

## Non-Adherence to Pain Medication Increases Risk of Postoperative Frozen Shoulder

### Abstract

**Background:** Postoperative frozen shoulder (FS) or adhesive capsulitis is a relatively frequent complication (5-20%), even after simple arthroscopic shoulder surgeries. The pathophysiology is still unclear, but psychological factors may play a pivotal role. From clinical experience, we hypothesized that patients, who are reluctant to take medications, particularly “pain-killers,” have an increased incidence of postoperative FS. **Methods:** We identified twenty patients who underwent limited arthroscopic operations of the shoulder and developed postoperative FS. Twenty patients with matching type of surgery, age, and gender served as control group (n = 20). All patients were at least one year postoperative and asymptomatic at the time of examination. Demographic data, the patient’s adherence to self-medication (including self-medication scale, SMS), development the Quality of life (QoL), and depression scale (PHQ-4-questionnaire) were assessed. **Results:** Patients with FS had a 2-fold longer rehabilitation and 3-fold longer work inability compared to the patients without FS ( $P < 0.009$  and  $P < 0.003$ , respectively). Subjective shoulder value SSV ( $P = 0.075$ ) and post-operative improvement of QoL ( $P = 0.292$ ) did not differ among the groups. There was a trend—but not significant—toward less coherence to self-medication in the FS-group (26.50 vs. 29.50;  $P = 0.094$ ). Patients with postoperative FS significantly more often stated not to have “taken pain-killers as prescribed” ( $P = 0.003$ ). **Conclusions:** Patients reporting unwillingness to take the prescribed pain medications had a significantly higher incidence of postoperative FS. It remains unclear whether the increased risk of developing FS is due to reduced postoperative analgesia or a critical attitude toward taking medication. However, patients who are reluctant to take painkillers should strongly be encouraged to take medications as prescribed.

**Keywords:** Adhesive capsulitis, frozen shoulder, painkillers, post-operative adherence, shoulder arthroscopy

### Introduction

Frozen shoulder (FS), also known as adhesive capsulitis,<sup>[1-3]</sup> is a condition characterized by stiffness and pain in the shoulder joint and affects about 2-5% of the general population.<sup>[4]</sup> By consensus, a distinction is made between primary FS (idiopathic) and secondary FS.<sup>[5]</sup> While idiopathic FS is characterized by an insidious onset, secondary FS is either associated with a systemic disease (i.e., diabetes, cardiovascular or oncologic disease, hypothyroidism, etc.) or follows a defined event—such as a trauma or shoulder surgery.

The latter condition may even occur after limited or simple arthroscopic shoulder surgery<sup>[6]</sup> and lead to a largely prolonged rehabilitation. The postoperative course in

these patients distinctively differs from a normal postoperatively restricted motion in that patients show signs of massive inflammatory pain and decreased external rotation in adduction. Not infrequently, these patients have a normal course in the first days and experience a sudden deterioration of pain and range of motion.

Since small arthroscopic shoulder interventions are frequently performed, this complication imposes a relevant burden on the healthcare system due to (unexpectedly) long inability to work.<sup>[7]</sup> Identification of patients a risk, besides the ones known for idiopathic FS, would be advantageous to apply prophylactic measures and to improve preoperative information on possible duration of inability to work.

Several studies have demonstrated that a patient’s psychological predisposition has a pivotal effect on postoperative outcome

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after shoulder surgeries.<sup>[8,9]</sup> However, there is no literature, whether psychological characteristics may also favor development of a postoperative FS. In particular, from our own personal observation, patients with primary or secondary FS have often a very critical attitude toward intake of any medication. We hypothesized that patients who develop postoperative FS had a different psychological predisposition, in particular a critical attitude toward intake of medications compared to those who did not develop a FS.

## Methods

We retrospectively identified 1,022 patients who had undergone a limited shoulder arthroscopy between January 2013 and December 2018 using our clinical information system. The following were defined as limited invasive or small arthroscopic surgeries: Tenotomy of the long head of the biceps, subacromial debridement of calcific deposits or a small (1 cm) rotator cuff repair with maximum utilizing one suture-anchor. All operations were performed by the same board-certified orthopedic surgeon.

Postoperative treatment protocol included immediate passive and actively assisted motion exercises without limitation, but within pain tolerance. Postoperatively, patients were immobilized in a sling for 2-3 weeks and were allowed to move their shoulder actively without resistance. After 6 weeks, slight strengthening exercises were begun. Patients were followed in the outpatient clinic at 6 weeks, 3 months, and 6 months postoperatively.

The postoperative pain prescription was based upon the analgesic ladder recommended by the WHO.<sup>[10]</sup> The base medication was paracetamol 4 × 1 gram per day and ibuprofen 2 × 600 milligram per day and -if necessary- an opioid reserve. Patients were advised to take the medication for at least 3 weeks after surgery before beginning careful reduction.

Patients were included in the study if they developed a postoperative FS at least a year ago and were asymptomatic at the time of data collection. Diagnosis of FS was made using the definition by the British Shoulder and Elbow Society. It includes the painful restriction of shoulder motion with a flexion limited to 100° and a reduced external rotation in adduction of more than 30 degrees compared to the non-operated shoulder.<sup>[6,8,11,12]</sup>

From the retrospectively determined patient group with FS, a patient cohort without FS was selected that matched as closely as possible with the type of surgery, age, and gender.

A self-developed four-part-questionnaire was used to evaluate the compliance with prescribed medication, the subjective shoulder outcome and the depression level by telephone interview. The surveys were carried out after receiving the written informed consent.

Part 1: A self-developed questionnaire (in German) with demographic aspects.

To assess postoperative restriction of shoulder function, a modification of the SF-36 questionnaire<sup>[13]</sup> was utilized: “How long do you had any problems with your work or other regular daily activities postoperatively.” Answers were given in months and termed as “restricted months” in the result section.

In addition, we asked the following dichotomous questions about quality-of-life (QoL): “Would you have the same surgery done again?”; “Did the surgery improve your quality of life?”; “Did you take painkillers as prescribed postoperatively?” (key-question).

Part 2: The subjective shoulder value (SSV) described by Gerber and Gilbart<sup>[14]</sup> was used to define patient’s subjective shoulder assessment, expressed as a percentage of a perfectly normal shoulder reaching a 100 percent.

Part 3: A German translation of the self-medication scale (SMS, Tab 1) by James and French<sup>[15]</sup> was used, which is validated to reflect patient’s adherence to medication. The patients answered nine Likert-scaled questions, which are rated with one to five points (total score at least 9, maximum 45 points). A high score indicates a greater adherence to self-medication [Table 1].

Part 4: The PHQ-4<sup>[16]</sup> validated in German is an ultra-short screening scale for the detection of anxiety and depressive disorders. It contains four questions regarding emotions and feelings and four answers to choose from: 0-not at all 1-some days, 2-more than half the days, 3-nearly every day. The added scores reflected the patients’ depressive disorders. It yields a total score between 0 and 12 (scores: 0–2 normal, 3–5 mild, 6–8 moderate, and 9–12 severe depressive or anxiety disorder).

Statistical Methods: A two-tailed Kolmogorov–Smirnov test was used to analyze the data distribution. Nonparametric continuous data are presented by median and range and are analyzed with the Mann–Whitney U-test. The parametric data are presented by mean ± standard deviation and analyzed with the Student t-Test. Categorical data were compared with a Chi-square test and a Kruskal–Wallis test. The results were considered significant when  $P < 0.05$ . The data was analyzed using IBM SPSS® Statistics for Windows (Version 22.0; IBM Corp., Armonk, NY, USA).

This Study has an Ethical Committee Approval: Swissethics ID 2019-01392 and is in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000.

## Results

From 1022 patients with small arthroscopic shoulder operations, we were able to identify twenty-two patients

with a clear diagnosis of an FS. Two of these refused to participate in the study for no specific reason. Demographic data of both groups (n = 20) were comparable. The FS group deferred slightly by the number of women (15 vs. 14 in control group) and patients with diabetes (2 vs. 1). Age (58.5 vs. 60.5 years; *P* = 0.371), BMI (25.2 vs. 23.1; *P* = 0.357), and time (in months) from operation (51.1 vs. 42.2; *P* = 0.153) were comparable [Table 2].

Restriction in daily activity was twice as long in the FS group then in the control group (11.1 vs 6.5 months, *P* = 0.009). The inability to work was 2.88 times longer in the FS-group compared to the control group (6.3 vs. 2.2 months, *P* = 0.003, see Tab. 2). Both patient groups were highly satisfied with the operation, with the mean subjective shoulder value (SSV) being 89% in the FS and 93% in the control group (see Tab. 2). Furthermore 15 of 20 patients with FS and 18 of the 20 patients in the control group would undergo the procedure again, which was also not significantly different (*P* = 0.212). The depression scale [PHQ-4 questionnaire, Figures 1 and 2] showed no

significant differences (*P* = 0.204) between the FS- and the control group.

The self-medication scale (9-45 points) showed a trend, but not significant (*P* = 0.094) toward a lower coherence to self-medication in the FS group (FS group: range 26-37, median 26.50; control group: range 17-40, median 29.5). In comparison to the control group, FS patients reported significantly more frequently that they had not taken painkillers as prescribed (*P* = 0.003).

### Discussion

Postoperative FS represents a significant complication even after small arthroscopic shoulder surgery. It is a cause of marked disability and has a profound effect on the patient's quality of life. Further, it has a relevant impact on healthcare system.<sup>[7]</sup> In the current study, presence of FS did prolong shoulder restriction by a factor 2 (11 months vs 6.5 months). This is remarkable, since small arthroscopic procedures are usually uneventful and a rapid recovery is usually expected both by the patient and the physician.

**Table 1: The Self-medicating-scale (SMS) - presentation of the used questionnaire. Scores were added after fulfilling the questionnaire. High scores indicate greater propensity to self-medicate**

	Very often (5)	Often (4)	Sometimes (3)	Not that often (2)	Rarely (1)
1. I take medication only when I'm in a lot of pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I only take something if it's really bad	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I only take medication when it's absolutely necessary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I always take something if I'm in pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If I'm in pain I need medication to fix it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I don't hesitate to take painkillers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I prefer to let my body fight it out (Reverse score statements for evaluation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I do nothing just let it pass (Reverse score statements for evaluation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I try to ignore it and get on with it (Reverse score statements for evaluation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Table 2: Results Overview-Depending on distribution, results were presented by using median and Range or total-mean and SD**

	FS-Group (n=20)	Control-Group (n=20)	<i>P</i>
Gender (Total Counts "Female")	15	14	<i>P</i> =0.732
Gender (Total Counts "Male")	5	6	
Age in Years (Median [Range])	58.5 [43-73]	60.5 [43-73]	<i>P</i> =0.371
BMI (Total mean [SD])	25.19 [4.78]	23.08 [8.87]	<i>P</i> =0.357
Postoperative months (Total mean [SD])	51.10 [19.46]	42.18 [19.22]	<i>P</i> =0.153
Diabetes (Total Counts "Yes")	2	1	
Restricted Months (Total mean [SD])	11.10 [4.56]	6.45 [6.05]	<i>P</i> =0.009*
Disability to work in months (if active worker) (Total mean [SD] (n))	6.29 [3.64] (12)	2.18 [1.50] (16)	<i>P</i> =0.003*
SSV in % (Median [Range])	95.00 [60-100]	100.00 [50-100]	<i>P</i> =0.075
Self-medication scale, SMS, 9-45 pts. (Median [Range])	26.50 [26-37]	29.50 [17-40]	<i>P</i> =0.094
Same surgery again? (Total counts "Yes")	15	18	<i>P</i> =0.212
Better Quality of Life? (Total Counts "Yes")	19	17	<i>P</i> =0.292
Have taken painkillers as prescribed? (Total Counts "Yes")	11	19	<i>P</i> =0.003*
Changings in taking painkillers? (Total Counts "Yes")	2	0	
Depression-scale, PhQ-4, 0-12 pts. (Counted if ≥3)	4	2	<i>P</i> =0.204

The results were considered significant if *P*<0.05 and marked by\*

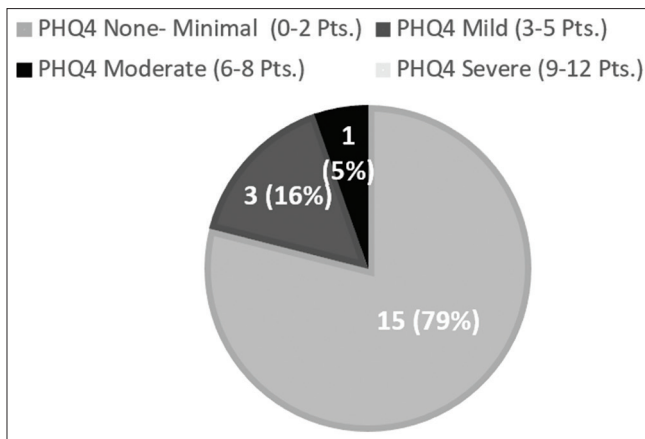


Figure 1: PHQ-4 Depression-Scale FS Group, illustration of the score-distribution in patient-counts and %

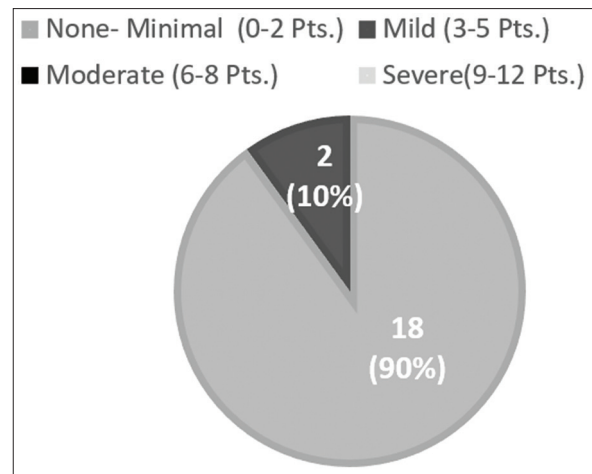


Figure 2: PHQ-4 Depression-Scale Control Group, illustration of the score-distribution in patient-counts and %

Furthermore, the duration of disability to work was almost tripled.

The main finding of this study, is that patients who developed postoperative FS significantly more frequently reported they had not taken pain killers as prescribed. ( $P = 0.003$ ). It might be well argued, that the—supposedly—reduced intake of painkillers had increased the rate of FSs. However, there is only weak evidence that NSAID alone prevent from a postoperative FS.<sup>[11,17]</sup> Therefore, the high incidence may rather be attributed to the patient characteristics than to the supposedly reduced intake of painkillers. In any case, a simply asked question on the willingness to take medications helps to identify patients with a higher risk to develop a postoperative FS, even after a small arthroscopic intervention.

The “self-medication scale,” which to our knowledge is the only established score on coherence to self-medication shows the same trend, even if the result was not significant ( $P = 0.094$ ). It may well be that this score is not specific enough or lost its value by the translation into German.

In contrast, depression had no or not a significant effect on the probability to develop postoperative FS. Using the PHQ-4<sup>[16]</sup> screening scale, we found no significant differences in terms of depression and anxiety between the two patient groups. However, this might be due to the small number of patients with a mild or moderate depression in both groups (FS-group ( $n = 4$ ) and in the control group ( $n = 2$ )). A larger number of patients might have shown some effect, which would be in line with previous studies.

Ding *et al.*<sup>[18]</sup> found that the prevalence of depression or anxiety was significantly higher in patients with idiopathic FS (28.2% and 24.2%, respectively) compared to healthy controls (16.9% and 13.8%, respectively).

There is abundant literature demonstrating that psychological factors have a strong impact on functional outcome after shoulder surgery, or even be more relevant than structural changes.<sup>[8,9]</sup> Of interest, Cuff *et al.*<sup>[19]</sup> found

that a high preoperative subjective pain tolerance was a strong predictor for pain in patients after rotator cuff repair, i.e., patients who thought they could tolerate the most pain rated their pain the most disabling. However, in the current literature no attention has been drawn to the psychological factors being predictive for postoperative FS. This is the first report to correlate the incidence of postoperative FS with the patient’s psychological characteristics, in particular the attitude toward intake of medication.

Of note, in the present study patient’s retrospective view toward the arthroscopic surgery is merely positive; even patients with postoperative FS almost uniquely stated an improved quality of life, represented by a high subjective shoulder value (SSV) of 89% on the affected side. Fifteen of the 20 patients (75%) would have had the same operation performed again. In the control group with a mean SSV of 93%, 18 of the patients would have the same operation performed again, the differences not being significant.

Limitations: We are aware that this study has limitations. It is a retrospective study and there are flaws with the matching of the patients. However, the groups are almost equally distributed for gender, age, and even for the known risk factors for FS; differences in the frequency diabetes are only marginal. In addition, patients were interviewed after they had gone through the operative procedure and may have a different psychological condition than before the operation. However, it is reasonable to state that the postoperative coherence to self-medication has been reported accurately by the patients or has even not changed.

Patients with postoperative FS showed a significantly prolonged rehabilitation and work incapacity, although SSV and satisfaction with the postoperative result were high

Patients with unwillingness to take medications are at significant risk to develop a postoperative FS. Therefore, patients with a critical attitude toward medications should be strongly recommended to take the NSAID



postoperatively and should be followed up more intensively to initiate timely therapeutic steps. Depression measured by the PHQ-4 did not increase the risk for postoperative FS.

### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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### Conflicts of interest

There are no conflicts of interest.

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