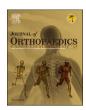
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The use of actigraphy to objectively define motion and function before and after shoulder arthroplasty

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ABSTRACT

Introduction: Actigraphy is a quantitative means of measuring activity data that has proven viable in post-surgery recovery analysis for arthroplasties in lower extremities, but scant literature has been published on the utilization actigraphy to evaluate shoulder motion and function before and after shoulder arthroplasty. The purpose of this prospective cohort study is to identify if actigraphy can serve as a valid means for objective evaluation of shoulder function and motion before and after shoulder arthroplasty. Secondarily, the data collected by the actigraphy can be analyzed with standard patient-reported outcomes to report correlations between the subjective and objective methods used in this study.

Materials and methods: Sixty-four subjects wore an actigraphy device for one day at pre-op, six, twelve and twenty-four weeks. In addition, subjects completed three patient-reported outcome surveys at each time-point. Student t-tests were used to compare percent activity preoperatively with 24-weeks and to compare PROs pre-operatively with 24-week results; categorical variables were compared with one-way ANOVAs.

Results: All Patient reported outcome scores significantly improved following arthroplasty (p-value < 0.001). The percent of physical activity was highly correlated with vector magnitude (p-value < 0.001), but neither percent activity or the vector magnitude were correlated with any of the PROs: UCLA Pain p-value = 0.656, SANE p-value = 0.328, UCLA Function p-value = 0.532.

Conclusions: Actigraphy results from this study mirror findings in previous literature utilizing the technology in similar manners and demonstrate its potential for motion and function analysis before and after total shoulder arthroplasties. Despite both being suitable methods independently for the evaluation of shoulder function, there was no significant correlation between standard actigraphy measurements and PROs at 24-weeks. Future research to determine clinical utility and an overall broader scope for actigraphy monitoring could benefit from improved technology, such as increased battery life for prolonged durations of data collection during observation periods.

1. Introduction

Total shoulder arthroplasty (TSA) has become a common surgical procedure for chronic shoulder pain and dysfunction. Both anatomic (TSA) and reverse (RTSA) have a high likelihood of pain relief and restoration of function. Due to operative success and an aging patient

population total shoulder arthroplasty has increased significantly in the US in the past two decades. $^{\!1}$

Operative success following shoulder arthroplasty can be measured through objective and subjective outcomes. Objective measurements commonly involve motion (e.g. flexion, extension, adduction, abduction, internal and external rotation), strength, and radiographic

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assessments. Subjective measures frequently include pain assessment (e. g. visual analog scale) and various validated patient self-reported outcome tools. $^{2-4}$ Both objective and subjective assessments may have wide variations based upon data collecting methods, quality of medical records and patient variables such as gender, psychosocial factors, past medical and surgical history. $^{5-8}$

A common objective measurement of shoulder arthroplasty is joint range of motion. The use of a goniometer is the most common assessment tool for motion however, there are limitations using this tool as a measuring device. First, differences of up to 10 % error have been identified based on measuring techniques for knee and hip flexion, \pm 11° for shoulder motion with dependency on scapular stabilization, with all requiring proper orientation of the goniometer. 9,10 Additionally, use of the goniometer requires the patient to present in person to a clinician, therapist, or research assistant for accurate measurement. New technologies have emerged with high degrees of reproducibility to objectively measure patient activity and motion which may have promising future clinical applications. One of the more prevalent physical activity measurement technologies is actigraphy. In actigraphy, small, portable tri-axial accelerometers are used to measure physical activity and gait. Activity counts (acceleration) are measured in each of the 3 axis (x, y, z)and summed as vector magnitude (VM). 11 While the use of actigraphy is prevalent in assessing sleep disturbances, there has been more emergence of its use for orthopedic applications. Previous literature has demonstrated the validity of actigraphy and has been used to measure physical activity along with sleep quality after hip and knee arthroplasty and non-orthopedic surgery such as breast reconstruction. 12,13 There is limited data regarding the use of actigraphy for clinically assessing motion before and after TSA and RTSA. The goal of this prospective cohort study is to compare subjective patient reported outcomes with objective actigraphy measurements before and after total shoulder arthroplasty with both TSA and RTSA.

2. Materials and Methods

This study was approved by the University of West Florida's Institutional Review Board (IRB 2017-056). Consecutive subjects from a single senior orthopedic surgeon with a high-volume shoulder arthroplasty practice (CO) being evaluated for TSA and RTSA consideration were invited to participate. All patients were enrolled over an 11-month time period. Motion and activity testing with actigraphy was performed at the following time periods based on a previously published protocol: pre-operatively, six, twelve- and twenty-four-weeks post-surgery. At each testing episode, subjects had an actigraphy device applied to the upper (biceps) operative arm. During this visit, patients also completed standardized patient reported outcome surveys using the Single Assessment Numeric Evaluation (SANE), UCLA Shoulder Score, and the American Shoulder and Elbow Surgeons Shoulder Score (ASES). All surgeries were performed at the same outpatient surgical facility and three different shoulder prostheses were utilized.

2.1. Actigraphy

The device used was the Actigraph GT9X Link (Pensacola, FL) that included triaxial accelerometers and an inertial measurement unit (IMU). The device was placed on the upper arm (biceps). The IMU contains a 3-axis gyroscope, 3-axis magnetometer, and secondary 3-axis accelerometer, which measures motion sensing in addition to the device's primary 3-axis accelerometer. The device was positioned on the arm in which the x-axis (Axis 1) reflects vertical arm movement, the y-axis (Axis 2) reflects lateral arm movement and the z-axis (Axis 3) reflects forward and backwards arm movement. Vector magnitude (VM) is calculated as the square root of each axis squared and added together or VM = $\sqrt{x^2 + y^2 + z^2}$. The percentage of time spent as active percent activity was calculated as light activity plus moderate activity divided

by the total activity time (sedentary, light and moderate activity).

2.2. Accelerometer data analysis

For each data collection period, the raw data was downloaded from the sensor to a computer workstation, ActiLife (version 6.0) software was utilized to extract the accelerometer measurements on all 3 axes and at 100 Hz (Fig. 1) (Actigraph, Pensacola, FL).

A MATLAB script (MathWorks, Natick, MA) was utilized to condense the 100-Hz accelerometer measurements into 1-s epochs. For each 1-s epoch, the accelerometer measurements' mean and standard deviation on each axis along with the mean and standard deviation of the vector magnitude were calculated. The resulting files were then loaded to a SQL Server (Microsoft, Redmond, WA) database for analysis. Analytical queries were written to calculate the following: 1) vector magnitude in the xy-, xz- and yz-planes for each 1 s epoch, 2) mean and standard deviation of the vector magnitude on each plane during the data collection period, 3) the number of epochs in which the planar vector magnitude exceeded the mean plus one standard deviation for epochs that did not have an acceleration value greater than 2 on any one axis as a means to reduce noise in the data.

Additionally, ActiLife software clinical reports include energy expenditure, MET rate, steps, and vector magnitude of motion. Using these variables, the software estimates the number of minutes spent (and percentage) in sedentary, light activity, moderate activity, vigorous activity and very vigorous activity for the time the device was worn. Use of the IMU functionality significantly decreased battery life. Almost all patients wore the devices for 400–600 min during their 24-h observational period, with the devices being removed at bedtime and during showers.

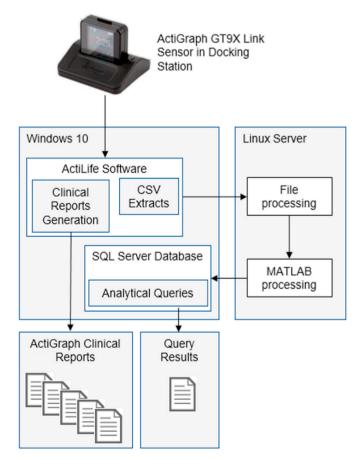


Fig. 1. Raw data processing pipeline.

2.3. Statistical methods

Patient, surgical characteristics and actigraphy analyses were analyzed with descriptive statistics, student t-tests were used to compare percent activity preoperatively with 24-weeks and to compare PROs preoperatively with 24-week results. Categorical variables were compared with one-way ANOVAs. Multiple numerical correlations were performed with a correlation matrix. All data were analyzed using R statistical software (version 4.2.0).

3. Results

A total of 71 subjects were enrolled over the eleven-month time period. One patient dropped out and three patients improperly wore the device and were excluded. Three more patients having only initial actigraphy data were excluded leaving a total of sixty-four subjects. TSA implants included Biomet, Tornier (Flex and Simpliciti), and RTSA implants included Biomet and Tornier.

Of the 64 subjects, four subjects (6.3 %) completed actigraphy at only one time period, eighteen at 2 periods (28.1 %), twelve at 3 periods (18.8 %) and thirty completed all 4 time periods (46.9 %). Forty-six subjects (71.9 %) had actigraphy data collected through 24-weeks. The average patient age was 68.7 years (range: 38–86). Male patients accounted for 60 % of subjects and handedness was about equal. A majority of subjects had the Biomet prostheses (40 patients, 63.8 %) followed by Tornier Flex (21 patients, 31.9 %), and Simpliciti (2 patients, 4.2 %). More patients included in the study had anatomic total shoulder arthroplasties (36 patients, 56.2 %) versus reverse total shoulder arthroplasties (28 patients, 43.8 %).

3.1. Actigraphy

Vertical acceleration (Axis 1) was slightly higher at all time periods (Table 1). Vector magnitude dropped after surgery, but by 24-weeks returned to baseline (Table 1). Vigorous or very vigorous activity classifications were not observed. Percent activity preoperatively and at 24-weeks showed no significant difference (t=-1.30, p-value = 0.20) (Table 1).

The two-dimensional planar vector magnitude of participants who wore the ActiGraph during pre-op and at 6, 12 and 24-weeks after surgery demonstrated differences between those who underwent the TSA versus the rTSA in the yz-plane which correlates to horizontal abduction and adduction of the arm (Fig. 2). The yz-plane showed a greater variance than the xy- and xz-planes which represent vertical abduction/adduction and forward flexion/backwards extension respectively (Fig. 2).

For TSA participants, the percentage of time when the vector magnitude in the yz-plane was greater than one standard deviation above average dropped significantly from 17.2 % at pre-op to 9.3 % at 6-weeks and then rose to 17.8 % at 24-weeks (Fig. 2). For the rTSA participants, this metric remained constant until 12-weeks, and increased between 12 and 24-weeks (Fig. 2).

3.2. Patient-reported outcomes

All Patient reported outcome scores significantly improved following

Table 1 Filtered actigraphy results, averaged activity counts (counts/sec).

	Pre-Op	6-weeks	12-weeks	24-weeks
Axis 1	239786	218054	214985	231435
Axis 2	210630	186966	178766	214051
Axis 3	219058	204178	183493	219536
Vector Magnitude	391047	355786	339226	393185
Active (%)	51 %	-	-	52 %

arthroplasty (p-value<0.001) (Table 2).

Multiple correlations were conducted to compare various actigraphy results with PRO results at 24-weeks (Table 3). The percent of physical activity was highly correlated with vector magnitude, but neither percent activity or the vector magnitude were correlated with any of the PROs. UCLA pain scores were highly correlated with UCLA function scores. UCLA pain and function were highly correlated with the 24-week SANE results. ASES scores at 24-weeks did not correlate with actigraphy or other PROs. Improvement in SANE scores at 24-weeks was stratified into moderate improvement (>50 % increase in SANE) and mild improvement (<50 % improvement in SANE).

3.3. Comparison of TSA and rTSA

Data from complete cases was analyzed on forty-five patients at 24-weeks (Table 4). A one-way ANOVA showed statistical significance between TSA and rTSA subjects only for age (Table 4).

4. Discussion

This prospective assessment in a consecutive cohort of 64 patients undergoing shoulder arthroplasty is the largest study in the literature using actigraphy to objectively measure activity and motion following anatomic and reverse total shoulder arthroplasty. We ultimately did not demonstrate significant increases in objective shoulder activity at 24 weeks post surgery, nor did we demonstrate that improved patient reported outcome measures were correlated to measured shoulder activity. Conventional wisdom assumes joint motion after months post arthroplasty correlates with reported function and outcomes. One of the most significant findings of this study is the lack of correlation between outcomes and actigraphy measured motion following both TSA and rTSA. We had hypothesized that there would be a significant correlation between activity, objectively measured motion with actigraphy and patient reported outcomes, which was not shown to be true. At the 24 week mark following surgery, neither the amount of joint activity or the degree of joint effort were correlated with the SANE, UCLA and ASES scores. These findings agree with prior reports using actigraphy in lower extremity joint arthroplasty. 15

While there is a growing body of literature using wearable monitoring devices following hip and knee arthroplasty, activity monitoring following shoulder arthroplasty is under-studied. Literature review demonstrated only two known reports using actigraphy in shoulder arthroplasty. ^{16,17} Hurd et al. (2014) utilized actigraphy devices on the wrist and biceps for 3 days in 15 rTSA patients. ¹⁶ Additionally, Hurd et al. (2018) utilized actigraphy before and after rTSA (14 patients), with no significant difference in arm activity at 1-year compared to preoperative activity. ¹⁷ These results mirror previous findings following total knee and hip arthroplasty. ^{6,14,16,18}

Technology to provide objective measurements following orthopedic surgery is an emerging field of interest that demonstrates promise for quantifying surgical success and recovery progression. Knowledge of real time, near-real time, or summarized data could allow for early intervention during the post operative recovery course if they were not appropriately progressing following total shoulder arthroplasty. The clinical use of Fitbit, another wearable activity tracking device has been previously published in hip and knee arthroplasty literature. 19–24 There is also a growing interest in the feasibility and application of activity measuring devices being directly implanted into prosthesis to objectively track patient activity and motion at the joint. 25–27 More published studies with objective data obtained by wearable devices may help resolve unanswered questions about implant design, optimal positioning of sensors, and further validate their clinical applications., etc.

The device used in this study is not standardized for wear on the upper arm but according to work by Hurd et al. there is little difference between wearing a device on the upper arm versus wrist.⁸ Our data shows little variation between the three axes when the actigraphy device

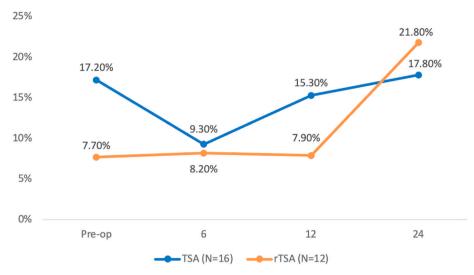


Fig. 2. Total Time Spent with YZ Vector Magnitude Greater than $\mu+1$ SD.

 Table 2

 Change in patient reported outcome scores.

Patient Reported Outcome	Pre-Op	24-weeks	T-Score	p-value
SANE	42.4	86.1	-10.8 -16.8 -21	<0.001
UCLA Pain	2.7	8.8		<0.001
UCLA Function	2.52	9.29		<0.001

is worn on the upper arm. This is similar to what has been reported for devices worn on the wrist. In our study, Pearson correlation showed that all three axes correlated highly with the VM (r =0.913 to 0.981), which was expected due to the direct relationship in the calculation of the VM. Limb activity dropped after surgery in all axes, and in turn VM, and returned to baseline at 24-weeks. Arm activity was generally 2–4 times greater than waist activity as it is likely that a device worn on the arm also recorded motion during walking and the activities of daily living, similar to data reported by Kim et al. 28 Interestingly, arm, but not waist (torso) activity dropped after surgery, which may be explained by compensatory motion through the torso when the arm is immobilized and or limited during post operative recovery.

Similar to previously published hip and knee arthroplasty studies, shoulder arthroplasty fails to show significant increase in activity magnitude over preoperative baseline. ^{6,12,16,17} In regard to knee and hip arthroplasties, age and other comorbidities may contribute to the lack of increased activity after surgery. It is similarly unclear why objective measurement of physical activity with actigraphy does not correlate with common subjective measurements of pain and function (PROs), suggesting that overall patient function may not correlate as much to patient satisfaction following shoulder arthroplasty versus improvements in their overall daily pain. A comparison of rTSA and TSA patients did not show any significant difference in actigraphy measurements or

PROM scores at 24-weeks, however no formal power analysis was conducted to estimate the sample size needed for this distinction. This does however demonstrate post operative satisfaction to not be significantly different following both TSA and rTSA. It also demonstrates that overall actigraphy measurements do not objectively show that a patient has better function with TSA or worse overall function with rTSA at 24 weeks, something that would be assumed to have a significant difference with higher objective function favoring TSA.

This study contains several limitations. Upper extremity device placement to measure shoulder activity includes some measurement of lower extremity activities such as walking. We also did not distinguish the duration of post operative physical therapy that each of the individual patients received, nor whether patients wore their devices during therapy sessions. Additionally, the ActiGraph device was worn for approximately 8–10 h per recording period and could have potentially missed moments of activity, as it is not expected that the patient be sleeping and showering for the remaining 14–16 h of the day. Actigraphy data at the four time periods was averaged for all users and reported as the mean for each time period. Lastly, actigraphy

Table 4Results of one-way ANOVA of TSA and rTSA subjects at 24-weeks.

	F	SS	p-value
Age	8.728	60.2	0.004
ASES Score	0.315	49.0	0.577
ASES Pain	2.564	33.4	0.119
UCLA Function	0.635	33.3	0.431
SANE	0.023	41.3	0.878
Percent Active	0.045	42.2	0.832
Vector Magnitude	0.010	39.1	0.920

Table 3 Correlation matrix of actigraphy and PROs at 24-weeks.

		% Active	ASES	VM	UCLA Pain	SANE	UCLA Function
		% Active	ASES	VIVI	UGLA Palli	SAINE	UCLA FUIICIIOII
ASES	Pearson r p-value	0.077					
		0.613					
VM	Pearson r p-value	0.695	0.081				
		< 0.001	0.592				
UCLA Pain	Pearson r p-value	0.072	0.226	0.054			
		0.656	0.136	0.737			
SANE	Pearson r p-value	0.157	0.273	0.091	0.764		
		0.328	0.069	0.573	< 0.001		
UCLA Function	Pearson r p-value	0.100	0.158	-0.053	0.871	0.824	
		0.532	0.301	0.742	< 0.001	< 0.001	

measurements and PROMs were only obtained for 24 weeks following the index operation. Ideally data would have been recorded out to at least 12 months following their operation to see if there were further improvements in objective activity measurements that lead to significant differences from preop motion, or significant differences between TSA and rTSA out to 1 full year.

5. Conclusions

This study confirms that actigraphy can be utilized to objectively evaluate shoulder function before and after TSA and rTSA; the vector magnitude of a tri-axial accelerometer can provide a convenient and accurate sum of physical activity. Objective measurement of physical activity (actigraphy) at 24-weeks succeeded in showing that shoulder activity had returned to preoperative levels but failed in showing substantial improvement past the baseline. This absence of change would indicate that the patient's perceived increase in function is largely related to pain relief as activity fails to show objective change between pre-and post-operative states. Additional studies with longer time periods are needed to track for possible further improvements over time. Despite both being suitable methods independently for the evaluation of shoulder function, we found no significant correlation between standard actigraphy measurements and PROs at 24-weeks. Further research is needed to determine the clinical utility of actigraphy monitoring, and its overall application predictor of post-surgical rehabilitation success following shoulder arthroplasty.

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Declaration of competing interest

None.

Ethical statement

This study was approved by the University of West Florida Institutional Review Board: IRB 2017-056. The authors agree that this study represents honest and original research.

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Guardian/patient's consent

Informed consent was obtained from all human subjects who participated in this study.

CRediT authorship contribution statement

Christopher Morgan: Conceptualization, Investigation, Writing – original draft, Writing – review & editing, Visualization, Data curation, Formal analysis. Mathew Hargreaves: Writing – review & editing, Visualization. Marshall Williams: Data curation, Formal analysis, Writing – review & editing. Robert E. Hoyt: Conceptualization, Methodology, Investigation, Writing – review & editing. Dallas H. Snider: Conceptualization, Methodology, Validation, Writing – review & editing. Mark Callanan: Writing – review & editing, Supervision. Andrea Nelson: Writing – review & editing, Supervision. Eugene W. Brabston: Writing – review & editing, Supervision, Project administration. Amit M. Momaya: Writing – review & editing, Supervision, Project administration. Brent A. Ponce: Conceptualization, Writing – review &

editing, Project administration. **Christopher O'Grady:** Conceptualization, Methodology, Validation, Formal analysis, Investigation, Writing – review & editing, Supervision, Project administration.

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