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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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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*

70   *both pre- and post-rTSA. The percent of time spent above 90° was equal between cohorts*

71   *pre-rTSA, rose significantly at 3 months post-rTSA, and returned to preop levels*

72   *thereafter.*

73   **Discussion:** *Although pain, satisfaction, and ROM measured clinically may improve*

74   *following rTSA, real-world utilization of improved ROM was not seen herein.*

75   *Improvements during the acute rehabilitation phase may be transient, indicating longer*

76   *or more specific rehabilitation protocols are necessary to see chronic improvements in*

77   *post-rTSA movement patterns.*

78   **Level of Evidence:** Prospective Prognosis Study-Defined Level 2

79   **Keywords**: Arthroplasty, Shoulder, Inertial Measurement Unit, Rehabilitation, Range of

80   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

104   individuals before/after total shoulder arthroplasty (TSA) [3,4]. Additionally, Van de Kleut

105   et al. recently published similar efforts quantifying shoulder elevation via IMUs pre-/post

106   rTSA [21]. While they did find changes in shoulder kinematics following rTSA, they only

107   captured 1-day prior to surgery and 1-day at 3/12 months post-rTSA. Their efforts do

108   indeed represent a leap forward, however 1-days' data may over- or under-estimate

109   patient performance. To our knowledge, no work exists using IMUs to evaluate patient

110   ROM after rTSA for long durations (i.e. weeks).

111   Accordingly, our focus was conducting a pilot study to evaluate the feasibility of

112   prospectively quantifying continuous, long-duration shoulder elevation from individuals

113   before/after rTSA using a previously validated method [3,4]. Because humeral elevation

114   captured clinically remains reduced immediately following rTSA compared to healthy

115   individuals [11], we hypothesize patients will have reduced elevation as measured by IMUs

116   compared to healthy subjects before and immediately after surgery. In contrast, because

117   long-term clinical improvement in ROM following rTSA has been shown clinically

118   [1,5,8,15], we hypothesize patients will improve shoulder elevation as measured by IMUs

119   following surgery at longer term follow ups (i.e. 1- and 2-years post-rTSA).

Materials and Methods

120

121   The method of prospectively capturing shoulder ROM used in this pilot study via

122 IMUs was previously validated and is detailed in previous studies [3,4]. Briefly, IMUs

123 (APDM, Inc., Portland, OR) were affixed to two bony landmarks (Figure 1A: sternum -

124 xyphoid process, humerus - deltoid tuberosity). Daily temporal synchronization between

125 IMUs occurred via manufacturer implemented wireless local area network 'sync-packet'

126 clock comparison. Both IMU's data were converted to 3D vectors and the relative

127 orientation between IMUs was utilized to compute shoulder elevation each day (Figure

128 1B). Subjects followed a daily sensor-use workflow (Figure 2), wherein subjects awoke,

129 removed IMUs from charging docks, donned IMUs, and wore them for the duration of

130 the day. 3D acceleration data were continuously captured (>8 hours per day) and stored

131 locally (16GB MicroSD, up to 18 hours per day/60 days). Following daily capture,

132 sensors were doffed/re-docked facilitating overnight recharging. This occurred daily for

133 the study duration. IMUs were then returned to researchers for data download and

134 processing.

135   Although this was a feasibility pilot study, pre-study statistics (α=0.05,

136 power=0.80) of historical maximum elevation comparing healthy subjects and patients

137 undergoing rTSA found minimum cohort sample size requirements of 9 subjects. Thus,

138 following IRB approval by the ethics review board, we were granted the ability to enroll

139 10 patients (1M, 82±5 years) undergoing rTSA. Under the same IRB approval, we were

140 granted the ability to enroll 10 healthy control subjects which have been described in

141 previous publications [3,4]. Briefly, healthy controls wore sensors for 1-week continuously,

142 similar to the pre-rTSA data capture for rTSA patients described below. We utilize those

143 control subject results herein as a comparison point to our rTSA patient population.

144 Patients were enrolled from a single surgeon's consecutive clinical caseload (inclusion:

145 age>21, presentation for unilateral rTSA surgery from rotator cuff arthropathy (n=9) or

146 osteoarthritis with irreparable rotator cuff tear (n=1), no other neuromuscular or

147 musculoskeletal disease impacting upper extremities, no terminal illness with expected

148 death within 1-year of enrollment). All patients previously failed conservative treatments

149 including PT and/or injections. After obtaining consent, handedness was assessed for

150 each subject via the Edinburgh Handedness Inventory [16] and utilized for correlation

151 calculations. After handedness assessment, subjects underwent sensor-use tutorial (~30

152 minutes: charging dock plugs, charging sensors, sensor donning). Subjects were allowed

153 to ask questions throughout and were given a pictorial/text instruction guide with contact

154 information for post-tutorial questions.

155   Patients wore sensors on their impacted arm and sternum for one-week pre-rTSA

156 without clinical interventions offered (e.g. PT, injections). Pre-rTSA clinical ROM via

157 goniometry and patient reported outcome measures (PROMs) were collected by the

158 senior resident physician on the day of surgery. This was the same individual throughout

159 the entire study. Goniometry was completed with the patient in a seated posture

160 performing active ROM. Patients then underwent rTSA performed by the attending

161 surgeon via the deltopectoral approach and received a single design implant (Zimmer

162 Biomet, Inc., Trabecular Metal™ Reverse Shoulder System, Warsaw, IN). Patients were

163 discharged home with a motion-restricting sling and clinician-limited passive ROM

164 allowed until post-rTSA week six. Active-assisted ROM was allowed after 6 weeks (i.e.

165 post-rTSA weeks 6-12). Following clinician clearance for unrestricted active ROM and

166 gentle strength exercises at three months post-rTSA, patients wore IMUs for six

167 consecutive weeks (i.e. post-rTSA 12-18). Clinical ROM and PROMs were re-captured at

168 the end of this 6-week period by the same senior resident physician. At 1- and 2-years

169 post-rTSA, 1-week IMU data captures were repeated alongside clinical goniometric

170 ROM measurement and PROMs.

171   Following return of IMU sensors, IMU data were retrospectively analyzed daily.

172 IMU-based elevation was divided into 0.5 second and 5° increments (e.g. 0-5°, etc.).

173 Average elevation within each 0.5 second time bin was quantified and the count within

174 the corresponding angle bin incremented. The total daily count in each angle bin was

175 converted to a percentage of the day spent within that angle bin. Additional IMU-based

176 ROM metrics were daily average and maximum elevation. Daily metrics were then

177 averaged within a week and weekly averages were averaged across subjects. Goniometric

178 ROM (active forward flexion and external rotation) and PROMs at the previously noted

179 time points were captured by the senior resident physician, including pain score,

180 American Shoulder and Elbow Surgeon (ASES) score, and Patient Reported Outcomes

181 Measurement Information System (PROMIS)-10 mental and physical component

182 summary (MCS and PCS) [9,14].

183   Although this study was a pilot investigation, statistical tests were conducted for

184 completeness to compare rTSA patient results to previously published healthy control

185 subjects. This included demographics, IMU-based ROM metrics, PROMs, and clinical

186 goniometric ROM. Specifically, statistical evaluations were two-tailed t-tests for

187 continuous variables, two-tailed t-tests of proportions for non-numeric categorical

188 variables, and two-tailed Mann-Whitney-U tests for numerical categorical variables.

189   Correlations were also calculated comparing demographics, IMU ROM metrics, PROMs,

190   and goniometric ROM. Alpha level (α) was set at 0.05 for all t-tests and following a

191   Bonferroni correction to 0.0015 (0.05/33=0.0015) for correlations.

192   **Results**

193   *Subject Demographics, Goniometric ROM, PROMs*

194   All patients were well healed postoperatively with no complications or

195   reoperations needed. 10 patients were initially enrolled with 3 lost to follow up at 2-years

196   post-rTSA (n=1 deceased, n=2 failed communication). No significant differences were

197   noted between the 3 subjects lost to follow up and the remaining enrolled subjects or

198   healthy subjects for any variable including demographics, clinical measures, or IMU

199   measures. No significant demographic differences were noted between rTSA patients and

200   previously published control subjects (Table 1). Previously published healthy control

201   PROMs and clinical goniometric ROM were greater than pre-rTSA values (Table 2; *).

202   At the immediate post-rTSA follow-up, goniometric flexion improved beyond pre-rTSA

203   levels (Table 2; ‡) but both goniometric flexion and external rotation (ER) remained less

204   than historical controls. Goniometric flexion remained above pre-rTSA and equaled

205   historical control values for the remainder of the study, whereas ER persisted below

206   historical control levels. Like ER, PROMIS PCS was less than historical controls

207   throughout the entire study. PROMIS MCS was equal to historical controls during first

208   post-rTSA follow up but returned below thereafter. Pain improved immediately following

209   surgery and remained improved throughout. Finally, ASES initially improved post-rTSA

210   but did not achieve historical control levels until 1-year postop and subsequently returned

211   below control levels at 2-year post-rTSA.

212   *IMU Outcome Measures*

213   IMU average elevation (Figure 3: historical controls, patient pre, and patient post

214   as solid, striped, and dotted bars, respectively) was equal between patients and historical

215   controls at all times (p>0.05). Similarly, IMU maximum elevation (Figure 4: displayed

216   similarly) was always equal between patients and historical controls (p>0.05).

217   Binned shoulder elevation in 15° bins under 90° (e.g. 0-15°, etc.) is shown in

218   Figure 5A. Pre-rTSA, no statistical difference was noted between patients and historical

219   controls (p=0.76), spending 94.6% and 96.2% of their time below 90° each day,

220   respectively. More specifically, pre-rTSA patients spent 41.1% between 0-30°, 38.3%

221   between 30-60°, and 15.2% between 60-90°. Historical controls spent 38.9%, 44.1%, and

222   13.2% in the same ranges. These values oscillated during postop follow-ups, however no

223   significant differences were noted.

224   Binned elevation percent above 90° is displayed in 45° increments in Figure 5B.

225   Similar to <90°, historical controls (3.8%) and patients pre-rTSA (5.4%) showed no

226   statistically significant differences for elevations above 90° (p=0.45). Following surgery,

227   patients increased the amount each day spent above 90° until post-rTSA week 3 (10.9%).

228   However, this value decreased thereafter returning to pre-rTSA levels (6.0%) at the end

229   of acute rehabilitation. Patient daily elevation percentage above 90° at 1-year (8.5%) and

230   2-years (7.7%) post-rTSA remained elevated above both preoperative and historical

231   control subject levels, however not at a statistically significant level (p>0.40).

232   Correlations are shown in Table 3. Following a Bonferroni correction, no

233   statistically significant correlations were found.

Discussion

234

235   Shoulder ROM measurements before and after surgical intervention are typically

236   recorded in well-controlled environments like the clinic or laboratory. While capturing

237   data in these environments has advantages (e.g. convenient, easy), the measures likely do

238   not accurately describe shoulder function during ADLs in patient's 'real world' settings.

239   To ameliorate these limitations, we deployed a previously validated method to establish

240   shoulder elevation via IMUs in patients pre-/post-rTSA in their own environments and

241   compared the results to previously published healthy individuals [3]. We saw

242   improvements in some clinical metrics after surgery (e.g. ASES, pain scores, and

243   goniometric flexion), yet most were still not equal to historical healthy controls.

244   Clinically, our patients did not see external rotation improvement after rTSA. These

245   results are similar to other rTSA studies, which may indicate our patients were typical

246   and well matched with those presented in the literature [1,8,11,15]. However, befitting a pilot

247   study our sample size was relatively small (n=10). In future investigations, increasing

248   subject quantity will improve the statistical strength of that sentiment.

249   Interestingly, despite pre-op rTSA patients having significantly lower goniometric

250   maximum ROM, IMU-based ROM (average, maximum, and movement percentage) pre-

251   rTSA was no different than controls. In other words, while pre-rTSA ROM deficits are

252   noted clinically, patients use their shoulder ROM equal to healthy counterparts in self-

253   selected settings as assessed using this IMU method. For average elevation, this likely

254   means that the vast majority of typical ADLs are completed at lower elevations (i.e. arm

255   elevated between waist and chest height) which subjects could do regardless of surgical

256   status. Prior investigations have found this to be true with the majority of ADLs requiring

257 less than 100° (e.g. washing face, eating/drinking, toileting) with notable exceptions of

258 combing one's hair and reaching behind one's own head [17].This finding might also imply

259 normal elderly individuals without shoulder pathology do not move their arms more

260 effectively than pre-rTSA patients in the real world, despite the capacity to do so.

261 However, several notable comorbidities in a number of patients were discovered

262 including anecdotal use of ambulatory assistive devices (e.g. walkers, canes). The use of

263 these devices could greatly influence how patients utilize their upper extremities for a

264 great deal of time. For example, several individuals indicated they utilized walkers in a

265 stooped posture (we estimate the torso would flex ~15-20°, humeri would elevate ~75-

266 90°) (Figure 6). Although this is indicative of relatively high humeral elevations,

267 elevations in this posture are grossly different than humeral elevations with an upright

268 torso as is often seen in healthy individuals. Using the described method, we are currently

269 incapable of differentiating 90° elevation in an upright posture from 90° elevation while

270 stooped over, using an assistive device. To ascertain these differences, future studies

271 should include torso kinematics to complete the picture of upper extremity function

272 before and after rTSA.

273 Despite these unanticipated findings, the validated IMU-based ROM

274 measurement method used herein provides a richer image of patient function. While it is

275 clear from this study and others that patients are incapable of high active forward flexion

276 measured goniometrically, they appear to be capable of achieving high thoracohumeral

277 angles in some manner (i.e. upright torso or forward flexed torso using assistive devices)

278 and in some situations before surgery as measured outside of the clinic via IMUs. As

279 described herein, achieving high thoracohumeral angles is possible in a number of

280   different ways outside the clinic (e.g. passive ROM in supine at PT, use of a walker in

281   bent trunk posture, etc.). However, in the present study we did not evaluate how this high

282   humeral elevation occurred. Despite this inability, it is clear that goniometric clinical

283   measures do not show the entire performance picture whereas IMU-based ROM

284   measures are capable of providing richer data.

285   Additionally, it could be argued that monitoring humeral elevation may not be the

286   best metric to measure if the question is about completion of upper extremity ADLs. For

287   example, reaching requires placing the hand in the appropriate position in space for the

288   task. This typically requires a combination of all three planes of motion (sagittal, frontal,

289   and transverse) which may not be encapsulated by humeral elevation alone. Moreover,

290   many upper extremity ADLs can be completed with $<100°$ humeral elevation. Thus,

291   future investigations should attempt capturing a wider range of kinematic variables. In

292   addition and as noted previously, patients may have completed specific ROM in a variety

293   of ways that required different effort levels with varying levels of pain. In the present

294   study, we have not differentiated which motions or ROM required greater effort or

295   caused increased pain. Future studies should evaluate these features.

296   Following surgery, rTSA patient IMU-based average and maximum ROM

297   remained equal to historical controls during all postoperative weeks. And, while there

298   were temporary differences in ROM utilization between patients and historical controls

299   (increased $\% > 90°$ elevation during post-rTSA week three), these differences

300   disappeared by the end of the rehabilitation period and persisted at 1- and 2-years post-

301   rTSA. These results do not support our hypothesis that rTSA patients would have

302   increased shoulder ROM utilization in the home environment postoperatively compared

303 to preoperative levels. Perhaps more critically, despite the advantage of capturing real-

304 world ROM via IMUs, these results indicate that average elevation, maximum elevation,

305 and the percent of the day in particular positions as established by IMUs are insufficient

306 for describing pre- or post-rTSA shoulder function. Future researchers should investigate

307 capturing other IMU-based ROM metrics including quantifying all three kinematic planes

308 of motion.

309 **Limitations**

310   Despite advantages IMU-based ROM measures offer, there are inherent

311 limitations in the efforts discussed. As this was a pilot investigation, our sample size was

312 small (n=10 patients). Moreover, three subjects were lost to at 2-year follow up (n=7 final

313 subjects). Accordingly, where we noted no significant differences in IMU-based

314 kinematic differences or results that may not align with previous publications, it is likely

315 with additional patients we will have stronger statistical surety of the results herein. In

316 addition, this study only investigated one rTSA implant make/model. As such, the results

317 herein may not apply to other device manufacturers or types. Additionally, we only

318 captured one IMU-based ROM measure at specific time points (i.e. one week continuous

319 pre-rTSA, 6 weeks continuously at 3 months post-rTSA, and 1-week at 1- and 2-years

320 post-rTSA). It is possible that other IMU-based ROM measures (e.g. differentiate

321 between sagittal/frontal/transverse planes) or other time periods would yield different

322 results. Other biomechanical limitations include not measuring the contralateral arm or

323 other body segments. It is also possible that patients altered their approach for

324 accomplishing ADL (e.g. increased trunk flexion, use of contralateral arm) however

325 conclusions about this in the present study are unknown. In addition, we confirmed the

326   work of many other studies on rTSA that show decreased external rotation after surgery

327   measured goniometrically, but it was not feasible to accurately measure external rotation

328   with the current IMU-based approach. Future experiments should incorporate monitoring

329   additional segments and/or the contralateral limb. Additionally, there may be non-

330   kinematic variables that might show more significant improvement post-rTSA (e.g.

331   strength). Lastly, the tasks that patients complete will have a great influence on how they

332   utilize their upper extremities. We only have anecdotal evidence of assistive device

333   utilization and do not know what hobbies and/or occupations each subject routinely

334   completed. Capturing this data in future studies would illuminate potential causative

335   factors for specific kinematic measure results. Future studies should incorporate these

336   metrics.

337 **Conclusion**

338   This study shows that ROM data captured in well-controlled environments like

339 the clinic or laboratory are not representative of what patients actually do with their

340 shoulders in their real-world environment. We deployed a validated IMU-based method

341 for capturing shoulder elevation continuously in patients' home environments, outside of

342 controlled clinic or laboratory environments. The cohort captured in this body of work

343 had similar post-op survey outcomes, clinically measured ROM, and pain relief when

344 compared to other rTSA studies. However, we did not see improved use of the arm after

345 surgery as assessed by 'real-world' IMU-based ROM metrics. This could indicate that

346 while rTSA does improve several clinic-based measures like pain, satisfaction, and

347 goniometric ROM, it does not have a similar impact on ROM utilization during ADL

348 outside of the clinic. However, we are currently unable to ascertain the specific strategy a

349 particular subject used to achieve a particular ROM. Thus, a movement that appears

350 similar before and after surgery may in fact have similar elevation ROM, but vastly

351 different effort levels required, pain experienced, plane of elevation, and/or compensatory

352 strategy. Additionally, these results may indicate that we should align our postoperative

353 ROM goals not with what is possible clinically, but with what patients require to regain

354 function in their home environment. Additionally, we noted several transient

355 improvements in movement patterns during the acute post-rTSA time period with

356 reductions in function chronically. As such, future work should endeavor to create

357 rehabilitation strategies that not only improve acute movement patterns but also chronic

358 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).

444 **Table Legends**

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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.

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