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Wrist-mounted accelerometers provide objective evidence of disease and recovery in patients with frozen shoulder

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Background: Commercially available wrist-mounted exercise monitors may offer objective data on disease and recovery. This study is the first to evaluate the potential of such devices in the assessment of frozen shoulder and the effects of treatment.

Methods: Twenty-one patients with isolated, unilateral frozen shoulder wore a wrist-mounted accelerometer (Fitbit Fire II, Fitbit Inc. 2007, California, USA) on each wrist for two separate seven-day periods, one week before and six months after treatment. The monitors produced an activity count for each 24-hour period, accounting for all movements of the upper limb. Three values were calculated for each time period: (1) the mean activity count for each limb, (2) the total activity count for both limbs, and (3) an activity count ratio calculated by dividing the activity of the frozen limb by the unaffected limb. Constant score, American Shoulder and Elbow Surgeons, visual analog scale—pain, and range of movement were recorded before and after treatment.

Results: Mean activity counts were significantly lower in the frozen shoulder limb than those in the unaffected limb over the initial seven-day period (6066 vs. 7516; $P = .04$). The activity count ratio significantly improved after treatment (0.83 vs. 096; p 0.01), whereas the mean total activity count remained similar before and after treatment (14915 vs. 12371; $P = .18$), demonstrating that activity transferred from the unaffected limb back to the previously frozen limb. Range of movement ($P < .01$), Constant ($P < .01$), American Shoulder and Elbow Surgeons ($P < .01$), and visual analog scale—pain ($P < .01$) scores all significantly improved after treatment, but there was no correlation with the data from the activity monitor.

Discussion: Wrist-mounted accelerometers are sufficiently sensitive to detect a difference in limb activity in patients affected by frozen shoulder. The movement deficit between the affected and unaffected limbs improved by 14% after treatment. These data could be used in conjunction with subjective scores to offer a clearer insight into patient disease burden and recovery.

Frozen shoulder, or adhesive capsulitis, affects 2% of the general population with an incidence of 2.4 per 1000 person-years.[18,24] There are various treatment options such as physical therapy, corticosteroid injection, and manipulation under anesthetic or arthroscopic capsular release (ACR). Quantifying the success of a particular intervention has graduated from relying solely on objective measures such as range of movement (ROM) assessment, to include subjective evidence in the form of validated patient-reported outcome measures (PROMs). The value of such scores is demonstrated in their use as the primary outcome measure in numerous randomized studies and meta-analyses.[2,13] However, PROMs are not infallible and are influenced by deprivation and mental well-being and only offer a snapshot of function at a single

North Shore Private Hospital Ethics Committee approved this study (NSPHEC 2016-LNR-003).

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time point.[3,16] The development of more advanced objective measures of outcomes would complement subjective scores and could potentially mitigate personal biases.

Wrist-mounted fitness monitors are widely available commercial products that offer users information on heart rate, oxygen saturation, distance traveled, and energy consumption. These devices quantify movement using an in-built 3-axis accelerometer to measure dynamic acceleration in relation to gravity, providing information on the frequency and range of arm movements. Most commonly, the movement vector is used to determine whether a person is walking, running, cycling, or swimming which is combined with Global Positioning Systems data, to provide feedback on exercise activity. Numerous clinical applications have been described such as monitoring activity in geriatric patients, assessing the effect of cancer treatments on daily activity, and evaluating recovery after hip fracture.[1,10,19] These studies concentrate on overall activity, most commonly reported as a step count, but the use of wrist-mounted devices offers opportunity for a more focused insight into upper limb movement. Each motion of the device can be recorded to provide a numerical representation of wrist and arm motion termed the "activity count". This basic measure may offer an objective assessment of illness and recovery in patients affected by conditions that limit upper limb movement, such as frozen shoulder. This study aimed to assess the ability of wrist-mounted accelerometers to detect the difference in the activity between the upper limbs of a patient with a unilateral frozen shoulder and whether the activity count in the affected arm would improve after treatment.

Materials and methods

This prospective study was registered with the North Shore Private Hospital Ethics committee (NSPHEC 2016-LNR-003). Twenty-one consecutive patients with a spontaneous, unilateral frozen shoulder were recruited by the senior author. Because of the novel nature of the study methodology, there was no previous evidence on which to base a sample size estimation. The diagnosis of frozen shoulder was made as per Codman's criteria: persistent pain including night disturbance, loss of passive external rotation >20 degrees compared with the contralateral side, and unremarkable plain radiographs of the shoulder.[4] Baseline demographics were collected for each patient including medical history. In 13 patients, a magnetic resonance scan was used to confirm adhesive capsulitis. Patients in whom the adhesive capsulitis was secondary to surgery, who had a previous contralateral frozen shoulder, or who had other shoulder pathology identified on further imaging were excluded.

Management

Treatment was undertaken after patient assessment and counseling, with either ultrasound-guided glenohumeral joint corticosteroid injection or ACR performed within one month of initial consultation. All glenohumeral joint injections were performed by a consultant radiologist. ACR was performed by the senior author (BC) in the lateral decubitus position as described by Lee.[11] Both surgical and nonsurgical patients followed a structured physiotherapy-led rehabilitation program that continued for six months until the final follow-up.

Data collection

Two commercially available wrist-mounted accelerometers (Fitbit Flex II, Fitbit Inc. California, USA) were provided to each patient (Fig. 1). One device was worn on each wrist for seven days and nights over two distinct time points: one week before intervention (injection or surgery) and six months after intervention. The data were collected remotely from each device at the end of each study period, providing two data points per day (one from each wrist). The patients were blinded to the results as the device did not have a built-in screen, and they were not provided access to the hardware or software for data download. The device uses a 3-axis accelerometer, which allows for recording of frequency, duration, intensity, and patterns of movement. The device expresses activity recording in a total numerical value, using quality of movement in the third dimension, and transferring to numerical quantity of movement. In this translation process, the quality of movement is lost and cannot be differentiated. The activity count was recorded as an absolute value, with an activity count ratio calculated by dividing the activity of the frozen limb by the unaffected limb. Four values were calculated for each time period: (1) the mean activity count for each limb, (2) the difference between each limb by subtracting the activity count of the frozen limb from the unaffected limb, (3) the total activity count for both limbs, and (4) an activity count ratio calculated by dividing the activity of the frozen limb by the unaffected limb. PROMs were recorded at the end of each assessment week and included the American Shoulder and Elbow Surgeons (ASES) and Constant scores.[5,14] As per the Constant score, range of abduction and flexion was measured in degrees, whereas internal and external rotation was scored out of ten. Pain was recorded in a 10-point Likert visual analog scale. The ROM was recorded as part of the Constant score and was analyzed separately in the analysis

Statistical analysis

Data were tested for normal distribution using the D'Agostino and Pearson test. Linear variables were assessed using the paired t-tests for parametric data or the Mann-Whitney U test for nonparametric data. The sample number precluded analysis between treatment methods. Pearson correlation was used to determine any links between the change in the activity count ration and the ASES and Constant scores after treatment. A P value of $< .05$ was considered significant. All data were analyzed using the Graphpad by Prism (Graphpad software LLC, San Diego, CA, USA).

Results

Twenty-one patients were included in the study, nine men and 12 women at a mean age of 55 years (range 44-73). The dominant arm was affected in nine patients. Eight of the frozen shoulders occurred after minor trauma, two due to diabetes and 11 with no identified stimulant. Eleven patients were treated with a single ultrasound-guided glenohumeral corticosteroid injection, whereas the remaining patients underwent ACR. There were no statistical differences in terms of age, gender, activity count monitoring, outcome scores, or ROM between the operative and nonoperative groups (Table I). The group who chose to undergo conservative management displayed slightly higher visual analog scale–pain scores.

Activity monitoring

Mean activity counts were significantly lower in the frozen shoulder limb than those in the unaffected limb over the initial seven-day period (6066 vs. 7516; $P = .04$) (Table II). After treatment, the mean activity counts for each limb became comparable (6579 vs. 6815; $P = .74$). The mean activity count ratio significantly improved from 0.82 to 0.93 ($P = .01$), whereas the total activity count remained unchanged ($P = .88$). Hand dominance affected

Figure 1 The patient wearing bilateral wrist-mounted accelerometers.

several measures (Table III). The activity count ratio was significantly higher in patients in whom the dominant hand was affected both before ($P = .01$) and after treatment ($P = .01$). Contrary to the group as a whole, a significant improvement in the mean activity count of the frozen limb was seen after treatment when the dominant hand was affected. When the nondominant hand was affected, there was no significant improvement in mean activity count or count ratio after treatment (Table III).

Subjective outcomes and ROM

There was a significant improvement in all PROMs after treatment (Table III). All ROM parameters improved significantly after treatment. There was no correlation between the change in the activity ratio with the Constant score ($P = .61$) or ASES scores ($P = .66$). There was no correlation between the change in the activity count ratio and the improvements in ASES (0.66) or Constant score (0.61).

Discussion

This is the first study to investigate the use of commercially available wrist-mounted accelerometers as a means of assessing disease and recovery of frozen shoulder. The mean activity ratio prior was 17% less than the unaffected side during the seven-day assessment period to intervention. Treatment consisted of recognized methods, with patients in each group having similar distributions of age, gender, preoperative PROMs, and activity monitoring data. The difference in the mean activity count between each limb resolved after intervention, whereas the total activity count for both limbs remained unchanged, suggesting a transfer of activity back to the frozen shoulder limb. This supposition is supported by the improvement in the activity count ratio between each limb, which increased from a deficit of 17% to only 4%. Hand dominance affected a number of the measured parameters. Patients in whom the dominant limb was affected had higher mean activity counts and activity ratios both before and after treatment. This suggests that patients affected by frozen shoulder continue to favor the dominant limb despite limitation due to pain or restricted ROM. While unsurprising, these data demonstrate the sensitivity of the monitors and their ability to reflect the real-life activity patterns of patients affected by frozen shoulder. When the activity counts were grouped as per hand dominance, the dominant group displayed a statistically significant improvement in mean activity counts in the affected appendage after treatment, whereas the nondominant group did not. Continuing, statistically and clinically significant changes were recorded before and after treatment for ASES and Constant scores. Although statistically significant changes of PROM were also noted, the isolated ranges of movement themselves might not be functionally significant if regarded in isolation. This further emphasizes the need of combining different data points to measure reality and the utility of scoring systems as they further fuse numerical data with clinically important changes in activities of daily living.

Common treatment strategies for frozen shoulder include but are not limited to the following: physiotherapy, glenohumeral corticosteroid injection, arthrographic distension, acupuncture, and manipulation under anesthetic and ACR.[6] A true evidence-based management model is yet to be defined, with widespread

Table I
Baseline characteristics of patients as per treatment methods.

	Nonoperative	Arthroscopic release	*P* value
Demographics			
Age (yrs, range)	53.4, 44-64	58.0, 46-73	.24
Gender (male: female)	4:6	6:5	.82
Wrist accelerometer data (mean, 95% CI)			
Frozen activity count	6765, 5143 to 8387	5431, 4678 to 6184	.09
Unaffected activity count	8150, 5966 to 10335	6940, 5555 to 8326	.27
Total activity count	14915, 11237 to 18594	12371, 10387 to 14355	.18
Activity count ratio	0.85, 0.76 to 0.93	0.81, 0.69 to 0.93	.60
Subjective scores (mean, 95% CI)			
Constant score	38.5, 27.8 to 49.2	38.7, 30.1 to 46.4	.97
ASES score	38.5, 24.6 to 52	48.7, 35.6 to 61.8	.19
VAS-pain	6.5, 2.6 to 6.2	4.6, 5.1 to 8.1	**.04***
Range of movement (mean, 95% CI)			
Abduction (°)	99, 80 to 100	103, 89 to 118	.61
Forward flexion (°)	99, 84 to 114	100, 84 to 117	.85
External rotation (n)	6.2, 3.6 to 8.7	5.5, 3.9 to 7.0	.57
Internal rotation (n)	3.6, 2.3 to 4.3	2.8, 1.9 to 3.7	.17

ASES, American Shoulder and Elbow Surgeons; *CI*, confidence interval; *VAS*, visual analog scale.
*Signifies a statistically significant result.

Table II
Mean objective and subjective outcomes before and after treatment.

	Pretreatment	Post-treatment	*P* value
Wrist accelerometer data (mean, 95% CI)			
Frozen activity count	6066, 5226 to 6909	6579, 5411 to 7747	.25
Unaffected activity count	7516, 6338 to 8695	6815, 5900 to 7730	.33
	P* = .04	*P* = .74	
Total activity count	13583, 11654 to 15512	13394, 11407 to 15381	.88
Activity count ratio	0.83, 0.76 to 0.89	0.96, 0.86 to 1.06	**.01***
Subjective scores (mean, 95% CI)			
Constant score	39, 23 to 44	67, 63 to 72	**<.01***
ASES	44, 33 to 53	78, 71 to 84	**<.01***
VAS-pain	5.4, 4.2 to 6.5	1.6, 0.9 to 2.3	**<.01***
Range of movement (°) (mean, 95% CI)			
Abduction (°)	97, 88 to 105	133, 116 to 150	**<.01***
Forward elevation (°)	100, 90 to 110	156, 148 to 164	**<.01***
External rotation (n)	5.8, 4.5 to 7.2	8.7, 7.9 to 9.4	**<.01***
Internal rotation (n)	3.2, 2.6 to 3.8	4.4, 3.7 to 5.0	**.01***

ASES, American Shoulder and Elbow Surgeons; *CI*, confidence interval; *VAS*, visual analog scale.
Data within the gray box show comparison between each limb at each time point. All data as mean with 95% confidence internals.
*Signifies a statistically significant result.

variation underpinned by a lack of good-quality evidence.[8] Capture of PROMs across trials comparing these treatments has allowed clinicians to better understand their relative strengths and weaknesses. The battery of PROMs used in the assessment of frozen shoulder treatment efficacy typically includes an upper limb–specific, general well-being and a pain score. There are multiple distinct assessment tools designed to quantify each of these domains. With regard to limb-specific PROMs, there is variation in the sensitivity and validation in the assessment of frozen shoulder treatment efficacy. The Constant score (0-100, higher = better) contains physical examination and subjective evaluation components. It is widely utilized, validated in the evaluation of frozen shoulder, and demonstrates excellent correlation with other commonly used PROMs, and the minimally clinically important difference score has been defined (10.4).[12,23] The ASES (0-100, higher = better) assesses pain and function and is entirely patient reported. It also demonstrates strong correlation with the Constant score and has a clearly defined minimally clinically important difference of 6.4, and systematic review shows it has the best EMPRO score of all shoulder-specific PROMs.[15] The use of the Constant and ASES scores in this study was thought to provide best in class assessments of treatment response and novel wearable data correlation. The effectiveness of PROMs alone can be limited by inherent ceiling effects and inaccurate and nonrepeatable patient-reported activity.[20] Integrated wearable and PROM data combined with remote monitoring through digital platforms have the potential to significantly enhance the ability to monitor treatment effectiveness, re-model service delivery, improve research methodology, and ultimately improve patient care.[9,17] Demonstration of these capabilities in other specialties is well established.[21] Although the utilization of these technologies in orthopedics is in its infancy, some authors have shown it is possible and effective.[7,20,22] The COVID-19 pandemic has amplified the importance and challenge of health care delivery against rising demand and constrained resources, with remote outcome data capture and wearable technologies offering potential solutions.

This is the first study to utilize wearable data in the assessment of frozen shoulder and has therefore identified new challenges to be addressed. There are limitations in both design and implementation of the technology within this study. Wrist-mounted wearable devices do not provide a direct measure of shoulder movement, and therefore, there may be some confounding or limitation in the validity of the results. Standard of errors are still undefined, and minimal clinically important differences utilizing activity counts have not been established. Despite this, we would expect background "noise" to be relatively constant, with increased

Table III
Comparison of activity monitoring data and PROMs in accordance with hand dominance.

	Pretreatment	Post-treatment	*P* value
Dominant limb affected (mean, 95% CI)			
Frozen activity count	6225, 4812 to 7632	7912, 5762 to 10063	**.02**
Unaffected activity count	6704, 5267 to 8212	7044, 5460 to 8628	.59
Total activity count	12965, 10234 to 15696	14956, 11262 to 18650	.33
Difference in activity count	514, −418 to 1148	−368, −1656 to −80	**<.01***
Mean activity count ratio	0.93, 0.81 to 1.05	1.11, 0.99 to 1.2	**<.01***
Constant score	34.5, 26.5 to 42.6	68, 57.8 to 78.1	**<.01***
ASES	43.2, 25.7 to 60.6	81.2, 57.8 to 78.1	**<.01***
VAS-pain	4.3, 2.2 to 6.5	1.1, −0.2 to 2.4	**<.01***
Nondominant limb affected (mean, 95% CI)			
Frozen activity count	5947, 4725 to 7169	5579, 4352 to 6806	.46
Unaffected activity count	8099, 6229 to 9969	6644, 5344 to 7943	.09
Total activity count	14046, 11004 to 17088	12222, 9815 to 14630	.31
Difference in activity count	2152, 1300 to 3004	1065, 295 to 1834	.08
Activity count ratio	0.74, 0.69 to 0.80	0.85, 0.71 to 0.99	.18
Constant score	41.25, 31.9 to 50.6	67, 61.2 to 72.8	**.08***
ASES	44. 1, 32.7 to 55.6	74.8, 66.1 to 72.8	**<.01***
VAS-pain	6.2, 4.9, to 7.4	1.9, 1.1 to 2.8	**<.01***

PROMs, patient-reported outcome measures; *ASES*, American Shoulder and Elbow Surgeons; *CI*, confidence interval; *VAS*, visual analog scale.
*Signifies a statistically significant result.

shoulder movement and function after treatment to be reflected in the post-treatment measurements. The lack of correlation between activity measurements and PROMS represents a type II error as a result of small sample size. Nonetheless, the device used in this study is affordable, readily available, and acceptable to patients. The results generated in this study are robust, and the opportunities identified through use of this technology are clear.

Conclusion

This study has clearly demonstrated the novel, proof-of-concept utilization of wearable activity data to assess the effectiveness of operative and nonoperative management of frozen shoulder. The ability to correlate PROMs with remotely captured wrist-mounted accelerometer activity tracking has the potential to offer new insights on the recovery of arm function after treatment. While no significant correlation between changes in activity data and PROM scores was demonstrated, sample sizes were small. Larger studies may allow us to define the relationship between increased limb activity and clinically significant improvement in patient outcomes. This could allow for a data-driven remote assessment of patient recovery, enable pro-active care driven by patient need, and improve our ability to compare subtle differences in treatment options.

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