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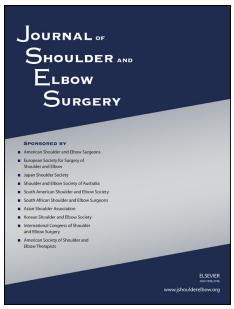

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A Double Blinded Randomized Controlled Trial

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The research protocol of the following study was approved by the ethics committee of the Hospital Italiano de Buenos Aires Institutional Review Board: 2381, study protocol No. 5269

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Abstract

Background: Studies evaluating the results of platelet-rich plasma (PRP) for the treatment of rotator cuff tendinopathy (RCT) have demonstrated conflicting results and have been confounded by small patient samples, the absence of a control group, the combined analysis of isolated tendinopathies and rotator cuff tears, insufficient reporting of PRP preparations, The purpose of this study was to perform a randomized controlled trial comparing platelet-rich plasma (PRP) with standard corticosteroid (CS) injections in providing pain relief and improved function in patients with rotator cuff tendinopathy.

Methods: This was a double-blind RCT at a single center. We evaluated patients between 18 and 50 years old who had both a clinical and magnetic resonance (MRI) diagnosis of supraspinatus tendinopathy refractory to conservative treatment. A total of 50 patients received PRP treatment, whereas 50 patients received a corticosteroid, as a control group. Patients completed patient-reported outcome assessments at baseline and at 1, 3, 6 and 12 months after injection. The primary outcome was improvement in the VAS score for pain. Secondary outcomes included changes in ASES score, SANE score and the Pittsburgh Sleep Quality Index (PSQI). Treatment failure was defined as persistent pain at 3 months which required a subsequent injection.

Results: The mean age was 27.7 (±7.4). All the patients completed 12 months clinical follow-up. At 12 months, patients in the PRP group showed a significantly greater improvement in the VAS than patients in the CS group 1.68(0.6) vs 2.3(1.0) ($p<0.001$). As

well, at 12 months follow-up, the 3 scores evaluated were significantly higher in patients treated with PRP than in patients treated with CS ASES 89.8 (6.3) vs 78.0 (8.6) (p<.001); SANE 89.2 (6.3) vs 80.5 (9.6) (p< .001) and PSQI 2.72 (0.6) vs 4.02 (1.7) (p< .001)

The overall failure rate, was significantly higher in the CS group (30%) than in the PRP group (12%) (p<0.01)

Conclusion: One subacromial PRP injection in patients with rotator cuff tendinopathy showed significantly superior and sustained pain-relieving and functional improvements compared with one corticosteroid subacromial injection assessed by 4 patient-reported outcome scales at 12 months of follow-up. Moreover, the overall failure rate, was significantly higher in the CS group than in the PRP group.

Level of Evidence: Level I; Randomized Controlled Trial; Treatment Study

Keywords: platelet rich plasma – corticosteroids - rotator cuff - tendinopathy

Rotator cuff tendinopathy constitutes the most common shoulder pathology and it is the leading reason for outpatient consultation in relation to shoulder-related pathologies.[7,20] The first line of treatment for rotator cuff tendinopathy typically involves introducing activity modifications, performing stretching and strengthening exercises, and taking oral anti-inflammatory medications.[6,8,13,22] In the event the abovementioned measures fail to be effective, local corticosteroid infiltrations are offered as a second line of treatment. [6,8,13,22] Although corticosteroid infiltrations constitute a common low-cost and effective treatment for reducing pain and improving motion, their clinical effects usually wear off quickly, according to most studies assessing their effectiveness in patients with rotator cuff tendinopathy.[22,15] In addition, corticosteroids have no biological effect in terms of regenerating or reversing the structural changes occurring in rotator cuff tendons that result from chronic inflammation.[22,15]

In this context, the use of platelet-rich plasma (PRP) becomes a promising alternative since it enables the release of pro-regenerative growth factors (GFs) and cytokines at the site of injury.[18,24] It has been shown that the GFs released by platelets can perform pro-regenerative functions in vitro, such as the promotion of stem and progenitor cell proliferation and recruitment, the modulation of inflammatory responses and the stimulation of angiogenesis.[10,18,24] Additionally, it has been demonstrated that platelet-released GFs can not only enhance the proliferation of tenocytes from the rotator cuff but also stimulate the production of key extracellular matrix proteins, which include collagen types I, II, and X; decorin; aggrecan; and biglycan. [10,18,24]

Furthermore, PRP is also protective against oxidative stress, thus preventing cell apoptosis following an injury, and it has the ability to inhibit the inflammation produced by interleukin-1b (IL1b), which can cause degeneration of the rotator cuff tendon.[10,18,24]

Although the clinical benefits of PRP in treating patients with rotator cuff tendinopathy have been studied in numerous small cohort studies as well as randomized controlled trials, the results of these works have been affected by confounders including small patient samples, lack of control groups, combined analysis of isolated tendinopathies and rotator cuff tears, variable or poor reporting of PRP preparations, and short follow-up periods.[10,12,23] Consequently, further high quality randomized controlled trials are required to delve more deeply into the merits of PRP as a treatment for early rotator cuff disease.[10]

This study consisted of a randomized controlled trial aimed to compare the ability of platelet-rich plasma (PRP) versus standard corticosteroid (CS) injections to relieve pain and improve function in patients suffering from rotator cuff tendinopathy. Our hypothesis was that PRP would offer better pain relief and function than the standard treatment with CS injections in patients with RCTs.

Materials and Methods

Study design

This was a double-blind, 1:1 randomized, prospective clinical trial (patients as well as clinical and structural evaluators were blinded). It was conducted at a university hospital, the Italian Hospital of Buenos Aires. This is a high-complexity third-level university hospital located in Buenos Aires. It has 750 beds and 38 critical care beds for adult patients. The study received the approval of the ethics committee of our institution (institutional review board: 2381, study protocol No. 5269) and it was registered at ClinicalTrials.gov (NCT06150378 protocol:5269). Informed consent was obtained in writing from all patients participating in this study. All reporting procedures for this trial followed the Consolidated Standards of Reporting Trial (CONSORT) guidelines.[17]

Study Population

The inclusion criteria for this study were patients: (1) aged between 18 and 50; (2) having a clinical as well as a magnetic resonance (MRI) diagnosis of supraspinatus tendinopathy refractory to conservative treatment. Refractory treatment was defined as (a) symptoms for at least 3 months and (b) have received an appropriate course of nonoperative treatment including physical therapy (PT) and nonsteroidal anti-inflammatory drugs (NSAIDs). For those patients who had not previously received a full course of physical therapy, a 3-month supervised PT program was provided at our institution. A fellowship-trained shoulder surgeon (LAR) first clinically diagnosed the cases of rotator cuff disease by evaluating positive Neer or Hawkins sign in addition to a positive painful arc or Jobe test. In the event of clinical suspicion, an MRI was indicated in order to ensure accurate diagnosis. The exclusion criteria were as follows: (1) presence of partial or full thickness rotator cuff tear; (2) cuff tear arthropathy, confirmed by MRI; (3) 25% limitation of both active and passive movements of

the shoulder joint in a minimum of 2 directions to exclude adhesive capsulitis; (4) previous subacromial or intraarticular injection; (5) Workers' Compensation patients (6) symptomatic cervical spine disorders, (7) previous surgery in the same shoulder (7) cancer (8) patients unwilling to participate. A maximum of 3 months prior to the infiltration, all patients underwent MRIs, which were graded on a scale from 0 to 5 [14], as follows: 0, no tendinopathy; 1, mild tendinopathy; 2, moderate tendinopathy; 3, moderate tendinopathy, partial-thickness tear present; 4, severe tendinopathy, partial-thickness tear present; 5, severe tendinopathy, full thickness tendon present. Only Grades 1 and 2 were considered in the inclusion criteria.

Randomization and Blinding

One of the team's shoulder surgeons performed the consecutive selection of patients in the shoulder pathology consultation and recruited only those who complied with the inclusion criteria. After being included, and once informed consent was obtained from all enrolled patients, one of team's shoulder surgeons randomly assigned each patient to either the CS injection group or the PRP injection group by means of permuted block randomization with randomly selected block sizes ratio using the REDCap software (Vanderbilt University, Nashville, TN, USA). The treatment given to patients was blinded to all patients, as well as to the fellow researcher who conducted the clinical evaluations and the musculoskeletal radiologist who performed the ultrasound at 1 year follow-up. To ensure blinding, venous blood was drawn from all patients before the injection and the injections were administered using a similar method, masking the syringes used for the infiltrations with a piece of black tape in order to prevent patients from recognizing their contents. All injections were administered under US guidance by 1 shoulder surgeon (LAR) who was unblinded to the intervention.

PRP Preparation

A leukocyte-poor preparation from a pre-packaged kit (RegenLab, Lausanne, Switzerland) was used in the PRP group. The samples underwent centrifugation at 1,500g for 5 minutes, yielding approximately 5.5 mL of 80% platelets at 1.6 concentration. The manufacturer has reported filtration rates of 99.7%, 87% to 89%, 70% to 75%, and 96.5% of red blood cells, white blood cells, mononuclear cells, and granulocytes, respectively.

US-guided PRP and steroid injection

Approximately 10 mL of venous blood was drawn from both groups of patients with a similar time delay for centrifugation before administering the injection. Patients were placed in a semi seated position with their arms in internal rotation. The injection site area was disinfected following strict aseptic precautions. Then, the supraspinatus tendon was located under US control in the lateral plane and the subacromial space was infiltrated (lateral subacromial approach). Patients in the PRP group were administered a 5 mL volume injection into the subacromial space, while for patients in the CS group, the blood sample was discarded and they received 1 mL of 40-mg/mL triamcinolone suspended in 2 mL of 0.5% Xylocaine. Patients in both groups were informed about possible adverse reactions to the injections received. They were allowed to perform their daily activities as tolerated after receiving the injection and were encouraged to follow an exercise program at home.

Outcome Assessment

A fellow researcher blinded to the type of injection received by each patient performed pre- and post-injection evaluations. As a result, patients were evaluated prior to treatment (baseline) and at 1, 3, 6 and 12 months of follow-up. The presence of pain while doing activities of daily living was the primary outcome, which was assessed using the visual analog scale (VAS). In turn, the secondary outcomes were general shoulder function, subjective satisfaction, and sleep disorders, which were assessed using the American

Shoulder and Elbow Surgeons (ASES) score, the Single Assessment Numeric Evaluation (SANE) score, and the Pittsburgh Sleep Quality Index (PSQI), respectively. For each group, we evaluated the percentage of patients who achieved the patient acceptable symptomatic state (PASS) for the VAS and ASES scores. The PASS for the VAS score was 1.7 and for the ASES score was 78.[4,11] In addition, patients were asked whether they had been able to return to their previous sports and whether they had done so at the same level prior to injury. Post-injection US was performed at 12 months in order to evaluate whether there had been any progression to a partial or full thickness rotator cuff tear. A musculoskeletal radiologist who was blinded to the treatment received by each patient performed all the postoperative US. We then calculated failure rates, for which failure was defined as persistent pain (VAS > 6) at 3 months which required a subsequent injection.

Sample size calculation

In order to calculate the minimal clinically important difference (MCID) in the primary outcome of the VAS pain score, this study was powered to 80% (β=.20). In the context of rotator cuff disease, the MCID has been previously calculated at 1.4 cm with a standard deviation of 2.41 cm on a 10-cm scale for pain in the dominant shoulder.[4] Using these parameters in a superiority formula, we calculated a sample size of 49 patients per group, giving a total of 98 patients.

Data analysis

Continuous variables were presented as mean and standard deviation, according to the observed distribution, while categorical variables were presented as absolute and relative frequencies in percentages. A P value below .05 was considered statistically significant. The VAS, ASES, SANE, and Pittsburgh Sleep Quality Index scales were compared at 1,3, 6, and 12 months after the administration of the injection. Both the primary and secondary outcome

analyses were performed as per the intention-to-treat principle. Since there were multiple hypothesis tests, a Bonferroni adjustment was made, defining a P value below .004 as statistically significant. The STATA/SE software, version 17 (StataCorp, College Station, TX, USA) was used to perform the data analyses.

Results

Demographic Characteristics

Between January 2022 and September 2022, 276 patients were assessed for study eligibility. Of these, 100 patients were randomized and received either PRP or CS injections. (Figure 1). All the 100 patients completed 12 months follow-up. There were no differences between the 2 groups in baseline clinical features (Table 1)

Primary Outcome

There were no statistically significant difference in baseline pain scores between Groups (Table 1). The VAS scores in the CS group improved by a greater amount when compared to the PRP group at one-month follow-up. Then both groups continued to improve pain without significant differences at 3 and 6 months follow-up. Finally, at 12 months follow-up, patients in the PRP group showed a significantly greater improvement than patients in the CS group (Figure 2 A and Table 2). The PASS for pain (1.7/10) was achieved in 96% of patients in the PRP group and in 84% of patients in the CS group at 12 months follow-up ($p<.001$).

Secondary Outcomes

There were no statistically significant differences in baseline ASES, SANE and Pittsburgh scores between Groups (Table 1). The three scores showed similar behavior during follow-up. In the first month they improved significantly faster in the group treated with CS.

However, then the improvement was equalized between the groups at 3 months. Finally, the 3 scores were significantly higher in patients treated with PRP than in patients treated with CS at 6 and 12 months of follow-up (Table 2, Figure 2 B-D). The PASS for the ASES score (78/100) was achieved in 100% of patients in the PRP group and in 86% of patients in the CS group at 12 months follow-up (p<.001).

A total of 83 patients played sports before infiltration. (Table 1) 93% (40/43) of the patients in the CS group and 90% (36/40) of the patients in the PRP group returned to sports (P=0.457). Of these, 84% (36/43) in the CS group and 80% (32/40) in the PRP group returned to competition at the same level with no significant differences between the groups (P=0.086).

Follow-up US was available at 12 months in 95 of 100 patients (unavailable in 2 patients in the PRP group and 3 patients in the CS group). In no patient was there evidence of progression of tendinopathy to partial or total rotator cuff tear.

Failures and adverse events

The overall failure rate within 12 months of injection, defined as a patient requesting a subsequent shoulder injection was 19%. The PRP and CS groups had failure rates of 12% and 30%, respectively (P <.001). Three adverse events were reported in the corticosteroid group, all allergic reactions to the injection, unknown to the patients and subsequently confirmed. There were no adverse events reported in the PRP group.

Discussion

This study had three main findings. Firstly, pain improvement at 12 months follow-up was significantly greater in the PRP group compared to the CS group. Secondly, the three functional scores used to evaluate overall shoulder function, patient satisfaction and sleep

disorders, namely ASES, SANE and Pittsburgh, respectively, had significantly higher values in the group treated with PRP when compared to the CS group at 12 months follow-up. Thirdly, the overall failure rate, defined as a patient requesting a subsequent shoulder injection, was significantly higher in the group treated with CS (30%) compared to the PRP group (12%).

The use of PRP for treating rotator cuff disease was recently evaluated in two systematic reviews of randomized controlled trials (RCTs). In one of these studies, A Hamid et al[1] analyzed the results of using PRP for the treatment of rotator cuff tendinopathy in 8 RCTs and concluded that PRP injections were safe and effective for long-term pain control and shoulder function in patients with this condition. In turn, Hurley et al[10] analyzed 5 randomized controlled trials (RCTs) in order to compare the use of PRP as a nonoperative treatment for rotator cuff tendinopathy. In their review, two of the studies analyzed revealed that PRP had better outcomes compared with the control group, one study showed no differences and the two other studies concluded that PRP alone had poorer outcomes when compared to the control group. The methodological limitations of the studies analyzed in these two systematic reviews were pointed out by the authors of both research works. Such limitations included the mixed variety of outcome measures, poor reporting of the PRP preparation method, and the small sample of patients studied, which might partially explain the variability of the results reported. In turn, our study showed that patients who had received PRP had significantly better results for both pain relief and functional outcomes from 6 months to 12 months. These findings are in line with previous research works reporting that corticosteroid injections offer limited and transient pain relief for patients with rotator cuff tendinopathy.[9,23] Another study by Mohamadi et al[16] evaluating the effects of CS injections in patients with rotator cuff tendinosis concluded that, even though some improvement in pain was observed when compared to placebo up to 2 months after the

injection, there were no differences at 3 months between the two groups. Likewise, in a recent pragmatic multicenter randomized controlled trial including 708 adult patients with a rotator cuff disorder, the authors assessed the clinical effectiveness and cost-effectiveness of progressive exercise compared with best-practice physiotherapeutic advice, with or without corticosteroid injections. Subacromial corticosteroid injections were reported to improve shoulder pain and function, although they only provided modest short-term benefits that wore off after 8 weeks.[16]

The first randomized controlled trial which compared platelet-rich plasma (PRP) injections with standard corticosteroid injections in patients suffering from rotator cuff tendinopathy for a 12-month follow-up period was conducted by Kwong et al.[12] The results of this study showed that although patients treated with PRP had better pain relief and function outcomes at short-term follow-up (3 months), PRP had no better sustained benefit compared to CS at a longer-term follow-up (12 months). Unlike this finding, our study showed that, at 12 months, both pain and all functional scores were significantly better in PRP patients. In addition, the percentage of patients for whom the treatment failed, that is, the number of cases requiring a second infiltration or surgery, was significantly higher in the CS group (30%) when compared to the PRP group (12%). These differences might be explained by some limitations in the study conducted by Kwong et al. [12] Firstly, although patients had been randomized into the study groups, patients in the PRP group had significantly worse baseline scores than patients in the CS group. Secondly, since patients in Kwong's study had received up to 3 previous corticosteroid infiltrations, it is difficult to determine whether these infiltrations might have affected functional outcomes. Last but not least, patients with tendinosis and partial RC tears were analyzed together without no subanalysis performed in relation to the stage of the disease. We consider this is not appropriate since PTRCTs constitute a more advanced stage of the disease, involving more severe structural deterioration as well as

permanent histological changes, which might more markedly affect clinical results than cases of patients with an isolated tendinopathy. [2,3] In relation to this, a recent prospective cohort study conducted by Rossi et al[19] evaluating the effect of subacromial PRP injections in patients with isolated rotator cuff tendinopathy compared to those with partial-thickness rotator cuff tears (PTRCTs) reported a significantly poorer improvement in symptoms and functional outcomes in PTRCT patients compared with patients suffering from an isolated tendinopathy.

Finally, there is still a lack of consensus in relation to how much PRP infiltration should be used to treat rotator cuff tendinopathies and whether the infiltration should be performed in the subacromial space, intratendinously, or at both sites. A recent double-blind randomized controlled trial conducted by Vaquerizo et al[23] evaluated the clinical results of PRP use in 39 patients (who received 3 intratendinous infiltrations, 1 every other week) compared to a control group of 40 patients treated with corticosteroids (3 infiltrations, 1 every other week). In line with our study, the results showed that the patients who had received PRP had significantly better and sustained pain-relieving and functional improvements than those treated with corticosteroid injections administered intratendinously, according to the UCLA, Quick DASH, and at 6 and 12 months of follow-up. In our study, unlike the authors, a single subacromial PRP infiltration was used. Our choice for the subacromial space over the intratendinous site for infiltration is explained by the fact that, in our experience, the latter technique causes strong pain in patients and, as demonstrated in this study as well as in previous studies, pain relief is usually effectively achieved with a single infiltration. [19,21] As a result, unless future comparative studies show the cost-effectiveness of applying multiple infiltrations, we believe that there is no additional benefit in performing more than one PRP infiltration. In this regard, further prospective comparative studies analyzing different PRP

application sites as well as different PRP doses should be conducted in order to elucidate these issues.

There are some limitations in this study which should be pointed out. First of all, our research only included patients between 18 and 50 years of age since our population of interest is mainly made up of active young patients. Consequently, it should be noted that the results we obtained may not be extrapolated to older patients whose tendons may be more deteriorated. Secondly, even though a complete clinical follow-up was achieved with all patients, only 95% completed the radiological follow-up since 5 of them were not able to undergo an ultrasound at 12 months of follow-up. Thirdly, our study was conducted in a single center and, therefore, in order to evaluate the generalizability of the results, multicenter studies should be carried out.

Conclusions

In patients suffering from rotator cuff tendinopathy, significantly superior and sustained pain-relieving and functional improvements were obtained with the administration of one subacromial PRP injection when compared to one corticosteroid subacromial injection, as assessed by 4 patient-reported outcome scales at 12 months of follow-up. Moreover, the overall failure rate, was significantly higher in the CS group than in the PRP group.

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383 **Legends**

384 **Figure 1:** CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the
385 randomized controlled trial. PRP: Platelet Rich Plasma

386 **Figure 2:** Change in baseline scores in platelet-rich plasma (PRP) group versus corticosteroid
387 (CS) group. (A) Visual analog scale (VAS) score. (B) American Shoulder and Elbow
388 Surgeons (ASES) score. (C) Single Assessment Numeric Evaluation (SANE) score. (D)
389 Pittsburgh Sleep Quality Index. Error bars show standard deviations.

390 **Table 1:** Patient Demographic Characteristics

391 **Table 2:** Comparison of Functional Outcomes and Return to Sports Between the Groups

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	All (N=100)	Control (N=50)	Intervention (N=50)
Age- mean(SD)	27.7 (7.4)	27.7 (7.5)	27.6 (7.3)
Female – n (%)	52 (52%)	27 (54%)	25 (50%)
Dominance n (%)	62 (62%)	31 (62%)	31 (62%)
BMI - mean(SD)	23.1 (2.8)	23.2 (2.9)	23.0 (2.7)
PCT (months) mean (range)	6.00 (5-8)	5.5 (5-7)	6.8 (5 -7)
Smoking status – n (%)	12 (12%)	7 (14%)	5 (10%)
Diabetes– n (%)	9 (9%)	5 (10%)	4 (8%)
No Sport - n (%)	17 (17%)	7 (14%)	10 (20%)
Type of Sport:			
No sport	17 (17%)	7 (14%)	10 (20%)
No collision/no overhead - n (%)	43 (43%)	20 (40%)	23 (46%)
Contact/collision - n (%)	21 (21%)	13 (26%)	8 (16%)
Overhead - n (%)	15 (15%)	10 (20%)	5 (10%)
Martial arts - n (%)	4 (4%)	0 (0%)	4 (9%)
Level:			
Competitive	50 (50%)	25 (50%)	25 (50%)
Recreational	33 (33%)	18 (36%)	15 (30%)
No sports	17 (17%)	7 (14%)	10 (20%)
VAS pre - mean (SD)	6.02 (0.7)	5.98 (0.6)	6.06 (0.7)
ASES pre - mean (SD)	52.5 (6.3)	52.5 (6.4)	52.4 (6.4)
SANE pre - mean (SD)	64.2 (6.5)	64.4 (6.4)	64.1 (6.6)
Pittsburgh pre - mean (SD)	11.6 (2.1)	11.8 (2.1)	11.1 (2.5)

2 PCT: preinjection conservative treatment
3 ASES, American Shoulder and Elbow Surgeons; SANE, Single Assessment Numeric Evaluation; VAS,
4 visual analog scale. Pittsburgh, Pittsburgh Sleep Quality Index
5 [a]Data are presented as mean (SD) unless otherwise indicated.
6 [b]Chi-square test.
7 [c]t-test.
8 [d]Mann-Whitney U-test.

	All (N=100)	Control (N=50)	Intervention (N=50)	*P.value*
VAS pre – mean (SD)	6.02 (0.7)	5.98 (0.6)	6.06 (0.7)	0.568[a]
VAS 1 month	2.94 (0.8)	2.44 (0.5)	3.44 (0.7)	<0.001[a]
VAS 3 month	1.87 (0.7)	1.90 (0.7)	1.84 (0.7)	0.679[a]
VAS 6 month	1.83 (0.7)	1.90 (0.7)	1.76 (0.7)	0.337[a]
VAS 12 month	1.99 (0.9)	2.30 (1.0)	1.68 (0.6)	0.001[a]
ASES pre – mean (SD)	52.5 (6.3)	52.5 (6.4)	52.4 (6.4)	0.95[a]
ASES 1 month	77.4 (7.6)	80.8 (6.0)	73.9 (7.6)	<0.001[a]
ASES 3 month	84.8 (5.8)	83.9 (5.6)	85.7 (6.0)	0.135[a]
ASES 6 month	84.4 (8.1)	80.2 (8.0)	88.5 (5.8)	<0.001[a]
ASES 12 month	83.9 (9.5)	78.0 (8.6)	89.8 (6.3)	<0.001[a]
SANE pre – mean (SD)	64.2 (6.5)	64.4 (6.4)	64.1 (6.6)	0.82 [a]
SANE 1 month	77.0 (8.5)	81.2 (8.3)	72.8 (6.4)	<0.001[a]
SANE 3 month	84.8 (8.0)	83.9 (8.5)	85.7 (7.5)	0.267[a]
SANE 6 month	86.1 (7.8)	83.9 (8.5)	88.3 (6.5)	0.005[a]
SANE 12 month	84.8 (9.2)	80.5 (9.6)	89.2 (6.3)	<0.001[a]
Pittsburgh pre – mean (SD)	11.6 (2.1)	11.8 (2.1)	11.1 (2.5)	0.95[a]
Pittsburgh 1 month	4.94 (1.2)	4.20 (0.9)	5.68 (1.1)	<0.001[a]
Pittsburgh 3 month	3.27 (0.9)	3.34 (1.0)	3.20 (0.9)	0.475[a]
Pittsburgh 6 month	3.07 (0.8)	3.34 (1.0)	2.80 (0.6)	0.002[a]
Pittsburgh 12 month	3.37 (1.4)	4.02 (1.7)	2.72 (0.6)	<0.001[a]

Data are presented as means SD unless otherwise indicated.
ASES, American Shoulder and Elbow Surgeons; SANE, Single Assessment Numeric Evaluation; VAS, visual analog scale. Pittsburgh; Pittsburgh Sleep Quality Index. [a]t- test.