Hand lesion after arthroscopic rotator cuff repair: Association with complex regional
 pain syndrome

3

4 Abstract

Background: It is known that complex regional pain syndrome (CRPS) occurs after $\mathbf{5}$ arthroscopic rotator cuff repair (ARCR); however, few studies have investigated this 6 complication. Therefore, the purpose of the present study was to evaluate CRPS after ARCR. $\overline{7}$ Methods: A total of 182 patients who underwent ARCR were enrolled in this study. The 8 average age of patients was 62.8±10.0 years, with an average follow-up period of 21.5±38.1 9 months. CRPS criteria outlined by the Ministry of Health, Labor, and Welfare study team for 10 11 CRPS in Japan (MHLWJ) and International Association for the Study of Pain (IASP 2005) 12were utilized for diagnosis. There are two rating systems for the "clinical purpose" and "research purpose" in both criteria, respectively. Clinical outcomes, including Japanese 13Orthopaedic Association (JOA) and University of California, Los Angeles scores, were 14evaluated using univariate and multivariate analysis. 15

Results: CRPS exclusively occurred in the hand of the operated limb, developing within 3 months of surgery. Two or more of the following symptoms were noted in patients with the hand lesion associated with CRPS: edema (93.4%), restricted range of motion (83.4%), hyperalgesia (30.1%), paridrosis (20.4%), and atrophic change (12.2%). Under these

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20	conditions, the incidences of CRPS were 24.2% (44/182) when evaluated by the MHLWJ
21	rating system for the "clinical purpose;" 11% (22/182) by the MHLWJ rating system for the
22	"research purpose;" 6% (11/182) by the IASP 2005 for the "clinical purpose;" and 0.5%
23	(1/182) by the IASP 2005 for the "research purpose." Results of multivariate analysis
24	demonstrated that "Function" in the JOA score was a risk factor for the development of
25	CRPS after ARCR, when evaluated by a system for the "clinical purpose" of the MHLWJ.
26	Conclusion: Following ARCR, CRPS-induced hand lesions occur more frequently than is
27	generally believed, thereby suggesting that its impact on surgical outcomes should be
28	clarified in the future.

29

30 Introduction

Rotator cuff tears often occur in middle-aged and elderly individuals. Recently, 3132arthroscopic rotator cuff repair (ARCR) is regarded as the gold standard treatment [1,2]. In previous studies, there were no differences in outcomes between the arthroscopic and 33mini-open rotator cuff repair techniques [3,4]; however, fewer complications were reported 34after ARCR than after open repair [5]. Vascular and neurologic injury, fluid extravasation, 35stiffness, and iatrogenic tendon injury may occur following surgery [6,7]. 36 Complex regional pain syndrome (CRPS) may occur after ARCR [8,9], which is 37induced by various etiologic factors, including minor traumas, fractures, sprains, 38 immobilization, and surgical interventions. CRPS induces atrophic change, range of motion 39(ROM) limitations, hyperalgesia, paridrosis, and edemas of the involved limb [10]. The 40incidence of CRPS after ARCR is reported to be 11.0-21.7% in Japanese literature [11-14]; 41however, little attention has been paid to this complication in studies in English literature. 42It is also well known that CRPS occurs after ARCR; however, few studies have 43investigated this complication. Therefore, the present study aimed to evaluate CRPS after 44ARCR. 4546

47 Methods

48 This retrospective study was approved by the institutional review board of the author's

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49 institution. Written consent was obtained from the patients of the study.

50 Patients

Between January 2009 and June 2014, 210 patients underwent ARCR for a rotator cuff 51tear at our institution. Inclusion criteria were as follows: (1) individuals who had arthroscopic 52rotator cuff repair, (2) individuals followed up with for at least 6 months, and (3) individuals 5354who underwent imaging and physical examination before surgery. Exclusion criteria were as follows: (1) individuals who underwent open repair, (2) individuals who had fractures and 55degenerative arthritis, and (3) individuals who had undergone bilateral surgery. Consequently, 56a total of 182 patients with rotator cuff tears were candidates for the present study. 57Surgical technique 58Arthroscopic surgery was considered for patients who did not respond to nonoperative 59treatment for 3 months or more, which included the administration of anti-inflammatory 60 medication, physical therapy, and subacromial/glenohumeral injections of corticosteroids or 61hyaluronic acid. 62All procedures were performed in a beach-chair position under general anesthesia. First, 63 64glenohumeral inspection was done through a posterior portal and then transferred to the subacromial bursa. Following the creation of a lateral portal, the detached tendon edge was 65identified, and its mobility was evaluated by grasping the edge of the tendon and reducing the 66tendon to the footprint. Using the anterior, anterolateral, or posterolateral portal, capsular 67

release, tenotomy/tenodesis of the long head of the biceps tendon and distal clavicle excision were performed as required. Acromioplasty was performed in all patients. Cuff repairs were accomplished using a single-row, double-row, or suture bridge technique depending on the tendon mobility and tear configuration.

72 Postoperative regimen

Postoperatively, patients were immobilized in a sling for 6 weeks, with an abduction pillow, and they were given instructions to maintain the shoulder at 30-40° of internal rotation and 20° of abduction. Elbow, wrist, and finger ROM exercises were initiated immediately after surgery. Passive forward elevation of the shoulder commenced the day after surgery. At 4 weeks post-surgery, active-assisted motion of the shoulder was initiated, and at 6 weeks, active motion was permitted. At 8 weeks, isometric muscle-strengthening exercises were introduced, and at 12 weeks, isotonic muscle strengthening was initiated.

80 Diagnosis of CRPS

The present study utilized the criteria suggested by the Ministry of Health, Labor, and Welfare CRPS study team in Japan (MHLWJ). A diagnosis of CRPS was determined when at least two or more corresponding items were fulfilled both subjectively and objectively in the rating system for the "clinical purpose," or when at least three or more items in the system for the "research purpose" were fulfilled. Details of the MHLWJ criteria are shown in Table 1 [15].

87	Diagnostic criteria outlined by the International Association for the Study of Pain in
88	2005 (IASP 2005) were also used for diagnosis. A diagnosis of CRPS was determined when
89	the three or more corresponding items were fulfilled subjectively and two or more items
90	objectively in the rating system for "clinical purpose," or when the four items were fulfilled
91	subjectively and two or more items objectively in the system for the "research purpose."
92	IASP 2005 criteria are shown in Table 2 [16,17].
93	A well-trained orthopedist blinded to the study diagnosed CRPS using these criteria.
94	Once diagnosed, Neurotropin [®] (Nippon Zoki Pharmaceutical Co., Osaka, Japan) was
95	administered orally. Tramadol or pregabalin, or both drugs were added if needed. A whirlpool
96	bath and stellate ganglion block using a laser beam were routinely applied. The patients in
97	whom the symptoms persistently continued were referred to an anesthesiologist who
98	specializes in nerve block.
99	Outcome measures

Patient information, including age, sex, and follow-up duration, were collected prior to surgery. Preoperative pain levels were assessed using the visual analog scale (VAS at rest/night and during motion). ROM was assessed using a goniometer, and muscle strength was measured using a hand-held dynamometer (Micro FET2; Hoggan Health Industry, Salt Lake City, UT, USA). The presence of contracture was determined when the manipulation or arthroscopic capsular release was performed during surgery. Clinical outcomes were assessed by the Japanese Orthopaedic Association (JOA) and University of California, Los Angeles
(UCLA) scores. Fatty degeneration of the rotator cuff muscles was evaluated by magnetic
resonance images taken before surgery, using the Goutallier classification [18]. The operating
time and circulating fluid used were estimated during surgery.

110 Statistical analysis

111 All statistical analysis was performed using JMP11 software (SAS Institute Inc., Cary, NC, USA). The level of significance was defined as P < .05 for all calculations. To analyze 112the risk factors of CRPS, univariate analysis was performed using chi-square or Fisher tests. 113Logistic multivariate analysis was performed to further evaluate the significant parameters 114obtained from univariate analysis. The presence of CRPS assessed by the MHLWJ "clinical 115116purpose" were set as the dependent variable, and the variables that were significantly different in univariate analysis (P < 0.05) were set as independent variables. However, 117variables associated with the high variable of the correlation coefficient were selected to 118 establish the last model of the multivariate analysis. 119

120

121 **Results**

Of 182 patients enrolled in the present study, CRPS exclusively occurred in the hand of the operated limb, developing within 3 months of surgery. The following two or more symptoms were noted in patients with the hand lesion associated with CRPS: edema (93.4%; Fig. 1a and 1b), restriction of ROM (83.4%), hyperalgesia (30.1%), paridrosis (20.4%), and atrophic change (12.2%; Fig. 2a and 2b). Under these conditions, the incidences of CRPS were 24.2% (44/182) when evaluated by the MHLWJ rating system for the "clinical purpose;" 11% (22/182) by the MHLWJ rating system for the "research purpose;" 6% (11/182) by the IASP 2005 for the "clinical purpose;" and 0.5% (1/182) by the IASP 2005 for the "research purpose."

Subsequently, we investigated risk factors for CRPS following ARCR, based on the data obtained by the rating system for the MHLWJ "clinical purpose." Using chi-square and Fisher exact tests, results of univariate analysis demonstrated that the following variables were potential risk factors: the tear size (P = 0.023), active and passive internal rotation (P = 0.012 and P = 0.011, respectively), "pain" in the JOA score (P = 0.007), "function" in the JOA score (P = 0.029), total JOA score (P = 0.005), and "pain" in the UCLA score (P = 0.009). Details are shown in Table 3 and Table 4.

Multivariate analysis was conducted following univariate analysis from a significantly different variable. Since correlation was high in active internal rotation and passive internal rotation (correlation coefficient: 0.963), "pain" in the JOA score, "pain" in the UCLA score (correlation coefficient: 0.936), and the total JOA score had a high correlation with active internal rotation (correlation coefficient: 0.510), "pain" in the JOA score (correlation coefficient: 0.692), and "function" in the JOA score (correlation coefficient: 0.562). We

144	removed passive internal rotation and "pain" in the UCLA score and total JOA score from the
145	last model. The last model of the multivariable analysis was comprised of the tear size, active
146	internal rotation, "pain" in the JOA score, "function" in the JOA score, and disease duration.
147	Results of multivariate analysis demonstrated that the "function" in the JOA score (odds
148	ratio: 1.15 with 95% confidence interval: 1.01-1.31) was a risk factor for the development of
149	CRPS following surgery (P < 0.05). Details are presented in Table 5. "Function" in the JOA
150	score reflects abduction strength.

151

152 **Discussion**

Specific complications associated with ARCR include failed repair, hardware problems, captured shoulder, traction in the lateral position, direct injury, compression secondary to fluid extravasation, and tourniquet-like problems associated with wrapping of the operative extremity [7]. CRPS also occurs after ARCR, although there have been few studies published in the English literature concerning this complication; its incidence is reported to be 0.4% (1/263 patients) and 1.9% (1/53 patients) [8,9]. Unfortunately, these studies did not detail how the diagnosis was determined.

160 Several studies in the Japanese literature have reported the incidence of CRPS following 161 ARCR: 21.7% (13 of 60 cases) in the rating system for the "clinical purpose" and 13.3% 162 (8/60) by the system for the "research purpose" according to the MHLWJ criteria [12], and

163	14.8% (5/37 cases) and 11.7% (22/187 cases) according to the modified MHLWJ criteria
164	[13,14]. These studies consistently demonstrated that CRPS-associated lesions occurred in
165	the hand of the operated limb within 3 months of surgery, as observed in the present study, in
166	which a similar incidence was observed (11-24.2%). However, the incidence rate decreased
167	to 6% (11/182 patients) when evaluated by the rating system for the "clinical purpose"
168	according to IASP 2005 criteria; this further reduced to 0.5% (1/182 patients) by the system
169	for the "research purpose" in this criteria. Therefore, these results indicate that the incidence
170	of CRPS is largely influenced by the criteria employed.
171	In 1994, the International Association for the Study of Pain (IASP) introduced the term

"CRPS" and advocated the criteria for its diagnosis [19-21]. Since the IASP criteria from 1721731994 lacked specificity (0.36) and were very sensitive (0.98) [22], IASP criteria were 174re-established in 2005 [16]. In 2010, the Ministry of Health, Labor, and Welfare study team in Japan developed CRPS criteria that are more specific (specificity 0.79; sensitivity 0.83) and 175appropriate for the Japanese population [15], i.e., the IASP 2005 criteria. As demonstrated, 176the incidence of CRPS after ARCR varied between these two criteria. Compared with the 177IASP 2005 criteria, the MHLWJ criteria were developed on a relatively loose basis, aiming to 178capture the patients with CRPS in the wider range and initiate therapy as early as possible to 179ensure the success of the treatment. In addition, a rating system for the clinical purpose, 180rather than the research purpose, was used in the MHLWJ criteria, since we focused on 181

182	evaluating the incidence of CRPS after ARCR, rather than on the research for CRPS itself.
183	Consequently, it was demonstrated that the hand lesion associated with CRPS occurs after
184	ARCR (incidence rate: 24.2%), and it is predominantly accompanied by edema and ROM
185	restriction at the site.
186	It was notable that although not in multivariate analysis, the tear size was significantly
187	associated with the development of CRPS in univariate analysis. Hirooka et al. reported that
188	the preoperative pain level in patients with small or medium tears is greater than in those with
189	large or massive tears [23]. Moriishi et al. demonstrated that the postoperative pain level in
190	patients with small or medium tears is greater than in those with large or massive tears [24].
191	Considering that in univariate analysis, "pain" in the JOA or UCLA score was also associated
192	with the development of CRPS, we thought there would be an association between the tear
193	size and pain level in the development of this sequelae after surgery.
194	There are three spread patterns of symptoms in CRPS due to the aberrant regulation of
195	the central nervous system (CNS), including contiguous spread, independent spread and
196	mirror-image spread [25]. A previous study utilized functional magnetic resonance imaging
197	(fMRI) and revealed that aberrant CNS regulation is closely associated with the development
198	of CRPS [26]. Furthermore, a recent study used fMRI to demonstrate that pain in patients
199	with a rotator cuff tear is significantly associated with neurophysiologic dysfunction in CNS
200	[27]. Based on these results, the CRPS-associated hand lesion in our patients may have

201 occurred in an independent spread pattern through aberrant regulation of the CNS after
 202 ARCR. This remains to be elucidated in the future.

203To substantiate the importance of CRPS after ARCR, it is of great importance that the clinical outcomes be evaluated in these patients. Kobayashi et al. [13] reported that there is 204no significant difference in UCLA scores at the 2-year postoperative time point between the 205206patients with or without CRPS, and they concluded that coexistence of CRPS does not affect shoulder function following surgery. However, the outcomes of the hand lesion associated 207with CRPS remain unclear. Studies investigating the clinical outcomes in patients with or 208without CRPS after ARCR are currently underway at our institution. 209 There were several limitations to the present study. First, the sample size of the present 210211study was small. Second, the present study was performed in a retrospective cohort. Third, 212CRPS may develop after 3 months post-surgery; however, previous studies have consistently

indicated that it occurred within this period [11-14]. A strength of the present study was thatby using multivariable analysis, the "function" in the JOA score (weak of abduction) prior to

ARCR was found to be a risk factor for CRPS after surgery.

216

217 Conclusions

The incidence of CRPS after ARCR was 0.5-24.2% in the present patients, and results of multivariate analysis demonstrated that weakness of abduction strength is significantly

220	associated with the development of CRPS after surgery. In conclusion, the findings of the
221	present study indicate that CRPS-induced hand lesions more frequently occur after ARCR
222	than is generally believed, thereby suggesting that the impact of CRPS on the surgical
223	outcomes should be clarified in the future.

Conflict of Interest: None.

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297	

Table 1 Japanese complex regional pain syndrome diagnostic criteria for clinical purposes

 299
 (MHLWJ) (SOURCE: Reproduced with permission from reference 15. Copyright 2010

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 Wolters Kluwer Health, Inc.)

A.1. Must report at least one symptom in	A.2. Must display at least one sign in					
two or more of the following five	two or more of the five following					
categories, at some time	categories, at the physical					
	examination					
1. Trophic changes: reports of trophic	1. Trophic changes: evidence of					
changes of hair and/or skin and/or nail	trophic changes of hair and/or skin					
and/or bone.	and/or nail and/or bone.					
2. Motor dysfunctions: reports of decreased	2. Motor dysfunctions: evidence of					
range of motion and/or motor dysfunction	decreased range of motion and/ or					
(muscle weakness, tremor, dystonia).	motor dysfunction (muscle weakness,					
	tremor, dystonia).					
3. Abnormal sensory processing: reports of	3. Abnormal sensory processing:					
pain disproportionate to the inciting event	evidence of allodynia (to light touch)					
and/or burning pain and/or hyperesthesia.	and/or hyperalgesia (to pin prick)					

4. Asymmetric sudomotor activity: reports	4. Asymmetric sudomotor activity	
of sweating changes and/or sweating	evidence of and/or sweating and/or	
asymmetry.	asymmetry.	
5. Asymmetric edema: reports of edema.	5. Asymmetric edema: evidence of	
	edema.	

For research purposes, diagnostic decisions were determined according to the existence of at
least one symptom in three or more categories and at least one sign (observed at evaluation)
in three or more categories.

Table 2 Proposed clinical diagnostic criteria for complex regional pain syndrome (IASP

 2005) (SOURCE: Reproduced with permission from reference 16. Copyright 2007

 Oxford University Press)

1) Continuing pain, which is disproportionate to any inciting event

2) Must report at least one symptom in three of the four following categories:

- Sensory: Reports of hyperalgesia and/or allodynia
- Vasomotor: Reports of temperature asymmetry and/or skin color

changes and/or skin color asymmetry

- Sudomotor/Edema: Reports of edema and/or sweating changes and/or sweating asymmetry
- Motor/Trophic: Reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)

3) Must display at least one sign at time of evaluation in two or more of the following categories:

• Sensory: Evidence of hyperalgesia (to pinprick) and/or allodynia (to

light touch and/or deep somatic pressure and/or joint movement)

- Vasomotor: Evidence of temperature asymmetry and/or skin color changes and/or asymmetry
- Sudomotor/Edema: Evidence of edema and/or sweating changes and/or sweating asymmetry
- Motor/Trophic: Evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)

4) There is no other diagnosis that better explains the signs and symptoms

For research purposes, diagnostic decision rule should be at least one symptom in all four symptom categories and at least one sign (observed at evaluation) in two or more categories.

Parameter		Patients with CRPS (N=44)	Patients without CRPS (N=138)	P-value
Age (years)		63.1 ± 9.2	62.8 ± 10.3	0.780
Sex				0.147
	Male	33	86	
	Female	11	52	
Side				0.862
	Right	25	81	
	Left	19	57	
Trauma				0.605
	Yes	20	70	
	No	24	68	
Diabetes				0.203
	Yes	3	21	
	No	41	117	
Contracture				0.201
	Yes	12	25	
	No	32	113	
Disease duration (months)		13.0 ± 20.6	24.2 ± 41.9	0.112
Tear size				0.023^{*}
	Small/Middle	25	51	
	Large/Massive	19	87	
Operating time (minutes)		127.0 ± 44.6	116.8 ± 39.6	0.183
Circulating fluid (L)		25.7 ± 12.3	25.5 ± 13.6	0.931

Table 3 Analysis of risk factors by univariate analysis (epidemiologic parameters)

Values are presented as mean \pm standard deviation; *P<0.05. Abbreviation: CRPS,

complex regional pain syndrome.

Parameter		Patients with CRPS (N=44)	Patients without CRPS (N=138)	P-value
Active ROM (°)	Flex	99.7 ± 28.3	106.7 ± 37.9	0.235
	External rotation	35.2 ± 17.0	36.6 ± 19.4	0.844
	Internal rotation	3.1 ± 2.7	4.7 ± 3.3	0.005^*
	Abduction	83.9 ± 36.2	96.3 ± 46.2	0.126
Passive ROM (°)	Flex	126.4 ± 23.4	133.2 ± 28.6	0.077
	External rotation	42.8 ± 19.4	43.3 ± 19.4	0.849
	Internal rotation	3.4 ± 2.9	5.1 ± 3.5	0.006^{*}
	Abduction	110.0 ± 38.1	120.9 ± 41.2	0.098
VAS	At rest	2.4 ± 2.5	2.9 ± 2.7	0.296
	At activity	6.0 ± 2.3	6.1 ± 2.9	0.588
	At night	6.0 ± 3.0	5.1 ± 3.1	0.125
JOA score	Pain	10.0 ± 4.6	12.9 ± 6.3	0.007^*
	Function	4.7 ± 2.8	5.8 ± 3.1	0.029^{*}
	ADL	7.0 ± 1.7	7.2 ± 1.9	0.061
	ROM	19.3 ± 5.0	20.2 ± 5.7	0.436
	Total	60.6 ± 8.4	66.2 ± 11.6	0.005^*
UCLA score	Pain	2.5 ± 1.7	3.5 ± 2.2	0.009^{*}
	Function	6.3 ± 2.0	6.5 ± 2.2	0.531
	ROM flex	3.1 ± 0.8	3.1 ± 1.1	0.817
	Strength flex	2.9 ± 2.2	3.0 ± 1.6	0.116
	Total	14.8 ± 3.9	16.1 ± 4.3	0.086
Goutallier classification	SSP	1.91 ± 0.84	1.98 ± 0.89	0.644
	SSC	1.27 ± 0.80	1.34 ± 0.75	0.642
	ISP/TM	1.25 ± 0.73	1.45 ± 0.78	0.148

Table 4 Analysis of risk factors by univariate analysis (clinical parameters)

Values are presented as mean ± standard deviation; *P<0.05. Abbreviations: CRPS,

complex regional pain syndrome; ROM, range of motion; VAS, visual analog scale; JOA, Japanese Orthopaedic Association; UCLA, University of California Los Angeles; SSP, supraspinatus; SSC, subscapularis; ISP/TM, infraspinatus/teres minor.

				95% for CI	
Variable		P-value	OR	Lower	Upper
Tear size	(Large/Small)	0.087	1.96	0.91	4.28
Active ROM	Internal rotation	0.058	1.13	1	1.3
JOA score	Pain	0.093	1.06	0.99	1.14
JOA score	Function	0.034*	1.15	1.01	1.31
Disease duration		0.39	1.01	0.99	1.03

Table 5 Analysis of risk factors according to multivariate analysis

*P<0.05. Odds ratios are presented as without complex regional pain syndrome/with complex regional pain syndrome. Abbreviations: CI, confidence interval; OR, odds ratio; ROM, range of motion; JOA, Japanese Orthopaedic Association.

Figure legends

Fig. 1 Swelling with edema on the opisthenar side (a) and the palm side (b) of the right hand.

Fig. 2 Atrophic changes on the opisthenar side (a) and the palm side (b) of the left hand







