

The Effect of Concomitant Elbow Injuries on the Outcomes of Radial Head Arthroplasty: A Cohort Comparison

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Abstract

Objectives:

To compare physical impairments and patient reported outcomes in patients following simple and complex elbow injuries who were treated with a radial head arthroplasty.

Design: Patients with isolated elbow trauma and no prior injury to the elbow were prospectively enrolled following radial head arthroplasty for an acute unreconstructable fracture. Injury patterns were classified as simple or complex based on the presence or absence of associated elbow fractures and/or dislocation.

Setting: Quaternary Upper Extremity referral Hospital

Patients/Participants: Patients (n= 148) were subgrouped into 67 simple and 81 associated fracture/dislocation injury patterns.

Intervention: Radial Head Arthroplasty

Main Outcome Measurements: PREE, QuickDASH, Range of Motion and Biodex measurements

Results:

At a minimum 1 year follow-up PREE and QuickDASH, and ROM and strength values were similar. Forty-four patients evaluated at a mean of 7 years demonstrated no effect of injury pattern on clinical outcomes at any time point. Continued statistical improvements in PREE, supination ROM, and flexion ROM at medium term compared to earlier follow up was observed. Eight patients required secondary surgery, 2 in the simple injury group and 6 complex injury patients.

50 Conclusions:

51 Concomitant elbow injuries do not affect the longer term outcomes of patients with unreconstructable
52 radial head fractures requiring radial head arthroplasty. Patient outcomes continued to improve beyond
53 two years of follow-up.

54 **Key Words:** Radial Head Arthroplasty;Elbow Injuries;terrible triad;Monteggia;Trans-olecranon
55 fractures;Radial Head Fractures;radial head

56 Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of
57 levels of evidence.

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60 Introduction

61 One-third of all elbow fractures and 3% of all fractures involve the radial head^{10,22}. Radial head
62 fractures may occur as an isolated injury or as part of a more complex injury pattern^{7,20,23}. A fall on an
63 outstretched arm is the most common mechanism of injury. Forearm position and load pattern (varus,
64 valgus, axial and rotational factors) as well as the energy of trauma and patient bone density are
65 considered responsible for concomitant injuries. The frequency of associated injuries with displaced
66 radial head fractures have been variably reported ranging from 7-100%^{3,7,20,21,23,35}. Elbow dislocations
67 and associated ligamentous injuries are more commonly seen with displaced or comminuted radial
68 head fractures^{7,23,35}. Coronoid fractures (terrible triad pattern), trans-olecranon fractures, and Monteggia
69 variant injury patterns represent higher energy elbow trauma and they disrupt the fundamental osseous
70 stabilizers of the elbow^{3,4,5,17,20,22,31,32,35}.

With associated injuries to the osseous structures of the elbow, restoring the radial head as a secondary stabilizer to the elbow is of critical importance^{3,5,8,12,13,19,24}. Establishing the most appropriate treatment modality for radial head injuries has remained elusive. Currently, both non-operative and operative management can be considered based on injury pattern, patient characteristics and surgeon experience. The only definitive surgical indication for isolated radial head fractures is an injury with an associated impendence to motion. Injuries associated with complex osseous-ligamentous patterns or elbow instability are also considered for surgery. Radial head arthroplasty (RHA) is indicated for unreconstructable radial head fractures; particularly if there are more than 3 fragments, or in the setting of concomitant soft tissue injuries whereby the reliable restoration of elbow stability is paramount^{19,25,33,36,37}. The outcomes of metallic radial head replacements in the short and medium term have been variable; with some authors reporting good and excellent results and others less favourable outcomes^{1,6-8,11-14,16-18,28-31,37,38}. The discrepancies noted in the literature may be related to injury pattern or implant design. Previous studies have suggested poorer outcomes in more complex radial head injuries with associated ligamentous or osseous injuries or in injuries treated in a delayed fashion^{14,18,29}. To date, no study has compared the outcomes of radial head replacement based on injury severity.

The present study compared impairment measures and patient-reported outcomes of patients treated with radial head replacement based on the presence or absence of concomitant elbow fractures and/or dislocations. Our hypothesis was that the outcome of simple radial head fractures treated with a radial head arthroplasty would be superior to those with concomitant fractures and/or dislocation of the elbow. We expected that the outcomes at one year would be similar to those at longer follow up.

Patients and Methods

One hundred and seventy patients were prospectively enrolled within our radial head arthroplasty cohort study between December 1999 until May 2015. Inclusion criteria were patients between the ages of 18 and 85 years at the time of injury, with simple elbow trauma and no prior injury to the elbow (Table 1). Inclusion within the study required a minimum of 1 year follow up from the index surgical procedure. Exclusion criteria included: inability to consent or provide clinical outcome measurements. Five upper extremity fellowship trained surgeons at a dedicated upper extremity facility were responsible for all surgical treatment and enrollment. The indication for a radial head arthroplasty was a displaced radial head fracture with comminution or poor bone quality preventing stable internal fixation.

Radial head arthroplasty was performed in all cases with a modular uncemented smooth stem prosthesis (Evolve radial head system, Wright Medical, Arlington, Tennessee). Patient injury patterns were grouped into two types: simple and complex. Simple injury patterns were classified as an isolated radial head fracture without an associated dislocation or significant fracture. The complex pattern involved additional fractures (coronoid, Monteggia variants, capitellar, or epicondyle) and/or an associated elbow dislocation. Data from clinical and intra-operative notes as well as pre-operative radiographs were used to stratify patients based on the presence of concomitant injuries. The prospective collection of outcome scores and impairment measurements (ROM, Strength) was overseen by a blinded research assistant.

The specific surgical treatment was at the discretion of the treating physician, however, accepted practice for osseous and soft tissue management for radial head fractures and terrible triad injuries was observed as reported by Pugh et al³⁴. Arthroplasty implant sizing was performed using established techniques outlined by Frank et al¹⁵. In addition to the radial head replacement, open reduction and internal fixation of larger coronoid fractures, proximal ulna and epicondyle fractures and collateral

ligament repairs were performed as appropriate for the concomitant injuries. A posterior skin incision was used in this study to allow universal access to both the lateral, posterior and medial elbow as dictated by associated injuries⁹. Post-operative follow-up included radiographic and clinical examination at 2-weeks, followed by routine follow-up as prescribed by the treating physician. Additional implant surveillance was carried out yearly or alternating years thereafter. Post-operative rehabilitation under the guidance of a therapist was standardized based on injury pattern and intra-operative findings. Patients enrolled in the database underwent standardized data collection. Baseline patient demographics, involvement of worker's compensation or litigation, and change in employment following injury, functional outcomes and complications including re-operation were evaluated. Patient reported outcomes and clinical outcome scores including: Disability of the Arm, Shoulder, and Hand (QuickDASH), Patient Rated Elbow Evaluation (PREE) as well as elbow range of motion (ROM), grip and strength about the elbow were recorded^{2,4,27,41}. Data points at the 3 month, 6 month, 1 year, and then yearly were collected. Patients without available data and follow-up values were removed from analysis. We analyzed radial head outcomes at early (6 months), short (minimum 1 year) and medium-terms (minimum of 4 years). Our primary outcome was the Patient Reported Elbow Evaluation (PREE)⁴¹. Secondary outcomes included: QuickDASH, range of motion, SF-36 and strength^{2,4,27,41}. Additionally, radiological outcomes were reviewed. The presence of capitellar osteopenia, heterotopic ossification/HO (reported using modified Brooker grade), ulnohumeral arthritis (Broberg & Morrey) and periprosthetic lucency were recorded and analyzed using previously described techniques^{16,28,30}. Normally distributed univariate data were analyzed by generalized linear modeling utilizing repeated measure ANOVA, dichotomous data and categorical data were analyzed by Chi square testing. All statistical analyses were performed using SPSS (ver. 18.01, SPSS Inc., Chicago, USA). Institutional Review Board (IRB) permission was obtained prior to patient chart review or radiographic analysis.

Results

One hundred and seventy patients underwent radial head arthroplasty at our center and after database and chart review 148 patients met all inclusion criteria for the study. One-hundred and forty-eight patients with a radial head arthroplasty met the inclusion criteria including 67 simple and 81 complex injury patterns. Excluded cases (22) included: two patients with RHA performed for failed ORIF, nine patients with delayed RHA (>6months) for non-union, ongoing pain or late presentation after radial head excision performed at another center and 11 for inadequate follow-up. Patient demographics were similar between groups ($p>0.05$) with the exception of an increased proportion of older women in the complex pattern group ($p=0.042$, Table 2). Total mean follow-up for all patients was 4.7 year (Range 1-14). The simple injury group contained 20 LCL injuries, 16 combined LCL and coronoid tip (Regan Morrey Type I) fractures, 2 coronoid tip fractures treated with excision or left in-situ and 29 isolated radial head fractures. The complex injury group contained 59 terrible triads, 19 transolecranon fracture/dislocations, 2 Monteggia injuries and 1 dislocated elbow without an associated coronoid fracture. Two injuries were open fractures, Gustillo grade 1.

Short-Term Clinical Outcomes

At short term follow-up (average of 1.7 years), objective clinical scores were not significantly different between the two cohorts for strength (grip, flexion, extension, or rotation), or range of motion. Patient reported outcome scores, including the PREE (0-100), QuickDASH (0-100), SF-36 (0-100), were also not significantly different (Table3). Patient rated surgical satisfaction scores were rated as 8.7 ± 2.3 out of ten for simple injuries and 8.95 ± 2.13 for complex injuries ($p=0.66$).

Long-Term Outcomes

A subgroup of 44 patients with follow-up beyond four years (mean 6.8 years, range 4-14) were further analyzed for medium-term comparison analysis. Documented follow-up outcomes were compared at 6 months, 2 years and beyond 4 years. Patient reported outcome scores were not significantly different at any time point regardless of initial injury pattern ($p>0.2$). Final mean PREE and QuickDASH scores were 17 ± 3 and 14 ± 3 for the simple cohort and 11 ± 4 and 13 ± 3 for the complex cohort. Continued statistical improvements were reported in PREE ($p=0.049$), supination ROM ($p=0.003$), and flexion ROM ($p=0.05$) parameters at longer term follow-up compared to shorter term values. The QuickDASH demonstrated a trend towards improvement out to medium term follow-up but did not reach statistical significance ($p=0.052$). All variables showed mean improvement from initial 6 month follow up until final evaluation (Figure 1&2).

Radiological Outcomes

Capitellar osteopenia was identified in 29% of patients with simple injury patterns and in 21% of complex injuries (all cases were graded mild in severity). Ulnohumeral arthritis was noted in 17 patients in the simple injury pattern (Grade 1 in 15 patients, Grade 2 in 1 patient and Grade 3 changes in 1 patient). Thirty-six patients demonstrated arthritic changes in the complex injury group (Grade 1;28, Grade 2;7 and Grade 3;1). Periprosthetic lucencies were radiographically apparent in 51% of patients (39% mild, and 12% moderate in severity). Heterotopic ossification (HO) was significantly higher in the complex group with 44% of patients showing some level of HO compared to just 18% in the simple group ($p=0.02$). One patient in the complex group had extensive heterotopic ossification, Brooker grade 4.

187 There was no statistically significant association between injury pattern and incidence of capitellar
188 osteopenia $\chi^2(9) = 1.1, p = 0.3$), ulnohumeral arthritis $\chi^2(9) = 5.3, p = 0.1$) or radiographic lucency $\chi^2(9) =$
189 $0.61, p = 0.7$). A statistically significant association was found between the injury pattern and the
190 incidence of heterotopic ossification ($\chi^2(9) = 11.658, p = 0.02$). The association was moderately strong,
191 (Cramer's $V = 0.283$).

192 **Complications**

193 Overall, 42 complications were reported by patients, 18 in the simple injury group (26%) and 24
194 complications in the complex injury group (30%, $p = 0.75$). Eight patients required secondary surgery
195 (5%), two in the simple injury group and 6 in the complex injury group ($p = 0.095$). Revision surgery
196 included four contracture releases for post-operative stiffness, one staged revision for deep infection,
197 one for an oversized radial head implant and one for removal of hardware. One patient in the simple
198 injury group had a five-degree supination arc due to heterotopic ossification but declined surgical
199 intervention. All neurologic complications resolved within 2 years without additional procedures. All
200 complications are reported in see Table, Supplemental Content 1.

201 **Discussion**

202 Our findings suggest that with the appropriate surgical management and rehabilitation of the
203 concomitant ligament injuries and fractures, the injury severity does not affect the clinical outcome in
204 patients requiring radial head arthroplasty. We recognize that concomitant injuries might be important
205 in other fracture situations and that patients who do require a radial head arthroplasty are a subset of
206 patients with unreconstructable injuries. It may be that the nature of unreconstructable injuries is that
207 the associated injuries do not add additional risk for poor outcome or that the impact of these injuries is
208 already accounted for in the decision to proceed to arthroplasty. Nevertheless, this is an important
209 finding as it is critical to tell patients requiring radial head arthroplasty that associated fractures or

210 dislocation may not lead to poorer outcomes in the longer term. Further, the residual disability
211 demonstrated was relatively low reflecting positive outcomes overall. These findings reflect specialty
212 upper extremity care and advances in surgical techniques, fixation strategies and post-operative
213 rehabilitation protocols that have drastically changed the landscape of orthopaedic treatment for these
214 once 'terrible' injuries.

215 Pike et al. (2014) evaluated the relationship of injury pattern following open reduction and internal
216 fixation³³. Similarly they found no difference in outcomes with appropriate management of both simple
217 and complex injury patterns. They did find a trend towards increased capsular stiffness in the more
218 complex fracture patterns, which was mirrored in our study population. Our study population
219 experienced fewer major complications with 3% reported in the simple group and 7% reported in the
220 complex group compared to 13% and 25% with ORIF^{33,37}.

221 Our outcome data appears consistent with the reported literature on radial head arthroplasty<sup>8,12-14,16-
222 18,28,29,30,38</sup>. Final DASH and PREE scores in this study were comparable to those previously
223 published^{8,28}. Patients undergoing radial head replacement for simple or complex injuries do return to
224 acceptable levels of clinical and self-reported function and are generally satisfied with the surgical
225 procedures.

226 Radial head replacement provides good to excellent functional outcomes for both fracture/dislocation
227 and simple injuries to the elbow in both the short and medium-term. Interestingly, patients in this study
228 population reported continued improvement beyond two years of follow-up. This may be true
229 improvement, or an adaption to their minor disability. Range of motion in supination and flexion also
230 improved with longer-term follow-up and may explain the continued improvement in patient-rated
231 outcome scores. Flexion range of motion demonstrated an improvement of more than 6 degrees for
232 both simple and complex injuries beyond 2 years, which likely reflects clinical and statistical
233 improvement². In comparison to similar injuries treated with ORIF the present study demonstrates a
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234 lower rate of capsular release, major complication rates and need for secondary surgery³³. Our sample's
235 PREE scores were higher than reported previously (18 & 19 vs. 5 & 15)³³. This may reflect our study
236 recruitment criteria; as only patients with unreconstructable radial heads were considered for review,
237 which inherently suggests a more significant injury.

238 The radiographic findings help to strengthen our conclusion that outcomes between these two injury
239 groups appear to be similar regardless of initial injury pattern. We found no increase in radiographic
240 differences between simple and complex injuries with the exception of heterotopic ossification(HO).
241 Inherently the presence of additional bony or soft tissue trauma potentiates the incidence of HO and,
242 therefore, explains the increased levels within the complex trauma group. The high incidence of
243 periprosthetic loosening found in the present study (51%) appears to support the findings recently
244 published in the literature^{28,29}. The clinical implications of this are currently unclear and do not appear
245 correlated to patient reported outcomes or initial injury pattern.

246 The strengths of this study are the prospective follow-up of this cohort and the validated clinical
247 outcome measurements. The inclusion of 44 patients with follow-up beyond 4 years helps to strengthen
248 our conclusions regarding the lack of clinical and patient-reported outcome differences between injury
249 patterns. Specific elbow and upper extremity related patient outcome scores were employed to optimize
250 the results specifically for elbow dysfunction. The Patient Rated Elbow Evaluation (PREE) score
251 provides a validated responsiveness and sensitivity to change in patients with elbow pathology³⁹⁻⁴¹.

252 The weaknesses of our study include: a small overall number of patients for whom longer-term follow-
253 up data was available, and the subspecialty care our patients received. Although only 148 patients were
254 included in the present study this represents one of the largest reported single implant radial head
255 populations. The generalizability of our results to non-subspecialty practices may be questioned since
256 the type of injuries and care may differ from an upper extremity specialty practice. One could argue,
257 however, that in a non-sub-specialized setting outcomes from both simple and complex patterns may

both be equally inferior. Although one might expect some areas of practice variation, these were minimized during the current study in that; all surgeries were performed within a single centre, used the same implant and had postoperative care managed by the same group of therapists. However, there were also many elements in this pragmatic cohort that were uncontrolled such as; the variations inherent in each surgeon's surgical technique, rehabilitation protocols across individual surgeons and therapists and the fact that some patients had all of their care within the specialized therapy unit while others from more remote distances would have had parts of their medical and/or rehabilitation care in other settings. Lack of strict standardization is essential given the context and need for patient customization. However, some of these variations may make it more difficult to detect statistical differences.

Our lack of statistical difference may demonstrate a 'ceiling effect' inherent to the prosthesis itself, whereby the nature of the prosthesis limits some aspect of outcome, and therefore no difference between injuries patterns could be detected. An additional limitation with our study is the relatively crude way in which patients were subgrouped into two categories. The criteria for defining these two subgroups may not have captured the critical injury specifics that would separate patients as having low versus high risk of poor outcomes. Radial head injuries with associated bony or ligamentous trauma represent a heterogeneous group including both injury severity and secondary trauma. These factors make data extrapolation and comparison problematic.

Finally, our study populations mean age (53 ± 13 years) was slightly older than previously published epidemiological studies on radial head fractures with a mean age of 48 years^{10,22,35}. This may have altered the patient reported outcomes as older patients may report lesser functional loss when compared to a younger cohort. Our study population, although older, remained within the main working-age demographic. We reported a high rate of return to manual labour occupations in our study population with only three patients unable to return to their previous employment (86% return rate). Additionally,

282 our complex injury pattern group contained a higher proportion of post-menopausal women which
283 theoretically suggests a lower demand population and thereby may artificially inflate the overall
284 outcomes in this group. Although this is a possibility we do not feel that this is a confounder as there
285 was no effect of sex or age on patient reported outcomes, strength or motion.

286 Our data suggests that injury severity does not affect impairment measures and patient reported
287 outcome measures in patients requiring radial head arthroplasty for unreconstructable fractures. There
288 was a trend for a greater need for secondary surgery in the patients with concomitant injuries, primarily
289 for residual stiffness. Patient outcomes continue to improve clinically beyond two years of follow-up,
290 which may reflect continual improvement in physical capabilities or adaption to their minor residual
291 impairment.

292 **Conclusion**

293 Concomitant elbow injuries do not affect the longer term functional and radiographic outcomes of
294 patients with unreconstructable radial head fractures requiring radial head arthroplasty. Patient
295 outcomes continued to improve clinically beyond two years of follow-up, which may be a true
296 improvement or an adaption to their minor disability.

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405

406 **Figure Legends**

407

408 **Figure 1:** Mean patient reported outcome scores and range of motion values (degrees) at early, short
409 and medium term follow-up based on injury pattern group.

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411 **Figure 2:** Mean strength outcomes reported as deficit compared to the uninjured arm based on injury
412 pattern group at early (6months), short (2 years) and medium term follow-up (>4yrs).

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415 **Table 1:** Injury Pattern Group Inclusion Criteria

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417 **Table 2:** Patient Demographics “*” denotes statistical significant values

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419 **Table 3:** Short-Term clinical outcomes comparing simple and complex groups

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Table 1: Injury Pattern Group Inclusion Criteria

Simple Injury Pattern	Complex Injury Pattern
Isolated radial head fracture w/o associated osseous injury (Isolated RHA)	Terrible triad injury (Radial head fracture, history of dislocation and coronoid fracture)
RHA with <u>either</u> lateral (LCL) or medial collateral ligament repair (MCL) without history of dislocation	Trans-olecranon fracture with associated radial head fracture
Radial head fracture with Type I coronoid fracture deemed non-structural and not requiring intra-operative repair	Monteggia Variant fracture dislocations
	Associated fractures about the elbow requiring operative fixation at the time of index surgery

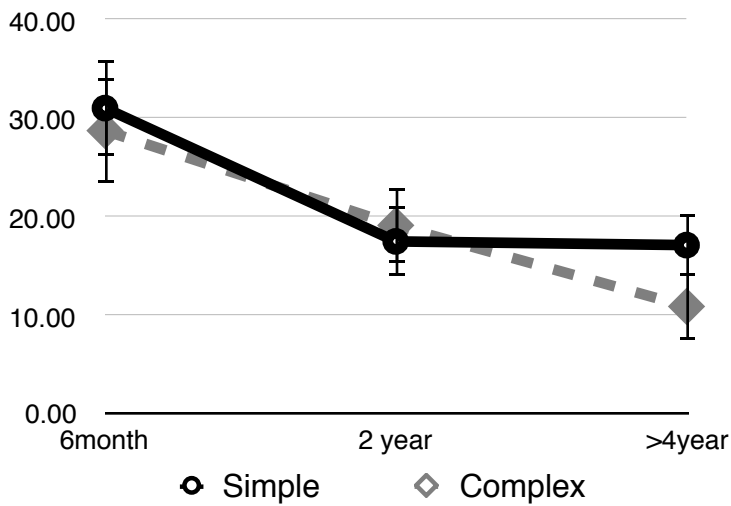
Table 2: Patient Demographics. “*” denotes statistical significant values

	Simple Pattern (67 Total)	Complex Pattern (81 Total)	<i>p</i> value
Age (Years)	55 ± 13std	55 ± 13std	0.97
Male (43 Total)	18	25	0.40
Female (105 Total)	49	56	0.40
Post-Menopausal (If not recorded represents female patients > 50 years old)	22 (45%)	40 (71%)	0.04*
Dominant side injury (n)	31	35	0.71
Medical			
Diabetes	3	3	0.81
Cardiac Disease	4	5	0.96
Osteoarthritis	3	5	0.65
Smoker	7	8	0.88
Occupation			
Occupation Change	4	8	0.39
Workers Compensation Claim	9	6	0.23

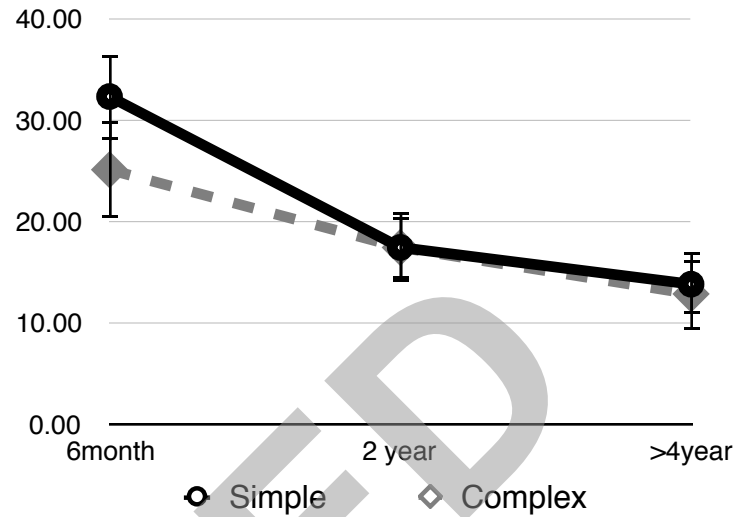
Table 3: Short-Term clinical outcomes comparing simple & associated fracture/dislocation group

	Simple Pattern (67 Total)	Complex Pattern (81 Total)	<i>p</i> value
PREE	18.49 ± 19.71	19.30 ± 20.30	0.83
DASH	15.84 ± 16.04	19.26 ± 19.36	0.34
SF-36 Physical	43.86 ± 10.40	44.82 ± 10.48	0.69
SF-36 Mental	53.29 ± 11.14	53.64 ± 8.37	0.87
ROM (Degree)			
Extension	14° ± 14	15° ± 15	0.60
Flexion	135° ± 15.55	135° ± 12	0.96
Supination	62° ± 18	59° ± 18	0.42
Pronation	75° ± 12	78° ± 14	0.30
STRENGTH			
Grip (N)	28N ± 15	27N ± 12	0.78
Extension Deficit	17% ± 29	9% ± 27	0.20
Flexion Deficit	15% ± 40	13% ± 26	0.81
Supination Deficit	13% ± 42	18% ± 24	0.47
Pronation Deficit	11% ± 44	10% ± 44	0.94

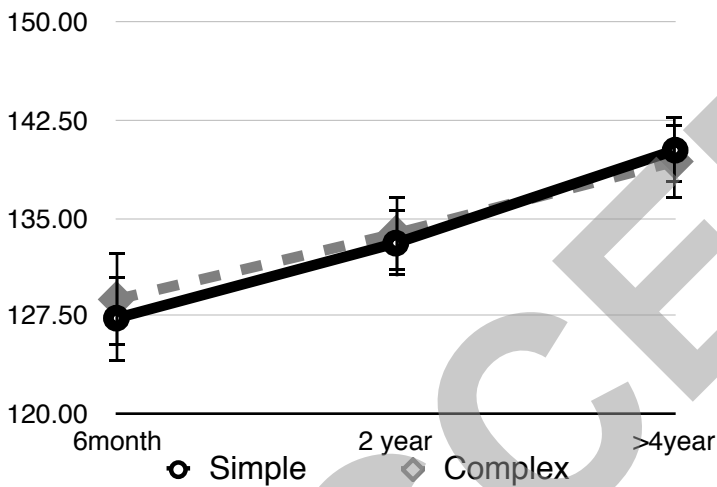
PREE Values



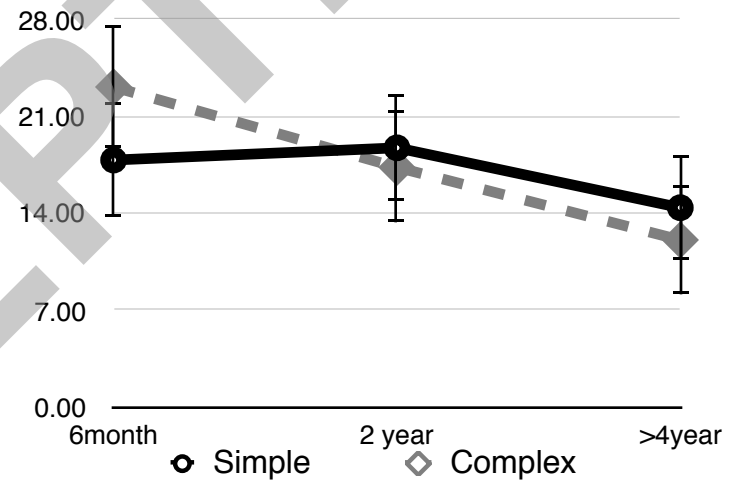
DASH Values



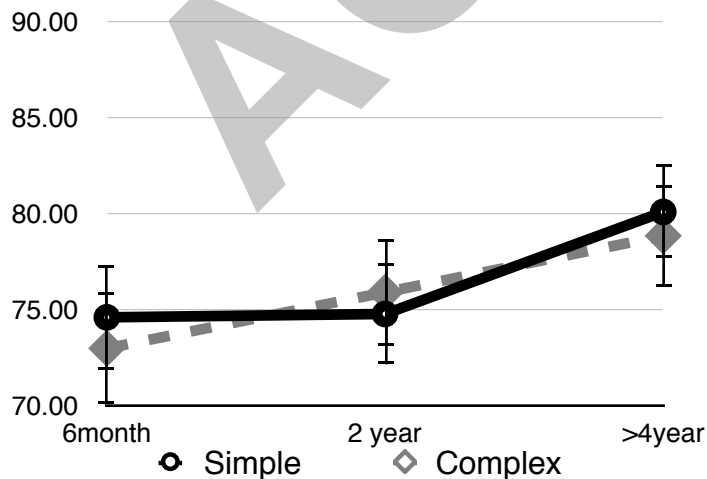
ROM Flexion Values



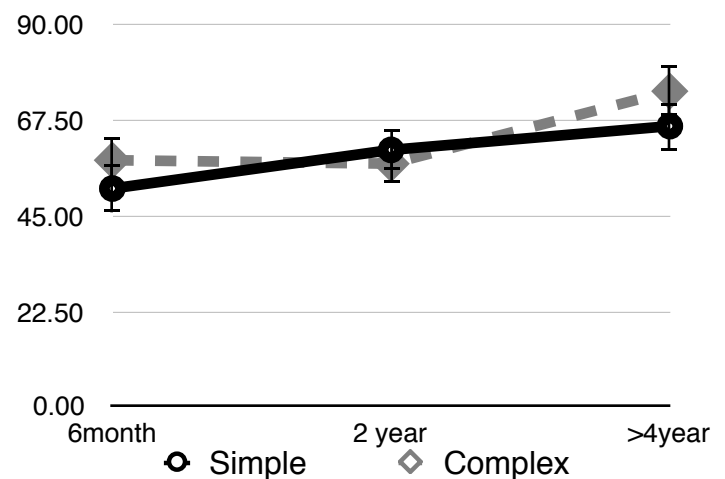
ROM Extension Values



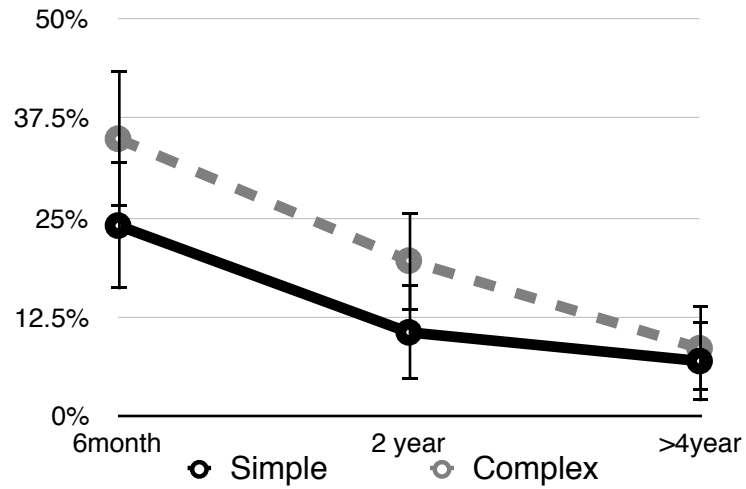
ROM Pronation Values



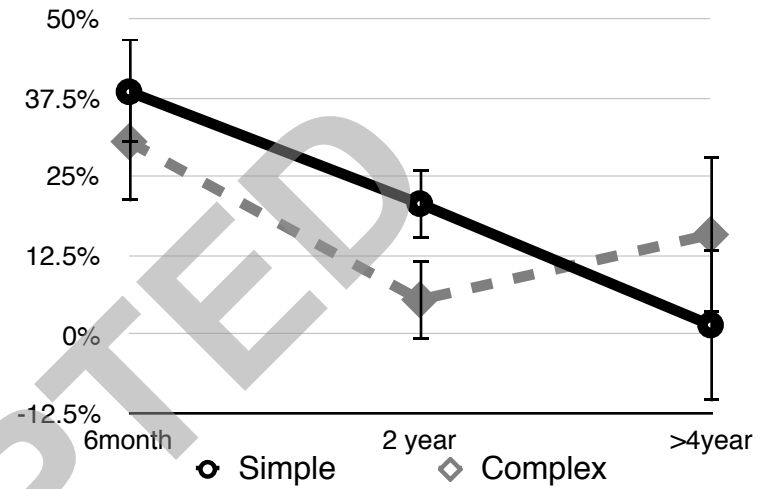
ROM Supination Values



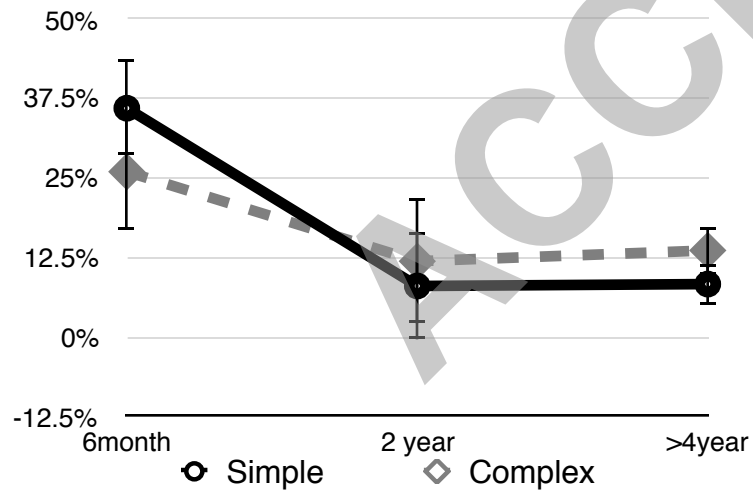
Extension Deficit Values



Supination Deficit Values



Flexion Deficit Values



Pronation Deficit Values

