6-30-2021

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Recommended Citation

Ruder MC, Zauel R, Diefenbach BJ, and Bey MJ. Quantifying shoulder activity after rotator cuff repair: Technique and preliminary results. J Orthop Res 2021.

Received: 20 November 2020 | Revised: 13 April 2021 | Accepted: 25 June 2021

DOI: 10.1002/jor.25122

RESEARCH ARTICLE

Journal of Orthopaedic Research®

Quantifying shoulder activity after rotator cuff repair: Technique and preliminary results

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Funding information
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Abstract

Repair tissue healing after rotator cuff repair remains a significant clinical problem, and excessive shoulder activity after surgical repair is believed to contribute to re-tears. In contrast, small animal studies have demonstrated that complete removal of activity impairs tendon healing and have advocated for an "appropriate" level of activity, but in humans the appropriate amount of shoulder activity to enhance healing is not known. As an initial step toward understanding the relationship between postoperative shoulder activity and repair tissue healing, the objectives of this study were to assess the precision, accuracy, and feasibility of a wrist-worn triaxial accelerometer for measuring shoulder activity. Following assessments of precision (±0.002 g) and accuracy (±0.006 g), feasibility was assessed by measuring 1 week of shoulder activity in 14 rotator cuff repair patients and 8 control subjects. Shoulder activity was reported in terms of volume (mean acceleration, activity count, mean activity index, active time) and intensity (intensity gradient). Patients had significantly less volume ($p \le .03$) and intensity ($p = .01$) than controls. Time post-surgery was significantly associated with the volume ($p \le .05$ for mean acceleration, activity count, and mean activity index) and intensity ($p = .03$) of shoulder activity, but not active time ($p = .08$). These findings indicate this approach has the accuracy and precision necessary to continuously monitor shoulder activity with a wrist-worn sensor. The preliminary data demonstrate the ability to discriminate between healthy control subjects and patients recovering from rotator cuff repair and provide support for using a wearable sensor to monitor changes over time in shoulder activity.

KEYWORDS

activity monitoring, rotator cuff repair, shoulder activity, wearable sensors

1 | INTRODUCTION

Rotator cuff tears affect about 40% of the population over age 60,[1,2] with approximately 250,000 rotator cuff repairs performed annually in the United States alone.[3] Unfortunately, healing of the rotator cuff repair tissues after surgery is a significant clinical problem. For example, 20%–76% of rotator cuff repairs fail,[4–9] with 42%–78% of these failures occurring within the first 12 weeks after surgery.[5,10–12] Factors believed to have a negative effect on repair tissue healing and clinical outcomes include patient age, tear size, muscle atrophy, and fatty degeneration,[8,9,13,13,14] but these factors do not fully explain the unacceptably high incidence of failed repairs. The healing process is also widely believed to be influenced by mechanical loading of the repair tissues, and recent research has directly implicated excessive shoulder activity after surgery as a risk factor for failed repairs.[15] In contrast, small animal studies have reported that complete removal of activity impairs tendon healing and have therefore advocated for an "appropriate" level of activity to provide the mechanical forces necessary to enhance healing.[16–18] Unfortunately, in humans the appropriate level of shoulder activity necessary to enhance healing is not known.

A large number of clinical studies have investigated how specific aspects of postoperative rehabilitation, such as when to initiate physical therapy (PT) exercises after surgery, influence repair tissue healing or clinical outcomes. Some evidence suggests that early shoulder mobilization after repair results in better ROM than delayed mobilization, but these differences in ROM are generally small and no longer apparent after 6 months.[19–22] In contrast, some studies suggest that early mobilization may result in more re-tears than delayed mobilization, but these differences are not statistically significant.[19,21–24] However, a major limitation of these studies is that none have objectively monitored shoulder activity levels throughout the study period, so it is unknown to what extent patients complied with postoperative guidelines (e.g., sling usage). Consequently, it is perhaps not surprising that the American Academy of Orthopaedic Surgeons' (AAOS) Appropriate Use Criteria for managing rotator cuff tears provides guidance on nonoperative care, partial repair, repair, reconstruction, and arthroplasty, but provides no guidance on postoperative rehabilitation.[25,26]

In addition to postoperative PT exercises, activities of daily living (ADLs) that only nominally involve the shoulder (e.g., walking, housework, desk work) elicit low levels of muscle activity that may compromise repair tissue healing. For example, immobilizing the shoulder with a sling is intended to protect the healing repair tissues, but EMG studies report a low level of muscle activity in the shoulders during gait even with the shoulder immobilized.[27,28] This muscle activity is not particularly high (5%–10% of maximum voluntary contraction),[28] but patients are unable to suppress this activity since it occurs through a CNS reflex which couples arm and leg movements. Thus, even with the shoulder immobilized in a sling, gait and other ADLs may impart muscle forces that compromise repair tissue healing. However, the extent to which all shoulder activity (i.e., PT exercises and ADLs) influences repair tissue healing after rotator cuff repair remains unknown.

One approach for investigating the role of shoulder activity on clinical outcomes after rotator cuff repair is through the use of wearable sensors. Wearable sensors are a promising technology for continuously monitoring shoulder activity, and it may be possible to continuously monitor postoperative shoulder activity with a wearable sensor and relate these data to repair tissue healing and clinical outcomes. As an initial step toward understanding the relationship between postoperative shoulder activity and clinical outcomes, the objectives of this study were to: (1) assess the precision and accuracy of a wrist-worn activity monitor, (2) determine to what extent a wrist-worn activity monitor can be used as a surrogate measure of upper arm activity, (3) present preliminary data comparing shoulder activity between control subjects and patients recovering from rotator cuff repair, and (4) present preliminary data regarding changes over time in shoulder activity after rotator cuff repair.

FIGURE 1 The wearable sensor (GENEActiv Original, ActiveInsights) for monitoring shoulder activity is an unobtrusive wrist-worn device that includes a triaxial accelerometer, thermistor, and light sensor. The device is capable of recording data continuously at 10 Hz for approximately 2 months [Color figure can be viewed at wileyonlinelibrary.com]

2 | METHODS

To provide continuous monitoring of shoulder activity, we have selected a medical grade wrist-worn activity monitor (GENEActiv Original, ActiveInsights) that is approximately the size and shape of a wristwatch (Figure 1). The device consists of a triaxial accelerometer (range: ±8*g* where 1*g* = 9.8 m/s^2, resolution: 0.0039*g*), light sensor (range: 0 to 3000 lux, resolution: 5 lux, accuracy: ±10%), and thermistor (range: 0°C to 60°C, resolution: 0.25°C, accuracy: ±1°C) for near-body temperature measurement to confirm wear time. A rechargeable lithium battery allows for approximately 2 months of continuous data collection at 10 Hz.

To assess precision, we acquired data for 60 h at 10 Hz with the activity monitor resting motionless on a mechanically isolated table. After downloading the acceleration data from the activity monitor, custom software calibrated the acceleration data to 1*g* (i.e., acceleration due to gravity),[29] and then total acceleration was calculated as the Euclidean norm of the three acceleration signals minus 1*g*.[30] Precision was assessed as the standard deviation of total acceleration over the entire data collection period.[31]

To assess accuracy, we secured the activity monitor to the actuator of a mechanical testing device (Instron 8501) and acquired acceleration data at 10 Hz as the actuator was oscillated cyclically at prescribed rates: ±2 mm at 4 Hz, ±10 mm at 2 Hz, ±20 mm at 1 Hz. Each trial involved 100 cycles and we acquired three trials for each testing condition. Following testing, the acceleration data were downloaded from the activity monitor, and then total acceleration was calculated as previously described. Acceleration was also calculated as the second derivative of the Instron actuator displacement. Accuracy was assessed by calculating the RMS error and correlation between the activity monitor and Instron-based measures of acceleration.[32]

As an additional assessment of accuracy, we compared accelerations measured with the wrist-worn activity monitor to accelerations determined with a video-based motion capture system. To accomplish this, we recruited five healthy participants to each perform a series of standardized motions. These motions included sagittal-plane shoulder elevation from arm at side to maximum elevation, coronal-plane elevation from arm at side to maximum elevation, and external rotation with arm at the participant's side from maximum internal rotation to maximum external rotation. Each subject performed three repetitions of the shoulder motions and each trial lasted approximately 1 min. Accelerations were recorded continuously with the wrist-worn sensor throughout each subject's trial. In addition, we affixed a single reflective marker to the face of the wrist-worn sensor and recorded three-dimensional position of the marker with a five-camera video-based motion capture system (Simi Motion). The accelerometer and video-based data were synchronized and recorded simultaneously at 100 Hz. Following data collection, the video-based marker accelerations were determined using the Simi proprietary software. To assess accuracy, we first calculated the mean acceleration from the wrist-worn sensor and the video-based data across each participant's trial. We also assessed measurement bias (i.e., average difference), RMS error, and correlation between the two measuring systems for each participant. Differences in mean acceleration across the five participants were assessed with a paired t-test.

To determine to what extent a wrist-worn sensor could be used as a surrogate measure of upper arm activity, 10 healthy participants (average age: 37.4 ± 16.2) were recruited following IRB approval. Each participant wore two activity monitors simultaneously on their dominant arm: one on their wrist and one secured to their upper arm (mid biceps) using a Velcro strap.[33] Acceleration data were acquired at 10 Hz from both devices as subjects performed the following activities: walking for 2 min, 1 min of scapular-plane elevation starting with the arm at the participant's side and elevating to 90°, 1 min of internal and external rotation from maximum internal rotation to maximum external rotation with the arm at the participant's side and elbow flexed to 90°, 10 min of simulated office/computer work, and 3 min of simulated dish washing ($n = 90$ total trials). These activities were chosen to represent a range of activities a patient may perform within the first 12 weeks after rotator cuff repair surgery.

To demonstrate the potential utility of this approach, we also recruited 8 control subjects with healthy shoulders (age: 60 ± 8) and 14 patients who had undergone rotator cuff repair in their dominant shoulder (age: 57 ± 8). All participants wore the activity sensor on their dominant wrist for 1 week, except when sleeping or showering/bathing. For the patients, shoulder activity data were recorded at 1–2 weeks post-surgery ($n = 3$), 6–7 weeks post-surgery ($n = 7$), and 12–13 weeks post-surgery ($n = 6$). Data were acquired from two of the patients at multiple time points.

To quantify activity from the acceleration data, it is important to first understand that physical activity is often reported in terms of volume and intensity—for example, bicycling 20 miles (volume) at

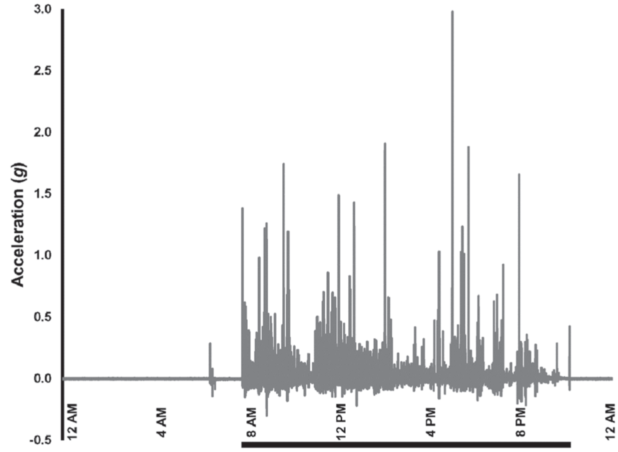

FIGURE 2 Total acceleration over a 24-h period for a representative control subject with normal shoulder function. The horizontal black line indicates the period over which data were included in the analysis of shoulder activity. The quiescent periods occurred because participants were allowed to remove the wrist-worn activity monitor while sleeping and showering/bathing. Despite the prominent peaks in acceleration, these data correspond to a mean acceleration of $0.017g$ and an intensity gradient of −2.112

18 miles per hour (intensity)—and that numerous variables have been used to estimate volume and intensity from acceleration data. To estimate the volume of activity, custom software was used to first calibrate the triaxial acceleration data to $1g$ (i.e., acceleration due to gravity),[29] and then total acceleration was calculated as the Euclidean norm of the three acceleration signals minus $1g$.[30] The acceleration data were then downsampled by averaging the data over 1-s intervals. Next, the averaged 1-s data were presented graphically so that the entire set of data could be manually segment into periods of activity and non-activity (Figure 2). For the comparison of rotator cuff repair patients and control subjects, this step involved retaining the daytime periods of activity and discarding the quiescent nighttime data. For each period of activity, the custom software estimated the volume of activity by calculating mean acceleration (i.e., arithmetic mean of the total acceleration[34–36]), activity count (i.e., fraction of data where total acceleration exceeded $0.006g$[37–41]), mean activity index (i.e., arithmetic mean over time of the acceleration variance[42]), and active time (i.e., fraction of time where total acceleration exceeded $0.006g$ for 50% or more of each 10-s interval within the period[37]). For each outcome measure, a higher value implies greater volume of activity.

To estimate the intensity of activity, we calculated the intensity gradient[34–36] by first generating a frequency distribution of the number of acceleration data points within each 10 milli-g bin (Figure 3A), and then converting these nonlinear data by taking the natural log of both the frequency and acceleration data (Figure 3B). The final step involves calculating the slope of the regression line of the natural log of frequency versus the natural log of acceleration (Figure 3B). This slope is defined as the intensity gradient. A shallower (i.e., less negative) slope of this regression line indicates more

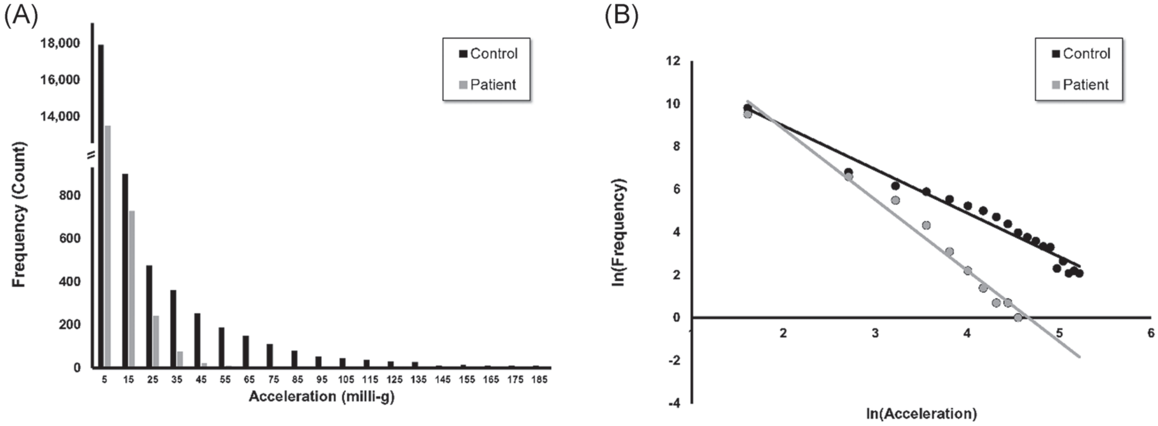

FIGURE 3 Representative data from a control subject and rotator cuff repair patient demonstrating the calculation of intensity gradient. The intensity gradient is calculated by generating a frequency distribution of the number of acceleration data points within each 10 milli-*g* bin (A), and then converting these nonlinear data by taking the natural log of both the frequency and acceleration data (B). The intensity gradient is the slope of the regression line of the natural log of frequency versus the natural log of acceleration (B). A shallower slope indicates more high-intensity shoulder activities, whereas a steeper slope indicates fewer high-intensity shoulder activities

high-intensity shoulder activities, whereas a steeper (i.e., more negative) slope indicates fewer high-intensity shoulder activities (Figure 3B). For the comparison of rotator cuff repair patients and control subjects, these outcome measures were calculated for all included periods of activity over the seven days to produce a single week-long value. We also calculated mean wear time (hours per day) for the comparison of rotator cuff repair patients and control subjects.

Associations between the wrist and upper arm measures of activity were assessed using linear regression and correlation. Differences in shoulder activity between the patient and control groups were assessed using unpaired *t* tests. Associations between measures of shoulder activity and time post-surgery were assessed using linear regression and correlation. Statistical significance was set at $p \leq .05$ for all tests.

3 | RESULTS

In terms of measurement precision, the standard deviation of the total acceleration was ±0.002*g*, indicating that any change less than ±0.002*g* is assumed to be a measurement error. In the assessment of measurement accuracy, there was excellent agreement between the activity sensor and Instron accelerations ($r > .94$), with an RMS error of ±0.006*g* across all displacements rates.

In comparing accelerations recorded by the wrist-worn sensor to marker accelerations determined using the video-based motion capture system, the average bias and RMS error between the measurement systems were 0.002 ± 0.04*g* and 0.58 ± 0.07*g*, respectively. The average correlation between the two measurement systems was 0.68 ± 0.09. No significant difference was detected between the accelerometer (0.378 ± 0.03 *g*) and video-based (0.380 ± 0.06 *g*) measures of mean acceleration ($p = .92$).

In the assessment of wrist versus upper arm activity, the data were found to be highly correlated across all activities ($p < .001$ for all outcome measures). Specifically, the data were significantly associated in terms of mean acceleration ($r = .55$), activity count ($r = .85$), mean activity index ($r = .71$), active time ($r = .85$), and intensity gradient ($r = .62$). Within the individual activities, correlations between the wrist and upper arm outcome measures ranged from 0 to 1.0 (Table 1).

When comparing the rotator cuff repair patients and control subjects, the data indicated that patients had significantly lower volume and intensity of activity than the control subjects (Table 2). No significant difference in mean wear time was detected between patients (13.5 ± 1.7 h per day) and control subjects (14.7 ± 1.2 h per day, $p = .07$). There was also no significant difference on average age between the patients (57.3 ± 8.4) and control subjects (60.0 ± 8.3, $p = .47$).

For the rotator cuff repair patients, time post-surgery was significantly associated with mean acceleration ($r = .50$, $p = .05$, Figure 4A), activity count ($r = .61$, $p = .01$), mean activity index ($r = .67$, $p = .005$), and intensity gradient ($r = .57$, $p = .03$, Figure 4B). However, time post-surgery was not found to be significantly associated with active time ($r = .46$, $p = .08$).

4 | DISCUSSION

The findings of this study indicate that the approach described here has the accuracy and precision necessary to continuously monitor shoulder activity with a wrist-worn sensor. The findings of the accuracy assessment are consistent with previous research reporting excellent agreement ($r = .97$) between a GENEActiv sensor and mechanical actuator,[32] and the significant association between the wrist and upper arm data is also consistent with previous studies.[43,44] Furthermore, the preliminary data reported here demonstrate the ability to discriminate between healthy control subjects and patients recovering from rotator cuff repair

TABLE 1 Correlation coefficients between wrist and upper arm outcome measures for individual activities

	Volume				Intensity
Activity	Mean acceleration	Activity count	Mean activity index	Active time	Intensity gradient
Walking	0.96	0.91	0.95	0.86	0.35
Scapular-plane elevation	0.23	0.84	0.66	1.00	0.80
Internal/external rotation	0.74	0.43	0.38	0.00	0.33
Office/computer work	0.68	0.32	0.97	0.73	0.89
Dish washing	0.95	0.96	0.99	0.75	0.72

TABLE 2 Comparison between rotator cuff repair patients and control subjects in terms of volume and intensity of shoulder activity.

	Volume				Intensity
Group	Mean acceleration (*g*)	Activity count (%)	Mean activity index (g^2)	Active time (%)	Intensity gradient
Patients	0.008 ± 0.005	36.2 ± 3.9	0.058 ± 0.022	20.0 ± 8.6	−2.78 ± 0.28
Control subjects	0.026 ± 0.015	39.3 ± 2.6	0.096 ± 0.025	28.2 ± 5.6	−2.35 ± 0.31
p value	.01	.03	.003	.01	.01

Note: All data are reported as mean ± standard deviation.

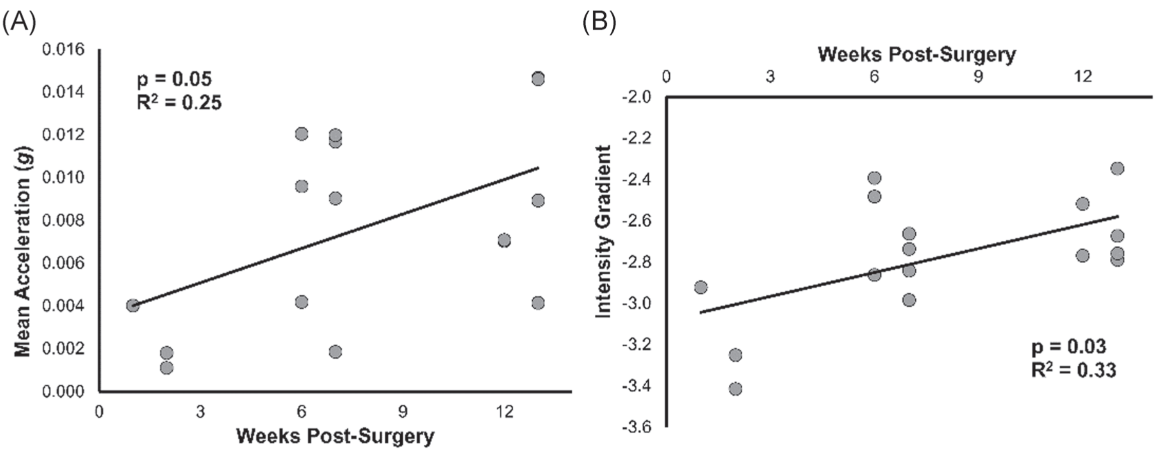

FIGURE 4 Time post-surgery was significantly associated with the volume of shoulder activity (mean acceleration, A) and the intensity of shoulder activity (intensity gradient, B). Each circle represents an individual patient

and provide support for using a wearable sensor to monitor changes over time in shoulder activity.

The outcome measures used in this study allow us to independently assess the volume and intensity of shoulder activity from acceleration data. There was substantial agreement between the outcome measures used to estimate the volume of activity (i.e., mean acceleration, activity count, mean activity index, active time) and therefore it may not be necessary to report all four of these outcome measures. In contrast, intensity gradient was the only parameter used to estimate the intensity of shoulder activity, though other approaches for estimating intensity do exist. The most common approach is to categorize activity as sedentary, light, moderate, or vigorous based on activity counts per minute. For example, for children ages 6 to 19, sedentary has been defined as <100 counts per minute, light activity is 100 to 220 counts per minute, and moderate to vigorous activity is >2020 counts per minutes.[40] Unfortunately, this approach has the potential to introduce bias since the various activity thresholds (referred to as "cutpoints") need to be determined for each specific population being studied. In contrast, intensity gradient provides an assessment of the entire intensity profile and therefore results in an unbiased measure of intensity that can be used for all subject populations. Furthermore, the use of intensity gradient in conjunction with mean acceleration[34,35] may be sufficient for independently documenting the volume and intensity of shoulder activity.

The finding that patients recovering from rotator cuff surgery have less shoulder activity than control subjects (Table 1) was not surprising. It was also not surprising that the volume and intensity of shoulder activity were associated with time post-surgery (Figure 4), since postoperative rehabilitation protocols often prescribe a gradual progression from passive range of motion exercises to active strengthening and functional activities over the first 12 weeks post-surgery.[45] However, what was surprising from these preliminary data was the substantial variability between patients in both the volume and intensity of activity (Figure 4). For example, there was approximately a five- to six-fold difference in the patients' volume of shoulder activity (i.e., mean acceleration, Figure 4A) at the 6–7- and 12–13-week postsurgical time points. This high variability between patients is likely the result of multiple factors, such as the size and chronicity of the rotator cuff tear and the physical therapists' biases regarding the optimal rehabilitation exercises. In addition, these data likely reflect a number of patient-related factors, such as the patient's inherent level of motivation, tolerance for pain, compliance with the prescribed home-based physical therapy activities, and the extent to which they participate in ADLs in addition to the prescribed rehabilitation exercises.

The approach of continuously monitoring shoulder activity with a wearable sensor has been reported previously within the context of shoulder surgery[46] and offers advantages over previous studies that have used less rigorous approaches to monitor patient compliance to a postoperative rehabilitation protocol. For example, Cuff and Pupello assessed compliance by documenting each time a patient was observed not using an immobilization sling when encountered by a home health aide or at a clinic appointment.[47] The study reported no association between compliance and clinical outcomes, likely because patients could be noncompliant when not being observed by clinicians. Ahmad and colleagues monitored patient compliance using open-ended questions (e.g., "What activities have you been doing?") and specific questions about sling usage, but the accuracy of assessing compliance via patient recall was not reported.[48] In a clever study, Grubhofer and colleagues implanted a hidden temperature sensor in a shoulder brace to measure actual brace usage (unbeknownst to the patients) and then asked patients to report their brace usage.[49] The patients reported compliance of 96%, but the temperature sensor indicated actual compliance of only 75%. In other words, patients overestimated their compliance by an average of 21%. Collectively, these studies indicate that measuring patient activity through compliance is difficult, that patient-reported measures of compliance have unknown or low accuracy, and that compliance with postoperative activity precautions is almost certainly less than 100%. Consequently, the approach of continuously monitoring shoulder activity with a wearable sensor is likely to provide a much more accurate indication of a patient's actual activity level after surgery and may lend insight into the role of shoulder activity on repair tissue healing and clinical outcomes.

Basic science studies have provided additional motivation for understanding how shoulder activity influences repair tissue healing.[50] Specifically, small animal studies have shown that complete removal of load from healing tissues is detrimental to healing, and that high forces can compromise the integrity of the healing repair tissues.[16–18] Unfortunately, there is currently no way to know if patients are advancing too quickly with all their shoulder activity (i.e., rehabilitation exercises and ADLs) and potentially compromising rotator cuff repair tissue healing, or if they are not doing enough activity to mechanically load the repair tissues in a way that enhances healing. Understanding how shoulder activity affects repair tissue healing, particularly during the critical healing period of the first 12 weeks after surgery, would be an important step towards translating the findings from basic science studies into clinical practice. Therefore, future research will determine the extent to which shoulder activity is associated with repair tissue healing and clinical outcomes.

The effects of surgical and nonsurgical clinical interventions are often evaluated in terms of subjective patient-reported outcomes (i.e., questionnaires) or imaging-based structural healing outcomes. These conventional clinical assessments can be highly subjective and potentially misleading, and therefore we believe that wearable devices can provide far more objective assessments of joint function. Furthermore, we anticipate that wearable sensors could be used by clinicians to monitor activity levels and rehabilitation progress for a wide range of clinical conditions. This approach not only has application to orthopaedic procedures (e.g., ACL reconstruction, joint arthroplasty, fracture repair) and monitoring of disease progression (e.g., osteoarthritis), but also may be applicable to general surgery procedures (e.g., bariatric surgery, organ transplantation) or any other clinical intervention where appropriate levels of activity are believed to enhance healing and/or physical function. Additionally, patients could also use this information (perhaps in conjunction with a mobile app) to monitor their daily activity levels and remain in a safe zone of activity that stimulates healing without potentially compromising the integrity of healing repair tissues.

As with any study, this one is not without limitations. Perhaps the most significant limitation is that the approach used here does not allow for the determination of specific shoulder motions (e.g., flexion/extension) or activities. Alternative approaches for acquiring this information may be to use deep learning analyses to identify specific activities from the acceleration data or inertial measurement units (IMUs) to measure shoulder kinematics. However, IMUs would need to be secured to the upper arm, thorax, and scapula to provide a mechanistic understanding of shoulder motion, and using multiple IMUs to acquire data for extended periods of free-living conditions is impractical. Another limitation is that data from the rotator cuff repair patients were acquired using a cross-sectional (vs. longitudinal) study design, and therefore these preliminary data do not unequivocally demonstrate changes over time in shoulder activity. Lastly, although the wearable sensor used in this study can confirm wear time via the sensor's thermistor data, we cannot confirm that the patients to whom we provided the sensor were actually the ones who wore it. In other words, it is possible that patients may have had a friend or family member wear the sensor. However, patients who volunteered to participate were highly engaged in the study, and it is unlikely that the data would reveal such substantial differences between patients and control subjects if patients had indeed undermined the study in this manner.

In conclusion, this study documented the precision and accuracy of a wrist-worn activity monitor, and demonstrated that a wrist-worn sensor can be used as a surrogate measure of upper arm activity. The study also reported outcome measures that allow us to independently examine the effects of the volume and intensity of shoulder activity. Furthermore, the preliminary data reported here demonstrated significant differences in shoulder activity between patients recovering from rotator cuff repair and control subjects, and demonstrated associations between time post-surgery and the volume and intensity of shoulder activity. Future efforts will utilize this approach to document the effect of shoulder activity after rotator cuff repair on repair tissue integrity and clinical outcomes.

AUTHOR CONTRIBUTIONS

All authors participated in: (1) design, acquisition, analysis, and interpretation of the data, (2) drafting the paper and revising it critically, and (3) approval of the submitted version. All authors have read and approved the final submitted manuscript.

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How to cite this article: Ruder MC, Zauel R, Diefenbach BJ, Bey MJ. Quantifying shoulder activity after rotator cuff repair: Technique and preliminary results. *J Orthop Res*. 2021;1-8. https://doi.org/10.1002/jor.25122