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FMUP FACULDADE DE MEDICINA
UNIVERSIDADE DO PORTO

MESTRADO INTEGRADO EM MEDICINA

2016/2017

Rosana Pereira Dias

Acromioplastia artroscópica: análise

imagiológica por ressonância

magnética de modificações na

morfologia acromial

Arthroscopic acromioplasty:

magnetic resonance imaging

analysis of modifications in acromial

morphology

março, 2017

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Mestrado Integrado em Medicina

Área: Ortopedia

Tipologia: Dissertação

Trabalho efetuado sob a Orientação de:

Prof. Doutor João Manuel Costa Ferreira Torres

Trabalho organizado de acordo com as normas da revista:

Journal of Shoulder and Elbow Surgery

março, 2017

FMUP

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DESIGNAÇÃO DA ÁREA DO PROJECTO

Ortopedia

TÍTULO DISSERTAÇÃO/MONOGRAFIA (riscar o que não interessa)

Arthroscopic acromioplasty: magnetic resonance imaging analysis of modifications in acromial morphology

ORIENTADOR

Doutor João Manuel Costa Ferreira Torres

COORIENTADOR (se aplicável)

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Rosana Pereira Dias

Para os meus pais, o meu porto seguro.

Para o João, o amor da minha vida.

MRI analysis of acromial morphology after acromioplasty

Arthroscopic acromioplasty: magnetic resonance imaging analysis of modifications in acromial morphology

MRI analysis of acromial morphology after acromioplasty

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Illustrations: must be published in color.

Disclaimer: None financial biases exist for any author.

Compliance with ethical standards: The authors of this article declare that there is no conflict of interest regarding this investigation. Besides, this paper does not contain any studies with human participants or animals performed by any of the authors. Therefore, informed consent from patients was not necessary, since this was a retrospective study, in which patient personal data were not used e/or accessed in any way. This investigation was conducted after obtaining approval from Ethical Committee at our institution (Hospital Lusíadas Porto, Porto, Portugal).

Acknowledgment: The authors of this investigation give a special thanks to Dr. Francisca Saraiva for statistical analysis and for assistance in preparing this manuscript.

1 **Abstract**

2

3 Background: Acromioplasty is a simple and routinely performed technique with controversial
4 indications and therapeutic value. No published article had determined the structural outcome
5 of the acromion after acromioplasty. Therefore, the aim of this study is to assess in which extent
6 does arthroscopic acromioplasty induces modifications in acromial morphology, using
7 preoperative and postoperative magnetic resonance imaging (MRI's).

8 Methods: The authors conducted a retrospective cross-sectional study, which enrolled patients
9 referenced to undergo a shoulder's arthroscopic acromioplasty; for each patient, preoperatively
10 and postoperatively shoulder's MRIs was performed. Those were then analyzed, in order to
11 find pre and postoperative acromial images which could be comparable. The measurements
12 implemented included: acromial thickness and depth of removed acromion.

13 Results: The comparison of the average of acromial thickness in pre and postoperative MRIs
14 showed a difference of $-2,0 \pm 1,5$ mm (95 % CI $-2,5$ to $-1,5$ mm), which was statistically
15 significant ($P = 0,000$). The difference between the average of depth of removed acromion in
16 pre and postoperative MRIs was $-1,2 \pm 1,3$ mm (95 % IC $-1,6$ to $-0,8$ mm) and was also
17 statistically significant ($P = 0,000$).

18 Discussion: This investigation demonstrated a significant difference in acromial thickness and
19 in depth of removed acromion between preoperative and postoperative MRIs. The performing
20 of imaging evaluation of the acromial morphology may serve as a starting point to assess de
21 value of this surgical procedure in clinical practice.

22 Conclusion: The results obtained suggest that arthroscopic acromioplasty induces modifications
23 in acromial morphology, which were observed and measured in MRIs.

24

25 **Level of evidence:** III (retrospective comparative study).

MRI analysis of acromial morphology after acromioplasty

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27 **Keywords:** Shoulder; acromion morphology; rotator cuff pathology; subacromial impingement

28 syndrome; magnetic resonance imaging; arthroscopic acromioplasty.

29 **Introduction**

30

31 Acromioplasty (open and arthroscopic) is a well-described technique and a commonly
32 performed procedure. In fact, it was reported by Vitale and colleagues a significant increase in
33 the overall volume and the population-based incidence of acromioplasties in recent years in the
34 United States.¹⁰

35 This procedure was first described by Neer in 1972. He related the acromial morphology with
36 the dysfunction of the rotator cuff and eventual tearing.⁶ There so, he proposed a new surgical
37 procedure to reshape the anterior acromial contact area for the rotator cuff, thereby
38 decompressing it.⁹ This procedure, which is call open anterior acromioplasty, consists in
39 removing the anterior edge and undersurface of the anterior acromion, as well as the
40 coracoacromial ligament. With time, many modifications were made to this procedure. An
41 example is the arthroscopic acromioplasty technique describe by Ellman, who performs a
42 coracoacromial ligament release, resection of the anterior acromion undersurface and bursal
43 debridement.^{3,4} Despite the existence of these two main procedures, many studies, including a
44 systematic review and a meta-analysis, didn't find appreciable differences between arthroscopic
45 and open acromioplasty.^{1,2,7,9}

46 Acromioplasty is considered a simple technique but with controversial indications and
47 therapeutic value. Nowadays, subacromial impingement refractory to nonoperative care and
48 during arthroscopic or open rotator cuff repair are the two most frequent indications for
49 acromioplasty. However, Jonathan et al. affirmed that current evidence does not support
50 acromioplasty over therapy and exercise, questioning its status as the gold standard for
51 subacromial impingement syndrome treatment.⁴ Those authors also refer that probably the
52 success in this cases requires strict criteria for identifying appropriate patients for
53 acromioplasty. Furthermore, reviews that studied rotator cuff problems concluded that there's

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54 no significant benefit in performing acromioplasty; in other words, evidence does not support
55 the routine use of acromioplasty in the treatment of rotator cuff disease.^{4,8} Despite all this data,
56 many authors perform acromioplasties routinely, during rotator cuff repair surgery, or as the
57 primary gesture, when treating subacromial conflict and/or calcific tendinitis of the rotator cuff,
58 resistant to conservative measures. They defend that besides the improvement in the
59 coracoacromial arch anatomy (to reduce extrinsic compression on the rotator cuff) and the
60 improvement in arthroscopic visualization, acromioplasty provides important biological factors
61 (growth factors and stem cells) that help in rotator cuff healing.^{4,8}

62 In addition, and as reported by Kyoung Hwan Koh and colleagues, many studies did not assess
63 the structural outcome of the acromion after acromioplasty⁵. Therefore, the performing of
64 imaging evaluation of the acromial morphology will have interest in determining if there are
65 significant structural acromial changes with acromioplasty. Furthermore, and as verified by
66 those last authors, magnetic resonance imaging (MRI) has become popular for investigating the
67 integrity of repair in rotator cuff tear patients. Currently, it is known that the shape of the
68 acromion after acromioplasty is well depicted in all axes of different planes, when assessing
69 postoperative MRI. Besides, it is easy to understand that, when compared with other imaging
70 techniques, MRI allows locating more accurately the site of acromioplasty and consequently
71 measuring the changes found more rigorously, because this imaging method has the ability to
72 identify osseous and non-osseous structures which can be used as reference points, thus
73 allowing comparing between different pre and post-operative MRI cut planes of the same
74 patient. There so, the performing of imaging evaluation of the acromial morphology may have
75 interest as a starting point to assess de value of this surgical procedure in clinical practice.

76 The objective of this investigation is to determine in which extent does arthroscopic
77 acromioplasty induces modifications in acromial morphology, using preoperative and
78 postoperative MRIs.

79 **Materials and Methods**

80

81 **Patient Selection**

82

83 In this retrospective cross-sectional study, we enrolled any patient referenced to undergo a
84 shoulder's arthroscopic acromioplasty, either isolated or as part of the treatment of rotator cuff
85 pathology, at a central hospital, from September, 2013 until February, 2016. From the initial
86 169 patients, only 51 had pre and postoperative MRIs. This number was reduced to the final 38
87 patients after application of the following exclusion criteria: (1) patients with previously
88 shoulder's surgery (n=10; 19,60%); (2) patients with poor quality MRIs, which didn't allow
89 comparing between different pre and postoperative MRI cut planes of the same patient (n=2;
90 3,92%); and (3) patients with congenital acromial modifications (n=1; 1,96%).

91

92 **Evaluation of Acromial Morphology**

93

94 For each patient, shoulder's MRI was preformed preoperatively and postoperatively. Two
95 observers, one with a Degree in Health Science and one Specialist in Musculoskeletal
96 Radiology, retrospectively reviewed 76 shoulder's MRIs, from 38 patients. For both pre and
97 postoperative MRIs, observers analyzed sagittal cuts, parallel to glenoid, with the acromial in
98 a lateral-medial orientation, seeking pre and postoperative acromial images which could be
99 comparable. Authors used the software OsiriX MD version 7.03 to assess all MRIs and to
100 perform all the measurements required for this study. In order to fulfil the objectives of the
101 study, the measurements performed included: acromial thickness and depth of removed
102 acromion.

103

104 Measurement of acromial thickness pre and postoperatively:

105 For each patient and for each pre and postoperative MRI, through an outer-to-outer technique,
106 the posterior acromial thickness was measured and served as control, because this anatomical
107 site was not affected by acromioplasty. Additionally, in the postoperative MRI, the acromial
108 thickness at the location corresponding to the acromioplasty (which was determined by the two
109 observers) was measured. This same location, by imaging comparison, was used to measure
110 acromial thickness in the preoperative MRI (Figure 1). Separately, pre and postoperative
111 acromial thickness was then calculated using the following formula, which expresses the results
112 in millimeters (mm):

113
$$[(\text{Posterior acromial thickness}) - (\text{acromial thickness of acromioplasty's location})]$$

114

115 Measurement of depth of removed acromion:

116 For each patient, on a sagittal cut in the postoperative MRI, the observers identified the place
117 where the acromioplasty was performed, and by drawing a tangent line to the acromion's
118 inferior cortical bone, the perpendicular distance between that line and the acromion's inferior
119 cortical bone was measured. This distance represents the depth of removed acromion and was
120 calculated in millimeters (mm). Through the comparison of pre and postoperative images, the
121 same location and the same calculation was performed in the preoperative MRI (Figure 2).

122

123 **Statistical Analysis**

124

125 Statistical analyses was performed using Microsoft Excel 2010 and IBM SPSS Statistics Base
126 24.0 software. In order to compare pre and postoperative acromial thickness and depth of
127 removed acromion after acromioplasty, the authors used a paired sample t-test for each type of
128 measurement performed. The significance level was 0.001, at which differences between the 2

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129 groups (preoperative MRIs and postoperative MRIs) were considered to be statistically
130 significant.

131 **Results**

132

133 The results obtained are summarized in Table I. Of the 38 patients, 19 were woman (50%) and
134 19 were men (50%); the average patient age was $51,2 \pm 9,4$ years (range, 28-75 years).
135 Regarding rotator cuff pathology, the included patients presented preoperatively: full-thickness
136 supraspinatus tears (n=10; 26,3%), full-thickness subscapularis tears (n=3; 7,9%), partial-
137 thickness supraspinatus tears (n=21; 55,3%), partial-thickness infraspinatus tears (n=4; 10,5%),
138 partial-thickness subscapularis tears (n=8; 21,1%), supraspinatus tendinosis (n=22; 57,9%),
139 infraspinatus tendinosis (n=21; 55,3%), subscapularis tendinosis (n=21; 55,3%), and
140 subacromial bursitis (n=12; 31,6%). This table also describes the average of time distance
141 (expressed in days) between preoperative MRI and surgery, as well as between surgery and
142 postoperative MRI. This imaging technique was performed at a mean of $49,7 \pm 35,9$ days
143 preoperatively, and at a mean of $117,0 \pm 71,4$ days postoperatively.

144 Table II shows the mean in acromial thickness and in depth of removed acromion (expressed
145 in mm), for pre and postoperative MRIs separately, as well as the results from paired sample t-
146 test. Considering all 38 patients, the average of acromial thickness in preoperative MRI was $0,2$
147 $\pm 1,0$ mm, and in postoperative MRI was $2,2 \pm 1,4$ mm. In addition, a paired sample t-test was
148 performed to compare this two moments of measurement, and showed a difference of $-2,0 \pm$
149 $1,5$ mm (95 % CI -2,5 to -1,5 mm). This difference was statistically significant ($P = 0,000$). The
150 average of depth of removed acromion in preoperative MRI was $0,4 \pm 0,6$ mm, and in
151 postoperative MRI was $1,6 \pm 1,3$ mm. Once more, a paired sample t-test was used and
152 demonstrated a difference of $-1,2 \pm 1,3$ mm (95 % IC -1,6 to -0,8 mm). This difference was also
153 statistically significant ($P = 0,000$).

154 **Discussion**

155

156 As explained above, the authors of this study used two methods of measurement based on pre
157 and postoperative MRIs, in order to investigate how much arthroscopic acromioplasty induces
158 modifications in acromial morphology. Although those measurements consisted in different
159 calculation techniques, theoretically they should serve to investigate the same aim. Besides the
160 fact that one showed a reduction in acromial thickness and the other demonstrated an increase
161 in depth of removed acromion, both revealed a significant modification in acromial
162 morphology.

163 The limitations of this study must also be mentioned. Several factors may have contributed to
164 measurement bias: results are expressed in millimeters, which represent numbers with small
165 order of magnitude; retrospective images were used, consequently not obtained exactly in the
166 same conditions (different patient's position during MRI, different sagittal cuts selected by
167 similarity of common reference points) and therefore complicated the comparison of pre and
168 postoperative MRIs; only sagittal cuts were used (other MRI cut planes could increase analysis'
169 perspectives); acromion's analysis was performed without taking into account that before
170 shoulder's surgery, different patients have different acromial morphologies, which can
171 condition the site and amount of bone removed by acromioplasty; and measurement techniques
172 and calculations were used that are not based on any mathematical model previously studied
173 and validated. Another important limitation for this study was the analysis of the 78 shoulder's
174 MRIs by two observers simultaneously and not independently, which does not allow to
175 minimize observer bias.

176 However, the results demonstrated a significant difference in acromial thickness and in depth
177 of removed acromion between preoperative and postoperative MRIs. A reduction of 2.0 (\pm 1,5)
178 mm in acromial thickness was evident in postoperative MRIs. This shows that after

179 acromioplasty, there were modifications in acromial morphology, in this case, in acromial
180 thickness, in a sagittal perspective. In this study, the results also showed a reduction of 1,2 (\pm
181 1,3) mm in the depth of removed acromion in postoperative MRIs. This specific measurement
182 calculates the direct effect of acromioplasty in acromial morphology, because all patients had
183 never been submitted to shoulder surgery, meaning that any acromial portion was ever changed
184 or removed. Therefore, this measure should be similar to zero in preoperative MRI, which
185 didn't happen in all the cases, probably due to lack of precision in measurements or to poor
186 choice of comparable sagittal cuts from pre and postoperative MRIs. Nevertheless, the
187 statistical analyses demonstrated a significant result for depth of removed acromion,
188 emphasizing once more the effect of acromioplasty in acromial morphology.

189 It's important to refer that, to the author's knowledge, there is no other paper published with
190 this purpose or methodology. This was one of the main reasons that motivated the authors to
191 perform this research, trying to create new measurement techniques that would boost future
192 investigation in this polemic subject.

193 The performing of imaging evaluation of the acromial morphology was interesting to determine
194 if there were significant structural acromial changes with arthroscopic acromioplasty, in order
195 to serve as a starting point to assess de value of this surgical procedure in clinical practice.
196 Furthermore, the authors suggest that future research should evaluate the relationship between
197 acromial morphological changes and clinical outcomes. Additionally, more information about
198 acromioplasty will be obtained if future research evaluates the 3-dimensional morphology of
199 the acromion.

200 **Conclusion**

201

202 No published study had assessed the structural outcome of the acromion after acromioplasty.

203 The authors of this article demonstrated that acromial thickness had a statistically significant

204 decrease in postoperative MRIs and that depth of bone removed after acromioplasty was

205 statistically significantly different in preoperative versus postoperative MRIs. Those results

206 suggest that arthroscopic acromioplasty induces modifications in acromial morphology, which

207 were observed and measured in MRIs.

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209

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237 **Figure and Table Legends**

238

239 **Figure 1** – Measurement of acromial thickness using pre and postoperative MRIs. Through an
240 outer-to-outer technique, the posterior acromial thickness was measured and served as control.
241 Additionally, in postoperative MRI (1B), the acromial thickness of the location corresponding
242 to acromioplasty was measured. This same location, by imaging comparison, was used to
243 measure acromial thickness in preoperative MRI (1A).

244

245 **Figure 2** – Measurement of depth of removed acromion using pre and postoperative MRIs. On
246 a sagittal cut in a postoperative MRI (2B), the place where the acromioplasty was performed
247 was identified; by drawing a tangent line to the acromion's inferior cortical bone, the
248 perpendicular distance between that line and the acromion's inferior cortical bone was
249 measured. Through the comparison with postoperative images, the same location and the same
250 calculation was performed in the preoperative MRI (2A).

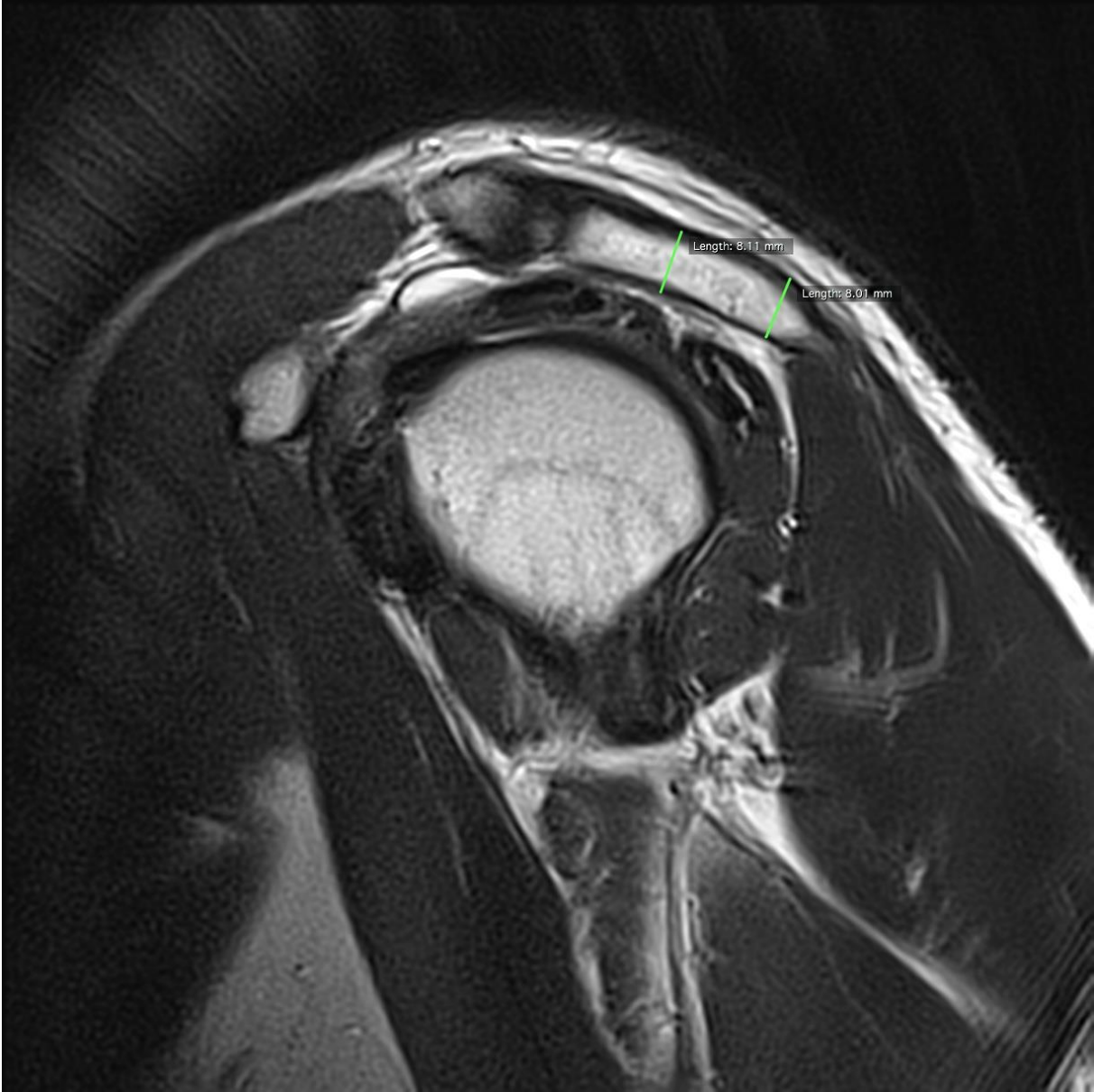
251

252 **Table I** – Descriptive analysis of all included patients, including demographic characteristics
253 (sex and gender) and pathological aspects (prevalence of rotator cuff pathology and period of
254 time between the date of each MRI (pre and postoperative) and the date of surgery.

255

256 **Table II** – Average of the measurements performed (acromial thickness and depth of removed
257 acromion) in pre and postoperative MRIs from all 38 patients, and *p* value obtained from paired
258 sample t-test used to compare the average calculated in preoperative MRIs with that founded
259 within postoperative MRIs, regarding both measurements separately.

260 **Figure 1 – 1A**



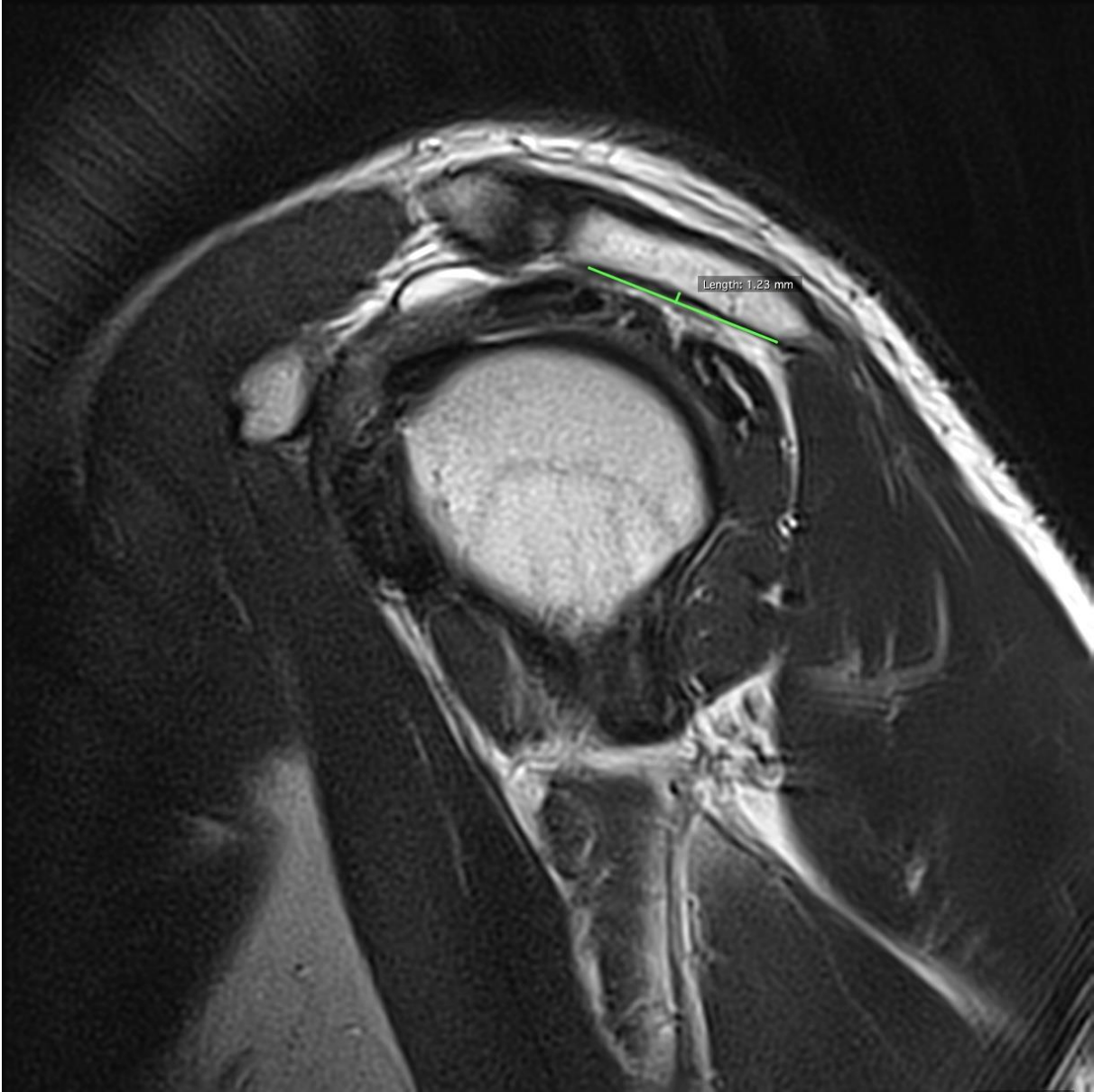
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262 **Figure 1 – 1B**



263

264 **Table 2 – 2A**



265

266 **Table 2 – 2B**



267

268

269 **Table I**

	Patients included in the study n = 38
Age [mean (SD)]	51,2 (\pm 9,4) years
Gender [n (%)]	
- Female	19 (50 %)
- Male	19 (50 %)
Rotator Cuff Pathology [n (%)]	
- full-thickness supraspinatus tear	10 (26,3 %)
- full-thickness subscapularis tear	3 (7,9 %)
- partial-thickness supraspinatus tear	21 (55,3 %)
- partial-thickness infraspinatus tear	4 (10,5 %)
- partial-thickness subscapularis tear	8 (21,1 %)
- supraspinatus tendinosis	22 (57,9 %)
- infraspinatus tendinosis	21 (55,3 %)
- subscapularis tendinosis	21 (55,3 %)
- subacromial bursitis	12 (31,6 %)
Time distance between preoperative MRI and surgery [mean (SD)]	49,7 (\pm 35,9) days
Time distance between surgery and postoperative MRI [mean (SD)]	117,0 (\pm 71,4) days

270 SD – Standard deviation

271 **Table II**

n = 38	Preoperative MRI [mean (SD)]	Postoperative MRI [mean (SD)]	Significance (<i>P</i> value)
Acromial thickness (mm)	0,2 (± 1,0)	2,2 (± 1,4)	0,000
Depth of removed acromion (mm)	0,4 (± 0,6)	1,6 (± 1,3)	0,000

272 SD – Standard deviation

Agradecimentos

Ao Doutor João Manuel Costa Ferreira Torres, pelo respeito e dedicação com que abraçou este projeto, pelo contributo intelectual, tempo e amabilidade despendida na orientação desta tese de mestrado. Ao Dr. Ricardo Sampaio, pelo contributo na análise dos dados imagiológicos. À Dra. Francisca Saraiva, pela análise estatística e auxílio na interpretação e escrita dos resultados. Ao Hospital Lusíadas Porto, pelo dispor de nos receber e fornecer as instalações e meios necessários para a colheita e análise dos dados. Aos meus colegas, que de alguma forma contribuíram na elaboração do presente trabalho. Aos meus amigos, que tanto me apoiaram neste percurso. E por último, mas não menos importante, ao João Pimenta e aos meus Pais, o meu suporte incondicional, pela presença e apoio constantes na minha vida.

Anexos

- Pedido de Aprovação à Comissão de Ética para a Saúde do Hospital Lusíadas Porto
- Normas de publicação da Revista *Journal of Shoulder and Elbow Surgery*

COMISSÃO DE ÉTICA PARA A SAÚDE

ESTUDOS NÃO ENVOLVENDO EXPERIMENTAÇÃO HUMANA (OBSERVACIONAL, INQUÉRITOS, ESTUDOS)

1. IDENTIFICAÇÃO DO PROJECTO

a) **Título do projecto** (de estudo, investigação, etc.)

Arthroscopic acromioplasty: magnetic resonance imaging analysis of modifications in acromial morphology

b) **Autores / Promotor**

i. **Promotor** (Indivíduo ou entidade responsável pela execução do estudo)

Rosana Pereira Dias

ii. **Investigador principal** (juntar resumo CV)

João Manuel da Costa Ferreira Torres

iii. **Colaboradores** (juntar resumo CV)

iv. **Há algum investigador/colaborador pertencente ao Hospital da Boavista?**

Sim: João Manuel da Costa Ferreira Torres

c) **Natureza do estudo**

Inquérito isolado	<input type="checkbox"/>	Estudo observacional	<input type="checkbox"/>
Inquéritos seriados	<input type="checkbox"/>	Estudo retrospectivo com colheita de dados pessoais	<input checked="" type="checkbox"/>
Outro/	<input type="checkbox"/>	Especificar:	

d) **Local onde decorre o estudo** (Serviço, Unidade, Laboratório, etc):

Serviço de Ortopedia e Traumatologia

e) **Existem outros centros, onde a mesma investigação será feita?**

Sim	<input type="checkbox"/>		
Nacionais	<input type="checkbox"/>	Internacionais	<input type="checkbox"/>
Não	<input checked="" type="checkbox"/>		

Em caso afirmativo, identifique esses centros:

Descrição sucinta do(s) objectivo(s) da investigação:

O objetivo desta investigação é determinar de que forma a acromioplastia artroscópica induz alterações no volume acromial, utilizando para isso a análise de ressonâncias magnéticas nucleares realizadas no pré e pós-operatório.

f) **Encargos e situações especiais** (se a investigação proposta envolver):

i. Envolvimento de pessoal administrativo - indicação do tipo, frequência e quantidade da amostra e especificar se:

- (1) O tempo ocupado com a sua colaboração se destina especialmente a esta investigação.
- (2) Seria executado no âmbito dos cuidados assistenciais habituais a prestar ao doente.

ii. Consultas / entrevistas de seguimento – especificar se:

- (1) As consultas são feitas especialmente para esta investigação ou se seriam executadas no âmbito dos cuidados médicos habituais a prestar ao doente;
 - (2) Os entrevistadores estão obrigados ao segredo médico ou - em alternativa - se foi assinado um acordo de confidencialidade com a Instituição.
-
-
-
-
-

g) **Caderno de recolha de dados** (CRF):

- i. Como serão recolhidos os dados? (**Nota:** juntar um exemplar do caderno de recolha de dados)

Será utilizada informação constante nos processos clínicos dos participantes, nomeadamente aquela referente às RMN realizadas, incluindo o resultado delas obtido.

- ii. Como será mantida a confidencialidade nos registos?

Apenas os investigadores responsáveis por este trabalho terão acesso aos dados recolhidos, os quais serão submetidos a uma análise cega (isto é, não tendo em conta nenhuma informação identificativa do doente).

h) **Comentários adicionais** (por favor, indicar a alínea a que se referem)

2. JUSTIFICAÇÃO CIENTÍFICA DA INVESTIGAÇÃO

Descrição sucinta dos fundamentos científicos da investigação, indicando se a investigação já foi feita anteriormente com seres humanos, qual o motivo que justifica a sua repetição; no caso da investigação nunca ter sido realizada em seres humanos, se o problema foi devidamente estudado a nível experimental de modo a otimizar os aspectos analíticos e técnicos e avaliar os possíveis danos.

A acromioplastia é uma técnica cirúrgica bem descrita e comumente realizada. Porém, as indicações para a sua realização e o seu valor terapêutico geram controvérsia. Muitos autores afirmam que esta técnica não traz benefícios no tratamento da patologia da coifa dos rotadores. No entanto, a acromioplastia continua a ser um procedimento de rotina, pois muitos médicos acreditam que este consegue melhorar a anatomia do arco coracoacromial e a visualização artroscópica, bem como permitir o crescimento de fatores de biológicos úteis no processo de cicatrização da patologia subjacente. Além disso, muitos estudos não avaliaram o *outcome* estrutural do acrómio após esta técnica cirúrgica. Por esse motivo, realizar uma avaliação imagiológica da morfologia acromial terá interesse para determinar se existem alterações estruturais acromiais significativas induzidas pela acromioplastia. A ressonância magnética nuclear tornou-se popular para investigar a integridade da reparação da patologia da coifa dos rotadores, sabendo-se ainda que, esta é uma técnica de imagem com elevada capacidade para avaliar a estrutura acromial. Assim sendo, avaliar imagiologicamente a morfologia acromial poderá ter interesse como ponto de partida da determinação do valor deste procedimento cirúrgico na prática clínica.

3. SUJEITOS

a) **Número de indivíduos previstos incluir**

169

b) **Critério de inclusão/exclusão:**

Os seguintes grupos de indivíduos estão excluídos?

- i. Mulheres grávidas
- ii. Mulheres puérperas / em aleitamento
- iii. Crianças
- iv. Indivíduos com compreensão comprometida

	SIM	NÃO
i.	X	
ii.	X	
iii.	X	
iv.	X	

4. DESCRIÇÃO RESUMIDA DO PLANO DA INVESTIGAÇÃO

a) Data prevista do início:

Janeiro 2017

b) Data prevista da conclusão

Março 2017

5. RISCO / BENEFÍCIO

a) Há benefícios directos ou potenciais para o doente pela participação no estudo

Com esta investigação não estão previstos benefícios diretos ou potenciais para os participantes.

b) Precauções a observar na realização do ensaio

Não existem precauções a observar.

c) Reacções adversas previsíveis

Não é previsível a ocorrência de reacções adversas nesta investigação.

d) **Considera que os meios utilizados no estudo podem violar a privacidade do doente?**

SIM

NÃO

Em caso afirmativo, indique que medidas serão tomadas para assegurar a confidencialidade

e) **Pagamento aos doentes**

SIM

NÃO

Pelas deslocações

	X
Pelas faltas ao serviço	X
Por danos resultantes da sua participação no estudo/ensaio	X

Pelas faltas ao serviço

Por danos resultantes da sua participação no estudo/ensaio

f) **Seguro:**

SIM

NÃO

Em caso afirmativo, juntar cópia da apólice ou certificado de seguro da

Companhia de Seguros:

6. FOLHA DE INFORMAÇÃO AO DOENTE (JUNTAR CÓPIA)

SIM

NÃO

a) Considera a linguagem acessível para a população em causa?

b) Há informação distinta para menores/ representante legal?	
c) Há informação distinta para doentes com dificuldades de compreensão/cuidadores?	

b) Há informação distinta para menores/ representante legal?

c) Há informação distinta para doentes com dificuldades de compreensão/cuidadores?

7. CONSENTIMENTO INFORMADO (JUNTAR CÓPIA)

	SIM	NÃO
A investigação ou estudo envolve		
a) Menores?		X
b) Inimputáveis?		X

Em caso afirmativo, juntar folha de consentimento para os representantes legais.

Caso o menor disponha de capacidade de entendimento e manifestação de vontade é necessário também o seu consentimento (recomendável a partir dos 7 anos, obrigatório a partir dos 14 anos).

8. BENEFÍCIOS PARA O INVESTIGADOR / INSTITUIÇÃO

a) Que tipo de benefícios resultarão do estudo, para o investigador e/ou instituição?

Não estão previstos benefícios para o investigador.

Juntar cópia do acordo financeiro, se aplicável.

b) Os dados obtidos constituirão propriedade exclusiva do promotor?

SIM

NÃO

Em caso de resposta negativa, que outras entidades têm acesso aos dados

c) A publicação dos resultados do estudo será da exclusiva responsabilidade do promotor?

SIM

NÃO

9. TERMO DE RESPONSABILIDADE (MINUTA)

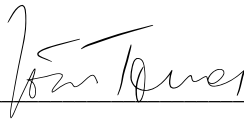
Data do pedido de submissão (08 / 01 / 2017)

Eu, abaixo assinado,

João Manuel da Costa Ferreira Torres, na qualidade de investigador principal, declaro por minha honra que as informações prestadas neste questionário são verdadeiras.

Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes das Declarações de Helsínquia a de Tóquio, da Organização Mundial de Saúde e da Comunidade Europeia, no que se refere à experimentação que envolva seres humanos, bem como o constante da Lei n.º 46/04, de 19 de Agosto.

Porto, 8 de Janeiro de 2017



Guide for Authors

INFORMATION FOR AUTHORS

PURPOSE AND POLICIES

The *Journal of Shoulder and Elbow Surgery* is a scientific medical journal containing information relative to the investigation of the development, preservation, and restoration of the form and function of the shoulder girdle, arm, elbow, and associated structures by medical, surgical, and physical means.

The objectives of the *Journal* are to enhance the professional study and practice of shoulder and elbow surgery, to act as a stimulant to research by providing a forum for discussion of new scientific advances, and to further international cooperation among shoulder and elbow societies by serving as an official publication for recognized societies.

To accomplish these goals, the *Journal* accepts for publication original articles, descriptions of surgical and other patient care techniques, case reports, historical and current reviews, editorials, comments on published material, and announcements or proceedings of participating societies.

The *Journal* requires at least a two-year follow-up for all patients enrolled in clinical treatment studies. Exceptions at the editor's discretion will be allowed when studies are stopped due to adverse events, or other significant or important differences are detected before the two-year minimum follow-up is reached (e.g. studies of fracture where union is the outcome measure of interest), or for certain case reports.

All manuscripts which deal with the study of human subjects must be accompanied by Institutional Review Board (IRB) or Ethical Committee Approval, or the national or regional equivalent in your geographic area. The name of the Board or Committee giving approval and the study number assigned must accompany the submission, preferably by a scanned copy of the IRB or Ethical Committee Approval uploaded to the submission.

All manuscripts which deal with animal subjects must be approved by an Institutional Review Board (IRB), Ethical Committee, or an Animal Utilization Study Committee, and this statement, and approval number, must accompany the submission, preferably by a scanned copy of the IRB or Ethical Committee Approval uploaded to the submission. The manuscript should contain information about any post-operative care and pain management for the animals.

Materials are accepted for exclusive publication in the *Journal of Shoulder and Elbow Surgery*, and published manuscripts along with their illustrations become the property of the *Journal*. Permission to reproduce material published in the *Journal* must be obtained from the publisher. Authors will also be consulted, when possible, in regard to republication of their material.

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Editor(s) and publisher disclaim any responsibility or liability for such material. Neither the Editor(s) nor the publisher guarantees, warrants, or endorses any product or service advertised in this publication and, they do not guarantee any claim made by the manufacturer of such product or service.

For authors of Case Reports and Database-Mining Articles in particular, you are encouraged to submit to the *JSES Open Access (JSESOA)* at <https://ees.elsevier.com/jsesoa/default.asp>. *JSESOA* will be a quarterly publication, online only. Other types of articles that should be submitted to the *JSESOA* include: National Arthroplasty Registry reports; Original articles; Review articles; Technique articles; and Validation studies of Outcome Instruments.

Author's guidelines, as well as the review process, are similar to those for the *JSES*.

To provide open access, the *JSESOA* has an open access fee (also known as: open access publication fee) which needs to be met by the authors or their research funders. Submission to the *JSESOA* is free of charge; however, if the paper is accepted for publication in the *JSESOA*, the open access publication fee will be charged. Fees at this time will be \$1,250 (US) for original or review articles, and \$750 (US) for case reports or technical notes.

The open access fee is all inclusive; Elsevier will not add any additional charges. Depending on local regulations, VAT can be charged by local authorities.

SUBMISSION OF MANUSCRIPTS

Manuscripts and all other communications for the Editor(s) must be written in English. Submission of the materials in the correct format will expedite the review process and prevent unnecessary delay in publication.

For authors whose primary language is not English, we urge you to consider a language review of your manuscript by a primary English speaker **prior** to submission to the journal. There are also now several such services available via the Internet which will review your paper, and improve the English grammar and syntax.

Authors must submit new manuscripts **and all related documentation** electronically via the Elsevier Editorial System (EES) at <http://ees.elsevier.com/jses>.

On receipt of the manuscript or other materials, peer review will be performed by an Editor and usually two additional reviewers. Should the material require revision, authors are requested to complete and submit revisions within three months.

Levels of Evidence: Although this will be reviewed by our Editorial Staff, and their opinion will be final, the *Journal* asks authors to assign a Level of Evidence to all clinically oriented manuscripts. The following table is offered to assist authors:

Type of Study	Treatment Study	Prognosis Study	Study of Diagnostic Test	Cost Effectiveness Study
LEVEL I	Randomized controlled trials with adequate statistical power to detect differences (narrow confidence intervals) and follow up >80%.	High-quality prospective cohort study with >80% follow-up, and all patients enrolled at same time point in disease	Testing previously developed diagnostic criteria in a consecutive series of patients and a universally applied "gold" standard	Reasonable costs and alternatives used in study with values obtained from many studies, study used multi-way sensitivity analysis
LEVEL II	Lower quality randomized trials (follow up <80%, improper randomization techniques, no masking Prospective comparative study	Lower quality prospective cohort study (<80% follow-up, patients enrolled at different time points in disease) Retrospective study Untreated controls from a randomized controlled trial	Development of diagnostic criteria in a consecutive series of patients and a universally applied "gold" standard	Reasonable costs and alternatives used in study with values obtained from limited studies, study uses multi-way sensitivity analysis
LEVEL III	Case-control study Retrospective comparative study	Case-control study	Study of nonconsecutive patients and/or without a universally applied "gold" standard	Analyses based on a limited section of alternatives and costs, or poor estimates of costs
LEVEL IV	Case series with no comparison group	Case series with no comparison groups	Use of a poor reference standard Case control study	No sensitivity analysis
LEVEL V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

Treatment Studies investigate the results of treatment on patient outcomes and complications.

Prognosis Studies investigate the natural history of a disease or disorder, and evaluate the effect of a patient characteristic on the outcome of the disease.

Diagnostic Studies evaluate the effectiveness of a diagnostic test or outcome assessment.

Economic/Decision Analysis or Modeling Studies explore costs and alternatives or may either develop or assess the effectiveness of decision models.

Systematic Reviews and Meta-Analyses are assigned a Level of Evidence equivalent to the lowest level of evidence used from the manuscripts analyzed.

Prospective Study-Defined is a study in which the research question was developed, (and the statistical analysis for determining power) were developed before data was collected.

Retrospective Study-Defined is a study in which the research question was determined after the data was collected (even for studies where the authors collected general data prospectively).

PATIENT CONSENT

Appropriate consents, permissions and releases must be obtained where authors wish to include case details or other personal information or images of patients and any other individuals in their JSES submission. It is generally *not sufficient* to anonymise a photograph simply by using eye bars or blurring the face of the individual concerned. Consent documents should be uploaded in the document category Figure Permissions, thus NOT seen by reviewers and NOT unblinding your submission.

PREPARATION OF MANUSCRIPTS

The *Journal* adheres to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (the Vancouver style) developed by the International Committee of Medical Journal Editors as described in the Journal of the American Medical Association (1993;269:2282-6) (also may be retrieved at <http://www.icmje.org/>), with the exception that the references must be placed in alphabetic order by author(s) name, numbered sequentially, and appear as superscript numbers in the text but without brackets (see section on "References").

Formatting Manuscripts: The *Journal* suggests that authors follow these guidelines when writing and formatting their work:

Randomized controlled trials should follow the CONSORT (Consolidated Standards of Reporting Trials) guidelines (<http://www.consort-statement.org>).

Case reports, case series, cross-sectional and other observational studies should follow the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (<http://www.strobe-statement.org>). If the detailed methods are explicitly stated in the manuscript for single case studies, STROBE is not needed.

Authors producing systematic reviews and meta-analyses should follow the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (<http://www.prisma-statement.org>).

Type the manuscript with margins of at least 25 mm (1 inch). Use double-line spacing throughout the entire manuscript, typing in Times New Roman font size 12, **and include continuous line numbering**. Please use Insert Page Break and begin each of the following sections on a new page: Abstract; Introduction; Materials and Methods; Results; Discussion; Conclusion; References; and Figure and Table Legends. **Figures and Tables should be uploaded separately and individually** (see below). Number the pages consecutively in the lower right-hand corner of each page beginning with the Title Page as number 1. Place a six-word short-form/running title in the header space of the manuscript document. The manuscript

file must be in a Word format. Manuscripts without continuous line numbering will be returned to the author.

Word Count Submissions of review and original articles (including abstract, introduction, materials and methods, results, discussion and conclusion) should have a maximum word count of 4,750; submissions which exceed this limit **will be returned to the author** for further revision without being reviewed. Case reports should not exceed 2,250 words.

Review and Technique Articles

The *Journal* has limited space to publish numerous review and technique articles and these are usually solicited by the Review Article and Special Projects Editors. Authors must remember the *Journal* only publishes one review paper per issue, or about 12 per year. In a typical year, the *Journal* receives in excess of 200 review articles submitted in consideration for publication. Hence, the acceptance rate of review articles for the *Journal* is usually around 3%-4%. Authors considering submission of a review article are encouraged to read "What is the value of a systematic review? (*J Shoulder Elbow Surg* 23:1-2, 2014; <http://dx.doi.org/10.1016/j.jse.2013.09.001>)" to critically evaluate whether their submission may be suitable for publication in the journal. Please contact the Review and Special Projects Editor (T. Bradley Edwards, M.D.) via jsesedit@gmail.com outlining your proposed article. Video Technique Articles are acceptable but will be published only on the website.

Title Page

The title page should include a concise but informative title of the article, plus a six-word short-form/running-title, and the first name, middle initial, and last name along with the highest earned academic degree of each author. The title page should also include the name of the department and the institution to which each author's work should be attributed. The name, mailing address, and e-mail address of the author responsible for correspondence should be identified, as should any source of support in the form of grants, equipment, or other items. The title page file must be in a Word format.

If illustrations must be published in color, note this explicitly on the title page of the article.

Disclaimer: List here (on the title page) any financial remuneration the authors, or any member of their family, may have received related to the subject of the article. If no such financial biases exist for any author, state "none". Please also include information about Institutional Review Board (IRB) or Ethical Committee approval related to the study, including the name of the IRB providing approval and the study number.

Please also include on your title page Acknowledgments of those who have contributed to the paper but whose contributions do not justify authorship. They may be named and their contribution described. Such persons must have given their permission to be so named, because readers may infer their endorsement of the data and the conclusions reached. Technical help may also be acknowledged.

Upload the title page on the EES system as Title Page. **Do not include** the above information in your manuscript text which for review purposes should be blinded.

Abstract

The first text page of observational and experimental articles and review articles should be an abstract of no more than 250 words. This abstract should state the purpose of the study, basic procedures, essential findings, and principal conclusions, and should be formatted into: Hypothesis and/or Background; Methods; Results; and Discussion and/or Conclusion. The abstract should emphasize new and important aspects of the observation or study, but may not contain data that are not presented in the main text.

Case reports do not require an abstract and are published without abstracts.

For full research articles, include the Level of Evidence of the study performed (see above) and Keywords at the end of the abstract. The authors should assign their own Level of Evidence although this will be reviewed by the *Journal's* Editorial Staff and should also list 6-8 Keywords that highlight the topic of the article, allowing for easier electronic retrieval.

Manuscript Text

The text of observational and experimental articles is divided into 5 sections with the headings: Introduction; Materials and Methods; Results; Discussion; and, Conclusions. Each section should start on a new page. Longer articles may need subheadings within headings to clarify their content. Other articles, such as reviews, case reports and editorials need not take the form of manuscripts describing observational or experimental studies. A case report should include Keywords at the end of the Introduction.

All manuscript texts should be blinded for review purposes. Blind institute location, author initials and references by same authors. To blind an item, use Black Text Highlight Color to black-out the text.

Introduction. The purpose of the article should be stated and the rationale for the study or observation summarized. Pertinent references should be given, but the subject should not be reviewed extensively.

Materials and Methods. Clearly describe the selection of the observational or experimental subject(s). Identify the methods, apparatus, and procedures in sufficient detail to allow others to reproduce the results. Give references to established methods, including statistical methods. Identify precisely all devices or drugs used, including generic names, manufacturers, and manufacturer locations.

Give numbers of observations. Report any losses to observation. Provide details about randomization. Describe statistical methods in enough detail to enable a knowledgeable reader who has access to the original data to verify reported results. Avoid sole reliance on statistical hypothesis testing, such as the use of *P* values, which might fail to convey important quantitative information. Avoid nontechnical uses of technical terms in statistics, such as random or significant. All recent clinical studies

should be performed with Institutional Review Board (IRB) approval, and confirmation of IRB approval should be given in this section.

In general, exact P-values or statistical measures should be given, rather than, e.g., $p < 0.05$. Please also remember the proper use of significant figures and do not overuse extra decimal places, taken as an average, which may imply a degree of precision which does not exist in the work.

Results. Results should be presented in a logical sequence in the text, illustrations and/or tables. Do not repeat in the text the data presented in tables and illustrations, but emphasize or summarize the important observations. For reports on reconstructive procedures, a minimum 2-year evaluation period is recommended.

Discussion. New and important aspects of the study should be emphasized, and conclusions that follow from them should be made. It is not desirable to repeat the data or material given in other sections of the manuscript. The discussion should describe the implications of the findings and their limitations, including suggested future research needs. The observations can be related to relevant studies. Unqualified statements and conclusions incompletely supported by the data should be avoided. Recommendations may be included.

Conclusions. A short concluding paragraph summarizing the hypothesis and reason for the study and its results should be included.

References

The Reference List should be in alphabetical order by authors' last name, in double-line spacing, and numbered sequentially. At the end of each reference, please include the Digital Object Identifier (DOI) (<http://www.doi.org/>) or ISBN number for all references dating from 2002 to today. References with identical author(s) should be listed by youngest first. If there is more than one reference with the same first author, use 2nd, 3rd author etc to decide the alphabetical order. When a reference citation has 6 or fewer authors, list all the authors; when there are 7 or more authors, list the first 6 then "et al." Identify references in the text, tables, and illustration legends by superscript Arabic numerals without brackets. References must conform to Vancouver style. Abbreviate titles of journals according to the style used in *PubMed*.

Examples of the correct forms of references are provided below:

Journal article: 1. Richards RS, Curl LA, Moorman CT, Mallon WJ. Sterile synovio-cutaneous fistula: A potential complication of repair of large and massive rotator cuff tears. *J Shoulder Elbow Surg* 2006;15:436-439. doi:10.1016/j.jse.2005.03.008

Book chapter: 2. Zarins B, Prodromos CC. Shoulder injuries in sports. In: Rowe CR, editor. *The shoulder*. New York: Churchill Livingstone; 1988. p. 411-33. (ISBN No. 978-0443084577)

Illustrations and Legends

Each figure should be uploaded as a separate file (and name/numbered in the Description box on the Attach Files page of the submission process). For photographic images upload your images in a standard acceptable digital format (e.g., *.tif or *.jpg) to the journal's online submission website (<http://ees.elsevier.com/jses>). For line

illustrations, use thick, solid lines and bold, solid type; avoid the use of shading or dotted patterns. If illustrations must be published in color, note this explicitly on the title page of article. For more detailed information on preparing your figures for submission, please visit: <http://www.elsevier.com/artworkinstructions>.

Letters, numbers, and symbols should be clear and of sufficient size that when reduced for publication each will be legible. Figures should be numbered in the order of their mention in the text and the number included in the Description box. Title and explanations of figures (and tables) belong on a dedicated legends page following the reference list in the manuscript, and not on the illustrations themselves. If a figure has been taken from previously copyrighted material, the legend must give full credit to the original source (see below).

Figure/Photograph Permissions: Photographs in which a person's face is recognizable *must* be accompanied by a letter of release from that person explicitly granting permission for publication in the *Journal*. X-rays should NOT show patient's name. For any previously published material, authors must obtain written permission for both print and electronic reprint rights from the copyright holder / publisher. This is necessary even if you are an author of the borrowed material. These permission letters must then be uploaded as part of the submission process or the author must state in an uploaded document that the permission has been requested and provide an approximate date when the permission is expected to be received. Authors are also responsible for paying any fees required by copyright holders to reprint material.

Tables

Each table should be uploaded as an individual Table document separate from the manuscript (and name/numbered in the Description Box). Tables should be uploaded in a format that can be edited, preferably .doc or .docx. Tables should be self-explanatory and numbered in Roman numerals. They should be mentioned in numerical order through the text. Table Legends (and figure legends) should be listed on a dedicated page of the manuscript text that follows the reference list. Abbreviations should be defined in a footnote at the end of the table. If any material in a table or a table itself has been taken from previously copyrighted material, a footnote must give full credit to the original source and permission of the author and publisher must be obtained. Table permission letters should be uploaded in the document category Figure/Photograph Permissions.

Big Data

Authors are requested to upload their full databases of studies, both clinical and basic science, as Supplemental Files. This information should be both blinded and anonymized. At present this is not mandatory, but recommended. Please use standard files types. Supplemental Files are published online as a link; the JSES print edition includes details of links.

Instructions for Submitting Videos

The *Journal* encourages authors to submit a video to be published on the *Journal's* web site at <http://www.jshoulderelbow.org/> as an illustration incorporated in an article that the author is submitting for publication or as video paired with a journal

cover illustration. All videos are subject to peer review. We expect professional quality and narration, regardless of method of production. A sound track is highly desirable and is requested.

These formats for video will be accepted

- MPEG-1 or MPEG-2 (.mpg)
- QuickTime (.mov)

The *Journal* will not edit any video, but a reviewer may suggest that the author make changes.

Requirements

- Include in your CoI statement (second cover letter) a statement confirming that the video is part of your submission and has been viewed by all authors.
- Submit a single video per manuscript, not multi-part videos.
- Maximum length of videos is 4.5 minutes.
- Video file cannot exceed 50 MB. The submission program will time out if the file size is larger than 50 MB.
- Please ZIP the file and upload the zipped file to hasten the upload time.
- A complete legend for the video must be included in the manuscript.
- The video must be cited in the text of your manuscript just like a figure.
- Sound narration is highly desirable and is requested.

Units of Measurement

Measurements of height, length, weight, or volume should be reported in metric units. Temperatures should be given in degrees Celsius; blood pressures should be given in millimeters of mercury. All laboratory measurements should be reported in the metric system.

Abbreviations

Only standard abbreviations should be used, and abbreviations should be avoided in the title or abstract. The full term for an abbreviation should precede its first use in the text unless it is a standard unit of measurement.

LETTERS TO THE EDITOR

Letters to the Editor should be sent to the Editor-in-Chief of the *Journal* via the EES system following the guidelines for all other submissions. Letters should be no longer than 2 pages in length. Letters should be signed by all authors and concern only articles that have been published recently in the *Journal of Shoulder and Elbow Surgery*. A response to the letter will be requested from the author of the article in question, and both the letter and response will be published together if there is a response.

ANNOUNCEMENTS

Announcements of participating society activities must be received at least 10 weeks before the desired issue of publication. Send announcements to the office of the Editor-in-Chief.

REPRINTS

Single reprints of articles must be obtained from the author. Reprint order forms will be sent to authors after articles are slated for publication in a specific issue.

June 2016