1	Efficacy of a Single Image-Guided Corticosteroid Injection for Glenohumeral Arthritis	
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1 Abstract

2 **Background**: There is limited data available on the efficacy of cortisone injection for 3 glenohumeral osteoarthritis (GHOA). The amount and longevity of pain relief provided by a 4 single cortisone injection is unclear. Additionally, it remains uncertain how the severity of radiographic GHOA and patient reported function and pain levels impact the efficacy of 5 6 injection. Therefore, we sought to describe relief provided by a single, image guided 7 glenohumeral injection for patients with GHOA. Additionally, we hypothesized that patients 8 with more severe radiographic GHOA and poorer baseline shoulder function would require 9 earlier secondary intervention. 10 Methods: Patients with symptomatic GHOA who elected to receive a corticosteroid injection for 11 pain relief were prospectively enrolled. A phone interview was conducted to record baseline OSS 12 and VAS scores prior to the injection, as well as at months 1, 2, 3, 4, 6, 9, and 12. Endpoints 13 were designated when patients required a second injection, progressed to surgery, or reached 14 month 12. Patients were grouped by their respective baseline OSS (mild, moderate/severe) and 15 Samilson-Prieto radiographic classification (mild, moderate, severe) for analysis. **Results:** Thirty shoulders (29 patients) were analyzed. 52% of patients were male. The average 16 17 age of 66.1 years. No significant difference was seen in overall survival (defined as no additional 18 intervention) between groups based on either OSS or Samilson-Prieto grades. Additionally, OSS 19 and VAS scores at each follow-up were compared to baseline. For the entire cohort, a clinically 20 significant difference was seen between baseline and months 1-4 for OSS and between baseline 21 and months 1-4, 6,9, and 12 for VAS. 22 **Discussion:** This study aimed to determine the efficacy of corticosteroid injections for GHOA.

23 There were no differences in the need for secondary interventions in this population based on

24	severity of either the OSS or the Samilson-Prieto radiographic classification. However, patients
25	with more severe shoulder dysfunction based on OSS did experience a statistically significant
26	greater symptomatic relief compared with patients with milder dysfunction. Additionally,
27	following a single injection, patients in this cohort experienced statistically and clinically
28	relevant improvements in shoulder function and pain up to 4 months post-injection.
29	
30	Level of evidence: Level IV; Case Series; Treatment Study
31	
32	Keywords: Corticosteroid Injections, Image-Guided, Glenohumeral Osteoarthritis, Samilson-
33	Prieto classification, Oxford Shoulder Score, Visual Analog Scale
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35	
36	Level 1 and 2 studies on the use of corticosteroid injections in the non-operative
37	management of glenohumeral osteoarthritis (GHOA) are lacking. ⁷ Because of this, the American
38	Academy of Orthopaedic Surgeons (AAOS) has been unable to make recommendations for or
39	against the use of corticosteroid injections for GHOA in their published clinical practice
40	guidelines. ¹⁵ Previous studies have shown intra-articular injections to be safe for the treatment of
41	osteoarthritis in other large joints. ¹⁰ However, these studies have not been performed exclusively
42	on the shoulder, nor have they given us data on the success of corticosteroid injections on
43	delaying the need for secondary intervention, either repeat corticosteroid injections or total
44	shoulder arthroplasty. Additionally, it is unknown if the severity of radiographic GHOA or the
45	patient's subjective shoulder pain and function, as documented by VAS pain score and patient
46	reported outcomes (PROS), affect the efficacy and longevity of a glenohumeral corticosteroid

47 injection for arthritis. These gaps in our understanding limit our ability to provide adequate
48 counseling to patients regarding the usefulness of corticosteroid injections as a non-operative
49 treatment for GHOA.

50 Previous studies have attempted to evaluate the benefit of corticosteroid injections on shoulder pain.^{3,16,17} However, the usefulness of these studies is limited by their heterogeneity, 51 52 including varying sources of shoulder pain (AC joint arthritis vs adhesive capsulitis), differing 53 methods of corticosteroid injections, retrospective nature, and their small sample sizes. The lack 54 of image-guided injections in many of these studies is of particular concern, as previous studies 55 have concluded that image-guided corticosteroid injections are more accurate than blind injections, and they may provide longer symptomatic relief in patients with shoulder pathology.¹, 56 ¹¹ Moreover, the available data does little to help us predict which patients will have limited, 57 short lived improvement in their symptoms, and which patients, if any, will enjoy a robust, long 58 59 lasting response.

We hoped to bridge some of the gaps in our knowledge surrounding conservative management of GHOA with corticosteroid injections by establishing a protocol that allows for accurate, image-guided glenohumeral corticosteroid injection and monthly patient follow-up using validated questionnaires for pain and shoulder function. We believe that our study will provide data on the amount and duration of pain relief to expect from a single corticosteroid injection for GHOA.

A second aim of this study is to evaluate the reliability of radiographic GHOA severity
and validated shoulder function questionnaires in predicting the amount and duration of pain
relief patients may expect from a single injection. We hypothesized that those patients with (1)
more severe radiographic osteoarthritis based on the Samilson-Prieto classification and (2) poor

baseline Oxford Shoulder Scores (OSS) would require earlier secondary intervention with either
 repeat injections or surgical intervention.

72

73 Materials and Methods

74 Twenty-nine patients (30 shoulders) were prospectively enrolled in an observational 75 study following institutional review board approval and patient informed consent. We included 76 shoulders that met these inclusion criteria: adults (>18 years old) with radiographically 77 documented, symptomatic GHOA, who were indicated for a corticosteroid injection as initial treatment of GHOA. Additionally, only patients who could cognitively consent to participate in 78 79 the study and continue monthly communication through phone interviews were included. 80 Patients <18 years old, and those with inflammatory arthritis, rotator cuff tear arthropathy, 81 significant cervical spine abnormalities, and those with shoulder pain but without GHOA were 82 excluded.

83 Patients were classified using two methods: Oxford Shoulder Score (OSS) questionnaire 84 to classify subjective shoulder function and the Samilson-Prieto classification system to classify 85 radiographic severity of osteoarthritis. The Samilson-Prieto classification system grades arthritis 86 as follows: Grade 0 (normal), Grade I (humeral neck osteophytes <3mm, mild), Grade II 87 (osteophytes 3mm-7mm, moderate), and Grade III (osteophytes >7mm, severe). The radiographs 88 of each shoulder were independently graded by a board-certified orthopedic surgeon sub-89 specializing in surgery of the upper extremity and an orthopedic surgery resident. When there 90 was disagreement between independent observers, we used the grade given by the attending 91 surgeon.

The OSS questionnaire consists of a series of twelve questions. A score of 0-4 was given for each patient response, and a cumulative score between 0-48 was calculated; the higher the score, the better the shoulder function. Mild, moderate, and severe shoulder dysfunction was determined by an initial OSS between 30-48, 20-29, and 0-19, respectively.^{5, 6} Patients with moderate and severe shoulder dysfunction were combined in the study to improve sample size for comparison.

98 Patients were identified in clinic by obtaining standard shoulder radiographs. Those who 99 agreed to participate in the study were scheduled for image-guided glenohumeral corticosteroid 100 injections. Prior to the injection, patients were contacted over the phone in order to obtain a 101 baseline OSS (0-48) and Likert (VAS) pain score (0-10). The anticipated injection date for each 102 patient was then recorded. Subsequent phone interviews were conducted in a similar manner, and 103 OSS and VAS scores were recorded at the following intervals: Month 1 (within 2 weeks of the 104 image-guided injection), 2, 3, 4, 6, 9, and 12. The endpoint of the study occurred when patients 105 required subsequent intervention with another corticosteroid injection, shoulder arthroplasty, or 106 after 12 months from the initial injection. For patients who underwent a second intervention 107 (cortisone injection or shoulder arthroplasty), we used the last recorded VAS and OSS score 108 prior to the intervention for the remainder of the time points. This methodology was chosen to 109 avoid artificially improving or worsening the PROS by the results of the second intervention. 110 Statistical analysis

111 The collected data was imported into SYSTAT 13 and SPSS statistical analysis software 112 and Kaplan-Meier survival plots were created. Based on the OSS, we compared the percentage 113 of patients with mild shoulder dysfunction versus percentage of patients with moderate/severe 114 dysfunction that did not require secondary intervention at twelve months post-injection. This was

115 repeated, comparing patients with mild, moderate, and severe osteoarthritis based on the 116 Samilson-Prieto classification system. Additionally, Mann-Whitney U tests were performed to 117 compare VAS scores between patients with mild or moderate/severe shoulder dysfunction based on the OSS at various time points, including baseline, months 1, 2, 3, 4, 6, 9, and 12. The Mann-118 119 Whitney U test was repeated to determine if the VAS scores varied significantly at all time 120 points based on the Samilson-Prieto classification. A student T-test was performed to compare 121 the change in OSS scores from baseline to month 1 between patients with mild or 122 moderate/severe shoulder dysfunction. The T-test was repeated to compare the change in VAS 123 scores from baseline to Month 1 between the two groups. Lastly, a student T-test was performed 124 to compare the change in OSS and VAS scores from baseline at each time point in the study for 125 the entire cohort.

126

127 Results

128 Twenty-nine shoulders were available for analysis with one shoulder being lost to followup at month 12. 52% of the patients were men. The average age of this cohort was 66.1 years 129 130 (range= 43-86 years). Of the twenty-nine shoulders, eight shoulders were classified as having 131 mild osteoarthritis based on the Samilson-Prieto classification, thirteen as moderate, and eight as 132 severe. The inter-observer agreement was 93.3% for Samilson-Prieto grades between the two 133 observers. Seventeen patients had mild shoulder dysfunction based on OSS, (Average score 134 35.5) while twelve patients had either moderate or severe dysfunction (average score 21.8) 135 (Figure 1). Additional demographic data are summarized in Table I. 136 The average baseline VAS score for the entire cohort was 5.8. The average VAS scores

137 for patients with mild, moderate, and severe radiographic osteoarthritis based on the Samilson-

138 Prieto classification were 4.9, 6.5, and 5.7, respectively. The average baseline VAS scores based 139 on our OSS subgrouping for mild and moderate/severe shoulder dysfunction were 5.12 and 7, 140 respectively (Figure 2). A Mann-Whitney U test was performed for VAS scores between the two 141 groups. The VAS scores were not significantly different at any time points between the groups. 142 Twelve patients in the study required secondary intervention with either arthroplasty or a 143 repeat injection prior to the end of the twelve-month study period. According to the Kaplan-144 Meier survival analysis, 58.6% of patients for the entire cohort made it to twelve months without 145 requiring secondary intervention overall. When analyzing our subgroups based on OSS, 64.7% of the mild group (Std. Error 11.6%, CI 95% [0.38-0.82]), and 50% of the moderate/severe group 146 147 (Std. Error 14.4%, CI 95% [0.21-0.74]) made it to twelve months without requiring secondary 148 intervention. At 6 months post injection, 82.4% of patients with mild shoulder dysfunction did 149 not require secondary intervention (Std. Error 9.2%, CI 95% [0.55-0.94]), and 83.3% of patients 150 in the moderate/severe group did not require secondary intervention (Std. Error 10.8% CI 95% 151 [0.48-0.96]). To further compare the survival distributions, we utilized a Log Rank analysis (a 152 nonparametric hypothesis test to compare the survival distributions of two samples) and failed to 153 show a difference in overall survival curves between the two groups (p=0.446). 154 A Kaplan-Meijer survival analysis was also performed for patients with mild, moderate, 155 and severe osteoarthritis based on the Samilson-Prieto classification. Patients with mild 156 radiographic osteoarthritis had an 87.5% chance of not requiring a second intervention at twelve 157 months (Std. Error 11.7%, CI 95% [0.39-0.98]). Patients with moderate radiographic 158 osteoarthritis had a 46.2% chance of not requiring a secondary intervention at twelve months 159 (Std. Error 13.8%, CI 95% [0.19-0.70]). Patients with severe radiographic osteoarthritis had a

160 62.5% chance of not requiring secondary intervention at twelve months (Std. Error 17.1%, CI

95% [0.23-0.86]). A Log rank analysis failed to show a difference in the survival curves betweengroups (p=0.08).

163 The student T-test was performed to compare the change in OSS scores from baseline to 164 month 1 after the injection. The mean increase in OSS in the mild group following the injection 165 was 6.2. The mean increase in OSS in the moderate/severe group following the injection was 166 12.8. The increase from baseline to month 1 was found to be significantly higher in the moderate/severe group when compared to the mild group (p=0.03, CI 95% [1.37-11.9]). A T-test 167 168 was repeated, comparing the change in VAS scores from baseline to month 1 after the injection. 169 The average improvement in VAS in the moderate/severe group was 3.4, whereas the average 170 improvement in VAS in the mild group was 2.4. This was not found to be significant (p=0.32, CI 171 95% [-1.21-2.99]).

The change in OSS scores from baseline was calculated for the entire cohort at each time point. A student T-test was then used to compare the change in OSS scores from baseline, which did show a significant difference in the mean at month 1, 2, 3, and 4. The difference was not significant at months 6, 9, and 12. This was compared against the Mean Clinically Important Difference for the OSS of 3.3, as defined by Xu et. al.¹⁴ This data showed an improvement in the OSS above the MCID during months 1-4 with the change in OSS falling below the MCID during months 6, 9, and 12 (**Figure 3**).

The change in VAS scores from baseline was calculated at each time point. A student Ttest was used to compare the change in VAS scores to baseline. This showed a statistically significant change in the mean at months 1, 2, 3, 4, 6, 9, and 12. The change in VAS was compared against the MCID for VAS of 1.4, which has been defined in previous studies.^{12, 13}

183 This demonstrated improvements in VAS above the MCID for the entirety of the study (Figure184 4).

185

186 **Discussion**

187 The goal of this study was to determine the efficacy of a single, image-guided 188 corticosteroid injection in the conservative management of GHOA and determine the magnitude 189 of symptom relief as well longevity. We also wanted to determine whether subjective shoulder 190 dysfunction and or radiographic severity of GHOA impacted the amount and duration of 191 symptom relief.

192 To accomplish this, we developed a protocol to provide standardized, image-guided 193 glenohumeral injections. We felt this was important for several reasons. Soh et al found that 194 patients who underwent image-guided injections had statistically significant improvements in their shoulder pain at 6 weeks compared with patients who had blind injections.¹¹ Additionally. 195 196 image-guided glenohumeral injections have been found to be better at achieving intra-articular 197 needle placement. Aly et al performed a systematic review which compared the accuracy of 198 image-guided versus blind injections surrounding the shoulder girdle. They found that image-199 guided injections into the glenohumeral joint were 92.5% accurate, whereas blind injections were only 72.5% accurate.¹ 200

In this study, there was no significant difference in the number of patients who underwent secondary intervention with a steroid injection vs total shoulder arthroplasty in the mild or moderate/severe groups based on the OSS. Additionally, radiographic severity of the GHOA based on the Samilson-Prieto classification did not impact the duration of pain relief to expect from a single injection. However, the value of "survival" to evaluate the efficacy of an injection

may be limited, due to the multiple factors involved when indicating a patient for total shoulder
arthroplasty, including both patient and surgeon factors. Of note, no formal guidelines were
provided to participating surgeons regarding timing of TSA following injection. There is some
concern that cortisone injection increases the risk of infection following TSA. It is our general
practice to avoid TSA within 3 months of an injection; this also has impacts on usefulness of
"survival".¹⁸

212 The OSS is a validated questionnaire that gives shoulder surgeons an indication how patients are doing functionally.⁵ Additionally, VAS is a validated score that has been used to 213 214 monitor changes in patient's pain with rotator cuff disease as well as patients following shoulder arthroplasty.^{12, 13} We used both OSS and VAS in this study to get an overall appreciation of how 215 216 patients were doing both functionally and symptomatically following the injection. Recently, Xu 217 et. al. sought to determine the MCID for the OSS. In their paper, they published the results on 218 over 300 patients following arthroscopic rotator cuff repair and followed them for 24 months 219 post operatively. They were able to determine that the MCID for the OSS was 3.3 (95% CI [2.1-4.6]) at 12 months post operatively.¹⁴ Given these results, we were able to extrapolate the MCID 220 221 to be 3.3 for our study cohort.

Importantly, we were able to illustrate that a single image-guided corticosteroid injection can improve the average OSS from baseline to above a MCID for 4 months (**Figure 3**). This suggests that the image guided corticosteroid injection did provide clinically significant improvements in shoulder function up to 4 months post-injection. Additionally, we were able to show that patients with worse baseline OSS scores may expect more functional improvements than patients with milder disease from a single corticosteroid injection. However, some of this could be a result of the ceiling effect of the OSS questionnaire.² Regardless, these findings can

prove useful when counseling patients on what to expect from a single injection and help managepatient expectations.

A prior study by Tashjian et al, determined the MCID for the VAS score for patients with rotator cuff disease and for patients who underwent shoulder arthroplasty to be 1.4.^{12, 13} We extrapolated this MCID to our cohort. Based on our results, the average VAS score did remain below baseline for the entirety of the study, and, somewhat surprisingly, that improvement was greater than the MCID throughout 12 months, suggesting that this difference was clinically significant (**Figure 4**).

237 One interesting finding was that patients with severe radiographic GHOA, on average, 238 had lower baseline VAS scores and had a trend towards a higher survival based on our Kaplan-239 Meier survival analysis when compared with moderate radiographic GHOA. This could be 240 coincidental given the relatively small sample size, or it could represent lower functionality, 241 older age, or more comorbidities in this population; this again points to the limitations of using 242 "survival" while evaluating the results of a cortisone injection. Nevertheless, radiographic 243 severity of disease did not predict the duration of pain relief to expect from an image-guided 244 corticosteroid injection in this study. There may be some concern that patients presenting with 245 severe GH OA and glenoid bone loss will sustain progression of bone loss during non-operative 246 management. No specific guidance was provided to study surgeons regarding this; rather, each 247 surgeon could use her or his own judgement when counseling patients regarding injection. 248 One of the strengths of this study is its prospective, cohort design, which can provide

strong evidence in the absence of a randomized controlled trial.¹⁹ Additionally, follow-up in this cohort was excellent. We were able to maintain contact with 28/29 patients (29 shoulders) for 12 months following the injection. Another strength is the standardization of our injection protocol.

252 By only using image-guided injections and limiting our study to only patients with GH OA, 253 potentially confounding factors were eliminated. Finally, our study includes not only 254 radiographic measures, but also patient reported outcomes of function and pain. 255 There were several limitations of to this study. First, our sample size is small. Increasing 256 the sample size may have improved the chances at finding a statistically significant difference in 257 survival curves between study groups and decreased the chances at a possible type II error. 258 Additionally, there was no evaluation of other modalities patients were concurrently using to 259 treat their arthritis, such as physical therapy or NSAIDs. Also, we did not examine possible 260 confounders, most notably the presence of a concomitant rotator cuff tear. However, it has been suggested that the likelihood of a rotator cuff tear in the setting of primary GHOA is low.^{4, 8} No 261 262 patients had rotator cuff arthropathy. Additional comorbidities such as diabetes, hypothyroidism, fibromyalgia, etc. could have a potential impact on subjective pain and function. 263

264

265 Conclusion

In conclusion, this study sought to prospectively determine the efficacy of a single, 266 image-guided corticosteroid injection. To accomplish this, we used a validated shoulder survey 267 268 and VAS scores obtained prospectively at routine intervals after injection in patient with 269 radiographically confirmed GH OA. Patients in this cohort experienced statistically and 270 clinically significant improvements in their shoulder function (OSS) for 4 months post injection, 271 with dwindling effects thereafter. Additionally, these patients reported statistically and clinically 272 significant improvements in their pain (VAS) for up to a year, most pronounced over the first 4 273 months. However, either baseline OSS severity, or radiographic severity of GHOA predicted the 274 amount of pain relief patients can expect from a single, image-guided glenohumeral injection.

275 These results may help shoulder surgeons counsel their patients on the duration and amount of 276 pain relief to expect from a single, image-guided steroid injection. Additional larger, prospective 277 studies, potentially performed in a randomized fashion with a control group, will be helpful to 278 draw more definite conclusions on the efficacy of cortisone for GH OA. 279 280 References 281 1. Aly AR, Rajasekaran S, Ashworth N. Ultrasound-guided shoulder girdle injections are 282 more accurate and more effective than landmark-guided injections: a systematic review and 283 meta-analysis. Br J Sports Med. 2015;49(16):1042-9. doi:10.1136/bjsports-2014-093573 284 2. Angst F, Schwyzer HK, Aeschlimann A, Simmen BR, Goldhahn J. Measures of adult 285 shoulder function: Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH) and its 286 short version (QuickDASH), Shoulder Pain and Disability Index (SPADI), American Shoulder 287 and Elbow Surgeons (ASES) Society standardized shoulder assessment form, Constant (Murley) Score (CS), Simple Shoulder Test (SST), Oxford Shoulder Score (OSS), Shoulder Disability 288 289 Questionnaire (SDQ), and Western Ontario Shoulder Instability Index (WOSI). Arthritis Care 290 Res (Hoboken). 2011;63 Suppl 11:S174-88. doi:10.1002/acr.20630 291 3. Buchbinder R, Green S, Youd JM. Corticosteroid injections for shoulder pain. Cochrane 292 Database Syst Rev. 2003(1):CD004016. doi:10.1002/14651858.CD004016 293 4. Choate WS, Shanley E, Washburn R, Tolan SJ, Salim TI, Tadlock J, et al. The incidence 294 and effect of fatty atrophy, positive tangent sign, and rotator cuff tears on outcomes after total 295 shoulder arthroplasty. J Shoulder Elbow Surg. 2017;26(12):2110-6. 296 doi:10.1016/j.jse.2017.05.022 297 5. Dawson J, Fitzpatrick R, Carr A. QUESTIONNAIRE ON THE PERCEPTIONS OF 298 PATIENTS ABOUT SHOULDER SURGERY. The Journal of Bone and Joint Surgery British 299 volume. 1996;78-B(4):593-600. doi:10.1302/0301-620x.78b4.0780593 300 6. Dawson J, Rogers K, Fitzpatrick R, Carr A. The Oxford shoulder score revisited. Arch

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341 **Figure and Table Legends:**

- 342 Figure 1: Average OSS for patients with mild and moderate/severe shoulder dysfunction
- 343 Figure 2: Average VAS for patients with mild and moderate/severe shoulder dysfunction
- 344 Figure 3: Kaplan-Meier survival curve comparing the 12-month survival from secondary
- 345 intervention for patients with mild and moderate/severe shoulder dysfunction based on the
- 346 Oxford Shoulder Score
- 347 Figure 4: Kaplan-Meijer survival curve comparing the 12-month survival from secondary
- 348 intervention for patient with mild, moderate, and severe radiographic shoulder arthritis based on
- 349 the Samilson-Prieto Classification
- 350 Figure 5: Monthly change in the OSS from baseline vs MCID
- 351 Figure 6: Monthly change in VAS from baseline vs MCID
- 352 Figure 7: Average OSS change from baseline through months 12 for the entire cohort
- 353 Figure 8: Average VAS change from baseline through month 12 for the entire cohort
- 354 Table I: Patient demographics, including the following: Age, Sex, Laterality, Samilson-Prieto
- 355 classification, Oxford Shoulder Score Group, Mild or Moderate/severe
- Table II: Average change in the OSS from baseline for months 1, 2, 3, 4, 6, 9, 12. This change
- 357 was above the MCID for months 1-4, falling below the MCID during months 6, 9, and 12.
- 358 Table III: Average change in VAS from baseline for months 1, 2, 3, 4, 6, 9, and 12. This change
- 359 was above the MCID for all time points in the study.

29 shoulders / 28 patients	Average
Age	66.1 y/o (range= 43-86 years)
Sex	52% Male
Laterality	59% Right-Sided
Samilson-Prieto Classification	
Class I	8/29 (27.5%)
Class II	13/29 (45.0%)
Class III	8/29 (27.5%)
Oxford Shoulder Score Classification	
Mild	17/29 (58.6%)
Moderate/Severe	12/29 (41.4%)







