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Patrick Grueninger, Nikola Nikolic, Joerg Schneider, Thomas Lattmann ...+3 more authors

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Year: 2014

**Arthroscopic repair of traumatic isolated subscapularis tendon lesions
(Lafosse Type III or IV): a prospective magnetic resonance
imaging-controlled case series with 1 year of follow-up**

Grueninger, Patrick ; Nikolic, Nikola ; Schneider, Joerg ; Lattmann, Thomas ; Platz, Andreas ; Chmiel, Corinne ; Meier, Christoph

Abstract: **PURPOSE** The purpose of this study was to prospectively assess the efficacy of arthroscopic repair of isolated high-grade subscapularis (SSC) tendon lesions by means of clinical follow-up combined with magnetic resonance imaging investigations. **METHODS** Between January 2008 and September 2010, 11 patients (9 men and 2 women; mean age, 45 ± 10 years) with Lafosse type III or IV traumatic isolated SSC tendon lesions underwent arthroscopic repair including tenodesis of the long head of the biceps tendon. All patients were preoperatively assessed by clinical examination (Constant-Murley score [CMS]) and contrast-enhanced magnetic resonance arthrography. At 1 year of follow-up, specific clinical SSC tests, the CMS, and the loss of external rotation were evaluated. A native magnetic resonance investigation was performed to assess the structural integrity of the repair. The SSC muscle was compared with its preoperative condition regarding fatty infiltration and size (cross-sectional area). Patient satisfaction was graded from 1 (poor) to 4 (excellent). **RESULTS** The mean time interval from trauma to surgery was 3.7 months. A concomitant lesion of the biceps tendon was observed in 10 patients (91%). The mean CMS improved from 44 to 89 points ($P < .001$). The functional tests showed a significant increase in strength ($P < .05$) (belly-press test, 4.8 v 2.9; lift-off test, 4.8 v 2.9). The mean loss of external rotation at 0° of abduction was 10° compared with the contralateral side ($P < .05$). Patient satisfaction was high. Magnetic resonance imaging evaluation showed complete structural integrity of the tendon repair in all studies. The SSC showed a significant decrease in fatty infiltration and increase in the cross-sectional area. **CONCLUSIONS** Arthroscopic repair of higher-grade isolated SSC lesions provides reliable tendon healing accompanied by excellent functional results 1 year after surgery. **LEVEL OF EVIDENCE** Level IV, prospective therapeutic case series.

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Title: Arthroscopic repair of traumatic isolated subscapularis tendon lesions Lafosse III-IV: a prospective MRI-controlled case series with one year follow-up

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Corresponding Author: Dr.Med. Christoph Meier, M.D.

Corresponding Author's Institution: Waid Hospital Zurich

First Author: Patrick Grueninger, M.D.

Order of Authors: Patrick Grueninger, M.D.; Nikola Nolic, M.D.; Joerg Schneider, M.D.; Thomas Lattmann, M.D.; Andreas Platz, M.D.; Corinne Chmiel, M.D.; Christoph Meier, M.D.

Abstract: Purpose: The purpose of this study was to prospectively assess the efficacy of arthroscopic repair of isolated high-grade subscapularis (SSC) tendon lesions by means of clinical follow-up combined with MRI investigations

Methods: Between January 2008 and September 2010 11 patients (9 male 2 female, mean age 45±10 years) with traumatic isolated SSC tendon lesions Lafosse III-IV underwent arthroscopic repair including long head of biceps tenodesis. All patients were preoperatively assessed by clinical examination (Constant-Murley score (CMS)) and contrast enhanced MR arthrography. At one year follow-up, specific clinical SSC tests, the CMS and the loss of external rotation were evaluated. A native MR investigation was performed to assess structural integrity of the repair. The SSC muscle was compared to its preoperative condition regarding fatty infiltration and size (cross-sectional area (CSA)). Patient satisfaction was graded between 4 (excellent) and 1 (poor).

Results: Mean time interval from trauma to surgery was 3.7 months. A concomitant lesion of the biceps tendon was observed in 10 patients (91%). Mean CMS improved from 44 to 89 points ($p<0.001$). The functional tests showed a significant increase of strength ($p<0.05$) (belly-press test: 4.8 vs. 2.9; lift-off test: 4.8 vs. 2.9). Mean loss of external rotation at 00 abduction was 100 compared to the contralateral side ($p<0.05$). Patient satisfaction was high. MRI evaluation showed complete structural integrity of the tendon repair in all studies. The SSC showed a significant decrease of fatty infiltration and increase of the CSA.

Conclusions: Arthroscopic repair of higher grade isolated SSC lesions provides reliable tendon healing accompanied by excellent functional results one year after surgery.

Level of Evidence: Level IV, prospective therapeutic case series.

1 Original Article

2

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6

7 **Running title:** Arthroscopic repair of subscapularis tendon lesions

8

9 Patrick Grueninger, M.D.¹, Nikola Nikolic, M.D.², Joerg Schneider, M.D.¹, Thomas Lattmann, M.D.³,
10 Andreas Platz, M.D.³, Corinne Chmiel, M.D.⁴, Christoph Meier, M.D.¹

11 ¹*Department of Surgery, Waid Hospital Zurich, Switzerland,* ²*Institute for Clinical Radiology, Waid*
12 *Hospital Zurich, Switzerland,* ³*Department of Surgery, Triemli Hospital Zurich, Switzerland,*
13 ⁴*Department of Internal Medicine, Waid Hospital Zurich and Institute of General Practice and*
14 *Health Services Research, University of Zurich, Switzerland*

15

16

17

18 **Address for correspondence:**

19

20 Christoph Meier, MD
21 Department of Surgery
22 Waid Hospital Zurich
23 Tièchestrasse 99
24 8037 Zurich
25 Switzerland
26 phone: +41 44 366 20 11
27 fax: +41 44 366 30 83
28 email: patrick.grueninger@waid.zuerich.ch

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10 **Abstract**

11

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14 with MRI investigations

15 **Methods:** Between January 2008 and September 2010 11 patients (9 male 2 female, mean age
16 45 ± 10 years) with traumatic isolated SSC tendon lesions Lafosse III-IV underwent arthroscopic
17 repair including long head of biceps tenodesis. All patients were preoperatively assessed by clinical
18 examination (Constant-Murley score (CMS)) and contrast enhanced MR arthrography. At one year
19 follow-up, specific clinical SSC tests, the CMS and the loss of external rotation were evaluated. A
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27 compared to the contralateral side ($p < 0.05$). Patient satisfaction was high. MRI evaluation showed
28 complete structural integrity of the tendon repair in all studies. The SSC showed a significant
29 decrease of fatty infiltration and increase of the CSA.

30 **Conclusions:** Arthroscopic repair of higher grade isolated SSC lesions provides reliable tendon
31 healing accompanied by excellent functional results one year after surgery.

32 ~~In our series we observed significant decrease in fatty SSC muscle infiltration and an increase of~~
33 ~~muscular mass.~~ **Level of Evidence:** ~~Therapeutic~~ Level IV, prospective therapeutic case series.

34 Introduction

35

36 Isolated lesions of the subscapularis (SSC) are ~~rare~~less common. Lafosse et al. reported a
37 prevalence of 10.1% comparing isolated SSC tears with all SSC lesions ¹. The importance of the
38 SSC regarding its biomechanical and functional properties has increasingly been ~~recognized over~~
39 ~~the last years~~. Its function includes internal rotation of the shoulder, force coupling in the transverse
40 plane and it also contributes to the anterior stability of the shoulder. Thus, patients with impaired
41 SSC function present with increased passive external rotation and pathological lift-off test ².
42 Complete tears of the SSC with retraction may cause an anterior displacement of the humeral
43 head onto the glenoid due to disruption of the force couple of the rotator cuff.

44

45 Open repair has been associated with good clinical outcomes in several studies ^{3,4}. In 2002, the
46 technique of arthroscopic SSC repair was described by Burkhart and Tehrany ⁵. However, some of
47 these studies also included anterosuperior lesions or did not distinguish between low-grade and
48 higher-grade lesions ^{5,6}. Only a few study groups included follow-up imaging such as CT
49 arthrography or MRI to assess structural integrity of the repair or muscular alterations such as fatty
50 infiltration or muscular atrophy ^{1, 7-11}~~40~~.

51

52 The purpose of the present study was to evaluate clinical outcome after arthroscopic repair of
53 isolated traumatic high-grade lesions of the SSC tendons. Furthermore, muscular alterations of the
54 SSC were assessed by means of degree of fatty infiltration and muscular mass in MRI at follow-up
55 after one year. Our hypothesis was that patients with traumatic high-grade lesion to the SSC
56 tendon would benefit from early arthroscopic repair.

57

58 Methods

59

60 **Patients.** Between 01/2008 and 09/2010 eleven consecutive patients with traumatic isolated
61 complete SSC tendon tears type III and IV according to the Lafosse classification ¹ undergoing an

62 | all arthroscopic repair were included in ~~the study~~this prospective case series. Patients with
63 | anterosuperior lesions or mass lesions were excluded. The study was approved by the local ethics
64 | committee and informed consent for operative treatment and all the follow-up investigations was
65 | obtained from all the patients. Follow-up after one year included a clinical examination and MRI to
66 | assess the structural integrity of the repair. Fatty infiltration and the muscular mass of the SSC,
67 | SSP and ISP were also evaluated and compared to preoperative imaging.

68 |

69 | **Operative technique.** All arthroscopic procedures were performed in general anesthesia with an
70 | interscalene catheter for postoperative pain control. The patient was seated in a standardized
71 | beach chair position with arm traction of 2-3 kg. A perioperative antibiotic prophylaxis with
72 | cefuroxim was routinely administered. A standard 30° arthroscope was used. According to Lafosse
73 | ¹ the portals were named from A (posterior "soft spot" portal) to E (anterosuperior portal). Before
74 | introducing the arthroscope into the glenohumeral joint through the A portal, the joint was
75 | infiltrated with 20ml of diluted adrenaline (1ml of adrenaline (1mg/ml) and 19ml of normal saline)
76 | to decrease intraoperative bleeding. Furthermore, systolic blood pressure was constantly kept at a
77 | maximum of 100mmHg during surgery. With these measures the intraarticular pressure could be
78 | kept as low as 35mmHg until the end of the intervention for most patients. In some cases, the
79 | pressure had to be increased in a stepwise manner during the procedure in order to provide good
80 | visibility. However, a maximum pressure of 60mmHg was never exceeded in this series.

81 | The diagnostic arthroscopy was performed and a probe was inserted through the D portal
82 | (anterolateral portal). After confirming the isolated lesion of the SSC, the lesion was classified
83 | according to the Lafosse classification ¹. Only type III and IV lesions were included (Fig 1A and B).
84 | The long head of biceps tendon (LHBT) was inspected with a probe. For the tenodesis of the LHBT
85 | one suture of a double loaded ~~threaded suture anchor screw anchor (HEALIX 4.5mm Ti™ Anchor~~
86 | ~~w/ORTHOCORD® violet / blue strand, Size 2, or Fastin® RC 5mm Anchor w/ORTHOCORD® violet /~~
87 | ~~blue strand, Size 2, Mitek Sports Medicine, Raynham, USA)~~ was used performing a "lasso-loop
88 | stitch" in all patients of this series ^{11,12}. The second suture of this anchor was used for the

89 reconstruction of the most superior part of the SSC tendon at a later stage. The rotator interval
90 was opened using a shaver and a bipolar diathermy (VAPR® 3 Premiere90 Electrode 90° or VAPR®
91 3 LDS electrode 90°, Mitek Sports Medicine, Raynham, USA). The tip of the coracoid process and
92 the conjoint tendon were dissected before the E portal (anterosuperior portal) was created under
93 direct visualization in an outside-in technique. To achieve a 270° release of the SSC the middle
94 glenohumeral ligament was debrided from the posterior aspect of the SSC. To facilitate
95 mobilization, a traction suture through the D portal was routinely used for retracted SSC tendons.
96 The superior glenohumeral ligament was also resected. A shaver and burr were used to prepare
97 the footprint of the SSC on the lesser tuberosity. The arthroscope was now placed through the D
98 portal and the instrumentation was changed from the D to the E portal. To complete the release of
99 the SSC all adhesions to the coracoid were released and the subcoracoidal bursa was removed. In
100 type IV lesions the axillary nerve was visualized routinely (Fig 2). In type III and IV lesions with no
101 or moderate tension the reconstruction of the SSC was performed with 2 ~~FASTIN® 5mm or~~
102 ~~4.5mm HEALIX Ti™ threaded suture anchors~~ usually applying U-stitches. The remaining suture of
103 the LHBT tenodesis anchor was used for a lasso-loop stitch at the upper border of the SSC
104 achieving a pseudo double-row reconstruction (Fig. 3). In type IV lesions with higher tension
105 (n=2) lasso-loops instead of U-stitches were used and the reconstruction was reinforced with a
106 double-row reconstruction in suture bridge technique ~~(VERSALOK™ Anchor, Mitek Sports Medicine,~~
107 ~~Raynham, USA). No coracoplasties were performed in the study group as we did not see any signs~~
108 ~~of coracoid impingement.~~ Surgery was completed with a routine acromioplasty. ~~However, a rather~~
109 ~~limited than a formal acromioplasty was performed in asymptomatic patients.~~ All operations were
110 performed by the corresponding author.

111

112

113 **Rehabilitation.** Postoperatively, all patients were immobilized on a 30° abduction pillow for six
114 weeks. Physiotherapy was initiated on the first postoperative day starting with passive and pain
115 free exercises for the shoulder for six weeks. During this period, external rotation was limited at

116 0°. Patients were encouraged to perform active wrist and elbow movements from the beginning.
117 For personal hygiene all patients were briefed to shower with a waterproof abduction wedge. After
118 six weeks, active exercises were started to regain full range of motion. Weight bearing and
119 strengthening exercises were allowed after twelve weeks. Depending on the kind of sports, a
120 gradual return to these activities was allowed not before six months postoperatively.

121
122 **Clinical evaluation.** Preoperatively, the patient's history in general and the trauma mechanism
123 and the time of the injury in particular were recorded. A standardized physical examination was
124 performed before the operation and at follow-up by the first author. The clinical examination
125 included a Constant-Murley score (CMS) ^{12,13}. The SSC function was tested with the modified belly-
126 press test and the modified lift-off test as described by Lafosse et. al.¹. Muscular strength was
127 graded from 0 to 5 according to the classification of neurological assessment. External rotation in
128 0° abduction was measured and the loss of external rotation compared to the contralateral side
129 was recorded. Internal rotation was assessed according to the CMS subscore for internal rotation.
130 The loss of internal rotation was defined by the loss of points compared to the contralateral side
131 (CMS subscore for internal rotation). At follow-up, our patients were also asked to rate their level
132 of satisfaction ranging from poor, fair and good to excellent.

133
134 **Radiological evaluation.** All patients underwent a standardized radiographic evaluation
135 including a true anteroposterior radiograph in neutral rotation and an axillary view before and
136 immediately after surgery. Preoperatively, all patients were also evaluated with contrast enhanced
137 Magnetic Resonance Imaging (Arthro-MRI). Fatty infiltration of the SSC was graded according to
138 Goutallier ^{13,14}, modified by Fuchs ^{14,15} for MRI from 0 to 4. Accordingly, grade 0 indicates no fatty
139 infiltration; grade 1, some fatty streaks; grade 2, less fat than muscle; grade 3, as much fat as
140 muscle; and grade 4, more fat than muscle. The cross-sectional area (CSA) of the SSC was
141 measured according to the method proposed by Zanetti et al. ^{15,16} employing standard
142 measurement tools in our PACS software. The CSA was measured in mm² at the most lateral

143 image on which the scapular spine was in contact with the rest of the scapula in the sagittal
144 reconstructions.

145
146 At follow-up after one year, an MRI investigation with a dedicated shoulder-coil (Magnetom Avanto
147 1.5T, Siemens Medical Solution, Erlangen, Germany) without contrast enhancement was obtained.
148 On the axial and paracoronal views the tendons of the supraspinatus (SSP), infraspinatus (ISP)
149 and SSC were evaluated regarding continuity and retraction. Tendon integrity was assessed in
150 axial and sagittal T2-weighted and proton density-weighted sequences (Fig. 4). A tendon re-rupture
151 was diagnosed if a clear retraction was present or if a gap in a tendon was filled with a water
152 equivalent signal. The fatty muscular infiltration and CSA of the SSP, ISP and SSC were determined
153 as described above (Fig. 5). The integrity of the tenodesis of the LHBT was evaluated on the most
154 superior axial cross-section where the bicipital groove was still visible. In contrast to the
155 preoperative MR arthrographies only native MRI studies were performed at follow-up. Acceptance
156 of an invasive technique for pure scientific reasons without direct benefit to the patient may be low
157 and may also be discussed controversially by ethical aspects. Furthermore, the superiority of MR
158 arthrography for evaluating structural integrity of SSC repair is not proven¹⁷. The application of
159 intraarticular gadolinium does not change the appearance of the muscles such as the SSC on the
160 images. The complete pre- and postoperative radiological assessment was performed by one
161 experienced MR-radiologist with special training in musculoskeletal imaging. This radiologist ~~who~~
162 was blinded to the clinical results.

163
164 **Statistical analysis.** Results were analyzed using statistical software (IBM SPSS version 20).
165 Statistical analysis was performed using the paired t-test and the Wilcoxon signed rank test when
166 appropriate. All data are presented as means with standard deviations (ranges are provided in
167 brackets). A double sided P-value of <0.05 was considered statistically significant.

168

169 **Results**

170
171 Between 01/2008 and 09/2010 a total of 11 traumatic isolated SSC tendon lesions Lafosse III/IV
172 were included into our prospective consecutive case series. Mean age of the patients was 45 ± 10
173 years (range 32-65), 9 males and 2 females. The dominant shoulder was affected in eight patients
174 (82%). In 5 patients, a forceful external rotation was reported, 3 patients fell on their outstretched
175 arm, and 2 patients suffered from a first episode of a traumatic anterior shoulder displacement. In 1
176 patient, the trauma mechanism could not be clarified.

177
178 Mean interval from trauma to surgery was 3.7 ± 4.7 months (range 0.3-13.3 months). All patients
179 had a full clinical follow-up investigation after 1 year. However, one patient who presented with an
180 excellent clinical outcome, refused MRI due to [agoraphobia/claustrophobia](#). Thus, a complete 1
181 year follow-up including clinical and MRI investigation was performed in 10 patients (90%).

182
183 **Intraoperative findings.** The arthroscopic evaluation of the eleven patients revealed nine type III
184 (82%) and two type IV (18%) SSC lesions. Thus, all patients showed at least complete lesions of
185 the tendon's superior two-thirds with some retraction from intermediate up to the level of the
186 glenoid rim. In three cases, minor PASTA lesions were seen. However, these lesions did not
187 require any surgical treatment due to their small size involving only the innermost part of the deep
188 tendon layer.

189
190 The LHBT was completely dislocated in three patients. Subluxation of the LHBT with the tendon
191 riding on the anterior aspect of the bicipital groove was seen in five cases (45%), whereas two
192 biceps tendons (18%) presented with a pronounced anterior instability due to a lesion to the
193 anterior pulley. A concomitant SLAP lesion was diagnosed in only one patient (9%). In two
194 patients a partial tear < 50% of the biceps tendon was evident (18%). Only one LHBT was
195 considered as normal.

196

197 **Follow-up.** One year postoperatively, nine patients (82%) were back at their previous work. One
198 patient was already retired at the time of the injury and one patient was already disabled due to a
199 cervical spine injury. Six patients reported a full return to their sports activities whereas one patient
200 had to reduce his sports due to some persistent shoulder problems. The remaining four patients
201 had never participated in any sports activities, not even before the injury.

202

203 **Clinical outcome.** The results of the clinical examination are shown in table 1. Preoperatively, all
204 patients were able to perform the belly-press test. However, muscular strength was reduced in all
205 patients compared to the contralateral side. ~~However, the test was considered positive in all-~~
206 ~~patients.~~ Seven patients (64%) presented with a positive lift-off test, in one case a lag sign was
207 evident. Four patients (36%) failed to demonstrate a correct lift-off test preoperatively due to limited
208 internal rotation or pain exacerbation. In contrast, at follow-up all patients correctly performed both
209 tests and a significant improvement of these specific SSC tests regarding strength was found.
210 Compared to the uninjured contralateral side, the mean loss of internal rotation was measured
211 1.5 ± 2.0 points (0-6) in the CMS subscore for internal rotation ($p < 0.05$). External rotation in 0°
212 abduction was $46 \pm 19^\circ$ (20-70 $^\circ$) on the operated side compared to $57 \pm 18^\circ$ (30-85 $^\circ$) on the
213 contralateral uninjured side ($p < 0.05$). Strength of external rotation was similar to the uninjured side.
214 The CMS and all its subscores, such as activities of daily living, pain, range of motion and strength
215 demonstrated a marked improvement at follow-up when compared to the preoperative situation.
216 Nine patients rated their outcome excellent (82%), one patient had a good result and one patient
217 was satisfied.

218

219 **MRI follow-up.** Complete structural integrity of the SSC tendon was seen in all investigated
220 patients ($n=10$). Neither a partial nor a complete re-rupture of the reconstruction was observed.
221 Alterations of the muscular mass and the course of the fatty infiltration of the SSC are shown in
222 table 2. The CSA of the SSP and ISP significantly increased although there was neither a
223 significant lesion found arthroscopically nor were these muscles/tendons involved in any surgery.

224 Interestingly, there was no change in fatty infiltration in these muscles. No failure of the LHBT
225 tenodesis was observed and all the humeral heads were anatomically centered in the glenoid.

226

227 **Discussion**

228

229 Arthroscopic repair of SSC lesion Lafosse III and IV is associated with a good clinical outcome
230 including high patient satisfaction. MRI follow-up at one year demonstrated complete healing of the
231 reconstructed tendon with no re-rupture.

232

233 Burkhart⁵ published the first article describing arthroscopic SSC tendon repair in 2002. Still, the
234 evidence for arthroscopic repair of isolated SSC tears is low. A recent systematic review
235 comparing open and arthroscopic surgical repair of isolated SSC lesions failed to demonstrate a
236 clear advantage for either method^{4,6,18}. However, one must realize that only level IV studies were
237 available for this evaluation. Good pain relief and excellent function may be achieved by open and
238 arthroscopic surgery. Edward et al.³ published the largest series so far describing open repair of
239 isolated SSC tears, either of traumatic origin or due degeneration. Of these, 23 were limited to the
240 superior one-third of the tendon leaving 64 patients with higher-grade lesions.

241

242 Furthermore, there are only a few studies available with a radiological follow-up by either CT
243 arthrography or MRI^{1,7-10,11}. In contrast to other studies, we focused on isolated traumatic SSC
244 lesion with at least moderate tendon retraction.

245

246 **Clinical outcome.** In general, with either open or arthroscopic repair of the SSC lesion good
247 clinical results can be achieved. In accordance with the literature, we observed a significant
248 improvement of the CMS and all its subcategories. CMS achieved after arthroscopic repair of
249 isolated SSC lesion ranges from 74 to 85^{9,10,11}. In our series, CMS after one year was 90. One
250 could hypothesize that this result was achieved due to short interval between trauma and surgery.
251 This view is supported by the observation that a delay in open SSC repair resulted in poorer

252 clinical outcome^{3,4}. In accordance with the CMS, the specific SSC tests such as the modified belly-
253 | press- and the lift-off test also improve significantly after surgery^{1,7-~~10~~11}.

254

255 **LHBT pathologies.** Beside the SSC tendon repair, we also performed an anchor tenodesis in all
256 patients no matter what the underlying pathology was. At follow-up, all tenodeses were intact. In a
257 series with 40 patients with isolated or combined rotator cuff tendon lesions a concomitant
258 pathology of the LHBT was found in 63%⁶. In the largest series investigating open repair of
259 isolated SSC tears, Edwards et al.³ could clearly demonstrate that the performance of either LHBT
260 tenodesis or tenotomy had a beneficial effect on the CMS and the subjective outcome regardless
261 of the preoperative condition of the LHBT. Thus, the authors suggested to perform routine LHBT
262 tenodesis or tenotomy at the time of the SSC repair.

263

264 | **Structural integrity of the SSC tendon repair.** In a human cadaver study Wellmann et al.^{~~17~~19}
265 compared single-row repair with a double row repair using a “suture bridge technique” as well. The
266 double-row technique restored 48% of the ultimate load of an intact tendon, whereas a single-row
267 repair failed significantly earlier at 34%. At one-year follow-up, all SSC tendon repairs of our study
268 group were intact as no re-rupture was evident on MRI one year postoperatively. We routinely
269 performed a “pseudo double-row” repair for Lafosse III tears. A double-row repair with suture
270 bridges was used for more retracted IV lesions. According to the current literature re-rupture rates
271 | range from 5-14%^{1,7,~~8-9~~1011}. In all these studies either CT arthrography or MRI studied structural
272 integrity at follow-up 20-~~36~~57 months postoperatively. In the largest published study so far,
273 Toussaint et al.^{~~9~~10} could evaluate 129 patients with either isolated lesions or in combination with
274 SSP tears with a radiological follow-up of at least 6 months. Re-rupture rate in this large series was
275 8%.

276

277 **Alterations of the SSC muscle.** Although MR evaluation demonstrated a significant decrease in
278 fatty SSC muscle infiltration and an increase of muscular mass at follow-up compared to the
279 preoperative images, the interpretation of these findings may be controversial. Our observations

280 | are in contrast to the results of some other studies found in the recent literature ^{9-10,11} which all
281 | reported a progression of fatty infiltration despite successful surgery. Interestingly, no correlation
282 | with clinical outcome was found. Only Bartl et al. ⁷ and Lafosse ¹ did not observe a progression of
283 | fatty infiltration. However, interval between trauma/onset of symptoms and surgery ranged from 5.8
284 | months ⁷ up to 35.7 months ^{10,11} in these studies. One could hypothesize that in our study, the SSC
285 | muscle improved in quantity (mass) and quality (less fatty infiltration) due to the fact that the mean
286 | interval from trauma to surgery was only 3.7 months and thus considerably shorter than in most
287 | other studies ^{1, 5, 7, 8, 10,11}. Interestingly, fatty degeneration was already evident on the preoperative
288 | images of our study group despite the short interval between trauma and diagnostic work-up. One
289 | could hypothesize that fatty degeneration may occur earlier and develop quicker in traumatic
290 | lesions than in degenerative SSC tears. However, to our knowledge, there is no scientific data
291 | available to support this clinical observation.

292 |
293 | Our findings may indicate that muscular changes of the SSC are reversible if the tendon is
294 | reattached shortly after trauma. However, the significance of fatty degeneration and muscle
295 | wasting is still unclear. In their multicentre study, Toussaint et al. ⁹⁻¹⁰ reported no adverse clinical
296 | effects despite marked muscle alterations. Furthermore, the comparison of the muscle mass and
297 | fatty degeneration pre- and postoperatively may be hazardous since the noted differences could
298 | also be attributed to a pure volumetric distortion once a retracted muscle is reattached. Moreover,
299 | preoperative MRI was contrast-enhanced, the follow-up MRI was not. This fact may have impaired
300 | the accuracy of our measurements. This view is supported by the fact that we also observed an
301 | increase of the CSA for the SSP and ISP although they were neither injured nor involved in any
302 | surgery. However, fatty infiltration was decreased in the SSC at follow-up whereas it remained
303 | unchanged in the other two studied muscles. In a recent study Jo et al. ^{18,20} compared
304 | preoperative MRI investigations to MRI studies obtained 3 days following surgery. In a first study, a
305 | significant increase of the CSA of the SSC was demonstrated despite no surgical cuff repair was
306 | performed in these patients. No conclusive reason for this finding was given by the authors. Thus,
307 | the CSA of the SSC was excluded from further evaluations. However, no difference was seen

308 regarding fatty infiltration of the SSC and no difference was found in the SSP and ISP regarding
309 both parameters. In a second study, patients with arthroscopic rotator cuff repair were evaluated.
310 Interestingly, rotator cuff repair significantly increased the CSA of the SSP by as much as 45% for
311 massive tears. The decrease of the fatty infiltration was significant as well, but only for the SSP
312 and ISP whereas no significant change was found for the SSC. To overcome this potential bias, the
313 authors suggested that images should also be obtained immediately after the surgical procedure
314 and compared with long-term follow-up for a true assessment of muscular alterations rather than
315 being compared with preoperative images.

316

317 **Limitations of the current study**

318

319 With ten patients available for a complete follow-up and one patient with a clinical follow-up only,
320 the sample size of this case series is small and the study design lacks a comparative control
321 group. We studied only complete isolated SSC tears (Lafosse III and IV) which are usually
322 considerably retracted. Since we did not include minor lesions such as Lafosse I and II, our results
323 are not falsely improved by the inclusion of clinically less significant tears. Furthermore,
324 anterosuperior tears and mass lesions of the rotator cuff were not included.

325

326 In the largest study published so far a total of 208 SSC tears, either isolated or associated with a
327 limited anterosuperior lesion, were analyzed^{9,10}. Of these, only 35 patients with isolated or “very
328 predominant” subscapularis lesions were available for follow-up. Heikenfeld et al.⁸ published a
329 case series with 20 patients. However, they also included 10 Lafosse II lesions. Other authors
330 published case series with similar sample sizes ranging from 7 to 17 patients when only tears
331 equivalent to Lafosse III and IV lesions were counted^{1,7,11+9}. In a recently published study, 46
332 patients with arthroscopic repair of only large SSC lesions (Lafosse III-IV) were investigated⁹.
333 However, only 6 SSC tears were isolated, either traumatic or of degenerative nature.

334

335 Furthermore, a thorough comparison between different studies may be compromised to different
336 inclusion criteria, the variety of different classification systems to grade SSC lesions, the measured
337 outcome parameters, the duration of follow-up and the low evidence (Level IV) of the available
338 literature ¹⁶¹⁸.

339

340 Conclusions

341

342 Arthroscopic repair of higher grade isolated SSC lesions provides reliable tendon healing
343 accompanied by excellent functional results one year after surgery. ~~In our series we observed~~
344 ~~significant decrease in fatty SSC muscle infiltration and an increase of muscular mass.~~

345

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347

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- 402 |
- 403 |

404 **Legends**

405

406 **Figure 1.** Lesion of the subscapularis tendon (SSC) Type Lafosse III (right shoulder). **A.** Lesion
 407 before repair (view through the posterior A portal). **B.** Subscapularis tendon with applied traction
 408 suture for better mobilization and reduction (view through the anterolateral D portal). SGHL,
 409 superior gelnohumeral ligament. HH, humeral head.

410

411 **Figure 2.** Visualisation and identification of the axillary nerve (AN) during mobilization of the
 412 subscapularis muscle (right shoulder, view through the anterolateral D portal).

413

414 **Figure 3.** Left shoulder, view through the dorsal A portal. Situation with applied anchors and
 415 sutures before final reduction and knot tying. The reconstruction is performed using U-stitches and
 416 a single lasso-loop stitch (*)-(black arrow) at the upper border of the subscapularis tendon (SSC).
 417 For better orientation violet and blue different colored strands are used. The traction suture (green-
 418 strand, **)white arrow) is removed before completion of the reconstruction.

419

420 **Figure 4. A.** Axial preoperative MR arthrography slice demonstrating lesion of the subscapularis
 421 tendon (*)-(SSC, white arrow) with anterior dislocation of the long head of biceps tendon (**)- (black
 422 arrow). **B.** Corresponding follow-up MR slice showing full structural integrity of the subscapularis
 423 repair (white arrow) -(#) and tenodesis of the long head of biceps tendon (\$)-(black arrow).

424

425 **Figure 5. A.** Preoperative axial MR slice with fatty infiltration of the subscapularis muscle (white
 426 arrow) -(*). **B.** The corresponding MR slice at one year follow-up shows a marked reduction of the
 427 fatty infiltration. SSC, subscapularis muscle; SSP, supraspinatus muscle; ISP, infraspinatus
 428 muscle. (**).

429

Table I Clinical Results

	Preoperative	1 year follow-up	P value
Modified belly-press test (strength, max 5 points)	2.9±0.3 (2-3)	4.8±0.6 (3-5)	< 0.05
Modified lift-off test (strength, max 5 points)	2.9±0.4 (2-3)	4.8±0.6 (3-5)	< 0.05
Internal rotation (strength, max 5 points)	3.1±1.6 (0-6)	7.8±2.6 (2-10)	< 0.05
CMS total (max 100 points)	43.5±21.3 (16-80)	89.3±15.0 (51-100)	< 0.001
CMS ADL (max. 20 points)	8.2±4.8 (2-18)	18.4±3.1 (10-20)	< 0.05
CMS Pain (max 15 points)	4.6±4.2 (0-10)	13.2±3.8 (5-15)	< 0.05
CMS ROM (max 40 points)	22.7±7.2 (12-32)	36.0±5.4 (22-40)	< 0.05
CMS Strength (max 25 points)	8.0±7.0 (0-20)	21.7±5.3 (10-25)	< 0.05

430

431 CMS, Constant-Murley score; ADL, activities of daily living; ROM, range of motion; Data given as

432 mean with standard deviation, the range is provided in brackets.

433

Table II MRI evaluation: Fatty infiltration and CSA of the rotator cuff muscles

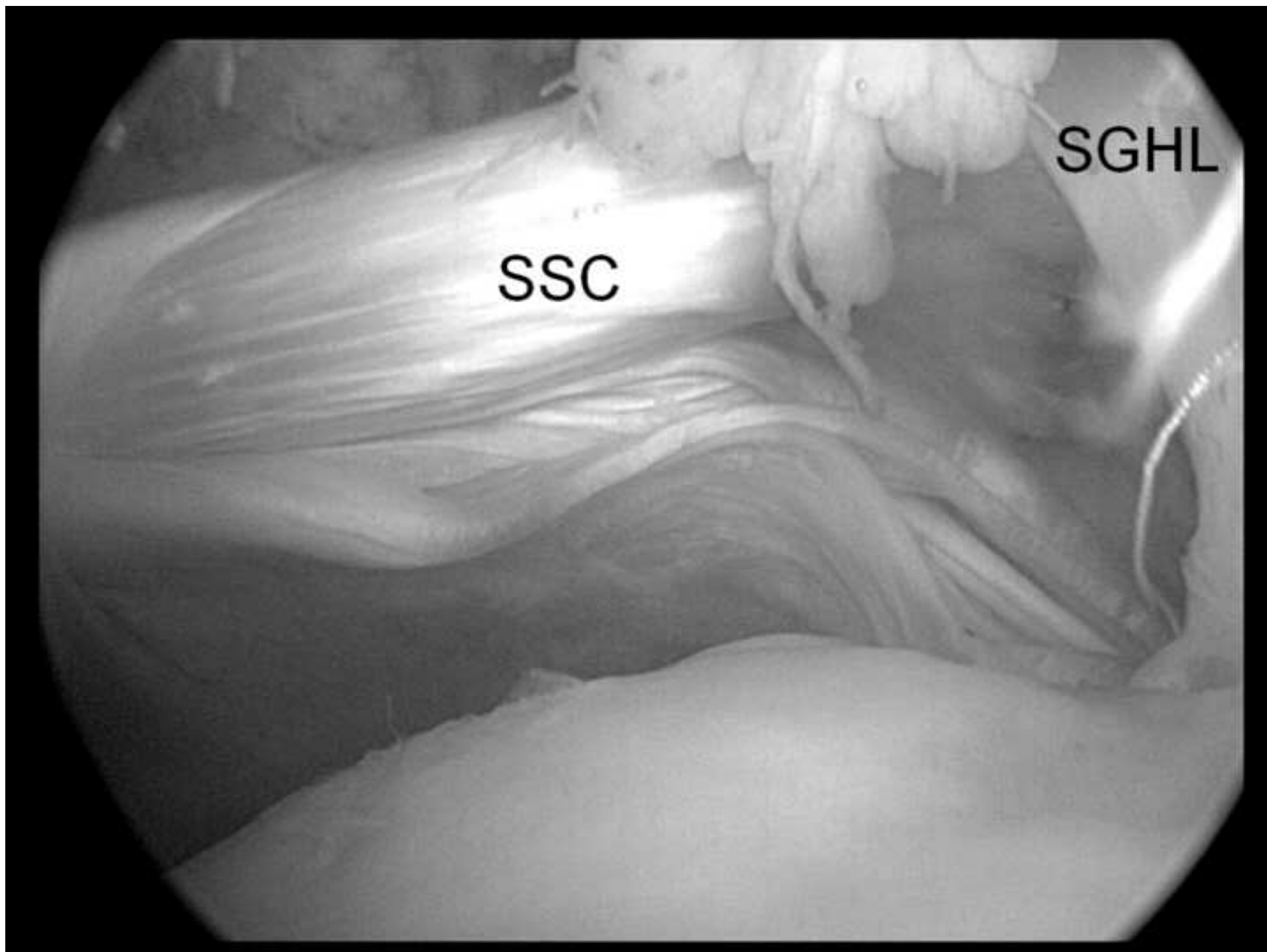
	Preoperative	1 year follow-up	P value
Fatty infiltration of SSC	1.7 (0-3)	0.7 (0-2)	< 0.05
CSA SSC (mm ²)	1491 (900-2120)	2158 (1370-3080)	< 0.001
Fatty infiltration of SSP	0.4 (0-2)	0.2 (0-2)	n.s.
CSA SSP (mm ²)	682 (350-940)	865 (480-1060)	< 0.001
Fatty infiltration of ISP	0.3 (0-2)	0.3 (0-2)	n.s.
CSA ISP (mm ²)	1441 (990-1830)	1716 (1020-2300)	< 0.001

434

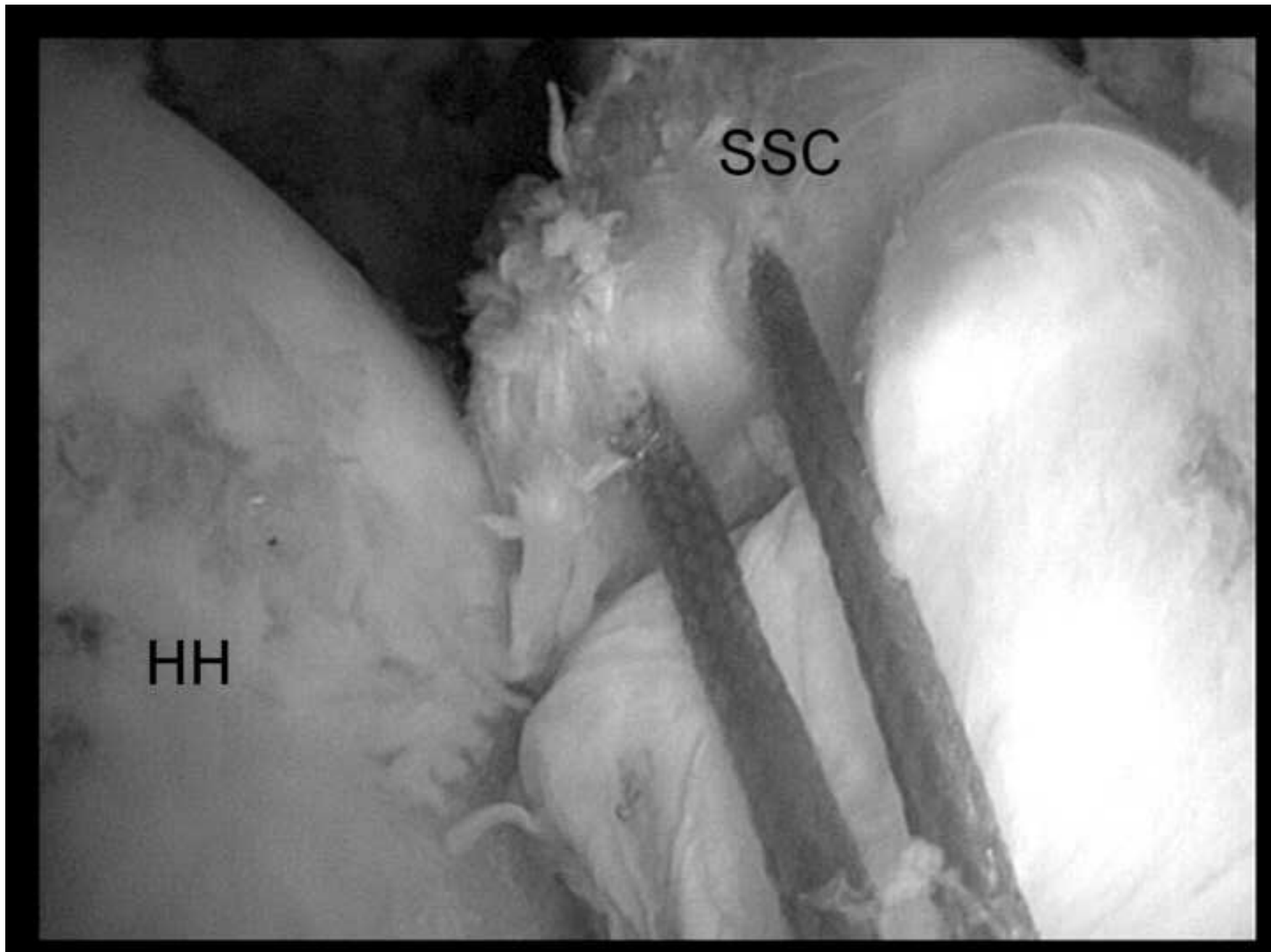
435 | Fatty infiltration of the SSC was graded according to Goutallier ¹³¹⁴, modified by Fuchs ¹⁴¹⁵. The
436 | cross-sectional area of the SSC was measured according to the method proposed by Zanetti et al.

437 | ¹⁵¹⁶. SSC, subscapularis muscle; SSP, supraspinatus muscle; ISP, infraspinatus muscle; CSA,
438 | cross sectional area; data given as mean with range in brackets

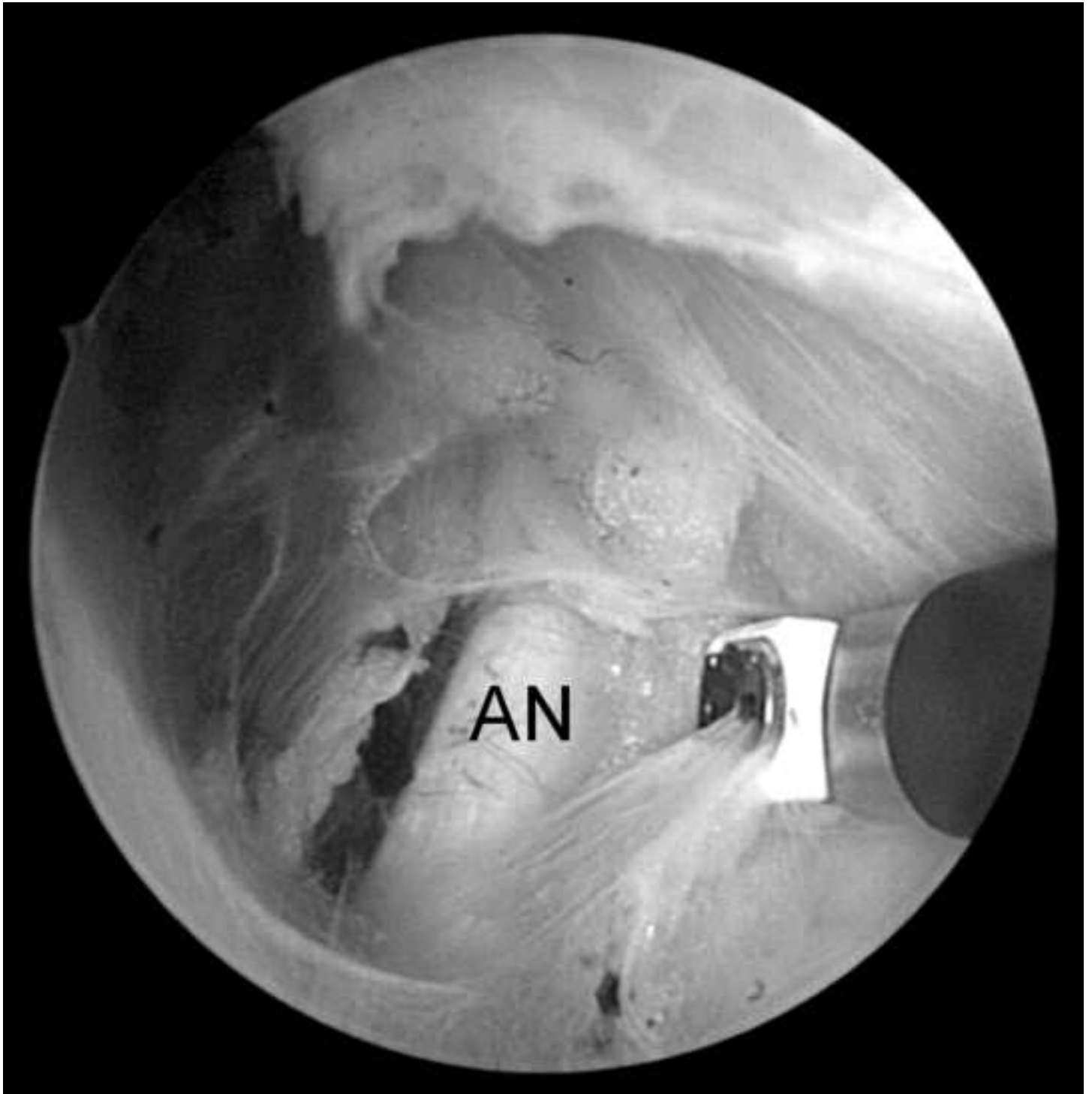
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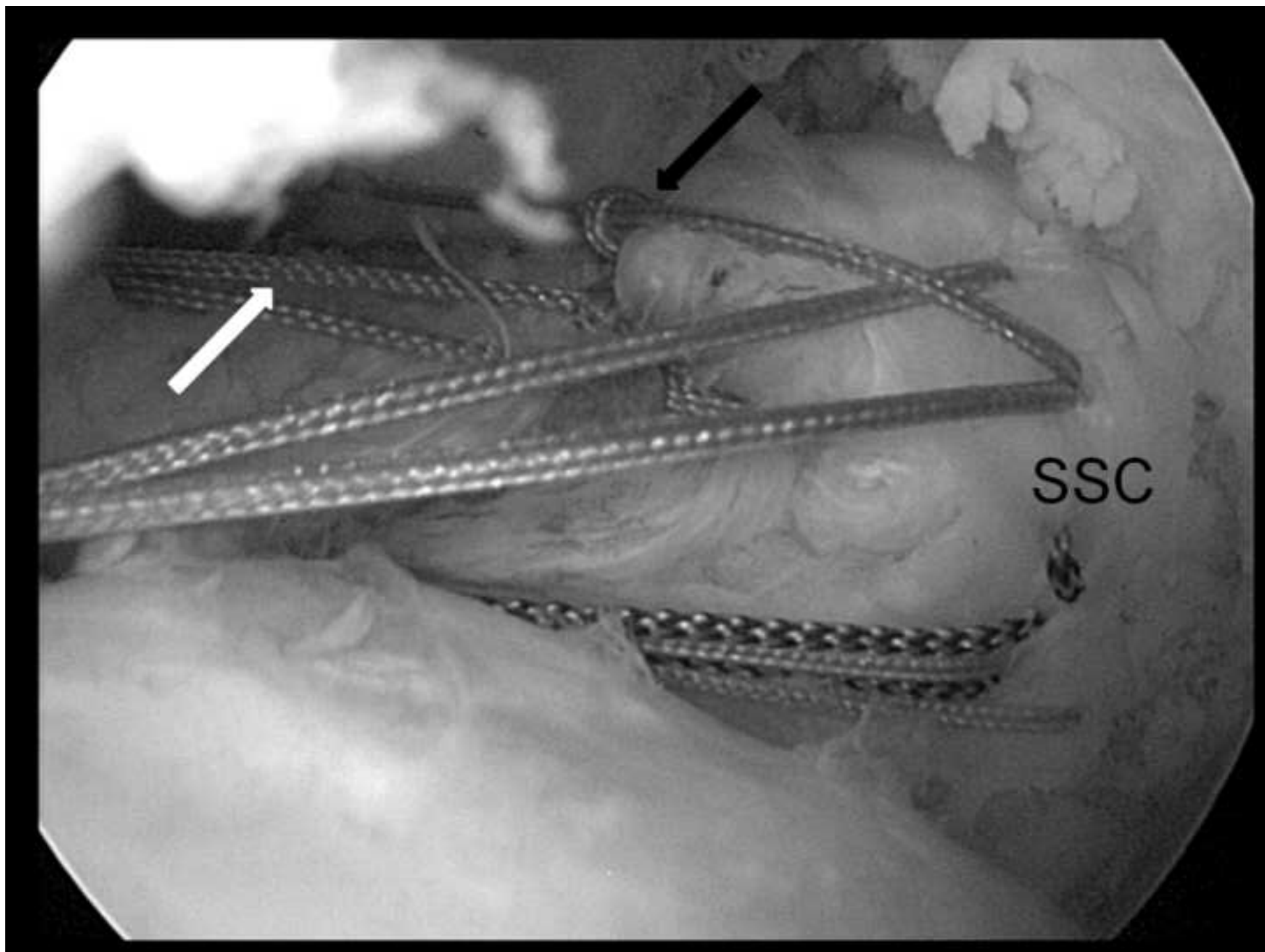
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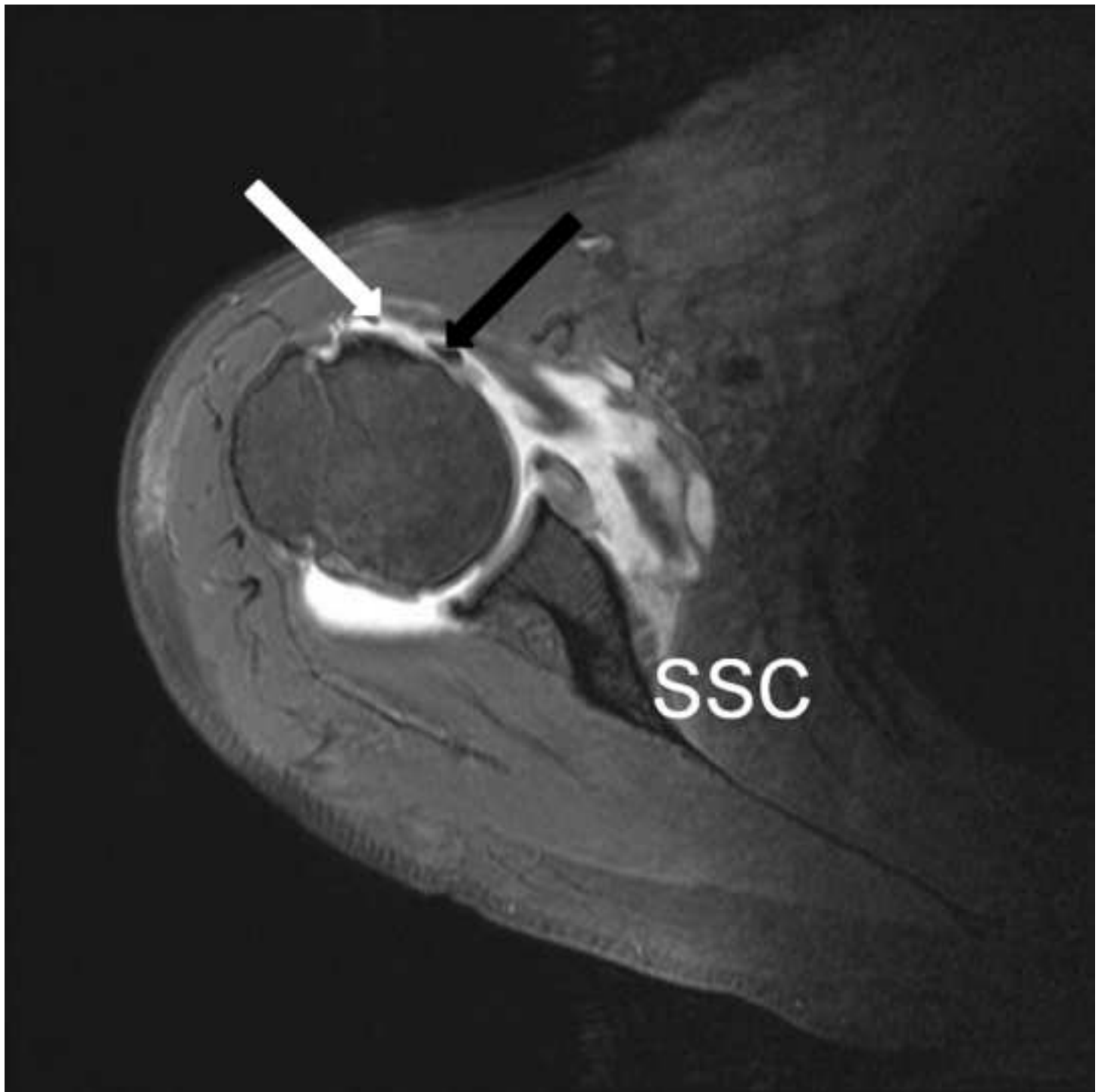


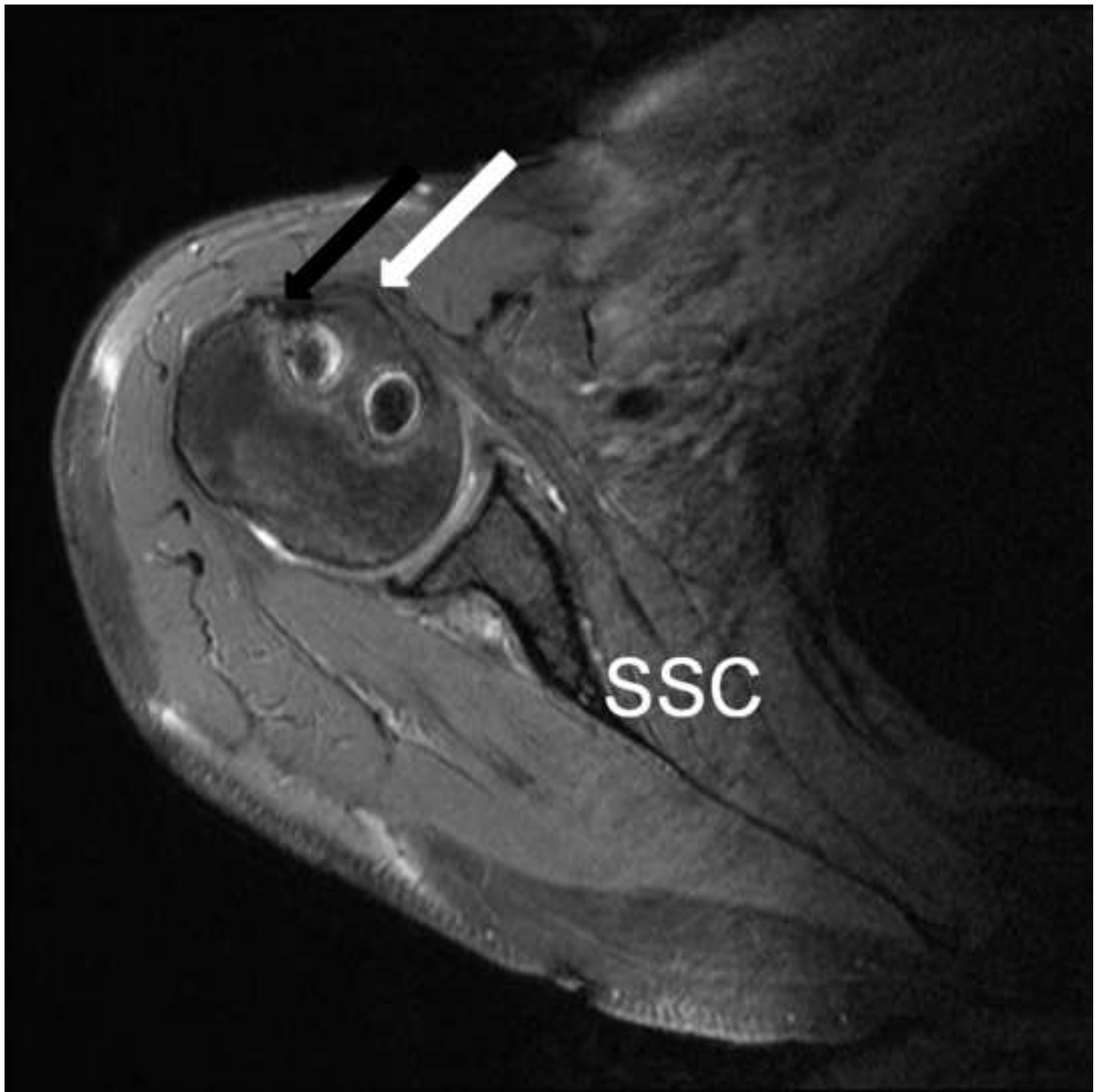
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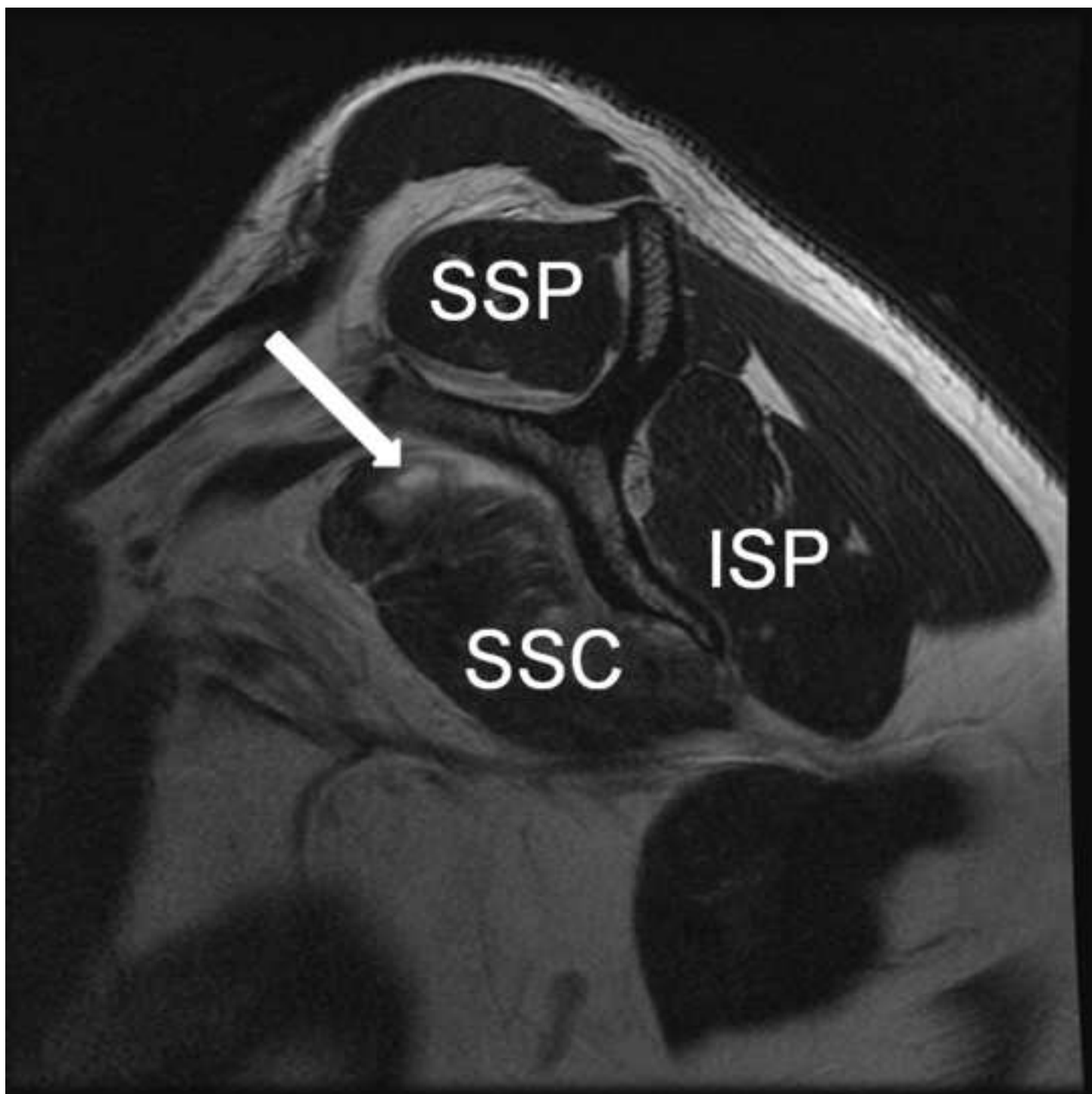


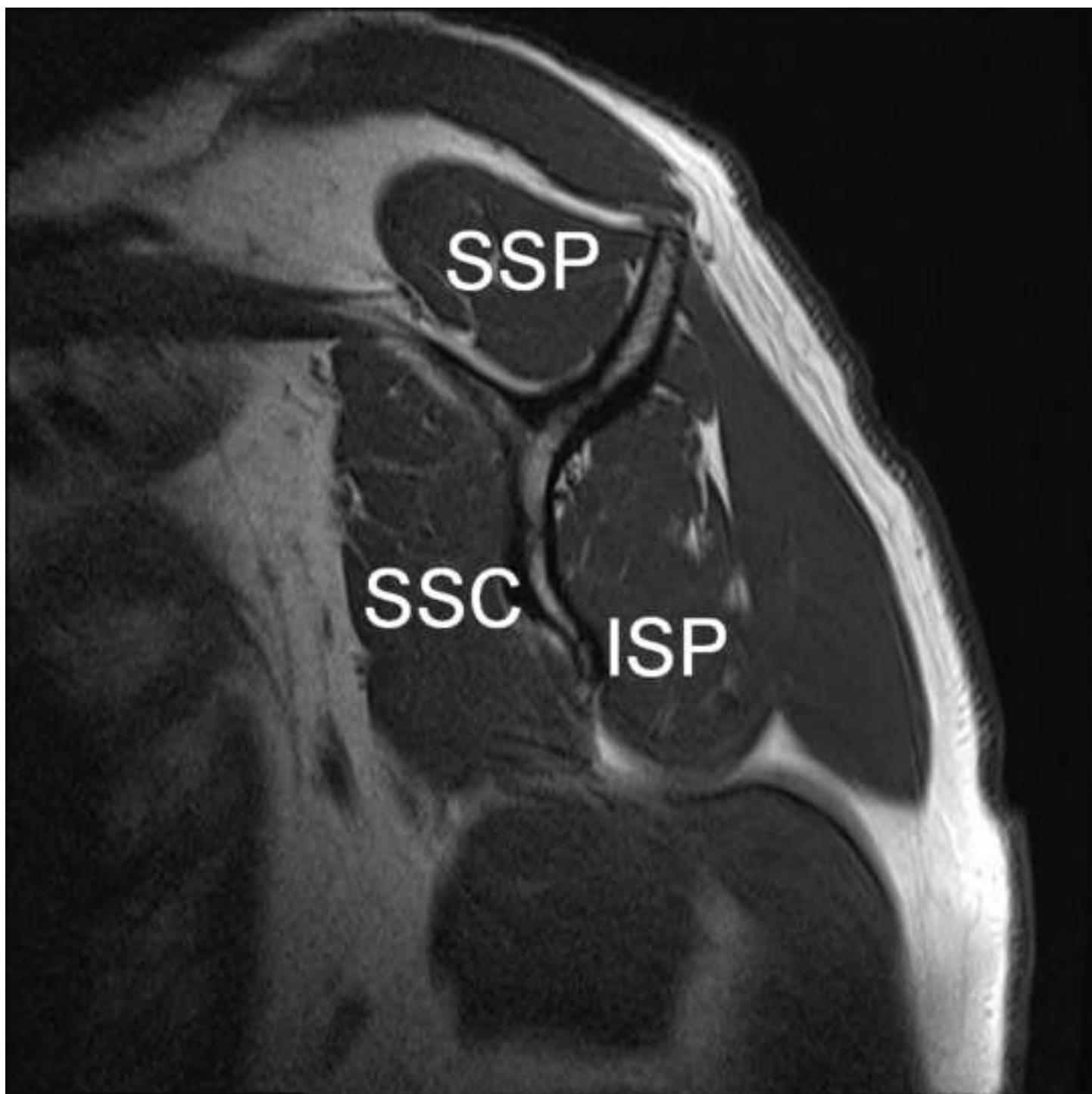
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To
Mr. G.G. Poehling, MD
Editor-in-Chief Intensive Arthroscopy
CompRehab Plaza
131 Miller Street
Winston-Salem, NC 27103
USA

January 16, 2014

Dear Sir

Please find enclosed our revised version of the manuscript

“Arthroscopic repair of traumatic isolated subscapularis tendon lesions Lafosse III-IV: a prospective MRI-controlled case series with one year follow-up”

Ref.: ARTH-13-784

by Patrick Grueninger et al.

which we like to resubmit for publication in *Arthroscopy: The Journal of Arthroscopic and Related Surgery*

We have appreciated the fair and constructive criticisms of the reviewers. In the following, please find our point-by-point reply to the reviewer's comments. Page and line numbers of changes made refer to the revised version of the manuscript to facilitate reading.

Associate Editor's Comments:

Authors, you should be commended on the quality of your scientific work. Your study has strict inclusion criteria with a well defined patient group. Your outcome measures are chosen appropriately and you have included imaging follow-up. However, the main limitation to your study is that the information is not new, and has been presented in the literature before, most recently by Lafosse in JBJS. With the small patient group you have reported on, there is no new information that is presented for the reader. The impact to clinical practice is limited.

Response: Thank you very much for your comment. We fully agree with your points and we are fully aware of our work's limitations. To overcome some of them, we have applied very strict inclusion criteria to enhance the scientific information provided by our study. In contrast to the study by Lafosse et al. (1), published in 2007, we have only included traumatic SSC lesions Lafosse III-IV. Non-traumatic lesions and low-grade lesions (I-II) were excluded.

The most recent study was published in *Arthroscopy* by L. Lafosse and his group in September 2013 (2). We were not aware of this publication when our manuscript was submitted. Thus, we have included this reference in our revised version of the manuscript. Accordingly, the following sentences were inserted into the *Discussion* section (see lines 349-351 in the revised manuscript). Furthermore, the references were adapted, accordingly.

1. Lafosse L, Jost B, Reiland Y, Audebert S, Toussaint B, Gobezie R. Structural integrity and clinical outcomes after arthroscopic repair of isolated subscapularis tears. *J Bone Joint Surg Am* 2007; 89: 1184-1193.

2. Lanz U, Fullick R, Bongiorno V, Saintmard B, Campens C, Lafosse L. Arthroscopic large subscapularis tendon tears: 2- to 4-year clinical and radiographic outcomes. *Arthroscopy* 2103; 29(9): 1471-1478.

Reviewer #1:

Comment 1: The introduction is well written and concisely states the purpose of the study. The authors point out the paucity of information on this subject in the literature. Line 36 "rare" should be replaced by "less common".

Response: The term "rare" is replaced by "less common" (see line 40 in the revised version of the manuscript).

Comment 2: The Methods are well described and do answer the central question. One criticism is the inclusion of determining reversal of fatty infiltration. If these are indeed acute traumatic events then there should be little if any fatty infiltration in the mean average of 3.7 months from injury to surgery. This should be eliminated.

Response: Thank you for this important comment. All our study patients sustained a trauma and there is no history of previous shoulder pain or impaired function. However, we do not know why some MR studies demonstrated fatty infiltration of the SSC so early after trauma. One could speculate that fatty degeneration may develop earlier in patients with large traumatic lesions than in cases with chronic degeneration. Furthermore, this fatty infiltration may be reversed when tendon repair is performed early enough. This view is derived from our clinical experience. However, this is pure speculation and to our knowledge there is no scientific data available neither to support nor to contradict this hypothesis. Nevertheless, our MR images were thoroughly analyzed and the occurrence of fatty infiltration was already evident on the preoperative MR images. Furthermore, statistically significant decrease of fatty degeneration was found at follow-up indicating that this process may be reversible. Thus, we do not think this data/information should be eliminated. However, we have included this important aspect in the *Discussion* section (see lines 305-309 in the revised manuscript).

Comment 3: All references to specific anchors and manufacturers should be replaced by "threaded suture anchors" since this paper is about success of surgery not testing specific anchors.

Response: These terms were corrected accordingly throughout the revised version of the manuscript (see line 113 and 117).

Comment 4: Muscle strength was grade from 0 to 5 according to the classification of neurological assessment. This is too subjective for inclusion in this study. Were the pre and post-op examinations performed by the same person?

Response: The clinical examinations were all performed by the first author (see line 139 in the revised manuscript) with exactly the same technique and muscular strength was compared with the uninjured contralateral shoulder. We absolutely agree with the reviewer's view that the classification of neurological assessment has its limitations regarding an accurate assessment of muscle strength. It would have been more accurate and objective to use a spring gauge. However, this grading system has also been used by other investigators for similar purposes such as Lafosse (2). Others (3) only graded between negative, asymmetric and positive. Thus, we considered the classification of neurological assessment appropriate when the current study was designed. We will certainly consider another measuring method for future research projects.

2. Lafosse L, Jost B, Reiland Y, Audebert S, Toussaint B, Gobezie R. Structural integrity and clinical outcomes after arthroscopic repair of isolated subscapularis tears. *J Bone Joint Surg Am* 2007; 89: 1184-1193.

3. Nové-Josserand L, Hardy M-B, Ogassawara RLN, Carrillion Y, Godenèche A. Clinical and structural results of arthroscopic repair of isolated subscapularis tear. *J Bone Joint Surg Am* 2012; 94: e125 (1-7)

Comment 5: Why were "routine acromioplasties" performed? Were coracoplasties performed?

Response: An acromioplasty was performed in all patients as a matter of routine. All our patients undergoing therapeutic shoulder arthroscopy receive subacromial debridement and an acromioplasty at the end of the procedure. However, in asymptomatic patients without a spur, we perform a very limited instead of a formal acromioplasty as it was the case in this study group (see lines 119-120 in the revised version of the manuscript). We did not perform any coracoplasties in this study group as we did not see any coracoid spurs or signs of impingement. None of our patients presented with a type V SSC tears (Lafosse classification) which would be associated with an eccentric head causing coracoid impingement. This aspect is now included in the revised version of the manuscript (see lines 118-119).

Comment 6: Was the radiologist MSK fellowship trained or a generalist? Did the same radiologist evaluate the pre and post-op studies?

Response: All pre- and postoperative MR studies were evaluated by the same radiologist who indeed is experienced and properly trained in musculoskeletal imaging techniques. He has repeatedly attended specialty courses for MSK radiology. This information was added in the revised version of the manuscript (see lines 174-175).

Comment 7: Pre-op MRIs were performed with intraarticular gadolinium whereas the post-op studies were performed without contrast. The authors need to address this discrepancy and how it skews to results.

Response: Preoperatively, all patients underwent MRA as the standard radiologic investigation technique for patients with suspected injury to the rotator cuff or SLAP lesions at our institution.

Our patients did all well accept arthrography to investigate their injured shoulder for a proper diagnosis and the planning of the following therapeutic steps. Since the number of our study group is quite small, we strongly depended on a complete or at least near complete follow-up of our patients. Acceptance of an invasive technique for pure scientific reasons without direct benefit to the patient may be low and may also be discussed controversially by ethical aspects. Furthermore, the superiority of MRA for evaluating structural integrity of SSC repair is not proven (4). Thus, only MR imaging was performed at follow-up. All SSC lesions were arthroscopically graded, not by MRA. Fatty infiltration and the cross-sectional area of the SSC were evaluated by MRA preoperatively and MRI at follow-up, respectively. However, the application of intra-articular gadolinium does not change the appearance of the muscles such as the SSC on the images and direct comparison may be eligible. This information including the reference (4) is now given in the revised version of the manuscript (see lines 168-173).

4. Duc SR, Mengiardi CWA, Jost B, Hodler J, Zanetti M. Diagnostic performance of MR arthrography after rotator cuff repair. *AJR* 2006; 186: 237-241.

Comment 8: The authors need to explain their statement "However, the test [belly press] was considered positive in all patients" and how this correlates to excellent results.

Response: All patients were able to perform the belly-press test. However, muscular strength was impaired in all patients as well. This is also shown in table 1. The sentence "However, the test was considered positive in all patients" is not correct. We apologize for this misleading expression. Our patients could perform the belly-press but not with the same strength as on the contralateral side. This mix-up is now corrected in the revised version of the manuscript (see lines 119-121).

Comment 9: The first part of the conclusion statement is supported by the evidence. The second part is clearly not supported and should be eliminated.

Response: We agree with the reviewer's opinion. Thus, the second part of the Conclusion was eliminated in the *Conclusion* section and the *Abstract* as well (see lines 32 and 360).

Comment 10: I concur this is a Therapeutic Level IV study.

Response: Yes. This information is given in the abstract (see line 32). Does it need to be mentioned anywhere else in the paper?

Comment 11: The title is adequate although not completely descriptive.

Response: The title was left unchanged.

Comment 12: The operative photos are identified in the legends but would be more readable if the photos themselves were labeled. Color photos are not necessary for publication. The MRI images should also be labeled.

Response: All color photos have been converted to black and white images in the revised version of the manuscript. Furthermore, all images were labelled and the legends adapted

accordingly (see lines 424-445 in the revised version of the manuscript and all revised figures (Fig 1A – 5B)).

Reviewer #2:

Comment 1: Line 38: Delete over the last years.

Response: This term is eliminated in the revised version of the manuscript (see line 42).

Comment 2: Line 45: outcomes.

Response: This typo is corrected (see line 49).

Comment 3: Line 60: Was this case series done retrospectively or prospectively?

Response: It is a prospective case series. This is now mentioned in the *Methods* section of the manuscript (see line 69).

Comment 4: Line 170: Claustrophobia?

Response: The reviewer is right, of course. We apologize for this embarrassing mix-up: “agoraphobia” was changed to “claustrophobia” (see line 195 in the revised version of the manuscript).

Comment 5: The title is too long in my opinion.

Response: We have considered a shorter title. However, we feel, that the original title quite accurately describes what the study is all about. With a shorter title some of this information would be lost and a mix-up with other studies such as the one mentioned below (1) would be more likely.

1. Lanz U, Fullick R, Bongiorno V, Saintmard B, Campens C, Lafosse L. Arthroscopic large subscapularis tendon tears: 2- to 4-year clinical and radiographic outcomes. *Arthroscopy* 21(9): 1471-1478.

Overall, the authors feel that the quality of the manuscript has markedly improved due to the changes made according to the suggestions of the reviewers, and we would be happy if it now meets the criteria for publication in *Arthroscopy: The Journal of Arthroscopic and Related Surgery*.

Sincerely yours

Patrick Grueninger
Christoph Meier

Arthroscopy: The Journal of Arthroscopic and Related Surgery

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Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

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 5. Manuscript Title Arthroscopic repair of traumatic isolated subscapularis tendon lesions Lafosse III-IV: a prospective MRI-controlled case series with one year follow-up
-

Section 2. The Work Under Consideration for Publication

Did you or your institution at any time receive payment or services from a third party for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc...)? No

Complete each item by typing an X in answer yes or not and completing the information requested if an answer is Yes. If you have more than one relationship, add lines.

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Comments† ___

5. Payment for writing or reviewing the manuscript

No ___ Yes, money paid to you ___ Yes, money paid to institution* Name of entity ___
Comments† ___

6. Provision of writing assistance, medicines, equipment, or administrative support

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1. Board membership

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

2. Consultancy

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13. Other (err on the side of full disclosure)

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name Joerg 2. Surname Schneider
3. Are you the corresponding author? Yes ___ No
4. Effective Date 5/11/13
5. Manuscript Title Arthroscopic repair of traumatic isolated subscapularis tendon lesions Lafosse III-IV: a prospective MRI-controlled case series with one year follow-up
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No ___ Yes, money paid to you ___ Yes, money paid to institution* Name of entity ___ Comments † ___

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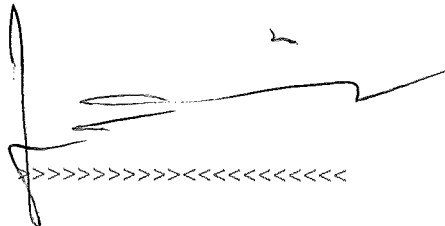
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Section 4. Other relationships

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

No other relationships/conditions/circumstances that present a potential conflict of interest

Yes, the following relationships/conditions/circumstances are present (explain below):

A handwritten signature in black ink, consisting of a vertical line on the left and a horizontal line extending to the right with a small flourish at the end. Below the signature is a horizontal line of small, repeating chevron-like symbols.

The International Committee of Medical Journal Editors

The ICMJE Disclosure of Potential Conflicts of Interest Form was adopted by *Arthroscopy: The Journal of Arthroscopic and Related Surgery* along with 17 other leading orthopaedic journals at the 2011 annual meeting of the American Academy of Orthopaedic Surgeons.

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1. Given Name Andreas_ 2. Surname Platz
 3. Are you the corresponding author? Yes No X
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 3. Are you the corresponding author? Yes No X
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8. Patents (planned, pending or issued)

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ICMJE Form for Disclosure of Potential Conflicts of Interest

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1. Given Name Christoph_ 2. Surname Meier
 3. Are you the corresponding author? Yes ___ No X
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No Yes, money paid to you Yes, money paid to institution* Name of entity____ Comments____

12. Travel/accommodations/ meeting expenses unrelated to activities listed**

No Yes, money paid to you Yes, money paid to institution* Name of entity____ Comments____

13. Other (err on the side of full disclosure)

No Yes, money paid to you Yes, money paid to institution* Name of entity____ Comments____

Arthroscopy: The Journal of Arthroscopic and Related Surgery

— Instructions —

ICMJE Form for Disclosure of Potential Conflicts of Interest

Each author of the manuscript must separately complete and save this form using his or her name in the file name. Each author's completed form must then be uploaded with the manuscript.

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is in four parts:

Section 1. Identifying information

Enter your full name and provide the manuscript title.

Section 2. The work under consideration for publication

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party — that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation, or commercial sponsor, check "Yes." Then complete the provide the information requested.

Section 3. Relevant financial activities outside the submitted work

This section asks about your financial relationships with entities in the biomedical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as entities or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations, or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

Section 4. Other relationships

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name Patrick_ 2. Surname Grueninger
 3. Are you the corresponding author? Yes X No
 4. Effective Date 04 November 2013
 5. Manuscript Title Arthroscopic repair of traumatic isolated subscapularis tendon lesions Lafosse III-IV: a prospective MRI-controlled case series with one year follow-up
-

Section 2. The Work Under Consideration for Publication

Did you or your institution at any time receive payment or services from a third party for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc...)? No

Complete each item by typing an X in answer yes or not and completing the information requested if an answer is Yes. If you have more than one relationship, add lines.

1. Grant

No Yes, money paid to you Yes, money paid to institution* Name of entity____
Comments†____

2. Consulting fee or honorarium

No Yes, money paid to you Yes, money paid to institution* Name of entity____
Comments†____

3. Support for travel to meetings for the study or other purposes

No Yes, money paid to you Yes, money paid to institution* Name of entity____
Comments†____

4. Fees for participation in review activities such as data monitoring boards, statistical analysis, end-point committees, and the like

No Yes, money paid to you Yes, money paid to institution* Name of entity____
Comments†____

5. Payment for writing or reviewing the manuscript

No Yes, money paid to you Yes, money paid to institution* Name of entity____
Comments†____

6. Provision of writing assistance, medicines, equipment, or administrative support

No Yes, money paid to you Yes, money paid to institution* Name of entity____
Comments†____

7. Other

No Yes, money paid to you Yes, money paid to institution* Name of entity____
Comments†____

* This means money that your institution received for your efforts on this study.

† Use this section to provide any needed explanation.

Section 3. Relevant financial activities outside the submitted work

1. Board membership

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

2. Consultancy

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

3. Employment

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments I'm currently employed at the University Hospital Basel, Section Vascular Surgery.

4. Expert testimony

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

5. Grants/grants pending

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

6. Payment for lectures including service on speakers bureaus

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

7. Payment for manuscript preparation

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

8. Patents (planned, pending or issued)

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

9. Royalties

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

10. Payment for development of educational presentations

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

11. Stock/stock options

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

12. Travel/accommodations/ meeting expenses unrelated to activities listed**

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

13. Other (err on the side of full disclosure)

No Yes, money paid to you Yes, money paid to institution* Name of entity___ Comments___

** For example, if you report a consultancy above there is no need to report travel related to that consultancy on this line.

