Short-Term Effectiveness of Precut Kinesiology Tape Versus an NSAID as Adjuvant Treatment to Exercise for Subacromial Impingement: A Randomized Controlled Trial

Moira Devereaux, MScPT, Kinny Quan Velanoski, BScPT,† Amanda Pennings, MScPT,† and Amr Elmaraghy, MD†*

Objective: To compare the short-term effectiveness of precut kinesiology tape (PCT) to a nonsteroidal anti-inflammatory drug (NSAID) as adjuvant treatment to exercise physiotherapy in improving pain and function in patients with shoulder impingement.

Design: Randomized, controlled assessor-blind parallel-design trial with 3 groups.

Setting: Academic-community hospital.

Patients: One hundred patients (mean age: 48 ± 12.3, 61 men, 39 women) with a diagnosis of subacromial impingement (SAI) syndrome were randomized to a treatment group from October 2009 to June 2012. Eighty-one patients completed the study.

Interventions: Patients were randomized to one of the 3 treatment groups: PCT and Exercise (n = 33), NSAID and Exercise (n = 29), or Exercise only (n = 38) for a 4 session 2-week intervention with a registered physiotherapist.

Main Outcome Measures: Numeric pain rating scales for pain at rest and pain with arm elevation, the Simple Shoulder Test (SST), and the Constant Score were assessed pretreatment and posttreatment.

Results: A statistically significant reduction in pain at rest and pain with arm elevation, as well as improvement in SST and Constant Score were observed in all 3 treatment groups, with minimal clinically important differences shown on pain with elevation and SST scores. Between-group differences on all outcome measures were not statistically significant or clinically meaningful.

Conclusions: The improvements in pain and function observed with an NSAID or PCT as adjuvant treatments were no greater than with rehabilitation exercise alone. If adjuvant treatment is desired, PCT seems to be better tolerated than an NSAID, although the difference did not reach significance.

Clinical Relevance: The routine addition of adjuvant treatment is not supported by the results of this study. As adjuvant therapy, PCT seems to be better tolerated than an NSAID. If desired, clinicians may consider incorporating PCT along with an exercise component in the conservative treatment of SAI syndrome.

Key Words: exercise, rehabilitation, kinesiology tape, shoulder, impingement

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INTRODUCTION

Shoulder pain is a common orthopedic complaint, with a reported lifetime prevalence ranging from 7% to 36% of the population.[1] Signs and symptoms of shoulder pathology are evidenced mainly by pain, decreased range of motion and strength, with resultant loss of shoulder functionality. "Subacromial impingement" (SAI) is one of the most frequently diagnosed shoulder disorders in adults with shoulder pain, and is associated with defects in posture, proprioception and motor coordination of the rotator cuff, deltoid, and scapulothoracic musculature.[1–5]

The initial management of patients with SAI is most often with noninvasive methods.[6] Physiotherapy, including exercise, modalities, massage, soft-tissue mobilization, and kinesiology taping can be effective in patients with shoulder pain.[3,5,7,8] A targeted exercise intervention focused on strengthening of the rotator cuff and scapular stabilizers, postural positioning, range of motion, and flexibility of the anterior and posterior shoulder can be an effective conservative treatment option for SAI.[2–4] In addition to physiotherapy, many clinicians will prescribe adjuvant treatment in the form of a nonsteroidal anti-inflammatory drug (NSAID) with the intention of reducing shoulder pain often attributable to tendon inflammation and/or bursitis, thereby allowing patients to actively participate in their rehabilitative exercise program.[2,9,10]

The use of kinesiology tape has become an increasingly popular treatment aimed at reducing musculoskeletal pain and improving function.[6,11] There are a number of proposed benefits to its application, including (1) pain modulation through the gate control theory, whereby the tape increases afferent feedback to stimulate neural pathways, (2) provision of

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From the *Fluid Motion Physiotherapy, Mahone Bay, Nova Scotia, Canada; and †Department of Surgery, St. Joseph's Health Centre, Toronto, Ontario, Canada.

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Corresponding Author: Amanda Pennings, MScPT, 27 Roncesvalles Ave, Suite 504, Toronto, Ontario, Canada M6R 3B2 (amanda.l.pennings@gmail.com).

a positional stimulus through the skin to assist or limit motion, and (3) improved microcirculatory flow beneath the dermis by lifting soft tissue and fascia above the area of pain/inflammation.[6,12–14]

There are few randomized control trials that substantiate the benefits of kinesiology tape, and the majority of these studies have been focused on applications at the knee and ankle.[15,16] Although there seems to be some merit in its use to improve range of motion and reduce pain in the shoulder,[6–8] to our knowledge there are no published, randomized clinical trials that compare the use of kinesiology tape to an NSAID as an adjunct to exercise therapy. Having an alternative to NSAIDs for pain control would be of significant benefit, given the associated gastrointestinal, cardiovascular, and allergic risks.

The purpose of this study was to assess the short-term effectiveness of precut kinesiology tape (PCT) versus an NSAID in reducing shoulder pain as adjuvant therapy to a targeted rehabilitative exercise program for SAI. Our main hypothesis was that PCT, together with exercise physiotherapy, would be superior to an NSAID and exercise physiotherapy at (1) reducing pain and (2) improving function in patients with SAI. Additionally, we hypothesized that PCT would be better tolerated and have fewer side effects than an NSAID.

METHODS

Study Design

This study was a prospective, single-center, assessor-blind parallel-group randomized control trial. Each participant was randomly assigned to one of the 3 groups: (1) PCT and exercise (PCT), (2) NSAID and exercise (NSAID), or (3) exercise only (Control). Participants were assessed pretreatment and post-treatment by a research assistant. A registered physiotherapist, who was not blinded to treatment allocation, led the treatment interventions. Approval was obtained from the Institutional Research Ethics Board.

Study Population

Patients referred to the senior author's orthopaedic clinic at an academic-community teaching hospital with a primary complaint of shoulder pain between October 2009 and June 2012 were eligible to participate in the study. Patients were screened by the senior author to ensure that they met all of the following inclusion criteria: (1) minimum 18 years of age; (2) primary complaint of anterolateral shoulder pain; (3) subacute onset of pain (<12 months); (4) a painful arc (60-120°); (5) a positive Hawkins–Kennedy test indicating SAI; (6) imaging consistent with impingement (eg, bony abnormalities of the coracoacromial arch, inflammation of the bursa, or rotator cuff tendons). Participants were excluded if they satisfied any of the following criteria: (1) previous history of shoulder surgery on the affected side; (2) previous history of therapeutic kinesiology taping of the shoulder; (3) medical contraindication to NSAIDs; (4) frozen shoulder; (5) labral tears; (6) soft-tissue imaging documenting high-grade or partial-thickness rotator cuff tears; (7) instability; (8) glenohumeral arthritis; (9) traumatic shoulder pathology (eg, fractures); (10) signs and symptoms because of referred pain (eg, cervical); (11) chronic pain (>12 months); and (12) previous history of contact dermatitis.

Study Procedure

After eligibility was ascertained by the senior author, written informed consent was obtained from all patients before participation in the study. A research assistant with a degree in physiotherapy, who was blinded to treatment allocation, performed the pretreatment (baseline) assessment using numeric pain rating scales (NPRS) for pain at rest and pain with arm elevation (scales range, 0-10), the Simple Shoulder Test (SST), and the Constant Score. After completion of the pretreatment assessment, the treating physiotherapist randomly assigned participants to a treatment group using a computer-generated random number table. Group 1 received PCT and exercise (PCT), Group 2 received an NSAID and exercise (NSAID), and Group 3 received exercise only (Control). The participants then completed a 2-week 4-session intervention (1 full hour session and 3 half hour sessions) in their randomly assigned group. To avoid bias, the physiotherapist was not involved in measurement of pretreatment and post-treatment outcomes or data analysis.

All 3 groups received identical exercise programs, established using guidelines in the literature, consisting of 3 phases that are based on the kinetic chain approach to shoulder rehabilitation (see **Appendix, Supplemental Digital Content 1**, http://links.lww.com/JSM/A69).[17,18] Phase 1 (proximal kinetic chain) included postural correction, core stabilization, and stretching exercises. Phase 2 (scapulothoracic) included scapular strengthening exercises. Phase 3 (glenohumeral) included isometric and active range of motion exercises. At each session, instructions were provided for 1 phase. The program was designed for participants to follow as a home exercise program during the intervention period.

All participants in the PCT group received a standardized application of the precut Shoulder Spider (SpiderTech Inc, Toronto, Ontario, Canada). This was performed by the registered physiotherapist who had received training in the application technique of the tape. The Shoulder Spider comes packaged as a precut continuous piece of kinesiology tape specifically designed for shoulder application (Figure 1). The physiotherapist applied the tape before initiation of the exercise program. Participants were instructed to wear the tape full time until their next treatment visit, which was typically scheduled 3-5 days apart. The tape was reapplied at each subsequent treatment session. Participants could remove the tape if they experienced any adverse reactions to it. Participants assigned to the NSAID group received a 2-week supply (28 pills) of Naprosyn EC (enteric-coated), 500 mg, with written instructions to take 1 pill, twice daily with meals for the duration of the treatment period. Participants were asked to take their first pill a minimum of 30 minutes in advance of initiating their exercise program.

During the 2-week treatment period, all participants were also provided with a usage diary to record their compliance with treatment protocol. At the end of the 2-week intervention period, a post-treatment assessment,

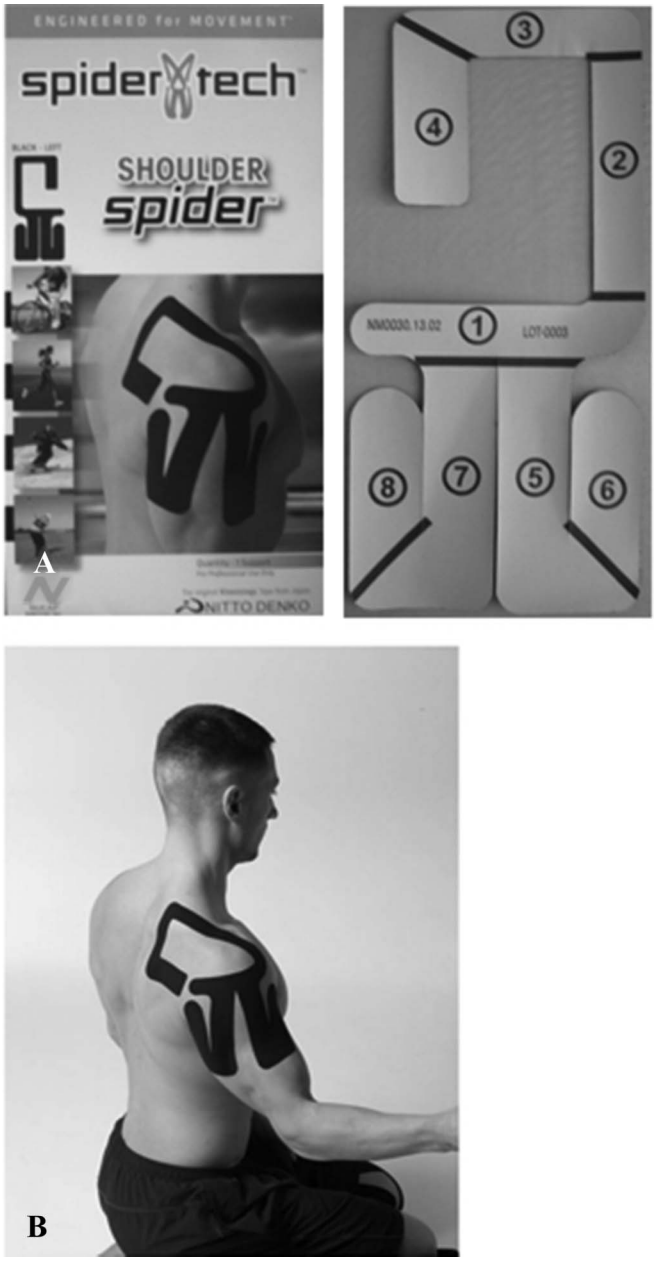

FIGURE 1. The Shoulder Spider precut application. A, Photograph of a package for a Shoulder Spider and its precut, numbered alignment markings, and step-by-step instructions. B, Photograph illustrating a Shoulder Spider applied to the right shoulder.

using identical outcome measures to the pretreatment assessment, was completed by the research assistant.

Statistical Analysis

All statistics were calculated using SAS version 9.3 software (SAS Inc, Cary, North Carolina). A minimum of 26 participants per treatment group (total, n = 78) were needed to obtain power of 80% and an alpha of 0.05. This calculation was based on a difference in pain intensity levels of 2 points on the NPRS, which has been shown to be the minimal clinically important difference (MCID), and a SD of 2.5.[19] Generalized linear models were fit to assess within-group and between-group differences in the pain scores from pre–post intervention. These analyses were carried out using both multiple imputation algorithm to account for missing data and complete case dataset. Chi-square tests were used to calculate the significance of categorical variables. A $P < 0.05$ was considered statistically significant.

Outcome Measures

Pain was the primary outcome measure, with level of shoulder function as a secondary outcome measure.

The NPRS was used to determine the patients' subjective assessment of pain level at rest and pain with arm elevation (0 = no pain, 10 = worst pain). This tool has been shown to be a valid and reliable measure of pain intensity with a 2-point change as the MCID.[19,20] The SST was used to determine the participants' subjective views of their level of shoulder function by asking the participant whether or not they could complete 12 functional shoulder activities of varying difficulty.[21] This measure has demonstrated acceptable test–retest reliability, as well as content and construct validity[22] with a 2-point change as the MCID.[23] The Constant Score was used to assess the participants' subjective and objective shoulder function, including pain (0 = severe, 15 = none), activities of daily living (2 = unable to do, 10 = able to perform all), functional arm use (2 = waist level, 10 = above head), ROM (0 = less than 30 degrees, 40 = full range), and strength (0 = min, 25 = max). It has been shown to be an easy-to-use valid measure of shoulder function with high intrarater and inter-rater reliability.[24,25] The MCID for the Constant Score is unknown.[26]

Improvements in NPRS were measured by negative change scores. Improvements in the SST and Constant Score were indicated by positive change scores.

Tolerability of treatment was measured by treatment compliance data gathered by participant self-report using usage diaries provided. Usage diaries gathered identical data for all groups relating to exercise frequency and performance, as well as other treatments sought by the patient. Additional data specific to each group were gathered for adjuvant treatment groups including level of discomfort with the tape (PCT group) and reasons for altering medication dosage (NSAID group). All patients had equal opportunity to report adverse events common to all groups including gastrointestinal discomfort.

RESULTS

One hundred participants were enrolled into the study, completed the pretreatment assessment, and were randomized to a treatment group (Figure 2). Thirty-three participants were randomly allocated to the PCT group, 29 to the NSAID group, and 38 to the Control group. Nineteen participants were lost to follow-up with an overall dropout rate of 19%, which was not significantly different between treatment groups. Seven participants completed zero treatment sessions,

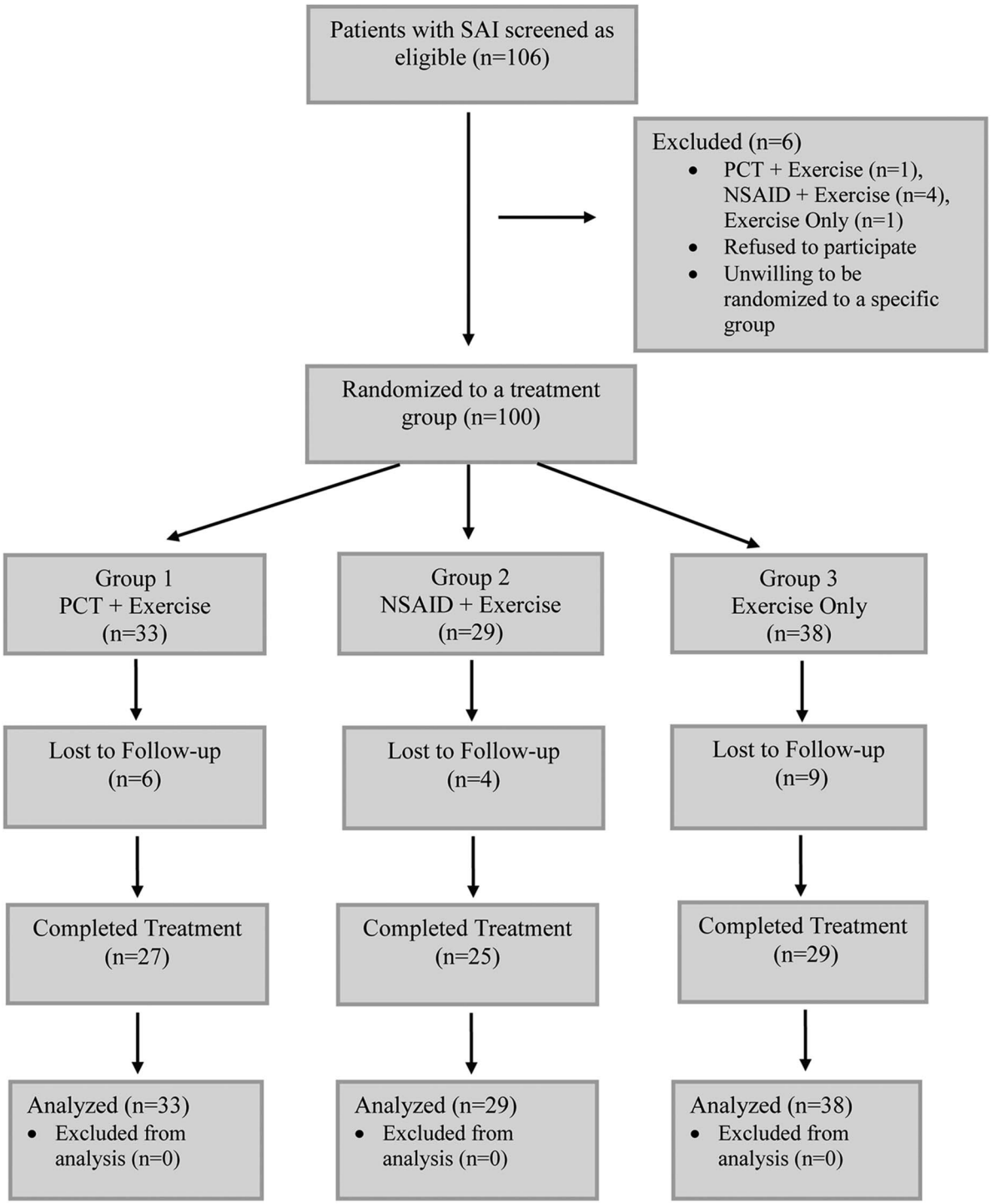

FIGURE 2. Participant flow chart.

5 completed 1 treatment session, 4 completed 2 treatment sessions, and 3 completed 3 treatment sessions.

Demographic characteristics for all treatment groups are presented in Table 1. Treatment groups were similar at baseline with no significant difference in demographics or baseline characteristics (pain at rest, pain with elevation, SST, and Constant Score). No significant differences were found in demographics or baseline characteristics between participants who completed the study and those that were lost to follow-up. Overall, the median (interquartile range) number of days between pre-assessment and post-assessment was 17 (12-24) days. No significant difference existed between groups in the

TABLE 1. Patient Demographics and Pre-Intervention Pain Scores

	PCT + Exercise (n = 33)	NSAID + Exercise (n = 29)	Exercise Only (n = 38)
Age (mean ± SD; range), yrs	50.0 ± 11.9 (29-75)	44.0 ± 10.5 (19-71)	50.0 ± 13.3 (25-75)
Gender, n (%)			
Male	22 (66.7)	21 (72.4)	18 (47.3)
Female	11 (33.3)	8 (27.6)	20 (52.7)
Affected side, n (%)			
Right	19 (57.6)	15 (51.7)	23 (60.5)
Left	14 (42.2)	14 (48.3)	15 (39.5)
Hand dominance, n (%)			
Right	33 (100)	28 (96.6)	36 (94.7)
Left	0	1 (3.4)	1 (2.6)
Dominant side affected, n (%)	19 (57.6)	16 (55.2)	23 (60.5)
Baseline pain and shoulder function measures (mean ± SD; range)			
Pain at rest	2.6 ± 2.8 (0-9)	3.1 ± 2.7 (0-8)	3.0 ± 2.6 (0-8)
Pain with elevation	6.5 ± 2.3 (2-10)	6.3 ± 2.5 (0-10)	6.3 ± 2.6 (0-10)
SST	6.5 ± 2.5 (2-12)	6.7 ± 2.7 (1-12)	6.1 ± 3.1 (1-12)
Constant Score	54.7 ± 11.9 (34-87)	58.2 ± 18.6 (13-93)	54.5 ± 18.3 (4-81)

number of days between pre-assessment and post-assessment of outcome measures.

All 3 treatment groups showed a statistically significant decrease in pain by all four measures when compared with pretreatment values (Table 2, Figure 3). The 95% confidence intervals cover the reported MCIDs for all three treatment groups on the NPRS for pain with arm elevation and SST scores. Between-group differences on all outcome measures were not statistically significant or clinically meaningful (Table 2). Results were unchanged using a complete case analysis excluding missing data.

Usage diaries were completed by 75.3% (61 of 81) of participants. Approximately 70% (42 of 61) of participants completed the exercises at least twice per day as directed, with no significant difference between treatment groups; although all of the participants completed the exercises at least once per day on average. Pain and lack of time were the 2 most common reasons cited for exercises not being performed. In the PCT group, 100% typically wore the tape all day (21 of 21) with the total duration of each application averaging 3.5 days. None of the participants assigned to the PCT group removed the tape because of itching or irritation. In the NSAID group, 84% (16 of 19) of participants took 2 pills per day as directed. Eleven percent of participants in the NSAID group noted that they discontinued taking the Naprosyn 500 mg twice daily (range, day 1-10) because of gastrointestinal discomfort/complications. There was not a significant difference ($P = 0.19$) in compliance between the PCT and NSAID groups. Adherence results are limited to those who completed the usage diaries.

DISCUSSION

Kinesiology taping is a technique that continues to gain popularity in the rehabilitation setting and widespread use among the athletic population, yet there is little scientific evidence of its clinical effectiveness.[27,28] Over the last decade, information on kinesiology tape applications suggesting improved function and decreased pain largely comes from case series and small pilot studies with lower levels of evidence.[11] Recent randomized control trials have examined the use of kinesiology tape for the treatment of shoulder pain and acute whiplash.[6,12,29] However, these studies compared kinesiology tape with an alternative or sham application of tape without a true control group. Other studies focusing on kinesiology tape in the treatment of SAI have used a less standardized application of tape, relying on clinician experience and expertise to achieve the desired application.[5,6,8,29] With the use of SpiderTech precut Shoulder Spider, we were able to achieve a more standardized application in our PCT group, eliminating the need for cutting of multiple pieces and providing uniform consistent application.

The literature on treatments for shoulder pain reports that physical therapy is as beneficial as surgery in addressing SAI.[10,30,31] We therefore believe it was important to incorporate an exercise program for shoulder pain based on published guidelines and to evaluate an "Exercise only" group as our control to avoid a placebo effect with the application of PCT or Naprosyn 500 mg twice daily. A recent study by Şimşek et al[29] also evaluated kinesiology tape as adjuvant treatment to exercise. Similar to our study, both study groups improved significantly compared with baseline suggesting as in our study that exercise alone is helpful, even in the short term, for impingement. Despite their interpretations and conclusions, further analysis of the data shows that the absolute differences between groups in Pain scores were less than 2, thus less than the MCID. The study by Şimşek et al[29] also had a very small sample size with only 19 participants per group and did not compare different adjuvant treatments for impingement. To our knowledge, the present study is the only study comparing different commonly used adjuvant treatments for impingement, added to an exercise program.

Adherence to adjuvant treatment in this study suggests that once the PCT is applied, the convenience and comfort of

TABLE 2. Outcome Measures: Difference Between Pre-Intervention and Postintervention Scores

	Imputed Missing Values		Complete Case	
	Mean	**95% CI**	**Mean**	**95% CI**
NPRS: pain at rest				
PCT + exercise	−0.84*	−1.66 to −0.01	−0.96*	−1.77 to −0.15
NSAID + exercise	−0.98*	−1.80 to −0.16	−1.00*	−1.84 to −0.16
Exercise only	−0.98*	−1.69 to −0.27	−0.86*	−1.64 to −0.08
Difference between intervention groups				
PCT + exercise vs exercise only	0.14	−0.94 to 1.22	−0.10	−1.23 to 1.02
NSAID + exercise vs exercise only	0.00	−1.10 to 1.10	−0.14	−1.29 to 1.01
PCT + exercise vs NSAID + exercise	0.14	−1.01 to 1.29	0.04	−1.13 to 1.20
NPRS: pain with elevation				
PCT + exercise	−1.46*	−2.46 to −0.45	−1.43*	−2.46 to −0.39
NSAID + exercise	−2.32*	−3.40 to −1.24	−2.48*	−3.56 to −1.40
Exercise only	−1.80*	−2.79 to −0.82	−1.69*	−2.69 to −0.69
Difference between intervention groups				
PCT + exercise vs Exercise Only	0.35	−1.13 to 1.82	0.26	−1.18 to 1.70
NSAID + exercise vs exercise only	−0.52	−2.00 to 0.97	−0.79	−2.26 to 0.68
PCT + exercise vs NSAID + exercise	0.87	−0.56 to 2.29	1.05	−0.44 to 2.55
SST				
PCT + exercise	1.97*	0.99 to 2.96	1.96*	1.01 to 2.91
NSAID + exercise	1.71*	0.67 to 2.75	1.76*	0.77 to 2.75
Exercise only	1.92*	1.04 to 2.80	1.83*	0.91 to 2.74
Difference between intervention groups				
PCT + exercise vs exercise only	0.06	−1.25 to 1.36	0.14	−1.18 to 1.46
NSAID + exercise vs exercise only	−0.21	−1.62 to 1.20	−0.07	−1.41 to 1.28
PCT + exercise vs NSAID + exercise	0.27	−1.10 to 1.63	0.2	−1.17 to 1.57
Constant Score				
PCT + exercise	9.92*	5.80 to 14.03	9.53*	5.44 to 13.61
NSAID + exercise	11.90*	7.78 to 16.03	12.71*	8.47 to 16.95
Exercise only	8.47*	4.54 to 12.41	8.29*	4.35 to 12.23
Difference between intervention groups				
PCT + exercise vs exercise only	1.45	−4.12 to 7.02	1.24	−4.43 to 6.91
NSAID + exercise vs exercise only	3.43	−2.36 to 9.23	4.43	−1.36 to 10.21
PCT + exercise vs NSAID + exercise	−1.99	−7.69 to 3.71	−3.19	−9.07 to 2.70

*Indicates a statistically significant difference, $P < 0.05$.
CI, confidence interval.

the tape may promote a high rate of patient compliance for its prescribed use. It is not uncommon for clinicians to prescribe adjuvant therapies to exercise in the treatment of shoulder disorders. Research on the effect of muscle pain on muscle activation strategies during dynamic exercise demonstrates that pain alters muscle control.[32] Helping to control pain with the additional use of PCT or Naprosyn 500 mg twice daily while participating in an exercise program may allow patients to demonstrate the correct motor patterning to gain strength and enhanced neuromuscular control. Medication in the form of NSAIDs is often the first-line treatment of choice and recent studies suggest that the treatment effect of NSAIDs can be better than placebo, although there are associated substantial risks and side effects even with short-term use that may be difficult for patients to tolerate.[10,31,33–35] As an adjuvant treatment, PCT seems to be better tolerated than

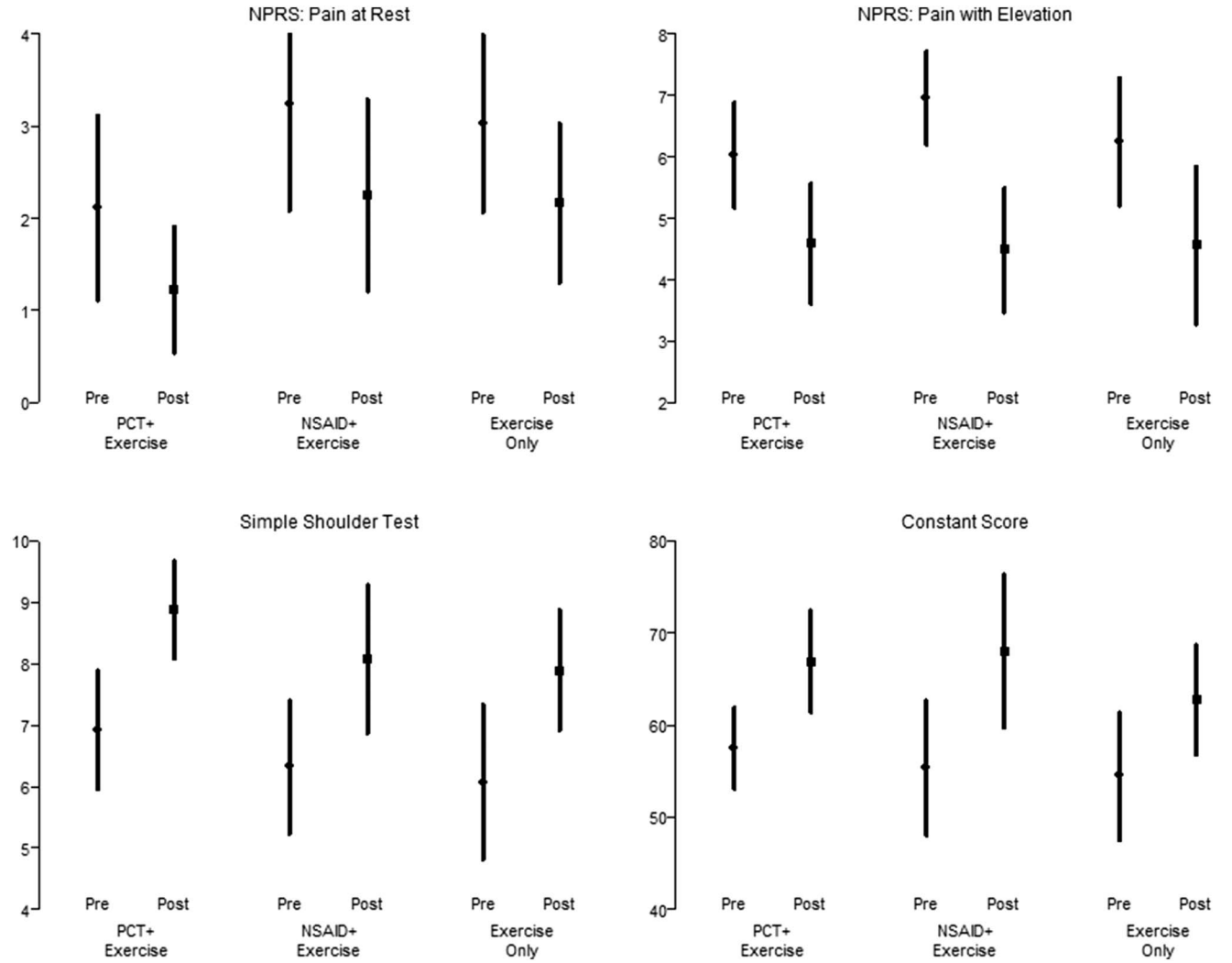

FIGURE 3. Outcome measures: pretreatment versus posttreatment (mean ± 95% confidence interval).

Naprosyn 500 mg twice daily, although the difference in tolerability did not reach statistical significance. In the clinical setting, PCT may therefore be a more feasible option for this subpopulation of patients with SAI for whom NSAID use is undesirable or contraindicated.

Our results indicate that pain and function improved in all 3 treatment groups over the course of the intervention, with MCIDs shown on the pain with arm elevation scores and SST. However, no statistically significant or clinically meaningful differences between groups were detected. The observed differences in mean values were so small that a larger sample size would have been necessary to conclude that any of the treatment groups were different. Although it seems that the 3 treatment groups are equivalent, our study does not have sufficient power to draw this conclusion. An equivalence study of the same design would require many more participants per group, which is not feasible in our clinical setting.

It is important to note that all groups participated in the same exercise component. This suggests that as a routine, clinicians may confidently prescribe exercise physiotherapy alone in the initial stages of conservative treatment for SAI, reserving the use of adjuvant therapy to aid in treatment if necessary. We believe these findings confirm past reports that exercise therapy is an essential component to the management of SAI, because exercise alone seems to reduce pain and improve shoulder function in a treatment period as little as 2 weeks.

One of the weaknesses of our study was the overall dropout rate of 19%, which is relatively high but similar to other randomized studies on kinesiology tape.[5,6] Also, the physiotherapist involved in the clinical treatment component of the study was not blinded to the assignment of treatment groups. The utilization of a sole physiotherapist for the treatment intervention was intended to ensure uniformity, although this approach may decrease the generalizability of our results. Study participants were also not blinded to the allocation process. In addition, tolerability of treatment was based on participant-reported compliance with treatment, which may introduce bias into the results.

The natural progression of SAI in the shoulder could not be fully appreciated during the short duration of this study. This study did not provide follow-up to the participants beyond the intervention period [median, 17 (12-24) days], thus long-term benefits with the continued use of the tape could not be substantiated. Similar studies have also used a short period of application to test the effectiveness of kinesiology tape[6,8,28,29,36]; however, the optimal duration of usage of kinesiology tape has not yet been determined. As clinicians, we generally try to limit the use of adjuvant therapies, given the potential side effects and/or perceived need for a "crutch" to assist with exercise. Adjuvant treatments may be used to decrease pain in the initial stages of an exercise program, but ultimately our goal would be to decrease reliance on adjuvant treatments as the exercise program progresses. Thus, we kept the treatment timeframe short, because it is important to ascertain if adjuvant therapies had an impact early in treatment. In addition, the pre-evaluation to post-evaluation period varied from the targeted 2-week duration. Implementing a 2-week 4-session intervention in a varied outpatient population within a strict time period represented a practical challenge. Additionally, the potential for floor effects must be noted because some of the baseline outcome scores were relatively low, particularly NPRS pain at rest scores. Adjunctive treatments are expected to have small incremental effects and a larger sample size on an outcome measure with proven ordinal level scaling may be necessary to detect these effects.

We studied a specific formulation of kinesiology tape, the precut Shoulder Spider. We chose this tape because of its uniformity of application, which we believed lent itself better to scientific study. Our results may not be generalizable to all kinesiology tape products or application techniques.

CONCLUSIONS

There seems to be no clinically meaningful difference between the use of Naprosyn 500 mg twice daily or PCT as adjuvant therapies to an exercise program versus exercise physiotherapy alone. The routine use of adjuvant treatment may therefore not be necessary. If adjuvant therapy is desired by either clinician or patient, PCT seems to be better tolerated than Naprosyn 500 mg twice daily, although the difference is not statistically significant. This study provides strong incentive for future prospective studies to evaluate the effectiveness, optimal duration, and mechanisms of kinesiology tape to decrease pain and enhance function in conjunction with a rehabilitation program when overcoming injury.

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