1	Effect of Preoperative Fatty Degeneration of the Rotator Cuff Muscles on the
2	Clinical Outcome of Patients with Intact Tendon after Arthroscopic Rotator Cuff
3	Repair of Large/Massive Cuff Tears
4	Running Title: Preoperative Fatty Degeneration after ARCR
5	Abstract
6	Background: Fatty degeneration of the rotator cuff muscle is associated not only with
7	postoperative retear but also with postoperative muscle weakness; therefore, fatty
8	changes in the muscles may affect the clinical outcome even in patients with these tears
9	who had intact tendon after arthroscopic rotator cuff repair (ARCR).
10	Purpose: To evaluate the effect of fatty infiltration on the clinical outcome in patients
11	with intact tendons after arthroscopic repair of large/massive cuff tears.
12	Study Design: Retrospective study
13	Methods: One hundred fifty-five consecutive patients with large/massive rotator cuff
14	tears underwent ARCR. Of these, 55 patients (average age, 64.4 ± 9.1 years) in whom
15	intact tendon after surgery was confirmed using magnetic resonance imaging at final
16	follow-up (average, 2.5 \pm 1.4 years) were included in this study. Depending on their

17	University of California Los Angeles (UCLA) score at the final follow-up, they were
18	assigned into either the unsatisfactory group (score ≤ 27 ; n = 12) or the satisfactory
19	group (score >27; $n = 43$). Various clinical parameters affecting the clinical outcome
20	were examined using univariate and multivariate analyses.
21	Results: The UCLA score of all patients significantly improved from 18.1 ± 4.4 points
22	preoperatively to 29.8 ± 4.5 points postoperatively (p < 0.0001). The mean preoperative
23	UCLA scores were not significantly different between the satisfactory and
24	unsatisfactory groups ($p = 0.39$). Multivariate analysis showed that the preoperative
25	Goutallier stages of the infraspinatus (odds ratio [OR], 8.87; 95% confidence interval
26	[CI], 1.51-52.0; p = 0.016) and/or subscapularis (OR, 7.53; 95% CI, 1.58-35.9; p =
27	0.011) were significantly associated with outcome. ROC curve analysis revealed that
28	the cutoff value is Goutallier stage 1 in both muscles, with area under the curve values
29	of 0.79 (sensitivity: 91% and specificity: 51%) and 0.84 (sensitivity: 100% and
30	specificity: 54%) in the infraspinatus and subscapularis, respectively.
31	Conclusion: Preoperative fatty degeneration of the infraspinatus and/or subscapularis
32	with Goutallier stage ≥ 2 was significantly associated with worse outcome in patients

33 with large/massive tears who had intact tendon after ARCR.

34 Key Terms: arthroscopic rotator cuff repair, fatty degeneration, factors for clinical
35 outcome

36	What is known about the subject: Previous studies reported the risk factor for worse
37	clinical outcome in patients with arthroscopic rotator cuff repair (ARCR), including
38	both retear and non-retear cases after surgery. Fatty degeneration of rotator cuff muscles
39	more or less progresses in large/massive cuff tears; therefore, the muscle changes may
40	affect the postoperative function even in these patients with intact tendon after surgery.
41 42	However, few studies have evaluated the risk factors for worse outcome particularly in patients with large/massive cuff tears who had intact tendon after ARCR.
43	What this study adds to existing knowledge: Even if arthroscopic repair is achieved
44	with postoperative intact tendon, preoperative fatty degeneration of the infraspinatus
45	and/or subscapularis is significantly associated with worse clinical outcome after

46 surgery.

47 Introduction

48	Rotator cuff tear causes pain and functional disorder of the shoulder, accounting for
49	more than 4.5 million physician visits per year in the United States. ²⁸ This disease can
50	be found in 30% to 50% of the population older than 50 years. ³¹ When individuals with
51	cuff tear become symptomatic, conservative treatment is performed first except in acute
52	or subacute traumatic injury. ² Once conservative treatment performed for a certain
53	periods fails, ^{3,12} open or arthroscopic rotator cuff repair (ARCR) is used.
54	The clinical outcome of ARCR is generally favorable, but postoperative retear is of
55	great concern, especially in large/massive cuff tears. A number of articles have
56	described the risk factors for retear after ARCR. ^{5,27} Recent review articles suggested
57	that older patients, larger tears, and fatty degeneration were the risk factors of
58	postoperative structural failure. ^{19,21} Fatty degeneration of the rotator cuff is closely
59	associated with retear after surgery, causing further propagation if untreated. ²³
60	Reversibility of fatty degeneration in patients with intact tendon after surgery
61	remains unclear. Fatty degeneration is mostly irreversible despite successful repair ^{8,9} ; by
62	contrast, reversal can be observed in patients with lower Goutallier stage without

63	retear. ³⁵ Fatty degeneration of the rotator cuff muscles is also involved in muscle
64	weakness, which affects shoulder function. ^{9,28} These results raised the hypothesis that
65	fatty degeneration of the rotator cuff muscles might affect the clinical outcome of
66	patients with large/massive tears, even in those with intact tendon after surgery.
67	Therefore, the purpose of the present study was to evaluate the factors affecting clinical
68	outcome in patients with intact tendon after arthroscopic repair of large/massive cuff
69	tears.
70	
71	Material and Methods
72	This retrospective study was approved by the institutional review board of Kurume
73	University (#12333).
74	
75	Subjects
76	Between April 2005 and December 2013, 155 patients with large/massive rotator cuff
77	tears underwent ARCR. Patients who had footprint of torn cuff covered completely,
78	patients who did not show retear on magnetic resonance images (MRI) at final

79	follow-up, patients who were followed up for at least 1 year, and patients whose
80	University of California Los Angeles (UCLA) score before and after surgery had been
81	evaluated were included. Exclusion criteria were advanced glenohumeral arthritis,
82	fractures of the shoulder, or revision surgeries. Consequently, we confirmed 55 patients
83	with healed tendons, 19 with retears and 14 with partial repairs. Five patients med
84	exclusion criteria, and 62 were lost to follow-up; the follow-up rate was 60% (93/155
85	cases).
86	
87	Surgical Technique and Postoperative Regimen
87 88	Surgical Technique and Postoperative Regimen ARCR was performed by two surgeons if the patients did not respond to conservative
88	ARCR was performed by two surgeons if the patients did not respond to conservative treatment (administrations of anti-inflammatory drugs, physical therapy, and
88 89	ARCR was performed by two surgeons if the patients did not respond to conservative treatment (administrations of anti-inflammatory drugs, physical therapy, and
88 89 90	ARCR was performed by two surgeons if the patients did not respond to conservative treatment (administrations of anti-inflammatory drugs, physical therapy, and intra-articular injections of corticosteroids or hyaluronic acid) for at least 3 months.
88 89 90 91	ARCR was performed by two surgeons if the patients did not respond to conservative treatment (administrations of anti-inflammatory drugs, physical therapy, and intra-articular injections of corticosteroids or hyaluronic acid) for at least 3 months. The patients underwent ARCR in the beach position under general anesthesia. The

95	with interrupted suture. For double-row repairs, one row of anchors was placed on the
96	medial and lateral aspects of the footprint, and the torn cuff was fixed with mattress and
97	interrupted sutures, respectively. For suture bridge repair, one row of anchors was
98	placed on the medial aspect of the footprint with or without tying, and the torn cuff was
99	transosseously fixed with the knotless anchor on the lateral aspect of the footprint.
100	Additional procedures including capsular release, tenotomy/tenodesis of the long head
101	of the biceps (LHB) tendon, and distal clavicle excision were used if needed.
102	Acromioplasty was performed in all cases.
103	The patients were immobilized in a sling with abduction pillow after surgery, with
104	the shoulder internally rotated at 30° to 40° and abducted at 20° . Passive range of
105	motion (ROM) exercise of the shoulder was commenced at postoperative day 4, and
106	active ROM exercise was allowed at postoperative week 6. Isotonic muscle
107	strengthening exercises were allowed at postoperative week 12.

108

109 Functional Assessment

110 UCLA scores were used as a clinical outcome measure. ROM was assessed using a

112	FET2; Hoggan Health Industry, West Jordan, UT, USA). Visual analogue scale (VAS)
113	scores at three states (at rest, at shoulder motion, and at night) were reported as patients'
114	subjective assessments. These measures were evaluated before and after surgery.
115	
116	Structural Assessment
117	Tear length, tear width, fatty degeneration, muscle atrophy before surgery, and structural
118	integrity after surgery were examined with MRI, according to a previous report. ²⁵
119	Postoperative "intact tendon" was defined as types I-III in the Sugaya classification. ³⁴
120	The tear length and width were evaluated as the coronal and sagittal oblique distance on
121	T2-weighted images, respectively. ¹³ Muscle atrophy was calculated as the
122	cross-sectional area of the rotator cuff muscle belly in relation to the cross-sectional
123	area of the supraspinatus fossa at Y-view on T2-weighted images,24 using Image J
124	software (NIH, Bethesda, MD, USA). The fatty degeneration of the rotator cuff muscles
125	at the Y view was evaluated according to the Goutallier classification. ⁷
126	

goniometer, and muscle strength was measured using a hand-held dynamometer (Micro

127 Assignment of the Satisfactory and Unsatisfactory Groups

128	According to the UCLA score at final follow-up, patients who had intact tendon after
129	ARCR were divided into two groups: the unsatisfactory group, comprising individuals
130	classified into the "poor or fair" criterion (≤ 27 points, n = 12), and the satisfactory
131	group, comprising those classified into the "good or excellent" criterion (>27 points, n =
132	43). ^{30,6,17}
133	Various variables were used to analyze the association with the satisfactory or
134	unsatisfactory outcome using univariate and multivariate analyses: patient's age, sex,
135	symptom duration, smoking, comorbidities, hand dominance, traumatic onset, worker's
136	compensation status, repair techniques, treatments of LHB tendon, tear length, tear
137	width, muscle atrophy, fatty degeneration, ROM, muscle strength, VAS score, and
138	preoperative UCLA score.
139	

140 Statistical Analysis

141 The JMP11 software (SAS Institute, Cary, NC, USA) was used for statistical analysis.

142 Wilcoxon test was used to compare between the UCLA scores before and after surgery.

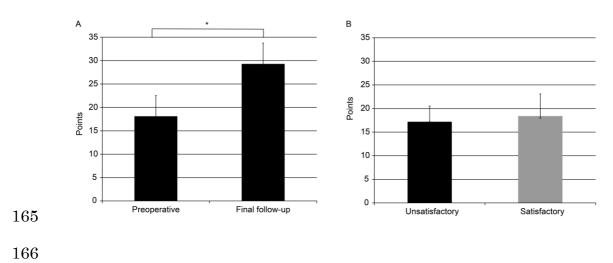
143	Univariate logistic analysis was used to compare the relationship between the clinical
144	parameters of the satisfactory and unsatisfactory groups and to analyze the relationship
145	between Goutallier stage in the rotator cuff muscles and sections in the UCLA score.
146	Multivariate logistic analysis with stepwise technique using the clinical variables (p $<$
147	0.1) was performed to evaluate the significant parameters affecting "satisfactory" or
148	"unsatisfactory" outcome in the UCLA score, accompanied by the odds ratio (OR) with
149	95% confidence intervals (CIs). Then, receiver operating characteristic (ROC) curve
150	analysis was performed to obtain the cutoff value of the parameters affecting the clinical
151	outcome. The cutoff value was determined as the maximum value of Youden Index
152	(sensitivity + $(1 - \text{specificity})$) on the ROC curve. The data are expressed as the mean
153	values with standard deviation. A p value <0.05 was considered significant.
154	
155	Results

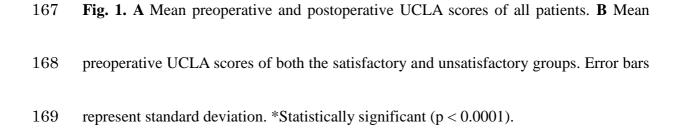
156 Functional Outcome in the Satisfactory and Unsatisfactory Groups

157 Fifty-five patients were included in this study. The mean age at surgery was 64.4 ± 9.1

158 years, with a mean follow-up period of 2.5 ± 1.4 years. The mean duration of symptom

- 159 before surgery was 36.9 ± 49.1 weeks.
- 160 The UCLA score of all patients significantly improved from 18.1 ± 4.4 points
- 161 preoperatively to 29.8 ± 4.5 points postoperatively (n = 55) (Fig. 1A). No significant
- 162 difference was found in the mean preoperative UCLA scores between patients with
- 163 satisfactory and unsatisfactory outcomes (p = 0.39) (Fig. 1B).
- 164





170

171 Univariate Analysis to Detect the Factors Affecting Clinical Outcome

172	The results of the univariate analysis showed that the preoperative Goutallier stage of
173	the infraspinatus and subscapularis, preoperative muscle abduction strength, and LHB
174	treatment during surgery are significantly associated with postoperative clinical
175	outcome ($p = .0021$, $p = .0024$, $p = .0051$, and $p = .0073$, respectively) (Table 1).

- Table 1. Comparison of Various Variables between the Satisfactory and Unsatisfactory 176
- 177Groups

Variables	Total	Satisfactory	Unsatisfactory	p Value
Preoperative demographic variables				
Age (years)	64.4	64.6	64.3	0.93
Sex (male/female)	28/27	22/21	6/6	0.94
Diabetes, n (%)	1 (2)	1 (2.5)	0 (0)	0.61
Dominant-side surgery, n (%)	40 (73)	32 (74)	8 (67)	0.59
Traumatic onset, n (%)	30 (58)	30 (73)	8 (54)	0.26
Symptom duration (weeks)	37	19	41	0.11
Hypertension, n (%)	18 (33)	5 (42)	13 (31)	0.49
Smokers, n (%)	13 (26)	9 (23)	4 (36)	0.35
Worker's compensation, n (%)	4 (8)	3 (6)	1 (10)	0.81
Follow-up (years)	3	3	3	0.98
Preoperative functional variables				
ROM, angle				
Elevation	114	119	95	0.10
Abduction	107	111	89.1	0.18
Internal rotation (vertebrae)	6	6	6	0.76
External rotation	43	44	43	0.9
Muscle strength, %				

Elevation	66.7	0.68	0.617	0.47
Abduction	65.5	0.7	0.489	0.0051*
Internal rotation	67.5	71.1	54.5	0.12
External rotation	74.3	71.3	85.3	0.17
VAS (mm)				
Rest	26.3	24.4	34.2	0.25
Motion	59.8	62.2	50	0.17
Night	52.3	54.8	42.1	0.2
Preoperative structural variables				
Tendon retraction (mm)	25.4	25.4	25.4	0.1
Tear width (mm)	21.8	21.5	23.2	0.6
Muscle atrophy (%)				
Supraspinatus	76	76	76	0.77
Infraspinatus	>100	>100	>100	0.21
Subscapularis	>100	>100	>100	0.21
Preoperative Goutallier classific	cation, n (%)		
Supraspinatus				
Stage 0	11 (23)	9 (25)	2 (18.2)	
Stage 1	13 (28)	12 (33)	1 (9.1)	
Stage 2	20 (43)	14 (39)	6 (54.6)	
Stage 3	2 (4)	1 (3)	1 (9)	
Stage 4	1 (2)	0	1 (9)	0.16
Infraspinatus				
Stage 0	1 (41)	18 (51)	1 (9)	
Stage 1	20 (43)	15 (43)	5 (46)	
Stage 2	7 (15)	2 (6)	5 (46)	
Stages 3 and 4	0	0	0	0.0021*
Subscapularis				
Stage 0	18 (39)	18 (51)	0 (0)	
Stage 1	17 (37)	12 (34)	5 (46)	
Stage 2	9 (20)	5 (14)	4 (37)	

Stage 3	2 (47)	0	2 (187)	
Stage 4	0	0	0	0.0024*
Intraoperative variables				
Treatment of the LHB tendon				
Untreated	27	17	10	
Treated	28	26	2	0.0073*
Repair technique				
Single-row	10	7	3	
Double-row	2	2	0	
Suture bridge	40	32	8	0.595

178 Statistics were evaluated by logistic analysis. *Statistically significant. ROM, range of

179 motion; VAS, visual analogue scale; LHB, long head of the biceps.

180

181 Multivariate Analysis to Detect Factors Affecting Clinical Outcome and

182 Calculation of Cutoff Value

183 The multivariate logistic regression analysis with stepwise technique showed that the

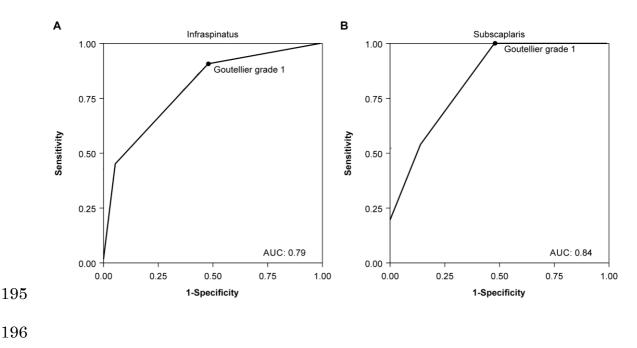
184 preoperative Goutallier stages of the infraspinatus and subscapularis are significantly

- 185 associated with clinical outcome (Table 2).
- 186 Table 2. Summary of Variables Associated with the Outcome that was Statistically
- 187 Verified by Multivariate Logistic Analysis

Goutallier Stage	OR	95% CI	p Value
Infraspinatus	8.87	1.51-52.0	0.016*
Subscapularis	7.53	1.58-35.9	0.011*

188 *Statistically significant. OR, odds ratio; CI, confidence interval.

ROC curve analysis revealed that the cutoff value to predict the "unsatisfactory" outcome is Goutallier stage 1 in both muscles, with area under the curve values of 0.79 (sensitivity: 91% and specificity: 51%) and 0.84 (sensitivity: 100% and specificity: 54%) in the infraspinatus and subscapularis, respectively (Fig. 2). These results indicate that patients with Goutallier stage 2 or more in both muscles are associated with



194 "unsatisfactory" outcome after surgery.

197	Fig. 2 Receiver operating characteristic curve to determine the predictive cutoff value
198	for the unsatisfactory score in the Goutallier stage of the infraspinatus and subscapularis.
199	Filled circle (\bullet) indicates cutoff value, shown as the point with the maximal Youden
200	index on the ROC curve
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202 Discussion
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Fatty degeneration of the rotator cuff muscles is associated not only with postoperative 203 retear but also with muscle weakness affecting shoulder function after surgery.⁹ The 204 205present study examined the patients with large/massive cuff tears who had intact tendon 206 after ARCR and demonstrated that the infraspinatus and/or subscapularis with fatty 207 degeneration of Goutallier stage 2 or more before surgery were at risk for unsatisfactory 208 outcome in patients with large/massive tears despite having intact tendon after surgery. Burkhart⁴ advocated the importance of "force couple mechanisms" by the 209 210infraspinatus and subscapularis in maintaining glenohumeral joint stability. In rotator 211cuff tears, the joint reaction force is affected by the integrity of the rotator cuff muscles, especially by the transverse force couple formed by the infraspinatus and subscapularis. 212

213	On the contrary, isolated supraspinatus tears are compensated by the rest of the rotator
214	cuff muscles, thus not contributing to joint instability. ²⁹ Rotator cuff tear progression to
215	half of the infraspinatus tendon was the critical tear size for significant changes in
216	rotational humeral head kinematics, specifically the superior and lateral shift of the
217	humeral head at maximum internal rotation and posterior shift at the midrange of
218	rotational motion. ²⁶ Thus, these reports consistently suggest the importance of the force
219	couple formed by the anterior and posterior aspects of the cuff (i.e., the infraspinatus
220	and subscapularis).
221	Previous studies reported a relationship between fatty degeneration of the rotator cuff
222	muscles and decreased postoperative muscle strength. ^{9,32,33} Postoperative strength in
222 223	
	muscles and decreased postoperative muscle strength. ^{9,32,33} Postoperative strength in
223	muscles and decreased postoperative muscle strength. ^{9,32,33} Postoperative strength in forward flexion, internal rotation, and external rotation at final follow-up correlated
223 224	muscles and decreased postoperative muscle strength. ^{9,32,33} Postoperative strength in forward flexion, internal rotation, and external rotation at final follow-up correlated highly with preoperative fatty degeneration, occupation ratio, and tangent sign. ³³
223 224 225	muscles and decreased postoperative muscle strength. ^{9,32,33} Postoperative strength in forward flexion, internal rotation, and external rotation at final follow-up correlated highly with preoperative fatty degeneration, occupation ratio, and tangent sign. ³³ Gladstone <i>et al.</i> ⁹ found that fatty degeneration of the infraspinatus or subscapularis

229 part of the infraspinatus is negatively correlated with both SSIs of abduction and 230 external rotation.

231The relationship between fatty degeneration of the infraspinatus or subscapularis and worsened clinical outcome is reported. Gladstone *et al.*⁹ reported that fatty degeneration 232233and rotator cuff atrophy of the infraspinatus are significant variables associated with poorer clinical scores. Magdes et al.²⁰ reported that patients with advanced fatty 234235degeneration of the subscapularis shows significantly lower score in anterosuperior 236rotator cuff tears. They suggested the negative influence of degenerative change of the 237infraspinatus or the subscapularis on clinical outcome after rotator cuff repair; however, 238 these studies included both retear and non-retear cases. Noteworthy, the present study revealed that preoperative fatty changes in the infraspinatus or subscapularis influenced 239240postoperative clinical outcome, even in those with intact tendon after surgery. Biceps treatment including tenotomy or tenodesis is often used in ARCR.¹⁵ In the 241242present study, the univariate analysis showed that biceps treatment significantly affected 243the clinical outcome, but the multivariate analysis did not. It is widely accepted that the remaining biceps tendon negatively affects clinical outcome after ARCR.³⁶ Although no 244

significant association between biceps treatment and clinical outcome was demonstrated in the present study, which has a small sample size, it remains to be elucidated in a larger-scale study.

248This study has the following limitations. First, because only a relatively small number 249of cases were assigned especially in the unsatisfactory outcome group, the power of the 250multivariable analysis is limited. Therefore, it may have missed one or more factors. 251Second, the present study was a retrospective cohort; therefore, selection bias and a 252confounding effect might be present. Third, the follow-up period was relatively short (2.5 years). As a majority of retear occurs within 12 months after surgery,^{11,14} cases in 253254which the follow-up period was at least 12 months or longer were included. Third, the 255reversibility of the degenerative change of the rotator cuff muscles was not considered, since the relatively small number of unsatisfactory results limits the power of the 256multivariable analysis; however, most studies supported the irreversibility of the fatty 257degeneration in these muscles.¹⁶ Fourth, the symptom duration prior to surgery was 258259relatively long, making it difficult to consider surgery before the progression of fatty infiltration. However, given the data in the present study, early surgical intervention 260

261may be encouraged when the surgeon encounters patients with cuff tear who have less 262 progression of fatty changes in the muscles. Fifth, most patients had undergone a variety 263of treatment including steroid injection, physical therapy, and anti-inflammatories under 264a local medical doctor before referring them to the hospital; consequently, the treatment 265details before the referral are unknown. Sixth, various surgical procedures were 266performed in the present study. Surgical variability influenced the retear rate after ARCR, but did not affect the clinical outcome after surgery.²² These might have 267 268affected the data obtained from the present study. 269This study has the following strengths. This was the first study to analyze the 270prognostic factors associated with worsened outcome in patients with intact tendon after 271surgery for large/massive cuff tears and clearly demonstrated that these patients are at 272significant risk for fatty degeneration of the infraspinatus and/or subscapularis before surgery. In addition, multivariate analysis excluded the influence of the worker's 273274compensation status on the outcome obtained from the present study because some 275articles reported independent negative influences of that variable on clinical outcome after surgery.^{1,10,18} 276

277 In conclusion, preoperative fatty degeneration of the infraspinatus and/or 278 subscapularis with Goutallier stage ≥ 2 was significantly associated with worse outcome

279 in patients with large/massive tears who had intact tendon after ARCR.

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