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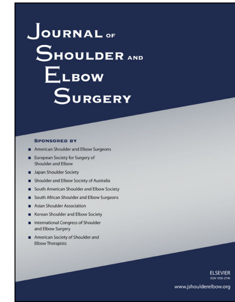

Long-term outcomes of reverse shoulder arthroplasty versus nonoperative treatment for 3- or 4- part proximal humerus fractures in elderly patients: Results from a prior randomized clinical trial

Yaiza Lopiz, MD PhD, Borja Alcobía-Díaz, MD PhD, Jaime Coderch, MD, Sara Rodrigo-Muro, MD, Carlos García-Fernandez, MD PhD, Marta Echevarría-Marín, MD, María Galán-Olleros, MD, Fernando Marco, MD PhD

PII: S1058-2746(24)00849-8

DOI: https://doi.org/10.1016/j.jse.2024.09.032

Reference: YMSE 7115

To appear in: *Journal of Shoulder and Elbow Surgery*

Received Date: 23 June 2024

Revised Date: 3 September 2024

Accepted Date: 23 September 2024

Please cite this article as: Lopiz Y, Alcobía-Díaz B, Coderch J, Rodrigo-Muro S, García-Fernandez C, Echevarría-Marín M, Galán-Olleros M, Marco F, Long-term outcomes of reverse shoulder arthroplasty versus nonoperative treatment for 3- or 4- part proximal humerus fractures in elderly patients: Results from a prior randomized clinical trial, *Journal of Shoulder and Elbow Surgery* (2024), doi: https://doi.org/10.1016/j.jse.2024.09.032.

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Long-term outcomes of reverse shoulder arthroplasty versus nonoperative treatment for 3- or 4- part proximal humerus fractures in elderly patients: Results from a prior randomized clinical trial

Short title: RSA vs non-operative in PHF

Yaiza Lopiz[1,2] MD PhD*, Borja Alcobía-Díaz MD PhD*, Jaime Coderch MD[1], Sara Rodrigo-Muro MD[1], Carlos García-Fernandez[1] MD PhD, Marta Echevarría-Marín[1] MD, María Galán-Olleros MD[3], Fernando Marco[1,2] MD PhD.

* These authors contributed equally to this work.

1- Shoulder and Elbow Unit. Traumatology and Orthopaedic Surgery Department. Clínico San Carlos Hospital. Madrid. Spain.

2- Surgery Department. Complutense University. Madrid. Spain

3- Orthopaedic Surgery and Traumatology Department, Hospital Infantil Universitario Niño Jesús.

Correspondence author: Yaiza Lópiz, MD, PhD, yaizalopiz@gmail.com, +34 609564029. Shoulder and Elbow Unit. Department of Traumatology and Orthopaedic Surgery. Clínico San Carlos. Madrid. Spain. 5º Planta, Ala Sur. Calle Profesor Martín Lagos s/n 28004, Madrid. España.

https://orcid.org/0000-0002-0678-5086

The Ethics Committee for Clinical Research (CEIC) from Clínico San Carlos Hospital (Madrid, Spain) approved the present study (Internal code: 14/099).

Disclaimers:

Funding: No funding was disclosed by the authors.

Conflicts of interest: The authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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1 **Background and Objectives:** Proximal humerus fractures (PHFs) are among the most
2 common fractures in elderly patients, yet there is insufficient evidence from randomized
3 controlled trials (RCTs) to determine the most appropriate interventions for their
4 management. This study presents the long-term results of the first prospective RCT
5 comparing surgical treatment with reverse shoulder arthroplasty (RSA) versus
6 nonoperative treatment in displaced PHFs in elderly patients.

7 **Materials and Methods:** Patients from a previously published RCT of 62 patients, in
8 which RSA was compared with nonoperative treatment, were followed up long term. All
9 patients were aged 80 years or older with 3- or 4-part displaced PHFs. Functional
10 (Constant, DASH, SF-12, and VAS) and radiographic outcomes were assessed.

11 **Results:** From the initial series, 12 patients treated conservatively and 17 with RSA were
12 included, with mean ages of 88 and 92 years (p=.004) and mean follow-up of 7.4 and 7.6
13 years (p=.171), respectively. Functional outcomes for RSA versus conservative treatment
14 were as follows: Constant 62/51 (p=.039), DASH 16/25 (p=.069), SF-12 Physical 42/43
15 (p=.808), SF-12 Mental 59/60 (p=.690), and VAS 1.5/1.4 (p=.274). All nonoperatively
16 treated fractures healed in malposition, but none required revision to RSA. Among
17 patients treated with RSA, one required revision surgery due to prosthesis dislocation.

18 **Conclusions:** These results suggest that long-term treatment with RSA for displaced 3-
19 or 4- part PHF provides better functional outcomes compared to nonoperative treatment.
20 This difference is attributed to the deterioration of functional outcomes of the non-
21 operative treatment over time.

22 **Keywords:** Proximal humerus fracture; reverse shoulder arthroplasty; conservative;
23 elderly; long-term; mid-term.

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24 **Level of evidence:** Level I; Randomized Controlled Trial; Treatment Study

25 Proximal humeral fractures (PHFs) are the third most common fragility fractures in the
26 elderly[9], with their incidence increasing due to ageing populations in many countries[12].
27 The poor bone quality in these patients, typically resulting from osteoporosis, leads to
28 complex fracture patterns that make open reduction–internal fixation (ORIF) impractical.
29 Despite technical advancements, ORIF is still associated with high complication and
30 reoperation rates[6,1,15,16]. Additionally, hemiarthroplasty often results in variable and
31 unpredictable functional outcomes[8,14]. Consequently, therapeutic options for elderly
32 patients are largely limited to nonoperative treatment or reverse shoulder arthroplasty
33 (RSA).

34 However, there is no clear consensus or guidelines on the optimal treatment. This
35 ambiguity arises from several issues with study designs, such as selection bias, unreliable
36 fracture classification, interobserver differences in assessing the Constant score, and a
37 lack of patient stratification by age or treatment. According to the latest Cochrane
38 Database Systematic Review[5], ten trials involving 717 participants examined whether
39 surgery for adults with displaced PHFs provided better outcomes than non-surgical
40 treatment. The review concluded that there is strong evidence of no significant differences
41 between surgical and non-surgical treatment in patient-reported shoulder function and
42 quality of life at one and two years.

43 Only two prospective randomized controlled trials (RCTs) have directly compared RSA
44 with nonoperative treatment for 3- or 4-part PHFs in elderly patients[10,11]. These studies,
45 however, only include short-term follow-up (one year). Although both studies conclude
46 that RSA provides a narrow benefit over nonoperative treatment for displaced PHFs in

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47 the short term, the use of RSA for treating PHFs is steadily increasing, especially in
48 elderly patients.

49 The purpose of this study was to analyze the long-term outcomes, quality of life and
50 complication rates from our previously published prospective RCT comparing RSA and
51 nonoperative treatment of comminuted PHFs in elderly patients[10].

52

53 **MATERIALS AND METHODS**

54 *Study design*

55 A retrospective review of a previously published RCT comparing RSA and nonoperative
56 treatment of 3- or 4- part displaced PHFs in elderly patients was conducted[10] (Fig. 1).
57 This RCT included 62 patients treated between 2014 and 2018. Inclusion criteria were
58 patients aged 80 years or older with a 3- or 4-part displaced PHF, available for follow-up
59 for at least 12 months, and able to understand the informed consent process. Exclusion
60 criteria included mental disorders (such as cognitive impairment measured using the
61 Mini-Mental State Examination), open fracture, pathologic fracture, fracture-dislocation
62 or head-splitting fracture (according to Neer), neurologic disorder, associated ipsilateral
63 or contralateral upper- or lower-limb fracture, prior surgery on the shoulder, or associated
64 comorbidity contraindicating surgery, and a lack of autonomy prior to the fracture
65 (determined using the Katz index). Formal follow-up for the RCT concluded at a
66 minimum follow-up period of 12 months postoperatively. Research ethics board approval
67 was obtained for both the initial RCT and the current study investigating long-term
68 outcomes.

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69 For the present study, patients were contacted via telephone and invited for a long-term
70 functional and radiographic evaluation. Of the original 62 patients, 30 were randomized
71 to RSA and 32 to nonoperative treatment. Of the 30 RSA, 13 were lost to follow-up (2
72 withdrew consent and 11 had died), resulting in a final sample of 17 patients. Of the 32
73 nonoperative treatment patients, 20 were lost to follow-up (1 withdrew consent, 1 was not
74 locatable, and 18 had died), resulting in a final analyzed sample of 12 patients. The mean
75 follow-up duration was 7.59 years (range 6-12) for RSA and 7.58 years (range 7-9) for
76 nonoperative treatment. The flowchart of the study is summarized in figure 2.

77

78 *Clinical and radiologic evaluation*

79 Functional and radiographic evaluation were performed by two independent examiners
80 (SR, JC), not involved in patient management. Functional evaluation was conducted using
81 the Constant score, the Disabilities of the Arm, Shoulder and Hand questionnaire
82 (DASH), the Short Form 12 (SF-12) and the visual analog scale (VAS). Health-related
83 quality of life (HRQoL) was measured with the EuroQol 5 Dimensions (EQ-5D) and the
84 EQ-VAS. The Charlson Comorbidity Index (CCI) was used to compare the medical status
85 of both groups of patients in terms of comorbidities. Radiographs were analyzed for the
86 presence or absence of baseplate or stem loosening and scapular notching. For the
87 nonoperative treatment, nonunion, malunion, avascular necrosis, and osteoarthrosis were
88 assessed.

89 Statistical analysis was performed using IBM SPSS software (version 22; IBM, Armonk,
90 NY, USA). For comparisons between groups, the Student t-test was used for parametric
91 continuous data, the Mann-Whitney U test for nonparametric continuous data, and the

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92 chi-square test for categorical data. For comparisons between preoperative and
93 postoperative data within a group, the paired t-test was used for normally distributed
94 parametric data, and the Wilcoxon signed-rank test was used if the data did not meet the
95 normality assumption. The significance level was set at $p < .05$.

96

97 **RESULTS**

98 *Epidemiologic Results*

99 Of the originally randomized 62 patients, the final long-term sample consisted of 29
100 patients (17 RSA vs 12 nonoperative). In the RSA, 82.2% were women (15 of 17), and in
101 the nonoperative treatment group, 100% were women. The mean ages were 88 and 92
102 years, respectively. Patient demographic characteristics are outlined in Table I.

103 All patients treated conservatively had fractures that united in malposition, but none
104 required revision surgery to RSA. Among patients treated with RSA, one patient
105 underwent revision surgery due to prosthetic dislocation.

106 *Functional and HRQoL Results.*

107 The main functional results are provided in Table I. The Constant score was 62.5 ± 16 in
108 the RSA group versus 50.7 ± 18 in the nonoperative group ($p = .039$). When the four
109 variables of the Constant score were analyzed at the final follow-up, the main difference
110 between the two groups was in range of motion (ROM), with a mean score of 27.8 points
111 in the RSA group versus 19.3 in the nonoperative group ($p = .059$). The Constant scores
112 for each item of the scale (nonoperative vs. RSA) are summarized in figure 3.

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113 The DASH score and VAS in the RSA/nonoperative groups were 16 ± 13 / 25 ± 20 (p =
114 .069) and 1.5 ± 2 / 2 ± 2.7 (p = .274), respectively. The scores for the two dimensions of
115 the SF-12, physical and mental, were 42 ± 12.4 / 43 ± 12 (p= .808) and 59.4 ± 6 / 60 ±
116 6.1 (p = .690), respectively.

117 There were no statistically significant differences between the RSA and nonoperative
118 groups in the EQ-5D score (0.83 vs. 0.89, p = .319) or EQ-VAS score (68.4 vs. 63.3, p =
119 .104). When comparing each dimension of the EQ-5D (mobility, self-care, usual activity,
120 pain/discomfort, and anxiety) between the treatment groups, no statistically significant
121 differences were found (p > .05). The percentage of reported problems in each item of the
122 EQ-5 D is summarized in figure 4.

123

124 *Radiographic results*

125 Regarding radiological results, osteonecrosis/osteoarthritis was present in all patients in
126 the nonoperative group. In the RSA group, tuberosities healed in an anatomical position
127 in 10 patients, while the remainder showed consolidation in non-anatomical position or
128 resorption of the tuberosities. One case in the RSA group presented with prosthetic
129 dislocation requiring revision surgery.

130

131 **DISCUSSION**

132 The present study significantly contributes to the literature by providing robust long-term
133 data on the functional outcomes of RSA versus nonoperative treatment in an elderly

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134 cohort, addressing a notable gap in the current evidence base. Our findings demonstrate
135 that RSA provides superior long-term functional outcomes compared to nonoperative
136 treatment in elderly patients with displaced 3- or 4-part PHF.

137 Initially, our research group conducted the first prospective RCT comparing RSA and
138 nonoperative treatment over a short-term follow-up period[10]. The 12-month follow-up
139 results suggested no short-term benefits of RSA over nonoperative treatment for
140 displaced PHF. However, the long-term follow-up presents a different picture. Over the
141 long-term, the RSA group exhibited a significantly higher mean Constant score than the
142 nonoperative group (62.5 vs 50.7; p = .039), indicating a clinically relevant difference[3].
143 Differences were found in the four variables of the Constant scale, especially in ROM,
144 highlighting the effectiveness of the surgical procedure in restoring shoulder mechanics.
145 Over time, the differences between both treatments become more pronounced, with RSA
146 showing stability or slightly improvement in functional outcomes, while the nonoperative
147 group experienced a decline.

148 Regarding complications, RSA as a first-line treatment in elderly proved to be a safe
149 surgical procedure with relatively low rates of complications and reoperations. Among
150 the initial sample of 30 patients with RSA, only one patient (3.3%) experienced a
151 prosthetic dislocation requiring revision surgery. In terms of HRQoL, measured by the
152 SF-12 and EQ-5D, no significant differences were observed between groups. This reflects
153 that patient-perceived health status and satisfaction with life are comparable in the long
154 term, regardless of whether they received RSA or nonoperative care. This similarity in
155 HRQoL could be attributed to the adaptability of elderly patients to their functional
156 limitation over time.

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157 Few studies have analyzed the outcomes of nonoperative versus surgical treatment,
158 typically focusing on short-term follow-ups of 12-24 months, arguing that both
159 nonoperative and surgical treatments reach their maximum functional capacity within a
160 year[13]. Zyto et al[17] were the first to suggest that non-surgical treatment should be
161 considered for displaced 3- or 4-part PHF, although not comparing with surgical
162 treatment, reporting a 10-year follow-up with a ROM below 90º for flexion and
163 abduction, and Constant scores of 59 and 47 for 3 and 4-part PHF respectively, which are
164 similar to our study's nonoperative score of 51. In another retrospective study, Roberson
165 et al[13] compared 19 nonoperative patients and 20 RSA, with mean follow-up periods of
166 29 and 53 months, respectively, and a mean age of 71 years for both groups, which is
167 12.5 years younger than our cohort. They concluded that RSA offers no benefits over
168 nonoperative treatment for 3- and 4-part PHFs in older adults regarding ROM and patient-
169 reported outcomes. However, the study had significant selection bias, as all patients were
170 initially offered RSA, and only those who refused it were included in the conservative
171 treatment group. Additionally, they did not account for the possible subsequent
172 deterioration in both types of treatment, which our study demonstrates is significantly
173 greater in patients treated nonoperatively.

174 Gallinet et al[4] conducted a retrospective multicenter study with 422 RSA following PHF
175 and 119 patients re-evaluated after more than five years, finding that the outcomes
176 achieved within the first postoperative year were sustained over time. Similarly, Chivot
177 et al[2] published a multicenter retrospective comparative study between RSA and
178 nonoperative treatment in patients older than 70 years, with a mean follow-up of
179 approximately 32 months, concluding that RSA offers significant benefit in functional
180 outcomes for elderly patients with a displaced 3- or 4-part PHF, with relatively low
181 complications rates (7%) and a reoperation rate similar to our study (3%). These authors

182 also noted that, regardless of treatment type, these fractures resulted in functional
183 impairment and decreased autonomy. In our study, RSA patients reported fewer issues
184 with self-care and daily activities compared to the nonoperative patients, though, as
185 reported by Chivot et al there was no significant difference in quality-of-life scores.

186 Further supporting these findings, Haws et al[7] concluded that in an age, comorbidity, and
187 fracture morphology-matched cohort, RSA led to greater gains in ROM, improved
188 physical function, and decreased pain over the first-year post-treatment compared to
189 nonoperative treatment, without a significant difference in complications. They also
190 found that RSA patients were much more likely to achieve satisfactory functional motion
191 and did so more rapidly than non-operative patients. However, their study included a high
192 percentage (57.8%) of 3- and 2-part fractures and only 42.2% of 4-part fractures, reported
193 only early outcomes (within one year), and involved a significantly younger cohort (9
194 years younger in the RSA group and 8 years younger in the non-operative group)
195 compared to our first RCT[10]. Recently, Miquel J et al[11] conducted a multicenter
196 prospective RCT with 66 patients over 70 years old with acute PHF (3 or 4 parts),
197 randomly assigning them to the RSA with tuberosities reattachment or nonoperative
198 treatment. This study found that RSA patients had better short-term Constant scores than
199 non-operative patients. However, the authors advised caution in interpreting these results,
200 as the positive effect of RSA did not reach the minimally clinically relevant difference
201 and had a complication rate of 6.5%.

202 In brief, there seems to be consistent findings that the RSA provides a narrow benefit for
203 the treatment of displaced PHFs over the nonoperative treatment in the short-term follow-
204 up. However, this benefit becomes more pronounced in the long-term follow-up due to
205 the progressive deterioration of function in the nonoperative group.

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206 The present study has several limitations. The retrospective nature and the relatively small
207 sample size, due to loss to follow-up and mortality, may affect the generalizability of the
208 findings, limiting the statistical power of our observations. We acknowledge that this long
209 follow-up inevitably led to many dropouts, considering that the patients initially included
210 were all above 80 years old. However, a major strength of this study is the initial
211 randomization of the patient population, which minimizes selection bias. Furthermore, all
212 surgeries were performed by a consistent team of senior shoulder surgeons, ensuring
213 procedural uniformity.

214

215 **Conclusion**

216 Although reverse shoulder arthroplasty (RSA) does not seem to provide better short-term
217 outcomes than non-operative treatment, this study reinforces the notion that RSA offers
218 superior long-term functional outcomes for elderly patients with displaced proximal
219 humeral fractures (PHFs). These differences are primarily due to the deterioration in the
220 functional outcomes of patients treated non-operatively over time. Therefore, surgical
221 indications must consider the patient's life expectancy and the adaptability of elderly
222 patients to functional limitations.

223

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293 **Figure and Table legends**

294 **Figure 1.** (a,b) Radiographic outcome of non-operative treatment of a 4- part PHF after
295 6.4 and 7.3 years of follow-up. (c,d) Radiographic outcomes in surgical treatment with
296 RSA after 4-part PHF showing migration of the tuberosities (c) and anatomic tuberosity
297 healing (d)

298 **Figure 2.** Flowchart of the study. *RCT, randomized control trial.

299 **Figure 3.** Scores for the four variables of the Constant score in the nonoperative group
300 and reverse shoulder arthroplasty (RSA) group. *ADL, activities of daily living.

301 **Figure 4.** Percentage of reported problems in each item of the EQ5D in the RSA and
302 nonoperative groups.

303 **Table 1.** Patient characteristics and outcomes

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Table 1. Patient characteristics and outcomes			
Patients	**RSA (n = 17)**	**Nonoperative (n = 12)**	***P value***
Age, yr*	88 (2.6)	92 (4.1)	.004
Female/male, n (%)	15/2 (82.2%)	12/0 (100%)	.262
CCI*	6.5 ± 1.3	6.3 ± 1.1	.163
Dominant/non dominant	10/7	8/4	.319
Mean follow-up, yr	7.5	7.7	.171
Secondary surgery	1(5.8)	0 (0%)	
Outcomes	**RSA (n = 17)**	**Nonoperative (n = 12)**	***P value***
Constant score*	62.5 ± 16	50.7 ± 18	.039
Pain	14.3	11.1	.493
ADL	18.6	16.2	.332
ROM	27.8	19.3	.059
Strength	4.97	3.14	.143
DASH score*	16 ± 13	25 ± 20	.069
VAS pain score*	1.5 ± 2	2 ± 2.7	.274
SF12 score Physical *	42 ± 12.4	43 ± 12	.808
SF12 score Mental *	59.4 ± 6	60 ± 6.1	.690
EQ-5D score	0.83	0.89	.319
EQ VAS score	68.4	63.3	.104

*RSA, Reverse shoulder arthroplasty; ADL, Activities of daily living; ROM, Range of motion. * Mean ± SD*

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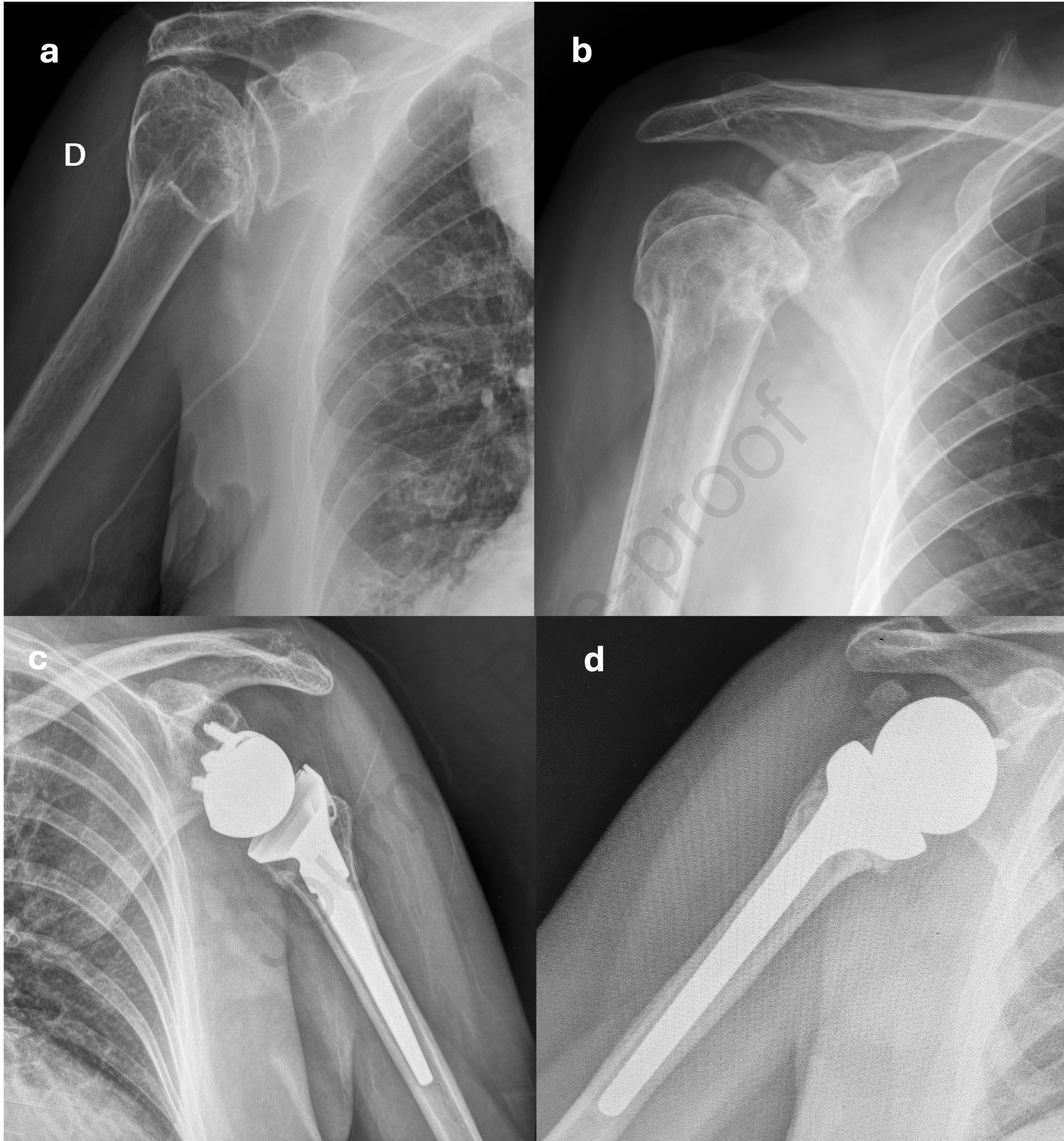
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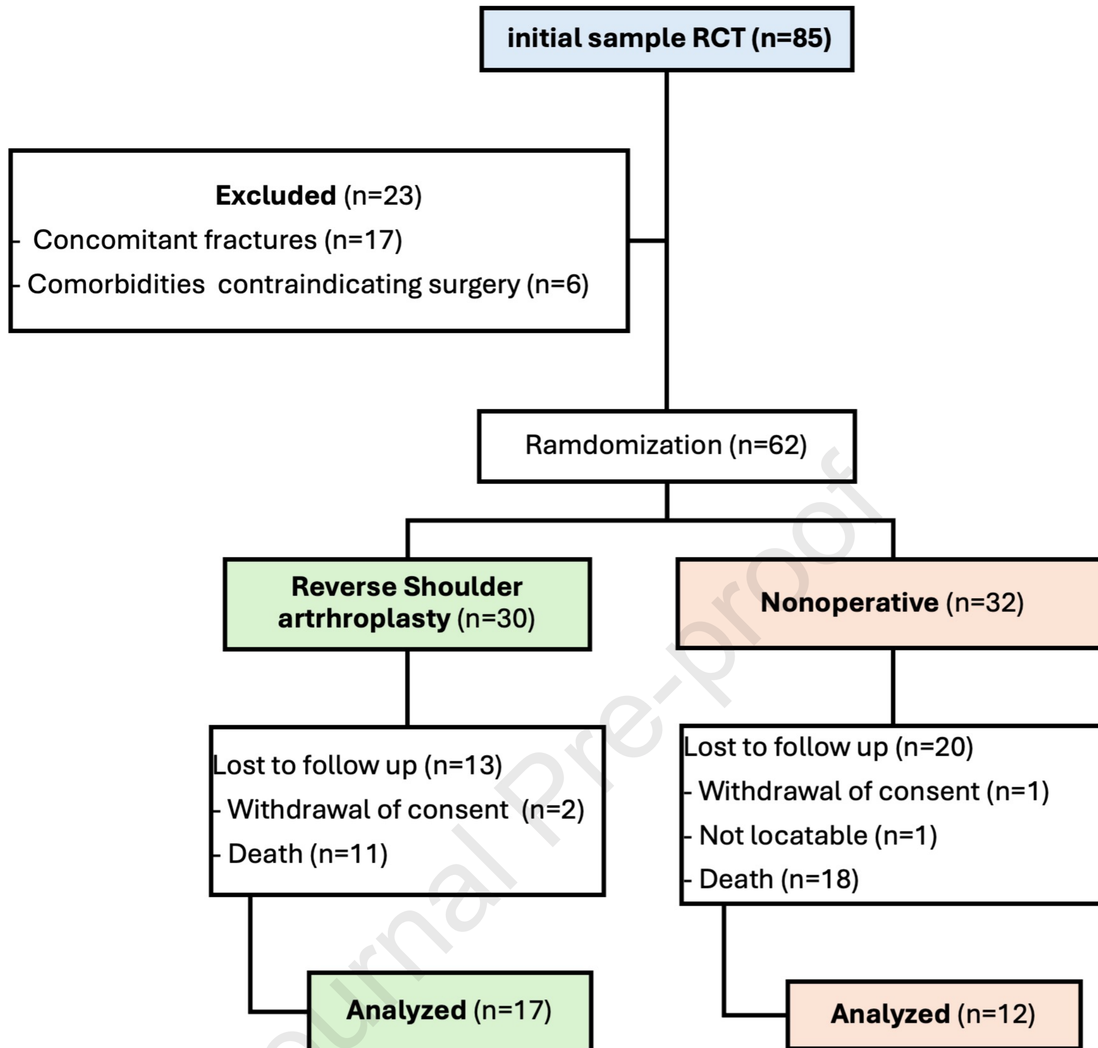

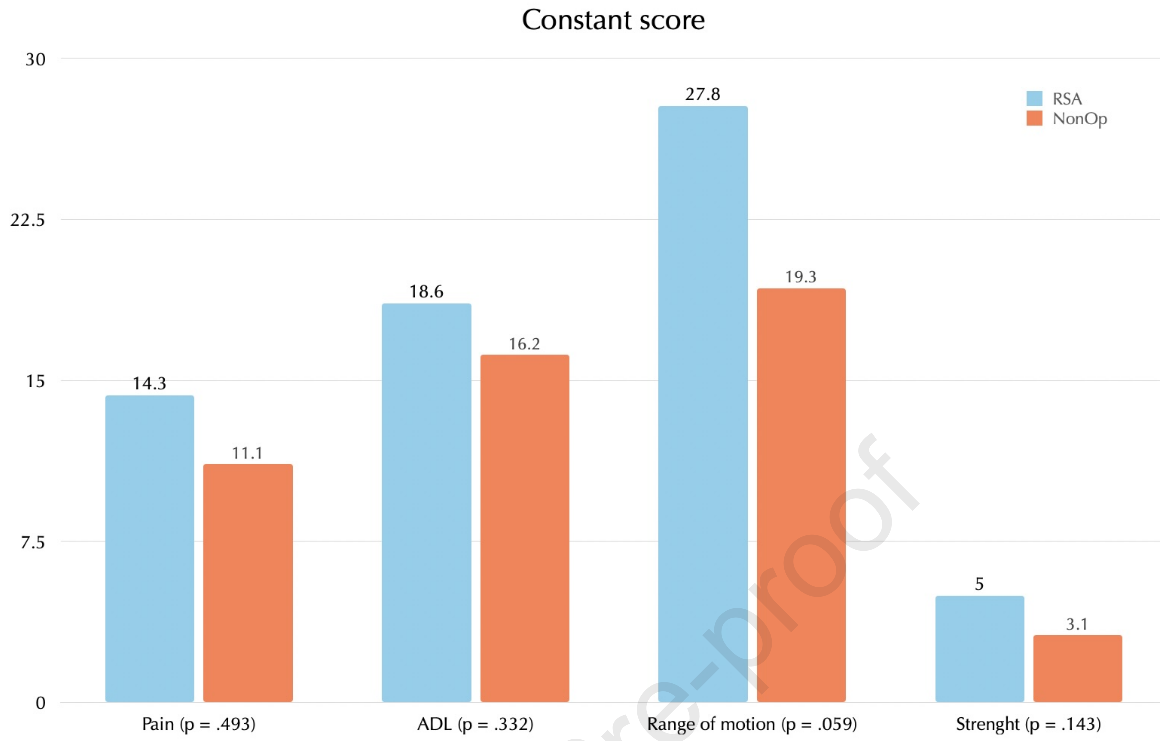

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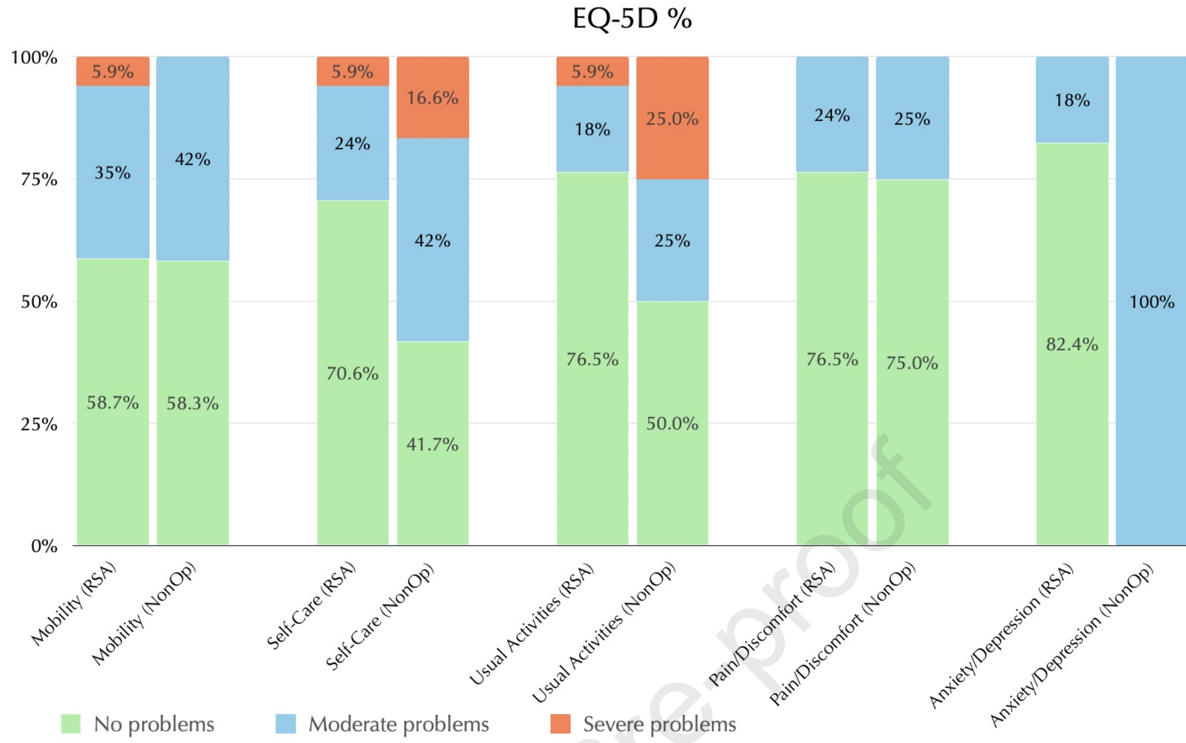

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