hamilton D, Ghert M, Simpson A. Interpreting regression models in clinical outcome studies. Bone Joint Res 2015;4:152.
[9] Luna I, Kehlet H, Peterson B, et al. Early patient-reported outcomes versus objective function after total hip and knee arthroplasty: a prospective cohort study. Bone Joint J 2017;99(9):1167.
[10] Brandes M, Ringling M, Winter C, Hillmann A, Rosenbaum D. Changes in physical activity and health-related quality of life during the first year after total knee arthroplasty. Arthritis Care Res (Hoboken) 2011;63(3):328.