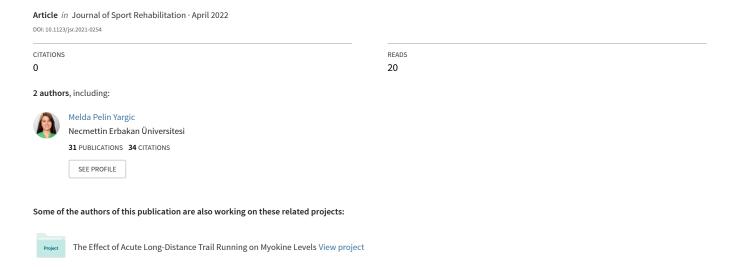
# Effectiveness of Ultrasound-Guided Corticosteroid Injections, Prolotherapy, and Exercise Therapy on Partial-Thickness Supraspinatus Tears





# Effectiveness of Ultrasound-Guided Corticosteroid Injections, Prolotherapy, and Exercise Therapy on Partial-Thickness Supraspinatus Tears

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Context: To investigate the effects of steroid injection (STE), prolotherapy (PRO), and exercise therapy in the treatment of partial tears of the supraspinatus. Design: A retrospective cohort study. Methods: A total of 64 patients with clinically and radiologically diagnosed partial-thickness supraspinatus tear who received either a cortisone injection (STE), dextrose PRO, or physical therapy combined with home-based exercise therapy were included. Main outcome measures were patients' visual analog scale scores, Western Ontario Rotator Cuff (WORC) Index scores, and the Shoulder Pain and Disability Index scores at the baseline, 3 weeks, and 3 months. Results: The effect of group, time, and group—time interaction on visual analog scale, WORC, and Shoulder Pain and Disability Index scores was statistically significant (P < .001). Visual analog scale and Shoulder Pain and Disability Index scores were the lowest in the STE group at week 3, and the lowest in the PRO group at month 3 (P < .001). WORC scores of the STE group were the highest at week 3 (P < .001). At month 3, WORC scores of STE and PRO groups were similar (P = .089), but significantly higher than exercise therapy. Conclusions: Corticosteroids provide a fast pain-relieving effect and improvement in function in partial-thickness rotator cuff tears, but these effects diminish over time, whereas PRO provides a long-lasting effect.

**Keywords:** rotator cuff tears, cortisone, physical therapy

Shoulder pain is a very common musculoskeletal complaint experienced among the general population and its incidence rate increases with age. Although lifetime prevalence rates of shoulder pain are divergent among different studies, it has been reported as high as 66.7%. Rotator cuff pathologies are the most common causes of shoulder pain, accounting for up to 70% of all cases. In cadaveric studies, partial tears were seen in 28.7% of the specimens and complete tears were seen in 30.3%.

There are several clinical practice guidelines for the treatment of rotator cuff pathologies.<sup>4,5</sup> Treatment options of rotator cuff pathologies can be either operative or conservative (such as exercise therapy [EXE], activity modification, physiotherapy, and nonsteroidal anti-inflammatory drugs or injection therapies). Having a partial-thickness tear is one of the predictors of better outcomes of the nonoperative treatment.<sup>6</sup> Therefore, clinical practice guides suggest nonoperative treatment for partial ruptures before surgical treatment, and almost always include EXE in the plan.<sup>4</sup> In addition to EXE, corticosteroid injections in the subacromial space are commonly recommended in the guidelines as an important part of the conservative treatment. However, there are some concerns regarding the safety of corticosteroid injections, such as the possibility that they may be causing long-term damage and worsening operative results in case of a later surgical repair.<sup>7,8</sup> Another injection therapy that can be implemented in the nonoperative treatment plan is prolotherapy (PRO), which is known to be an effective and safe treatment option in rotator cuff diseases. The effectiveness of these treatment options and their superiority to each other is an important research topic. To choose the most appropriate treatment for the patient, treatment

This study aims to investigate the short- and medium-term effects of 3 commonly used treatment options (STE, PRO, and EXE) in the treatment of partial tears of the supraspinatus.

# **Methods**

# **Study Design**

This retrospective cohort study received approval from the Local Medical Ethics Committee (No.:2021/3192) and followed the guidelines of the Declaration of Helsinki. Independent variables of the study design were the treatment procedures, whereas dependent variables were visual analog scale (VAS), Shoulder Pain and Disability Index (SPADI), and WORC scores.

efficacy should be known in the long term and in comparison with other options. In the meta-analysis of studies conducted for this purpose, when steroid injection (STE), PRO, and platelet-rich plasma injections were compared, it was determined that the short-term effects of steroids were high, but the long-term effects of platelet-rich plasma and PRO were higher. 10 To the best of our knowledge, there is no study comparing the efficacy of two of the most commonly used injection treatments (PRO and corticosteroids) and physical therapy with home EXE in patients with partial-thickness rotator cuff tears. We hypothesize that the physical symptoms, including pain, of patients receiving either injection therapy will improve more than those of patients who receive physical therapy. Similarly, we expect that injection treatments will be superior to physical therapy in increasing functionality and reducing disability. On the other hand, we hypothesize that STE will be more effective in reducing pain scores between both injection treatments.

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#### **Patients**

A retrospective chart review was performed to select patients who had been diagnosed with partial-thickness supraspinatus tear between January 2020 and January 2021. Patients who suffered from pain during overhead activities for at least 6 months were selected. All patients who were included in the study had either ultrasonography, or magnetic resonance imaging reports proving partial tear. Patients who received STE, PRO, or physical therapy combined with home exercises were included in the study.

Exclusion criteria were having received an injection therapy before the visit that was selected for study, being diagnosed with an illness that may alter pain perception, using medication that may alter pain perception, patients who had previous surgery at shoulder level, subscapularis or infraspinatus pathologies (tendinosis/full rupture/partial rupture), rotator cuff calcific tendinopathy, biceps tenosynovitis; labral tear; significant degenerative glenohumeral osteoarthritis; rheumatalogical, neuromuscular, or autoimmune disease; and symptomatic cervical disc herniation. Patients who used nonsteroidal anti-inflammatory drugs or acetaminophen at the time or in the following 3 months were also excluded.

#### **Procedures**

Patients were categorized into 3 groups according to the treatment they received: physical therapy and home exercises (EXE), STE, PRO. A minimum of 20 patients were selected for each treatment group (n = 20 in EXE and PRO, n = 24 in STE).

Physical therapy lasted for 3 weeks (6 d/wk) followed by home exercises for another 3 weeks. Physical therapy consisted of electrotherapy and EXE (pendulum exercises, rotator cuff strengthening, scapular mobilization, abduction and adduction exercises with a resistance band, active progressive resisted flexion, and internal and external rotation). Home exercises consisted of the same exercise protocol at the hospital, only without the electrotherapy. Exercise protocol took 30 to 45 minutes per session. Patients applied ice at the end of each home exercise session for 5 minutes.

All injections were performed ultrasound guided (7.5-Hz linear probe, Toshiba Aplio 300). PRO was performed in 2 sessions, 3 weeks apart. Patients were injected with a maximum of 0.5 mL of 20% hyperosmolar dextrose into the paratenon using a 21G needle with a lateral approach.

Patients who received a corticosteroid injection were injected with 1 mL of 40 mg/mL methylprednisolone acetate and 1 mL of lidocaine hydrochloride subacromially in a single session.

# **Main Outcome Measures**

Patients' VAS scores, Western Ontario Rotator Cuff (WORC) Index scores, and the SPADI scores at the baseline (before treatment), at 3 weeks, and 3 months were collected from their charts.

**Visual Analog Scale.** Patients rated the intensity of their pain on a 10-cm VAS. The scale was positioned horizontally and ends were labeled with the remarks "the least possible pain" and "the worst possible pain." The VAS is an accurate and robust measure for estimating the severity of pain.<sup>11</sup>

**The SPADI.** The SPADI is a self-administered questionnaire with 13 items, 5 of which constitute the pain subscale and the remaining

8 items constitute the disability subscale. <sup>12</sup> Each question is answered between 0 and 10. The total score ranges between 0 and 130 but the final score is reported as a percentage. Higher scores indicate worse conditions. SPADI has reliability coefficients of intraclass correlation coefficients  $\geq$ .89 and high internal consistency (Cronbach  $\alpha$  exceeding .90). Turkish adaptation of SPADI was found to be valid and reliable. <sup>13</sup>

**WORC Index.** The WORC Index is a self-administered, disease-specific quality of life questionnaire that assesses the change in particular signs, symptoms, and functional limitations associated with rotator cuff tendinopathy. There are 21 items that explore the following 5 domains: physical symptoms, sports and recreation, work, social function, and emotions. Leach question is answered using a VAS, ranging from 0 to 100. The maximum score is 2100 and the minimum score is 0. Final scores are reported as percentages in this study. Therefore, the final scores range from 0% (lowest functional status level) to 100% (the highest functional status). A reliable and valid Turkish adaptation of WORC is also available. Leach guestion and status as a self-administered, disease specific quality as a self-administered particular self-admi

# **Statistical Analysis**

A priori power analysis was conducted using G\*Power 3.<sup>16</sup> Results showed that a total sample size of 51 was required to achieve a power of .95 for analysis of variance (ANOVA) testing with repeated measures (between and within factors) when a medium effect size ( $\eta^2 = .60$ ), and an alpha of .05 was determined.

The variables were investigated using visual (histograms and probability plots) and analytical methods (Kolmogorov–Smirnov test) to determine normal or nonnormal distributions. Descriptive analyses are presented using mean (SD) for continuous variables and using frequency counts and percentages for categorical variables. A 2-way repeated-measures ANOVA was performed to evaluate the effects of group (EXE, STE, and PRO); time (before, 3 wk, and 3 months); and time–group interaction regarding VAS, WORC, and SPADI scores. Pairwise comparisons were made using a series of pairwise *t* test with Bonferroni correction when significant effects were observed. All statistical analyses were performed using R Studio (version 3.6.2; ColdFusion). Alpha level was set to .05.

## Results

Patient characteristics are given in Table 1. All patients were either active or veteran athletes, as the study was conducted in a sports medicine clinic. Patients' sports disciplines were tennis (n = 18),

**Table 1 Patient Characteristics** 

	PRO, n = 20	<b>EXE</b> , n = 20	STE, n = 24
Age, y	45.3 (8.64)	46.6 (7.78)	45.4 (8.25)
Sex			
Female	19 (95%)	16 (80%)	10 (41.7%)
Male	1 (5%)	4 (20%)	14 (58.3%)
Weight, kg	77.2 (5.47)	79 (9.07)	80.1 (10.5)
Height, cm	162 (6.63)	168 (7.92)	174 (7.57)
Body mass index, kg/m <sup>2</sup>	29.4 (1.96)	28.3 (3.88)	26.4 (2.62)

Abbreviations: EXE, exercise therapy; PRO, prolotherapy; STE, steroid injection.

Table 2 VAS, SPADI, and WORC Scores of Patients From Different Treatment Groups at 3 Time Points

	PRO, n = 20	EXE, n = 20	STE, n = 24
VAS			
Baseline $(t_1)$	6.7 (1.03)	6.45 (0.94)	6.42 (1.02)
Week 3 $(t_2)$	5.75 (1.48)	5.95 (0.82)	2.42 (1.02)
Month 3 $(t_3)$	3.4 (0.88)	5.6 (0.68)	4.17 (0.86)
SPADI			
Baseline $(t_1)$	74.9 (6.65)	75.1 (6.26)	74.2 (5.79)
Week 3 $(t_2)$	64.8 (6.83)	71.5 (5.74)	35.7 (2.68)
Month 3 $(t_3)$	56.5 (4.72)	69.0 (5.53)	63.7 (5.17)
WORC			
Baseline $(t_1)$	67.6 (3.75)	67.3 (2.38)	66.9 (3.36)
Week 3 $(t_2)$	69.1 (3.23)	68.9 (2.37)	83.0 (2.05)
Month 3 $(t_3)$	73.9 (2.68)	69.8 (1.64)	72.1 (3.35)

Abbreviations: EXE, exercise therapy; PRO, prolotherapy; SPADI, Shoulder Pain and Disability Index; STE, steroid injection; VAS, visual analog scale; WORC, Western Ontario Rotator Cuff.

swimming (n = 12), cycling (n = 11), triathlon (n = 11), mountain climbing (n = 8), and track and field (n = 4). According to the ANOVA results, participants' age did not vary significantly among treatment groups ( $F_{2,61} = 0.174$ , P = .84).

Mean SPADI, WORC, and VAS scores of 3 treatment groups at 3 time points are presented in Table 2.

#### **VAS Scores**

The VAS scores of participants according to treatment group are given in Figure 1. The effects of group ( $F_{2,61} = 29.724$ , P < .001), time ( $F_{2,122} = 119.996$ , P < .001), and group–time interaction ( $F_{4,122} = 48.404$ , P < .001) were significant. Then, the simple main effect of the group on each time point was investigated. No significant effect of the group was found on baseline ( $F_{2,61} = 0.501$ , P = .609). A significant effect of treatment was observed at week 3 ( $F_{2,61} = 68.8$ , P < .001) and at month 3 ( $F_{2,61} = 37.3$ , P < .001). Pairwise comparisons showed that the difference between VAS scores at week 3 was insignificant between EXE and PRO (P = .579), and both EXE and PRO were significantly higher than STE (P < .001, both). At month 3, VAS scores were as follows: EXE > STE > PRO, all comparisons significant with a P < .001.

Additionally, VAS scores of EXE were significantly lower at week 3 compared to baseline (P = .025), but the improvement at month 3 compared to week 3 was insignificant (P = .269). VAS scores of the PRO group improved significantly over measurements: baseline > week 3 > month 3 (all comparisons P < .001). STE group improved dramatically at week 3 (baseline vs week 3, P < .001). However, worsened later at month 3: baseline > month 3 > week 3 (all comparisons, P < .001).

#### **SPADI Scores**

The SPADI scores of participants from different treatment groups at 3 time points are visualized in Figure 2. A 2-way repeated-measures ANOVA revealed a significant effect of group  $(F_{2,61} = 45.455, \ P < .001)$ , time  $(F_{2,122} = 469.008, \ P < .001)$ , and group-time interaction  $(F_{4,122} = 264.963, \ P < .001)$ . Then,

the simple main effect of the group on each time point was investigated. Similar to VAS, no significant effect of group was found on baseline ( $F_{2,61} = 0.147$ , P = .864). However, there was a significant effect of treatment at week 3 ( $F_{2,61} = 295$ , P < .001) and at month 3 ( $F_{2,61} = 29.5$ , P < .001). Later, pairwise comparisons were performed. SPADI scores at week 3 were as follows: EXE > PRO > STE (all pairwise comparisons were P < .001). At month 3, the scores were: EXE > STE > PRO (all pairwise comparisons were P < .001). Additionally, in EXE and PRO groups, SPADI scores decreased significantly at each measurement (P < .001). Although SPADI scores of the STE group at week 3 were lower than baseline (P < .01), they increased back significantly at month 3 (P < .01), remaining lower than baseline (P < .01).

#### **WORC Scores**

The WORC scores of different treatment groups are presented in Figure 3. The effects of group  $(F_{2,61} = 37.179, P < .001)$ , time  $(F_{2,122} = 130.942, P < .001)$ , and group-time interaction  $(F_{4,122} = 98.648, P < .001)$  were significant. Then, the simple main effect of the group on each time point was investigated. Like SPADI and VAS results, no significant effect of group was found on baseline ( $F_{2,61} = 0.226$ , P = .798). A significant effect of treatment was observed at week 3 ( $F_{2,61} = 225.0$ , P < .001) and at month 3 ( $F_{2.61} = 11.4$ , P < .001). According to pairwise comparisons, at week 3, the STE group's WORC scores were significantly higher than both EXE and PRO (P < .001, both), whereas EXE and PRO had similar WORC scores (P = .824). The fast improvement observed in the STE group declined at month 3. Consequently, WORC scores of STE and PRO were similar at month 3 (P = .089). However, both STE and PRO groups had significantly higher WORC scores than the EXE group at month 3 (P = .002 and P < .001, respectively).

The EXE group improved their WORC score at each time point significantly ( $t_1$  vs  $t_2$ : P < .001,  $t_1$  vs  $t_3$ : P < .001, and  $t_2$  vs  $t_3$ : P = .005). PRO group only improved their WORC scores significantly at month 3 ( $t_1$  vs  $t_2$ : P = .106,  $t_1$  vs  $t_3$ : P < .001, and  $t_2$  vs  $t_3$ : P < .001). Finally, STE group improved significantly at week 3 ( $t_1$  vs  $t_2$ : P < .001), but later had lower WORC scores at month 3 than at week 3. However, the overall improvement at month 3 was still statistically significant ( $t_1$  vs  $t_3$ : P < .001).

#### **Effect of Sex**

Although our hypothesis does not involve the effect of sex, due to the unequal distribution of participants' sex in treatment groups, we analyzed the effects of sex, sex–group, sex–time, and group–sex–time interactions for all outcome measures. For SPADI, WORC, and VAS, the effects of sex ( $F_{1.58}=0.529$ , P=.470;  $F_{1.58}=0.745$ , P=.392;  $F_{1.58}=0.354$ , P=.554, respectively), sex–group interaction ( $F_{2.58}=0.468$ , P=.629;  $F_{2.58}=1.636$ , P=.204;  $F_{2.58}=1.130$ , P=.330, respectively), sex–time interaction ( $F_{2.116}=0.592$ , P=.555;  $F_{2.116}=0.072$ , P=.931;  $F_{2.116}=0.127$ , P=.881, respectively), and sex–group–time interaction ( $F_{4.116}=0.787$ , P=.536;  $F_{4.116}=0.545$ , P=.703;  $F_{4.116}=0.319$ , P=.865, respectively) were nonsignificant.

## **Discussion**

In this retrospective study, we have examined and compared pain and function of the shoulder of patients with a partial tear in

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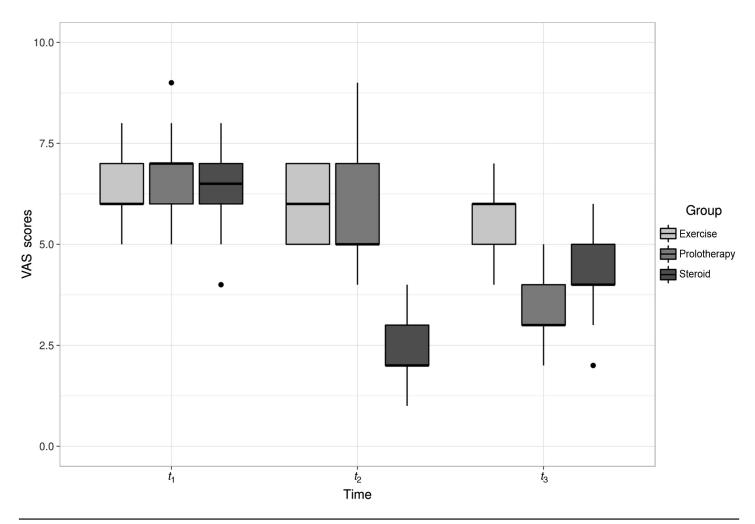


Figure 1 — The VAS scores of participants. VAS indicates visual analog scale.

supraspinatus, who received either an ultrasound-guided corticosteroid injection, ultrasound-guided dextrose PRO, or physiotherapy combined with EXE. We hypothesized that either injection therapy would result in a more significant improvement in the functionality of patients and a greater reduction in pain scores than those of patients who had physical therapy. In addition, STEs would be more effective than PRO in pain relief. Our hypotheses were only partly confirmed. In our study, the outcome of EXE was modest and both injection therapies had better results in the short term and at the third month (except for the WORC scores at the third week, which was not statistically significant). According to our findings, in the short term, the biggest improvement was observed with a corticosteroid injection. Improvement in pain and function was modest with PRO or EXE in the short term. However, in the third month, PRO group displayed better outcomes both in pain and function than steroid or EXE. The early effects of corticosteroids regressed in 3 months.

Limitations of statistical significance in clinical trials are well-documented and it is widely recommended to interpret results with regard to the minimal clinically important differences (MCID) instead. <sup>17</sup> An important point to emphasize is that the magnitude of the early improvement in pain due to corticosteroid injections exceeds the MCID. The MCID in VAS score was reported as 1.37 cm for patients who had nonoperative treatment for rotator cuff disease. <sup>18</sup> The decline in VAS scores was the most prominent

in the steroid group (4.0 cm) in the third week. Even though there was a loss of effect with time, the difference between the VAS score at the third month and baseline (2.25 cm) was still bigger than the MCID. The exercise group showed a consistent decline in VAS scores. Albeit the statistical significance, it never exceeded the MCID. PRO has also resulted in a consistent improvement in VAS scores. The PRO group also managed to exceed the MCID at the third month, with a 3.3 cm decline when compared to the baseline measurement.

The MCID values for a meaningful improvement in disability in patients with shoulder pain associated with partial-thickness rotator cuff tear was reported as a –300 change in WORC scores by Braun and Handoll. <sup>19</sup> Importantly, the authors used the WORC index on a 0 to 2100 scale, instead of reporting in percentages. The MCID value equals 14.8 when converted to a percentage. The largest improvement in the WORC score in our study was observed in the corticosteroid group at the third week by 16.1 points, which exceeds the MCID. All other statistically significant improvements in WORC failed to pass the MCID value.

The smallest detectable change in SPADI results that is important to the patient was reported as 8.0 by Paul et al.<sup>20</sup> Both PRO and STEs resulted in meaningful changes in SPADI, both at the third week and third month. Although the exercise group also improved consistently, the change was not big enough to be clinically important.

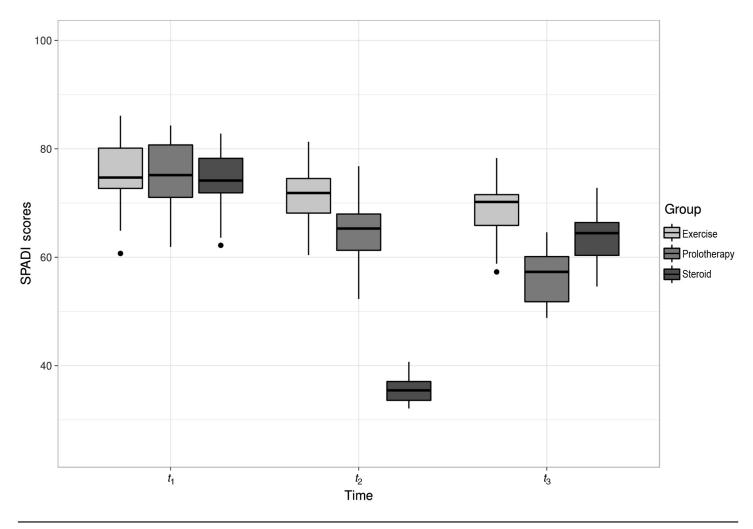


Figure 2 — The SPADI scores of participants. SPADI indicates Shoulder Pain and Disability Index.

Early pain-relieving effects of corticosteroids are well demonstrated in many other studies. 10,21-24 A randomized controlled trial on the treatment of rotator cuff disease conducted by Jo et al<sup>22</sup> has shown that corticosteroids improve pain at rest, pain at motion, pain at night, worst pain, and mean pain most prominently at the first week, but toward the sixth month this pain-relieving effect begins to fade. A systematic review compared the effectiveness of corticosteroid injections to anesthetic injections in the subacromial area in patients with rotator cuff-related shoulder pain and found that corticosteroid injections are more beneficial than anesthetic injections in the short term (up to 6 wk).<sup>23</sup> Some patients experience persistent pain following arthroscopic repair of the rotator cuff. Corticosteroid injection is also an effective and safe method of pain control during the postoperative recovery phase in such cases.<sup>21,25</sup> In our study, corticosteroid injections have not only improved pain, but also disability and function. Our study results indicate that subacromial injection of corticosteroids as an early treatment option is reasonable, but it needs to be supported with therapy modalities with longer effects.

We observed that PRO also significantly reduced pain in the third month. It consistently improved SPADI scores, although its effect on WORC score was not of clinical significance. Although the pain-relieving effect was more limited than the steroid in the acute period, the effects of the third month were superior to the steroid. Considering its long-term effects, PRO can be considered as an effective treatment option. Ryu et al<sup>26</sup> showed that dextrose PRO improves pain and disability in patients with rotator cuff tendinopathy. Furthermore, a systematic review of the literature found that PRO is a safe and effective method of therapy for patients with rotator cuff pathologies ranging from tendinosis to partial-thickness and small full-thickness tears.<sup>27</sup>

There are several limitations of this study. Physical therapy combined with home exercises resulted in clinically inadequate improvements in many aspects. However, physical therapy and EXE are known to be effective methods of conservative treatment in rotator cuff diseases.<sup>28</sup> It is possible that patient compliance with home-based EXE was inadequate. A limitation of this study is that we failed to measure the EXE compliance of patients. Also, patients did not receive a personalized EXE, which may have diminished the therapeutic effects of exercise. Another limitation of our study is that we could not report the changes in the range of motion. Some of the factors affecting the rate of tissue healing, such as vitamin D deficiency, which can be common among patients who visit the sports medicine clinic were not noted in the study.<sup>29</sup> Another methodological limitation is that we preferred excluding patients that used pain killers, although nonsteroidal anti-inflammatory drugs are recommended in the conservative treatment. Considering that athletes' use of painkillers is often extreme,

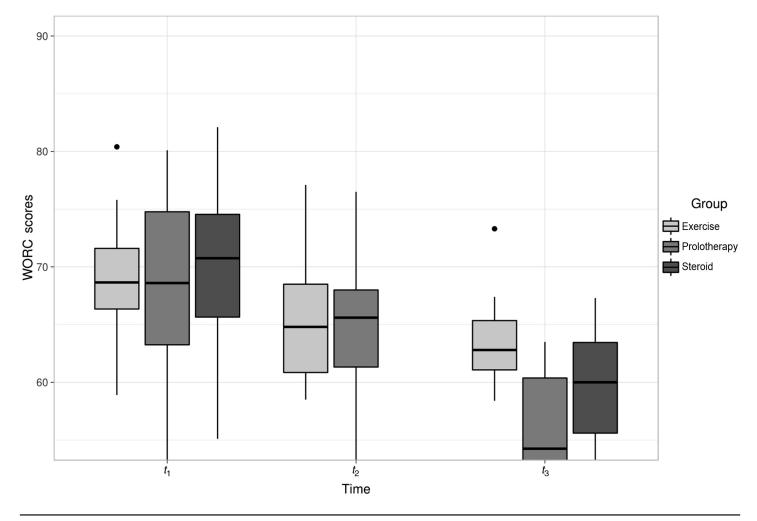


Figure 3 — The WORC scores of participants. WORC indicates Western Ontario Rotator Cuff.

this choice hopefully makes our study results more interpretable.<sup>30</sup> Finally, this is not a randomized control trial, but a retrospective study. However, the fact that baseline values of patients are similar diminishes the possibility of a selection bias.

In conclusion, our study findings add to the body of studies suggesting therapeutic benefits of dextrose PRO and corticosteroid injections in the management of partial-thickness supraspinatus tears, but nonpersonalized and nonmonitored EXE fails to provide clinically significant improvements in partial thickness supraspinatus tears. The duration of the analgesic and functionenhancing effects should be considered when planning an injection therapy. STEs may be preferred when a faster onset effect is desired, but it would be reasonable to plan to introduce other treatment modalities, anticipating that this effect will gradually decrease within a few months. Combination therapies of steroid and dextrose injections lack scientific evidence and the most effective and safest timing of such combinations should be the subject of new research.

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