2023

Using inertial measurement units to quantify shoulder elevation after reverse total shoulder arthroplasty: a pilot study comparing goniometric measures captured clinically to inertial measures captured 'in-the-wild'

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Citation/Publisher Attribution

Chapman, R. M., Torchia, M. T., Bell, J.-E., & Van Citters, D. W. (2023). Using inertial measurement units to quantify shoulder elevation after reverse total shoulder arthroplasty: a pilot study comparing goniometric measures captured clinically to inertial measures captured 'in-the-wild'. *Seminars in Arthoplasty: JSES, 33*(1), 85-93. https://doi.org/10.1053/j.sart.2022.08.002
Available at: https://doi.org/10.1053/j.sart.2022.08.002

Abstract

Background: *Reverse total shoulder arthroplasty (rTSA) is utilized for a variety of indications, but most commonly for patients with rotator cuff arthropathy. This procedure reduces pain, improves satisfaction, and increases clinically measured range of motion (ROM). However, traditional clinical ROM measurements captured via goniometer may not accurately represent 'real-world' utilization of ROM. In contrast, inertial measurement units (IMUs) are useful for establishing ROM outside the clinical setting. We sought to measure 'real-world' ROM after rTSA using IMUs.*

Methods: *A previously validated IMU-based method for continuously capturing shoulder elevation was used to assess 10 individuals receiving rTSA (82±5 years) and compared to a previously captured 10 healthy individuals (4M, 69±20 years) without shoulder dysfunction. Control subject data was previously collected over 1-week of continuous use. Patients undergoing rTSA donned sensors for 1-week pre-rTSA, 6-weeks at 3-months post-rTSA following clearance to perform active-independent ROM, and 1-week at 1- & 2-years post-rTSA. Shoulder elevation was computed continuously each day. Daily continuous elevation was broken into 5° angle 'bins' (e.g. 0-5°, 5-10°, etc.) and converted to percentage of the total day. IMU-based outcome measures were ROM binned percent (as described previously) and maximum/average elevation each week. Clinical goniometric ROM and patient reported outcome measures (PROMs) were also captured.*

Results: *No differences existed between patient and healthy control demographics. While patients showed improvement in ASES score, pain score, and goniometric ROM, IMU-based average and maximum elevation were equal between control subjects and patients* *both pre- and post-rTSA. The percent of time spent above 90° was equal between cohorts pre-rTSA, rose significantly at 3 months post-rTSA, and returned to preop levels thereafter.*

Discussion: *Although pain, satisfaction, and ROM measured clinically may improve following rTSA, real-world utilization of improved ROM was not seen herein. Improvements during the acute rehabilitation phase may be transient, indicating longer or more specific rehabilitation protocols are necessary to see chronic improvements in post-rTSA movement patterns.*

Level of Evidence: Prospective Prognosis Study-Defined Level 2

Keywords: Arthroplasty, Shoulder, Inertial Measurement Unit, Rehabilitation, Range of Motion, IMU, Wearable

Introduction

Reverse total shoulder arthroplasty (rTSA) is indicated for many shoulder pathologies, most commonly rotator cuff arthropathy. rTSA is typically utilized after non-operative treatments have failed to provide adequate relief. Studies have shown rTSA has high success improving pain, satisfaction, and clinical range of motion (ROM) [1,5,8,15]. However, pain and satisfaction are largely subjective whereas ROM is objective and captured readily in clinical settings using several methods (e.g. goniometry). Unfortunately, clinical ROM measures may not accurately represent patient movement capabilities outside those captured in clinic/laboratory environments. As such, it is unknown if patients utilize the entirety of clinically measured ROM improvements in the 'real world.'

Inertial measurement units (IMUs) provide a method for capturing shoulder ROM outside well-controlled clinic/laboratory environments. IMUs are wearable, electromechanical devices that capture linear acceleration, angular velocity, and magnetic field strength via accelerometers, gyroscopes, and magnetometers, respectively. This information can quantify IMU orientation in 3D [10,13,20]. Utilizing the relative motion between multiple IMUs rigidly affixed to distinct bony segments subsequently allows computation of joint angles (e.g. shoulder elevation) [2,7,12]. This approach has been utilized to capture sagittal shoulder kinematics (i.e. elevation). Yet, the vast majority of studies have attempted to improve measurement precision in well-controlled environments while subjects performed prescribed movements [6,18,19]. In contrast, we previously developed, validated, and deployed an IMU-based method for capturing long-duration, 'real-world' shoulder elevation including from healthy elderly individuals and individuals before/after total shoulder arthroplasty (TSA) [3,4]. Additionally, Van de Kleut et al. recently published similar efforts quantifying shoulder elevation via IMUs pre-/post rTSA [21]. While they did find changes in shoulder kinematics following rTSA, they only captured 1-day prior to surgery and 1-day at 3/12 months post-rTSA. Their efforts do indeed represent a leap forward, however 1-days' data may over- or under-estimate patient performance. To our knowledge, no work exists using IMUs to evaluate patient ROM after rTSA for long durations (i.e. weeks).

Accordingly, our focus was conducting a pilot study to evaluate the feasibility of prospectively quantifying continuous, long-duration shoulder elevation from individuals before/after rTSA using a previously validated method [3,4]. Because humeral elevation captured clinically remains reduced immediately following rTSA compared to healthy individuals [11], we hypothesize patients will have reduced elevation as measured by IMUs compared to healthy subjects before and immediately after surgery. In contrast, because long-term clinical improvement in ROM following rTSA has been shown clinically [1,5,8,15], we hypothesize patients will improve shoulder elevation as measured by IMUs following surgery at longer term follow ups (i.e. 1- and 2-years post-rTSA).

Materials and Methods

The method of prospectively capturing shoulder ROM used in this pilot study via IMUs was previously validated and is detailed in previous studies [3,4]. Briefly, IMUs (APDM, Inc., Portland, OR) were affixed to two bony landmarks (Figure 1A: sternum - xyphoid process, humerus - deltoid tuberosity). Daily temporal synchronization between IMUs occurred via manufacturer implemented wireless local area network 'sync-packet' clock comparison. Both IMU's data were converted to 3D vectors and the relative orientation between IMUs was utilized to compute shoulder elevation each day (Figure 1B). Subjects followed a daily sensor-use workflow (Figure 2), wherein subjects awoke, removed IMUs from charging docks, donned IMUs, and wore them for the duration of the day. 3D acceleration data were continuously captured (>8 hours per day) and stored locally (16GB MicroSD, up to 18 hours per day/60 days). Following daily capture, sensors were doffed/re-docked facilitating overnight recharging. This occurred daily for the study duration. IMUs were then returned to researchers for data download and processing.

Although this was a feasibility pilot study, pre-study statistics (α=0.05, power=0.80) of historical maximum elevation comparing healthy subjects and patients undergoing rTSA found minimum cohort sample size requirements of 9 subjects. Thus, following IRB approval by the ethics review board, we were granted the ability to enroll 10 patients (1M, 82±5 years) undergoing rTSA. Under the same IRB approval, we were granted the ability to enroll 10 healthy control subjects which have been described in previous publications [3,4]. Briefly, healthy controls wore sensors for 1-week continuously, similar to the pre-rTSA data capture for rTSA patients described below. We utilize those control subject results herein as a comparison point to our rTSA patient population. Patients were enrolled from a single surgeon's consecutive clinical caseload (inclusion: age>21, presentation for unilateral rTSA surgery from rotator cuff arthropathy (n=9) or osteoarthritis with irreparable rotator cuff tear (n=1), no other neuromuscular or musculoskeletal disease impacting upper extremities, no terminal illness with expected death within 1-year of enrollment). All patients previously failed conservative treatments including PT and/or injections. After obtaining consent, handedness was assessed for each subject via the Edinburgh Handedness Inventory [16] and utilized for correlation calculations. After handedness assessment, subjects underwent sensor-use tutorial (~30 minutes: charging dock plugs, charging sensors, sensor donning). Subjects were allowed to ask questions throughout and were given a pictorial/text instruction guide with contact information for post-tutorial questions.

Patients wore sensors on their impacted arm and sternum for one-week pre-rTSA without clinical interventions offered (e.g. PT, injections). Pre-rTSA clinical ROM via goniometry and patient reported outcome measures (PROMs) were collected by the senior resident physician on the day of surgery. This was the same individual throughout the entire study. Goniometry was completed with the patient in a seated posture performing active ROM. Patients then underwent rTSA performed by the attending surgeon via the deltopectoral approach and received a single design implant (Zimmer Biomet, Inc., Trabecular Metal™ Reverse Shoulder System, Warsaw, IN). Patients were discharged home with a motion-restricting sling and clinician-limited passive ROM allowed until post-rTSA week six. Active-assisted ROM was allowed after 6 weeks (i.e. post-rTSA weeks 6-12). Following clinician clearance for unrestricted active ROM and gentle strength exercises at three months post-rTSA, patients wore IMUs for six consecutive weeks (i.e. post-rTSA 12-18). Clinical ROM and PROMs were re-captured at the end of this 6-week period by the same senior resident physician. At 1- and 2-years post-rTSA, 1-week IMU data captures were repeated alongside clinical goniometric ROM measurement and PROMs.

Following return of IMU sensors, IMU data were retrospectively analyzed daily. IMU-based elevation was divided into 0.5 second and 5° increments (e.g. 0-5°, etc.). Average elevation within each 0.5 second time bin was quantified and the count within the corresponding angle bin incremented. The total daily count in each angle bin was converted to a percentage of the day spent within that angle bin. Additional IMU-based ROM metrics were daily average and maximum elevation. Daily metrics were then averaged within a week and weekly averages were averaged across subjects. Goniometric ROM (active forward flexion and external rotation) and PROMs at the previously noted time points were captured by the senior resident physician, including pain score, American Shoulder and Elbow Surgeon (ASES) score, and Patient Reported Outcomes Measurement Information System (PROMIS)-10 mental and physical component summary (MCS and PCS) [9,14].

Although this study was a pilot investigation, statistical tests were conducted for completeness to compare rTSA patient results to previously published healthy control subjects. This included demographics, IMU-based ROM metrics, PROMs, and clinical goniometric ROM. Specifically, statistical evaluations were two-tailed t-tests for continuous variables, two-tailed t-tests of proportions for non-numeric categorical variables, and two-tailed Mann-Whitney-U tests for numerical categorical variables.

Correlations were also calculated comparing demographics, IMU ROM metrics, PROMs, and goniometric ROM. Alpha level (α) was set at 0.05 for all t-tests and following a Bonferroni correction to 0.0015 (0.05/33=0.0015) for correlations.

Results

Subject Demographics, Goniometric ROM, PROMs

All patients were well healed postoperatively with no complications or reoperations needed. 10 patients were initially enrolled with 3 lost to follow up at 2-years post-rTSA (n=1 deceased, n=2 failed communication). No significant differences were noted between the 3 subjects lost to follow up and the remaining enrolled subjects or healthy subjects for any variable including demographics, clinical measures, or IMU measures. No significant demographic differences were noted between rTSA patients and previously published control subjects (Table 1). Previously published healthy control PROMs and clinical goniometric ROM were greater than pre-rTSA values (Table 2; *). At the immediate post-rTSA follow-up, goniometric flexion improved beyond pre-rTSA levels (Table 2; ‡) but both goniometric flexion and external rotation (ER) remained less than historical controls. Goniometric flexion remained above pre-rTSA and equaled historical control values for the remainder of the study, whereas ER persisted below historical control levels. Like ER, PROMIS PCS was less than historical controls throughout the entire study. PROMIS MCS was equal to historical controls during first post-rTSA follow up but returned below thereafter. Pain improved immediately following surgery and remained improved throughout. Finally, ASES initially improved post-rTSA but did not achieve historical control levels until 1-year postop and subsequently returned below control levels at 2-year post-rTSA.

IMU Outcome Measures

IMU average elevation (Figure 3: historical controls, patient pre, and patient post as solid, striped, and dotted bars, respectively) was equal between patients and historical controls at all times ($p>0.05$). Similarly, IMU maximum elevation (Figure 4: displayed similarly) was always equal between patients and historical controls ($p>0.05$).

Binned shoulder elevation in 15° bins under 90° (e.g. 0-15°, etc.) is shown in Figure 5A. Pre-rTSA, no statistical difference was noted between patients and historical controls ($p=0.76$), spending 94.6% and 96.2% of their time below 90° each day, respectively. More specifically, pre-rTSA patients spent 41.1% between 0-30°, 38.3% between 30-60°, and 15.2% between 60-90°. Historical controls spent 38.9%, 44.1%, and 13.2% in the same ranges. These values oscillated during postop follow-ups, however no significant differences were noted.

Binned elevation percent above 90° is displayed in 45° increments in Figure 5B. Similar to <90°, historical controls (3.8%) and patients pre-rTSA (5.4%) showed no statistically significant differences for elevations above 90° ($p=0.45$). Following surgery, patients increased the amount each day spent above 90° until post-rTSA week 3 (10.9%). However, this value decreased thereafter returning to pre-rTSA levels (6.0%) at the end of acute rehabilitation. Patient daily elevation percentage above 90° at 1-year (8.5%) and 2-years (7.7%) post-rTSA remained elevated above both preoperative and historical control subject levels, however not at a statistically significant level ($p>0.40$).

Correlations are shown in Table 3. Following a Bonferroni correction, no statistically significant correlations were found.

Discussion

Shoulder ROM measurements before and after surgical intervention are typically recorded in well-controlled environments like the clinic or laboratory. While capturing data in these environments has advantages (e.g. convenient, easy), the measures likely do not accurately describe shoulder function during ADLs in patient's 'real world' settings. To ameliorate these limitations, we deployed a previously validated method to establish shoulder elevation via IMUs in patients pre-/post-rTSA in their own environments and compared the results to previously published healthy individuals [3]. We saw improvements in some clinical metrics after surgery (e.g. ASES, pain scores, and goniometric flexion), yet most were still not equal to historical healthy controls. Clinically, our patients did not see external rotation improvement after rTSA. These results are similar to other rTSA studies, which may indicate our patients were typical and well matched with those presented in the literature [1,8,11,15]. However, befitting a pilot study our sample size was relatively small (n=10). In future investigations, increasing subject quantity will improve the statistical strength of that sentiment.

Interestingly, despite pre-op rTSA patients having significantly lower goniometric maximum ROM, IMU-based ROM (average, maximum, and movement percentage) pre-rTSA was no different than controls. In other words, while pre-rTSA ROM deficits are noted clinically, patients use their shoulder ROM equal to healthy counterparts in self-selected settings as assessed using this IMU method. For average elevation, this likely means that the vast majority of typical ADLs are completed at lower elevations (i.e. arm elevated between waist and chest height) which subjects could do regardless of surgical status. Prior investigations have found this to be true with the majority of ADLs requiring less than 100° (e.g. washing face, eating/drinking, toileting) with notable exceptions of combing one's hair and reaching behind one's own head [17].This finding might also imply normal elderly individuals without shoulder pathology do not move their arms more effectively than pre-rTSA patients in the real world, despite the capacity to do so. However, several notable comorbidities in a number of patients were discovered including anecdotal use of ambulatory assistive devices (e.g. walkers, canes). The use of these devices could greatly influence how patients utilize their upper extremities for a great deal of time. For example, several individuals indicated they utilized walkers in a stooped posture (we estimate the torso would flex ~15-20°, humeri would elevate ~75-90°) (Figure 6). Although this is indicative of relatively high humeral elevations, elevations in this posture are grossly different than humeral elevations with an upright torso as is often seen in healthy individuals. Using the described method, we are currently incapable of differentiating 90° elevation in an upright posture from 90° elevation while stooped over, using an assistive device. To ascertain these differences, future studies should include torso kinematics to complete the picture of upper extremity function before and after rTSA.

Despite these unanticipated findings, the validated IMU-based ROM measurement method used herein provides a richer image of patient function. While it is clear from this study and others that patients are incapable of high active forward flexion measured goniometrically, they appear to be capable of achieving high thoracohumeral angles in some manner (i.e. upright torso or forward flexed torso using assistive devices) and in some situations before surgery as measured outside of the clinic via IMUs. As described herein, achieving high thoracohumeral angles is possible in a number of different ways outside the clinic (e.g. passive ROM in supine at PT, use of a walker in bent trunk posture, etc.). However, in the present study we did not evaluate how this high humeral elevation occurred. Despite this inability, it is clear that goniometric clinical measures do not show the entire performance picture whereas IMU-based ROM measures are capable of providing richer data.

Additionally, it could be argued that monitoring humeral elevation may not be the best metric to measure if the question is about completion of upper extremity ADLs. For example, reaching requires placing the hand in the appropriate position in space for the task. This typically requires a combination of all three planes of motion (sagittal, frontal, and transverse) which may not be encapsulated by humeral elevation alone. Moreover, many upper extremity ADLs can be completed with <100° humeral elevation. Thus, future investigations should attempt capturing a wider range of kinematic variables. In addition and as noted previously, patients may have completed specific ROM in a variety of ways that required different effort levels with varying levels of pain. In the present study, we have not differentiated which motions or ROM required greater effort or caused increased pain. Future studies should evaluate these features.

Following surgery, rTSA patient IMU-based average and maximum ROM remained equal to historical controls during all postoperative weeks. And, while there were temporary differences in ROM utilization between patients and historical controls (increased % > 90° elevation during post-rTSA week three), these differences disappeared by the end of the rehabilitation period and persisted at 1- and 2-years post-rTSA. These results do not support our hypothesis that rTSA patients would have increased shoulder ROM utilization in the home environment postoperatively compared to preoperative levels. Perhaps more critically, despite the advantage of capturing real-world ROM via IMUs, these results indicate that average elevation, maximum elevation, and the percent of the day in particular positions as established by IMUs are insufficient for describing pre- or post-rTSA shoulder function. Future researchers should investigate capturing other IMU-based ROM metrics including quantifying all three kinematic planes of motion.

Limitations

Despite advantages IMU-based ROM measures offer, there are inherent limitations in the efforts discussed. As this was a pilot investigation, our sample size was small (n=10 patients). Moreover, three subjects were lost to at 2-year follow up (n=7 final subjects). Accordingly, where we noted no significant differences in IMU-based kinematic differences or results that may not align with previous publications, it is likely with additional patients we will have stronger statistical surety of the results herein. In addition, this study only investigated one rTSA implant make/model. As such, the results herein may not apply to other device manufacturers or types. Additionally, we only captured one IMU-based ROM measure at specific time points (i.e. one week continuous pre-rTSA, 6 weeks continuously at 3 months post-rTSA, and 1-week at 1- and 2-years post-rTSA). It is possible that other IMU-based ROM measures (e.g. differentiate between sagittal/frontal/transverse planes) or other time periods would yield different results. Other biomechanical limitations include not measuring the contralateral arm or other body segments. It is also possible that patients altered their approach for accomplishing ADL (e.g. increased trunk flexion, use of contralateral arm) however conclusions about this in the present study are unknown. In addition, we confirmed the work of many other studies on rTSA that show decreased external rotation after surgery measured goniometrically, but it was not feasible to accurately measure external rotation with the current IMU-based approach. Future experiments should incorporate monitoring additional segments and/or the contralateral limb. Additionally, there may be non-kinematic variables that might show more significant improvement post-rTSA (e.g. strength). Lastly, the tasks that patients complete will have a great influence on how they utilize their upper extremities. We only have anecdotal evidence of assistive device utilization and do not know what hobbies and/or occupations each subject routinely completed. Capturing this data in future studies would illuminate potential causative factors for specific kinematic measure results. Future studies should incorporate these metrics.

Conclusion

This study shows that ROM data captured in well-controlled environments like the clinic or laboratory are not representative of what patients actually do with their shoulders in their real-world environment. We deployed a validated IMU-based method for capturing shoulder elevation continuously in patients' home environments, outside of controlled clinic or laboratory environments. The cohort captured in this body of work had similar post-op survey outcomes, clinically measured ROM, and pain relief when compared to other rTSA studies. However, we did not see improved use of the arm after surgery as assessed by 'real-world' IMU-based ROM metrics. This could indicate that while rTSA does improve several clinic-based measures like pain, satisfaction, and goniometric ROM, it does not have a similar impact on ROM utilization during ADL outside of the clinic. However, we are currently unable to ascertain the specific strategy a particular subject used to achieve a particular ROM. Thus, a movement that appears similar before and after surgery may in fact have similar elevation ROM, but vastly different effort levels required, pain experienced, plane of elevation, and/or compensatory strategy. Additionally, these results may indicate that we should align our postoperative ROM goals not with what is possible clinically, but with what patients require to regain function in their home environment. Additionally, we noted several transient improvements in movement patterns during the acute post-rTSA time period with reductions in function chronically. As such, future work should endeavor to create rehabilitation strategies that not only improve acute movement patterns but also chronic movement capabilities following rTSA.

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Figure Legends

Figure 1.	Example instrumentation including **A)** IMU donning locations on the sternum and humerus [4, 5] and **B)** angle computation between gravity and acceleration data.
Figure 2.	Data processing workflow including **1)** raw accelerometer signal input, **2)** processing accelerometer signals (bony segment differentiation, low pass filtration, offsetting anatomical/sensor misalignment, and distal to proximal coordinate transformation), **3)** continuous shoulder elevation calculation, **4)** daily metric calculation (average, maximum bin > 10x, maximum elevation, binned movement rate, binned percentage), **5)** weekly metric averages, and **6)** total subject averages.
Figure 3.	IMU-based average shoulder elevation for controls (solid), patients pre-rTSA (striped), and patients post-rTSA (dotted).
Figure 4.	IMU-based maximum shoulder elevation for controls (solid), patients pre-rTSA (striped), and patients post-rTSA (dotted).
Figure 5.	Movement percentage **A)** less than 90° binned in 15° increments and **B)** more than 90° binned in 45° increments.
Figure 6.	Examples of expected humeral elevation (as was typical in healthy controls) and unexpected humeral elevations (as was seen in comorbid patients using assistive devices).

Table Legends

Table 1.	Subject demographics and associated p-values for statistical comparisons between control subjects and patients undergoing rTSA.
Table 2.	Patient reported outcome measures (PROMs) and clinical goniometric ROM. Statistical significance ($p<0.05$) between control/patient values and between pre-/post-rTSA values are indicated by asterisks (*) and by double-cross (‡), respectively. Pain is listed as median ± MAD; PROMIS P, PROMIS M, and ASES, and clinical ROM are listed as mean ± SD.
Table 3.	Patient Spearman (discrete variables) and Pearson (continuous variables) correlations including comparisons between IMU-based metrics, clinical ROM, and PROMs. Data are displayed as correlation coefficient and p-values.