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# Adding Manual Therapy to an Exercise Program Improves Long-Term Patient Outcomes Over Exercise Alone in Patients With Subacromial Shoulder Pain: A Randomized Clinical Trial

■ **OBJECTIVE:** Guidelines include manual therapy and exercise for subacromial shoulder pain, but there is low certainty for these recommendations. Here, we evaluated if adding manual therapy to a resistance exercise program improved patient outcomes.

■ **DESIGN:** Randomized parallel controlled clinical trial.

■ **METHODS:** Individuals with subacromial pain syndrome (N = 93) were randomized to exercise (EX; n = 41) or exercise plus spine and shoulder manual therapy (EX+MT; n = 52). Primary outcome of Disabilities of the Arm, Shoulder and Hand (DASH) and secondary outcome of satisfaction with shoulder use (Satisfaction-shoulder) at baseline, 2, 4, 6, 26, and 52 weeks were compared between groups. Secondary outcomes of additional health care use were compared at 26 and 52 weeks and GROC success (≥"moderately better") at 2, 4, 6, 26, and 52 week prevalence were compared between groups.

■ **RESULTS:** The EX+MT group had better DASH scores at 26 weeks (mean difference = 4.9 [95% CI: 9.8, 0.1], $P = 0.047$) and 52 weeks (mean difference = 6.7 [95% CI: 11.4, 2.1], $P = 0.005$) compared to the EX group. The EX+MT group had better Satisfaction-shoulder scores at 26 weeks (mean difference = 0.8 [95% CI: 0.2, 1.5], $P = 0.012$) and 52 weeks (mean difference = 1.2 [95% CI: 0.5, 1.8], $P<0.001$) compared to the EX group. Higher GROC success was found at 26 and 52 weeks in EX+MT ($P<0.05$). There were no differences for additional health care use ($P>0.171$).

■ **CONCLUSION:** Manual therapy added to a resistance exercise program improved long-term shoulder disability, satisfaction, and perceived benefit in patients with subacromial pain. Both groups had improved outcomes over time, with greater effects for the EX+MT group at 26 and 52 weeks. *JOSPT Open 2024;2(1):29-48. Epub 11 December 2023. doi:10.2519/josptopen.2023.1134*

■ **KEY WORDS:** *rotator cuff, clinical trials/intervention studies, Research design, manual therapy, exercise therapy*

Subacromial shoulder pain, an umbrella term indicating pain arising from structures in the subacromial space that includes the rotator cuff tendons, bursitis, and long head of the biceps,[14,50,60] is the most frequent cause of musculoskeletal-related shoulder pain.[22,45,57] Recovery is limited, with 40% to 50% of patients developing recurrent chronic pain.[16,33] Physical therapy, specifically resistance exercise, is recommended as the first line treatment.[17] Resistance exercise improves patient-reported outcomes, but response rates are highly variable.[3,43] Manual therapy is recommended as an addition to resistance exercise, but there are inconsistent effects in systematic reviews.[3,46,55] Importantly, a recent meta-analysis[3] noted low certainty for the superiority of resistance exercise plus manual therapy over exercise only. Limitations of prior studies include the inconsistency of a comprehensive and standardized approach, and the heterogeneity in what is delivered for both manual therapy and exercise. Low certainty may also be due to the types of manual therapy delivered. The question as to whether or not the addition of manual therapy is beneficial to an exercise program has not been definitively answered.[3,46,55]

Individuals experiencing subacromial shoulder pain frequently have rotator cuff tendon structural deficits.[1,10,29,37,39,50] Resistance exercise aims to activate the muscles to impart load to the tendon to stimulate remodeling. However, the ability to perform resistance exercise may be limited by the often present muscle performance deficits in activity and coordination during reaching and elevation tasks.[9,18,19,35] Muscle function can also be negatively impacted by pain and sensorimotor processing deficits of the central nervous system. Reduced shoulder muscle activity and joint force production occur with experimentally induced shoulder pain[6,52–54] and sensorimotor cortical processing deficits.[4,11,44] Manual therapy can serve as a conduit to improve muscle

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performance and pain,[26] via changes in pain and sensorimotor processing in the central nervous system that have been demonstrated with manual therapy.[2,7,15,23,24,26]

This study aimed to assess the additive effects of manual therapy with a resistance exercise program compared to exercise alone, on the primary outcomes of patient-reported pain and disability and secondary measures of global effect of treatment, satisfaction with shoulder, and additional health care use after discharge from treatment. We hypothesized that the addition of manual therapy would enhance the benefits of resistance exercise.

# METHODS

## Study Design and Participants

This multicenter parallel randomized controlled clinical trial following CONSORT guidelines was performed at 6 clinics at Brooks Rehabilitation in Jacksonville, Florida, and ATI Physical Therapy in Greenville, South Carolina were recruited, enrolled, and followed up for 1 year between December 2008 and January 2011. Potentially eligible consecutive participants presenting to physical therapy were screened for inclusion and exclusion criteria during their physical therapy evaluation. If they met the criteria, they were then invited to participate and signed an informed consent to protect their rights prior to participation. Inclusion criteria were between 18 and 75 years of age, shoulder disability (Disabilities of the Arm, Shoulder and Hand [DASH]) ≥25%, diagnosis of subacromial shoulder pain as defined by positive on all 3 tests of Hawkins-Kennedy or Neer, painful arc, and weakness or pain with resisted elevation (empty can) or external rotation.[27,38] The exclusion criteria were pain rating of > 7/10, prior surgery of the involved shoulder, traumatic dislocation in the last 3 months, previous rehabilitation in the past 6 months for this episode of shoulder pain, shoulder pain reproduced with cervical motion, neurological symptoms of the shoulder, systemic inflammatory joint disease, adhesive capsulitis (global loss of shoulder range of motion), full thickness rotator cuff tear, or contraindications for manual therapy of the spine or shoulder. This study was approved by Virginia Commonwealth University Institutional Review Board, and registered on ClinicalTrials.gov (NCT00633451). A flow diagram of recruitment and retention is depicted in **FIGURE 1**. Patients were asked to participate after the routine physical therapy evaluation indicated they were eligible based on inclusion and exclusion criteria.

## Randomization and Blinding

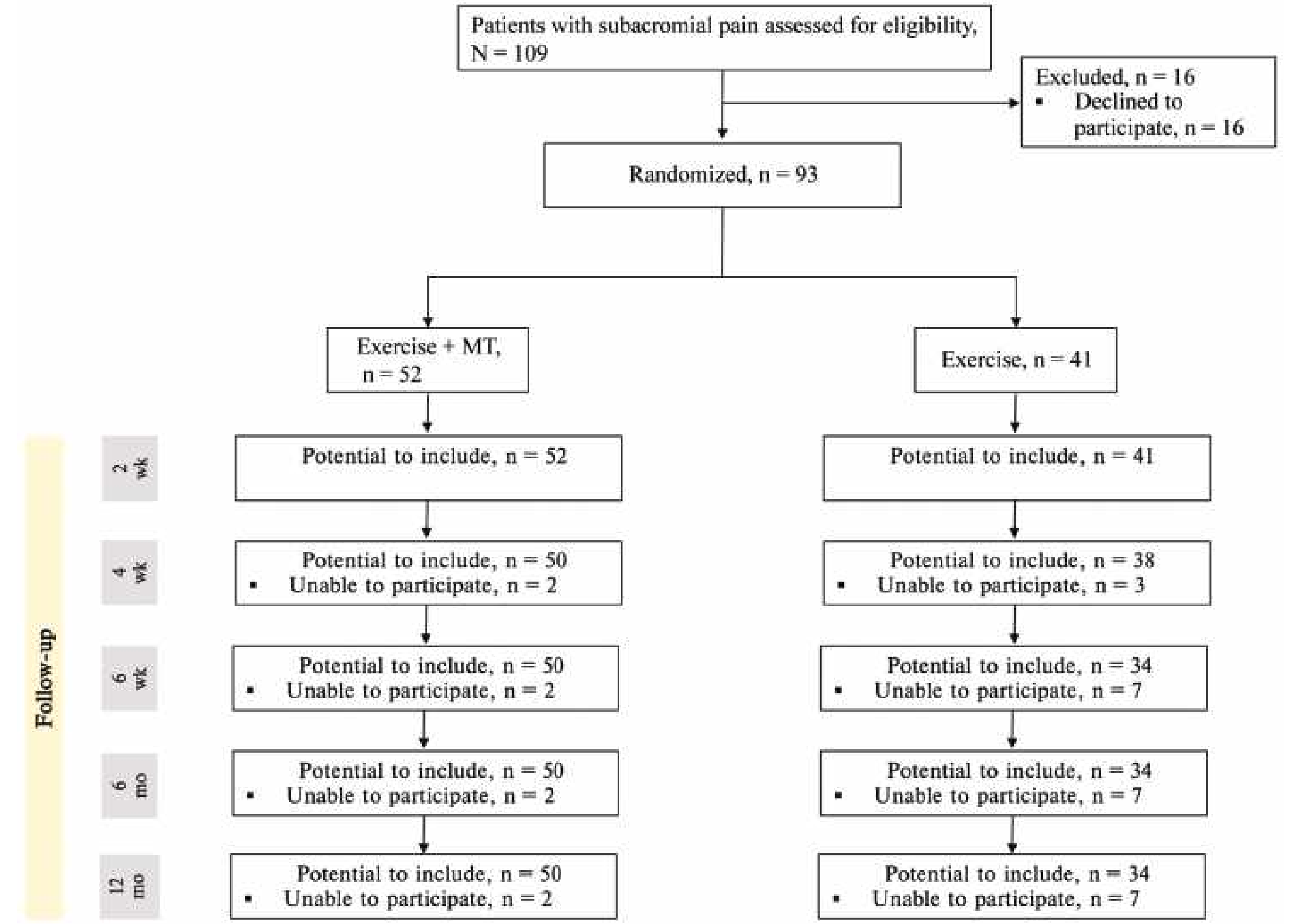
Consented participants were randomly assigned to one of 2 groups: resistance exercise program (EX) or resistance exercise plus manual therapy of the shoulder and spine (EX+MT) described in **TABLE 1**. Block randomization with a 1:1 allocation with variable blocks of 4, 6, and 8 for each clinical site was used, computer generated by an independent research assistant. Each clinical site coordinator sequentially assigned participants to treatment group from concealed assignment until group assignment was made. Physical therapists who delivered the intervention were not blinded to treatment group. Participants were informed they would be receiving one of 2 standardized treatments for their condition. Patient blinding was assessed at the end of treatment (6 weeks) by asking "please choose the types of treatment you believe you received," with choices of manual therapy exercise.

## Interventions

Participants underwent EX or EX+MT treatment. Treatment was delivered for 6 weeks, 2 times per week for a maximum of 10 visits according to the CERT[51] guideline.

**Exercise Program** The 3-phase standardized progressive resistance exercise with stretching[40,56] was designed using evidence and clinical expertise of 5 physical therapists with 5 to 22 years of experience in treating patients with musculoskeletal shoulder pain. The treatment was designed to be comprehensive to target common impairments summarized in **TABLE 2** and **APPENDIX**. Each of the 3 phases consisted of resistance exercises using body weight or exercise bands to target the shoulder muscles with particular focus on scapular stabilizers and rotator cuff, flexibility exercises, and exercises to promote an erect posture through chin tucks and scapular retraction. Individuals performed strengthening exercises with 2 to 3 sets of 10 repetitions using latex-free Thera-Band (Hygenic Corporation, Akron, OH). Phase 1 of the program consisted of resistance exercise for the rotator cuff muscles with the humerus in neutral and serratus, motor control training with shoulder elevation while avoiding excessive upper trapezius activation. Phase 2 of the exercise program continued with resistance exercises of the shoulder external and internal rotators with a focus on the rotator cuff muscles at 45 to 90 degrees of elevation in shoulder scaption, shoulder elevation exercises, and the addition of progressive strengthening of serratus and middle and lower trapezius. Phase 3 continued with all Phase 2 exercises with the addition of higher-level resistance exercises including the lawn mower pull, protraction plank and use of the Bodyblade (Mad Dogg Athletics, Venice, CA) at multiple angles of shoulder elevation. Individuals progressed to increased resistive band difficulty (in the sequence yellow, red, green, blue) when they were able to perform 2 to 3 sets of 10 repetitions with minimal symptoms or fatigue. Individuals progressed from Phase 1 to Phase 2 when they were able to perform full sets and repetitions of the exercises with a red resistive band. Individuals progressed from Phase 2 to Phase 3 when they could perform all exercises in Phase 2 for 1 week with minimal symptoms. Participants were advised to maintain usual

**FIGURE 1**
Flow diagram.




activities that did not increase symptoms and to avoid all activities that exacerbated their symptoms.

**Manual Therapy** The manual therapy treatment techniques (**TABLE 2**, **APPENDIX**),[40,56] was designed by the same clinicians designing the exercise component. The EX+MT group received manual therapy of both thrust manipulation and nonthrust mobilization. The manual therapy techniques were aimed at 3 areas: the thoracic spine, posterior shoulder, and glenohumeral joint. Clinicians were instructed to perform manual techniques for a total of 10 to 15 minutes and were required to use at least 1 technique for each of the 3 body regions. Clinicians could select low-grade techniques for those with moderate to high irritability, whereas high-grade techniques could be used those with low irritability.[36]

**Participating Physical Therapists and Training** There were a total of 14 physical therapists participating in this study, with a mean of 5.2 years of clinical experience. All physical therapists underwent a standardized training regimen that consisted of an in-person 6-hour training session, a 90-minute training video, and an accompanying manual of operating procedures for all treatment and assessment procedures. Exercise and manual therapy procedures were reviewed and checked for accuracy in the training session. Competency was assessed using a standardized test in which all participating clinicians had to score ≥80% to participate. The training video and manual of operating procedures were provided to clinicians to review at periodic later dates. Treatment compliance was audited by a research assistant performing a random documentation audit, assessing treatment records for performance of all required components of exercises and manual therapy and patient education.

## Outcomes

After randomization, all outcome measures were assessed at baseline, 2, 4, 6, 26, and 52 weeks. Outcomes at 2, 4, and 6 weeks were assessed by paper for the

**TABLE 1**
Demographics and Baseline Characteristics (N = 93)

| Variable | Total (N = 93) | EX+MT Group (n = 52) | EX Group (n = 41) |
|---|---|---|---|
| Age, years | 53.1 (12.4)<br>21-75 | 52.3 (13.3)<br>23-75 | 54.0 (11.1)<br>21-73 |
| Height, m | 170.1 (11.9)<br>121.9-200.7 | 170.9 (11.3)<br>121.9-188.0 | 169.1 (12.7)<br>137.2-200.7 |
| Weight, kg | 88.5 (19.1)<br>52.2-147.0 | 89.1 (19.1)<br>52.2-147.0 | 87.7 (19.2)<br>59.0-145.2 |
| Sex | | | |
| Female, n (%) | 46 (49.5) | 22 (42.3) | 24 (58.5) |
| Male, n (%) | 47 (50.5) | 30 (57.7) | 17 (41.5) |
| Race | | | |
| Asian | 1 (1.1) | 0 (0) | 1 (2.4) |
| Pacific Islander | 1 (1.1) | 1 (1.9) | 0 (0) |
| Black/African American | 15 (16.1) | 7 (13.5) | 8 (19.5) |
| Hispanic | 73 (78.5) | 42 (80.8) | 31 (75.6) |
| | 3 (2.2) | 2 (3.8) | 1 (2.4) |
| Shoulder painful | | | |
| Dominant | 44 (47.3) | 26 (50.0) | 18 (43.9) |
| Nondominant | 37 (39.8) | 20 (38.5) | 17 (41.5) |
| Ambidextrous | 1 (1.1) | 1 (1.9) | 0 (0) |
| Missing | 11 (11.8) | 5 (9.6) | 6 (14.6) |
| Frequency shoulder pain | | | |
| Constant | 49 (52.7) | 26 (50.0) | 23 (56.1) |
| Sometimes | 42 (45.2) | 24 (46.2) | 18 (43.9) |
| Missing | 2 (2.2) | 2 (3.8) | 0 (0) |
| Symptom length (weeks) | 47.5 (129.5)<br>1.1-1120.1 | 59.1 (167.0)<br>1.1-1120.1 | 32.9 (52.8)<br>4.9-335.7 |
| Onset | | | |
| Specific trauma event | 32 (34.4) | 21 (40.4) | 11 (26.8) |
| Gradual onset | 58 (62.4) | 30 (57.7) | 28 (68.3) |
| Missing | 90 (96.8) | 1 (1.9) | 2 (4.9) |

*Continuous data are represented as mean (standard deviation), range. Categorical data are represented as n (%).*
*Abbreviations: EX, exercise group; EX+MT, exercise-plus-manual therapy group.*

patient to independently complete without interaction by the treating physical therapists, and by postal questionnaires at 26 and 52 weeks. If participants did not return the 26- and 52-week measures, we followed up via email and telephone to facilitation completion. All completed outcomes were collected at the principal investigator's site and scanned into an electronic database. To promote data quality, all data were checked for errors during scanning by manual comparison between the paper forms and the values in the database for any value outside the predefined range and for any values that were unreadable. Outcomes were predefined and described in the clinical trial registration. The registration described assessment at 3 months, but after the trial commenced, consensus of clinicians and researchers deemed data collection at 3 months presented an undue time burden for participants. As another deviation from the trial registration, we planned on collecting the 36-item Short Form Health Survey (SF-36), a generic measure of health-related quality of life.[59]

The primary outcome was shoulder pain and disability measured on the Disabilities of the Arm, Shoulder and Hand (DASH), is a 30-item patient-reported outcome that assesses symptoms and physical function of the upper limb (0%-100%, 0% = no disability).[5] The DASH score was used for data analysis. The DASH has demonstrated reliability, validity, and responsiveness for use in patients with shoulder disorders, with a reported minimal clinically important difference (MCID) of 10.2% and minimal detectable change of 10.5%.[48,49]

The secondary outcomes were patient satisfaction with shoulder use, patient-perceived global rating of effect, and use of additional health care. Patient satisfaction with shoulder use (Satisfaction-shoulder) was measured using a satisfaction question from the Pennsylvania Shoulder Score, scored from 0 to10 (0 = not satisfied with shoulder use and 10 = fully satisfied).[34] The Satisfaction-shoulder has demonstrated reliability, validity, and responsiveness for use in patients with shoulder disorders, with reported minimal detectable change of 1.8 points.[34] The global rating of change (GROC) measured the patient-perceived global impression of change from the start of the intervention and has demonstrated reliability and validity.[28,30] A 15-point GROC was used with scores of +4 "moderately better" or higher indicate moderate change.[28,30] The GROC was analyzed as a categorical variable. Individuals who rated their perceived recovery on the GROC as "moderately better" or higher[28,30] at any follow-up time points were classified as having a successful outcome. Additional health care use was measured by asking participants if they have received any additional care of injections, surgery, nonsurgical care of chiropractic, massage therapy, occupational therapy, physical therapy, or medications for their current shoulder condition.

## Power Analysis

An a priori power analysis indicated 76 participants were needed for 80% power to demonstrate a difference between

**TABLE 2**
Intervention Program Summary

| Manual Therapy All Phases | Stretching All Phases | Resistance Exercise: Motor Control/Strengthening | Home Exercise Program |
|---|---|---|---|
| Thoracic Spine<br>1. PA glides in prone<br>2. PA glides seated<br>3. Thrust in prone<br>4. Thrust in supine<br>5. Distraction thrust seated<br>Posterior Shoulder<br>1. GH posterior glide<br>2. GH posterior glide with active elevation (MWM)<br>3. Cross-body posterior capsule stretch<br>4. Internal rotation passive stretching<br>Inferior Shoulder<br>1. GH inferior glide<br>2. AC joint (optional)<br>3. Anterior-inferior glide of clavicle (seated or supine) | 1. Upper thoracic extension<br>2. Shoulder internal rotation "towel" stretch<br>3. Shoulder internal rotation "towel" stretch<br>4. Doorway pectoral stretch<br>5. Shoulder flexion stretch "supine cane flexion" (Phase 1) progression to standing wall stretch (Phases 2 and 3) | **PHASE 1**<br>1. Shoulder external rotation<br>2. Shoulder internal rotation<br>3. Scapular retraction<br>4. Shoulder extension<br>5. Scapular protraction in supine<br>6. Active elevation with upper trap relaxation<br>7. Chin tuck with scapular retraction<br>**PHASE 2**<br>1. Shoulder abduction in scapular plane<br>2. Shoulder external rotation with abduction<br>3. Shoulder internal rotation with abduction<br>4. Quadruped push-up plus "camel"<br>5. Prone scapular retraction and shoulder elevation "Y"<br>6. Prone shoulder elevation in external rotation with scapular retraction "T"<br>**PHASE 3**<br>Continue Phase 2 and add the following:<br>1. Bodyblade *below* 60°<br>2. Bodyblade *above* 60°<br>3. Lawn mower pull<br>4. Protraction plank | **PHASE 1**<br>1. Shoulder external rotation<br>2. Shoulder internal rotation<br>3. Scapular retraction<br>4. Upper thoracic extension stretch<br>5. Cross-body stretch<br>Other stretches optional<br>**PHASE 2**<br>1. Shoulder abduction in scapular plane<br>2. Shoulder external rotation with abduction<br>3. Quadruped push-up plus "camel"<br>4. Prone scapular retraction and shoulder elevation "Y"<br>5. Upper thoracic extension stretch<br>6. Cross-body stretch<br>Other stretches optional<br>**PHASE 3**<br>1. Shoulder abduction in scapular plane<br>2. Prone scapular retraction and shoulder elevation "Y"<br>3. Prone shoulder elevation in external rotation with scapular retraction "T"<br>4. Lawn mower pull<br>5. Protraction plank<br>6. Cross-body stretch<br>Other stretches optional |

*See* **APPENDIX** *for more details. This table was reproduced with permission from JOSPT.*[56]
*Abbreviations: AC, acromioclavicular; GH, glenohumeral; MWM, mobilization with movement; PA, posterior-anterior.*

groups in the DASH primary outcome of a minimal detectable change of 10.2% with a baseline standard deviation of 15%.[49] To account for 20% drop out, we aimed to recruit 92 participants. There was no interim analysis or stopping guidelines for this clinical trial.

## Data Analysis

We performed an intention-to-treat analysis, with participants analyzed by group assignment. To determine the effect of treatment group (EX, EX+MT) over time on the primary outcome of the DASH and the continuous secondary outcome of Satisfaction-shoulder, a linear mixed model with restricted maximum likelihood estimation for estimating parameters was used. The linear mixed model automatically handles missing data using maximum likelihood estimation. This model included a random intercept for participants to account for the repeated measures of time, fixed effects for group and time, interaction of group × time (defined as continuous), and including a covariate of the baseline scores. The analysis included screening for outliers using standardized residuals; absolute values >3 were deemed outliers for removal. Adjusted values from the model, separated by group and time, were used for post hoc testing when there was an interaction (group × time) to compare groups at all time points except baseline. Between group effect sizes for continuous outcomes were evaluated with Cohen's $d$ (95% CI) and were considered as large (absolute value 0.8), moderate (absolute value 0.5), and small (absolute value 0.2).[12] For categorical secondary outcomes of GROC successful outcome (success: GROC≥4 "moderately better," nonsuccess: GROC<4) comparisons between treatment groups (EX, EX+MT) were conducted using chi-square tests or Fisher's exact test when cell counts were <5. To account for missing data, the last value was pulled forward. Additional health care use (yes/no) was assessed using chi-square tests or Fisher's exact test when cell counts were <5 for any type of health care use, injection, surgical, or nonsurgical. We assessed adequacy of patient blinding by comparing treatment groups on the belief of treatment received at discharge from treatment, using Fisher's exact test (cell counts were <5). All statistical analyses were performed using SPSS (Version 27, Chicago, IL) and a custom MATLAB script (MathWorks, Inc, Natick, MA); alpha set at 0.05.

## Role of the Funding Source

The funders of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the manuscript.

# RESULTS

Baseline characteristics for the sample (n = 93) and by randomized treatment group are shown in **TABLE 1**. The

EX group received 7.9±1.4 visits, and the EX+MT group received 7.8±1.6 visits.

### Primary Outcome

DASH scores are in **TABLE 3**, and plotted adjusted values over time are in **FIGURE 2**. There was a significant main effect for time ($P$<.001) but not treatment group ($P$ = .561). There was a significant group × time interaction ($P$ = .011), and post hoc $t$ tests were performed. At 2, 4, and 6 weeks, no group effect was found (all $P$>.098). However, at 6 and 12 months, there were significantly lower DASH scores for the EX+MT over EX (6 months: mean difference = −4.9 [95% CI: −9.8, −0.1], $P$ =.047; 12 months: mean difference = −6.7 [95% CI: −11.4, −2.1], $P$ = .005). Cohen's $d$ showed moderate between-group effect sizes at 6 months (−0.42 [95% CI: −0.85, 0.04]) and 12 months (−0.60 [95% CI: −1.0, −0.19]).

### Secondary Outcomes

The Satisfaction-shoulder scores are shown in **TABLE 3**, and plotted adjusted scores are in **FIGURE 3**. There was a significant main effect for time ($P$<.001) but not for treatment group ($P$ = .176). There was a significant group × time interaction ($P$ = .030), and post hoc $t$ tests were performed at all time points except baseline. At 2, 4, and 6 weeks, no group effect was found (all $P$>.104). However, at 6 and 12 months, there were significantly higher Satisfaction-shoulder scores for the EX+MT over EX (6 months: mean difference = 0.8 [95% CI: 0.2, 1.5], $P$ = .012; 12 months: mean difference = 1.2 [95% CI: 0.5, 1.8], $P$<.001). Cohen's $d$ showed approximately moderate and large group effect sizes at 6 months (0.53 [95% CI: 0.10, 0.94]) and 12 months (0.73 [95% CI: 0.30, 1.14]), respectively.

The GROC prevalence of success is shown in **TABLE 3**. There was higher prevalence of GROC≥"moderately better" at 26 and 52 weeks in the EX+MT group ($P$<.05) (**FIGURE 4**). Additional health care use is shown in **TABLE 3**. There was no difference in the percentage of patients receiving additional treatment at 6 or 12 months (all $P$>.171).

No adverse events were reported. No participant crossed over to the other treatment group than assigned. Patient blinding analysis indicated the percentage of participants who believed they received the treatment they were assigned to was significantly different between groups ($P$<.001). The EX+MT group had a lower correct guess rate (80.0%; 36 out of 45 participants) than the EX-only group (89.5%; 17 of 19 participants).

## DISCUSSION

Adding manual therapy to a progressive resistance and stretching exercise program yielded higher long-term improvements in shoulder pain and disability, patient satisfaction, and perceived successful benefit with shoulder use. The DASH primary outcome and Satisfaction-shoulder secondary outcome both had better scores for the EX+MT as compared to the EX group. Importantly, the GROC secondary outcome indicated a greater perceived benefit of EX+MT over EX alone at both long-term time points. Clinicians should consider adding manual therapy to a progressive resistance exercise program for patients with subacromial shoulder pain. It is also important to note that both treatment groups appear to improve over time in the primary outcome (DASH) and secondary outcomes (shoulder satisfaction and GROC), indicating EX alone may also be beneficial.

The effect sizes, as quantified by Cohen's $d$[12] were moderate to large for between-group differences of higher scores on the DASH and Satisfaction-shoulder for EX+MT over EX alone at 6 and 12 months. The effect sizes are noteworthy given the chronic nature of symptoms in our study sample, and the significant effects were observed at long term. The effect sizes suggest EX+MT was an effective approach for pain, disability, and satisfaction with shoulder use. These effect sizes aligned with prior clinical trials,[3] providing consistency for the evidence that EX+MT can deliver greater benefits over EX alone for patients with subacromial shoulder pain. Another way to interpret these findings is use of meaningful improvement metrics, such as the MCID. The differences in the DASH (4.9% and 6.7%) and shoulder-satisfaction (0.8 and 1.2 points) were smaller in magnitude than reported thresholds for meaningful improvement – MCID or minimal detectable change values. However, these metrics have limited utility to define clinical meaningfulness in clinical research.[8,20,58] Baseline scores impact how much change is considered meaningful and, thus, a growing consensus to adopt tailored clinically meaningful difference metrics that consider baseline values.[8,13,58] This approach ensures that valid metrics are derived only for patients within defined bounds of baseline scores. Therefore, to determine whether the improvements observed in the current study for DASH and Satisfaction-shoulder are clinically meaningful, further research is needed to establish thresholds based on the baseline value. Effects sizes are not impacted by the issues related to the MICD; this study indicates moderate-to-large effects for the DASH and Satisfaction-shoulder scores.

The GROC secondary outcome indicated that participants perceived a greater benefit of EX+MT over EX alone at 26 and 52 weeks. This may be meaningful, as a modest addition of manual therapy of 10 to 15 minutes per session improved the episodic improvement at 1 year by >20%. Considering patients with subacromial pain are the most common shoulder diagnosis and shoulder conditions are in the top 5 musculoskeletal conditions, this approach has an important opportunity to improve patient outcomes and reduce the cost of health care. Global rating of change has been criticized for recall bias.[30] It is possible that if we had measured success

**TABLE 3**
Primary outcome of the DASH, and Secondary outcomes of Satisfaction-shoulder, GROC, and Additional Health Care Use by Treatment Group

| | Treatment Groups: Unadjusted Raw Data[a] | | Treatment Groups: Adjusted Scores[a] | | | | |
|---|---|---|---|---|---|---|---|
| | EX+MT (n = 52) | EX (n = 41) | EX+MT | EX | Between Group Difference[b] | *P* Value[c] | Effect Size[d] |
| **DASH (0-100, 0 = no symptoms or disability)** | | | | | | | |
| Baseline | 30.1 ± 17.2 | 30.0 ± 13.7 | 30.0 ± 11.8 | 30.0 ± 11.5 | 0 (−4.8, 4.8) | 0.996 | 0 (−0.41, 0.39) |
| 2 weeks | 23.4 ± 13.0 | 25.6 ± 15.2 | 24.0 ± 11.8 | 25.4 ± 11.5 | −1.4 (−6.2, 3.5) | 0.577 | −0.12 (−0.53, 0.29) |
| 4 weeks | 15.3 ± 11.1 | 17.5 ± 12.7 | 16.7 ± 11.8 | 19.4 ± 11.5 | −2.7 (−7.5, 2.1) | 0.268 | −0.23 (−0.64, 0.21) |
| 6 weeks | 13.4 ± 14.1 | 16.4 ± 16.5 | 13.7 ± 11.8 | 17.7 ± 11.5 | −4.1 (−8.9, 0.8) | 0.099 | −0.35 (−0.76, 0.07) |
| 26 weeks | 17.2 ± 18.4 | 21.5 ± 12.9 | 15.3 ± 11.7 | 20.2 ± 11.5 | −4.9 (−9.8, −0.1) | **0.047** | −0.42 (−0.85, 0.04) |
| 52 weeks | 10.3 ± 18.0 | 17.6 ± 15.6 | 10.1 ± 11.1 | 16.8 ± 11.0 | −6.7 (−11.4, −2.1) | **0.005** | −0.60 (−1.0, −0.19) |
| **Satisfaction-Shoulder (0-10, 0 = not satisfied)** | | | | | | | |
| Baseline | 3.1 ± 2.8 | 3.1 ± 2.8 | 2.9 ± 1.5 | 3.3 ± 1.6 | −0.4 (−1.0, 0.3) | 0.245 | −0.24 (−0.66, 0.19) |
| 2 weeks | 4.4 ± 2.8 | 4.8 ± 2.9 | 4.6 ± 1.5 | 4.6 ± 1.6 | 0 (−0.7, 0.6) | 0.904 | −0.03 (−0.44, 0.40) |
| 4 weeks | 6.5 ± 2.6 | 6.4 ± 2.7 | 6.4 ± 1.5 | 6.2 ± 1.6 | 0.2 (−0.4, 0.9) | 0.484 | 0.15 (−0.30, 0.56) |
| 6 weeks | 7.0 ± 2.9 | 6.0 ± 3.5 | 6.9 ± 1.5 | 6.3 ± 1.6 | 0.5 (−0.1, 1.2) | 0.105 | 0.34 (−0.07, 0.76) |
| 26 weeks | 7.3 ± 2.6 | 7.1 ± 2.3 | 7.8 ± 1.5 | 7.0 ± 1.6 | 0.8 (0.2, 1.5) | **0.012** | 0.53 (0.10, 0.94) |
| 52 weeks | 7.8 ± 2.6 | 5.3 ± 3.0 | 7.7 ± 1.5 | 6.5 ± 1.6 | 1.2 (0.5, 1.8) | **<.001** | 0.73 (0.30, 1.14) |
| **GROC; N (%) improved[e]** | | | | | | | |
| 2 weeks | 3 (6.8) | 2 (6.7) | 3 (6.8) | 2 (6.7) | | 1.0 | |
| 4 weeks | 14 (36.8) | 8 (38.1) | 14 (31.8) | 8 (25.0) | | 0.518 | |
| 6 weeks | 23 (53.5) | 11 (40.7) | 24 (51.1) | 11 (34.4) | | 0.143 | |
| 26 weeks | 17 (70.8) | 8 (47.1) | 28 (59.6) | 12 (34.3) | | **0.023** | |
| 52 weeks | 18 (75.0) | 9 (47.4) | 31 (64.6) | 15 (42.9) | | **0.049** | |
| **Additional care; N (%)** | | | | | | | |
| **26 weeks** | | | | | | | |
| Any type | 5 (9.6) | 8 (19.5) | | | | 0.172 | |
| Injection | 1 (1.9) | 0 (0) | | | | 1.0 | |
| Surgical | 2 (3.8) | 2 (4.9) | | | | 1.0 | |
| Nonsurgical | 3 (5.8) | 6 (14.6) | | | | 0.176 | |
| **52 weeks** | | | | | | | |
| Any type | 5 (9.6) | 3 (7.3) | | | | 1.0 | |
| Injection | 2 (3.8) | 0 (0) | | | | 0.502 | |
| Surgical | 1 (1.9) | 1 (2.4) | | | | 1.0 | |
| Nonsurgical | 4 (7.7) | 2 (4.9) | | | | 0.691 | |

*Abbreviations: CI, confidence interval; DASH, Disabilities of the Arm, Shoulder and Hand; GROC, global rating of change; SD, standard deviation.*
[a]*Mean ± SD, unless otherwise indicated. Adjusted scores for DASH and Satisfaction-shoulder after imputation for missing data, calculated from predicted values from the mixed model. Adjusted scores for GROC using the last value pulled forward for missing data.*
[b]*Difference (95% CI) expressed as exercise-plus-manual therapy group (EX+MT) − exercise group (EX), using adjusted scores.*
[c]*Paired comparisons (adjusted scores). Independent t test if continuous vs chi-square (or Fisher's exact test when cell counts were <5) if categorical.*
[d]*Cohen's d (95% CI).*
[e]*Those who reported +4 ("moderately better") were categorized as "improved."*

using a different rating rubric that does not require recall, such as Patient-Acceptable Symptom State, the perceived benefit may have been different. Additional health care use at 6 and 12 months did not differ between groups.

This clinical trial suggests that manual therapy was a beneficial addition to a resistance exercise program, but the effects were not consistent across all participants; patient-specific treatment may be indicated. The implementation of stepped and matched care pathways can be a conduit to deliver patient-specific treatment. Stepped care directs patients to different treatment options if they are nonresponsive to their current treatment. Matched care, on the other hand, tailors the treatment to address patient-specific needs, such as pronounced muscle deficits or psychological factors.[42] We did not assess muscle nor psychological factors. A stepped-matched care approach has the potential to optimize care for patients

**FIGURE 2**
DASH (Disabilities of the Arm, Shoulder, and Hand) across time for both groups; 0-100 = no disability. Data derived from predicted values from linear mixed model, which included fixed effects (group and time) and covariates (group*time interaction and baseline outcome). Mean ± Standard Error for circles and squares. The asterisks (*) denote significant differences between groups for the indicated time (*P*<.05).

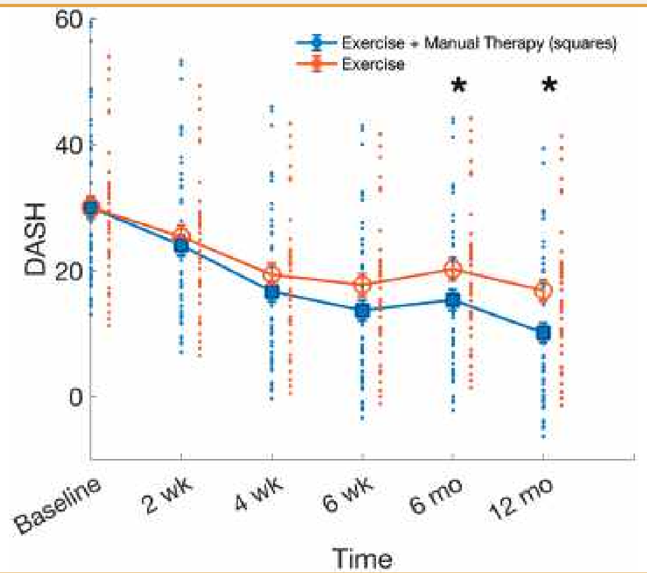
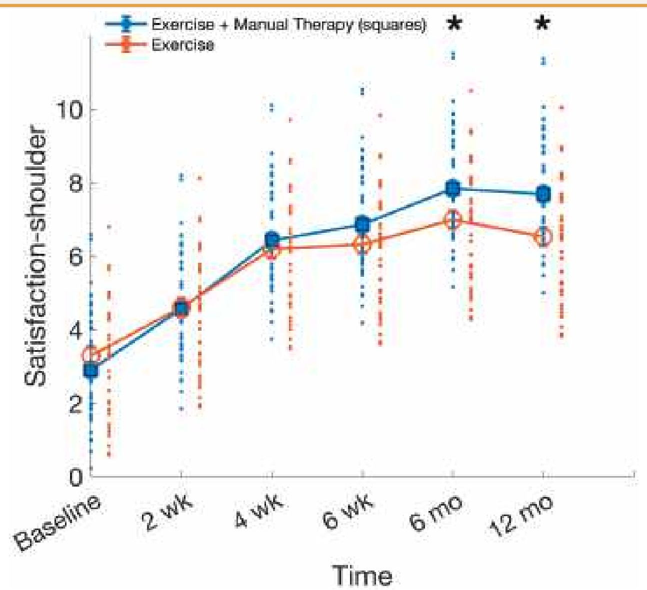



**FIGURE 3**
Satisfaction-shoulder across time for both groups 0-10, 10 = fully satisfied with shoulder use. Data derived from predicted values from linear mixed model, which included fixed effects (group and time) and covariates (group*time interaction and baseline outcome). Mean ± Standard Error for circles and squares. The asterisks (*) denote significant differences between groups for the indicated time (*P*<.05).




with subacromial shoulder pain, but current guidelines have not defined care pathways.[19] Matched and stepped approaches are recommended to improve care and improve outcomes for musculoskeletal conditions.[21,32,47] The addition of manual therapy may only be needed by some patients.

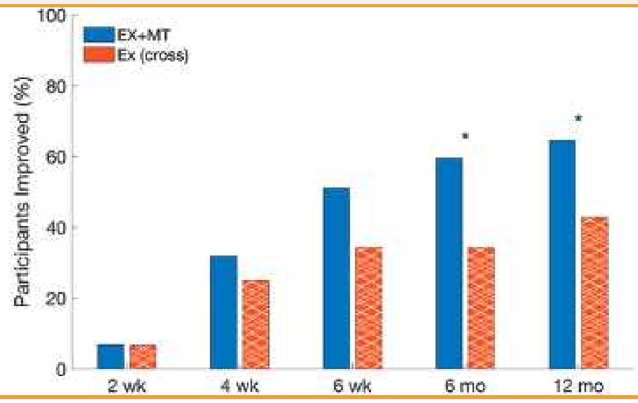
Explanations for the effect of manual therapy are likely not related to biomechanical mechanisms, as evidence indicates no meaningful changes in spinal and scapular kinematics after spinal manipulation in those with subacromial shoulder pain.[25,31,41] By contrast, neurophysiological mechanisms demonstrate changes in information processing in the pain and sensorimotor loops in the central nervous system.[7,15,23,24,26] Manual therapy may provide effects to by positively affecting central neurophysiological and pain-processing deficits.[2,23,24,26]

This clinical trial found better outcomes at long-term only. We hypothesize that the delayed improvement at 6 and 12 months may be due to a combination of other mechanisms and benefits of manual therapy. The manual therapy techniques used in this study aimed to increase shoulder mobility and reduce pain, which may have helped patients to perform the exercise program. The manual therapy may have increased their adherence to the lifestyle recommendations due to increase physical contact with the physical therapist, and greater therapeutic alliance. Unfortunately, we did not measure these factors. Future studies should evaluate these potential mechanisms underlying the effects of treatment.

Our results should be viewed in the context of the limitations. We used a standardized resistance exercise and manual therapy approach used in prior clinical trials.[31,40,56] Treatment was not based on individual patient impairments. Patient participation in randomized clinical trials is important to consider as the consent detailed clinical equipoise, which implies clinician neutrality to the treatment. However, clinician and patient beliefs may have influenced outcomes.

This study was completed 12 years ago. This calls into question, would we design the study the same way today? Yes, we would. The question of whether adding

**FIGURE 4**
Adjusted global rating of change (GROC) (≥ +4: "Moderately Better") frequencies by group and time. Adjusted scores for GROC used the last value pulled forward for missing data. *$P<.05$ between treatment groups.




manual therapy to a resistance exercise program is beneficial has not been definitively answered.[3,46,55] The lack of a standardized comprehensive delivery of exercise and manual therapy in prior clinical trials makes it unclear if the effects (or lack thereof) are due to manual therapy in general or individual techniques delivered. Moreover, only short-term effects up to 6 weeks have shown higher probability of effectiveness, with limited investigation of long-term effects.

## CONCLUSION

Adding shoulder and thoracic spine manual therapy to a resistance exercise program provided greater improvement in shoulder disability, satisfaction with shoulder use, and perceived benefit at 6 and 12 months over exercise alone. The effects were moderate to large. The magnitudes of between-group differences were relatively small. The addition of manual therapy did not alter the use of additional health care in the following year. This work adds consistency to the body of literature indicating that the addition of manual therapy can be helpful in patients with subacromial shoulder pain at long term, although it remains unclear which specific patients may benefit most from the addition of manual therapy. ■

## KEY POINTS

**FINDINGS:** The addition of manual therapy to the spine and shoulder to resistance exercise and stretching program had moderate-to-large effects for greater improvements shoulder disability, satisfaction with shoulder use, and perceived benefit of success at 6 and 12 months for patients with subacromial shoulder pain. There were no differences in additional health care use.

**IMPLICATIONS:** This clinical trial supports the addition of manual therapy to an exercise program of resistance, stretching, and patient education.

**CAUTION:** Patients in this study were from 2 geographic regions in the United States of America. The addition of manual therapy did not yield benefit in the short term, and the relative magnitude of differences between groups were small.

## STUDY DETAILS

**AUTHOR CONTRIBUTIONS:** Concept/research design/methods: Michener, McClure, Tate, Thigpen; Data curation/acquisition: Michener, McClure, Tate, Bailey, Seitz, Thigpen; Data analysis and interpretation of data: Michener, McClure, Straub, Thigpen; Acquisition of funding: Michener, McClure, Thigpen; Providing subjects: Michener, McClure, Tate, Seitz, Bailey, Thigpen; Writing initial manuscript: Michener, McClure, Straub, Thigpen; Editing and final approval of manuscript: all authors.

**DATA SHARING:** All data relevant to the study are included in the article or are available by reasonable request.

**PATIENT AND PUBLIC INVOLVEMENT:** There were no patients involved in the development of this study.

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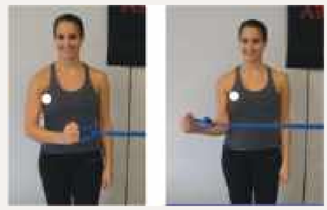
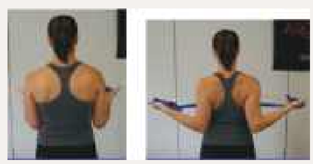
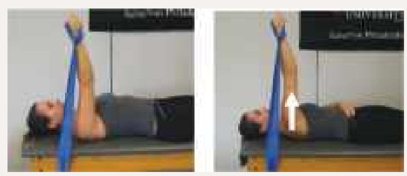
## APPENDIX

### INTERVENTION PROGRAM; REPRODUCED WITH PERMISSION FROM *JOSPT*[49]

| Resistance Exercise: Motor Control/Strengthening<br>*2-3 sets of 10 repetitions, progressing from yellow> red> green> blue band* | | |
|---|---|---|
| Intervention<br>Phase 1 | Details | Figures |
| **1. Resisted shoulder external rotation (neutral)** | 1. Begin with hand in front the stomach. Pull away from abdomen, then slowly release. Can use towel in armpit if more comfortable. |  |
| **2. Resisted shoulder internal rotation (neutral)** | 2. Begin with forearm out to the side and elbow against body. Pull toward your abdomen, then slowly release. Can use towel in armpit if more comfortable. |  |
| **3. Resisted scapular extension** | 3. Begin with arms forward flexed about 45°. Pull band toward you keeping your elbow bent. |  |
| **4. Resisted scapular retraction** | 4. Grasp band with both hands, elbows bent. Pinch your shoulder blades together which will stretch the band, then slowly release. |  |
| **5. Resisted scapular protraction supine** | 5. Grasp band while lying on your back with arm flexed to 90°. Punch arm up toward the ceiling while keeping arm straight. Your shoulder blade should lift off table. |  |
| **6. Active elevation with upper trap relaxation** | 6. Lift your arm upwards while keeping your shoulder relaxed (avoid shrugging). You may use a mirror or your other hand to check to see if your shoulder is lifting up. |  |

*(Table continues on next page.)*

## APPENDIX (CONTINUED)

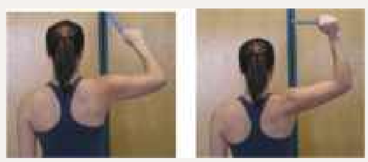
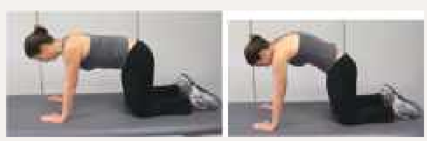
**Resistance Exercise: Motor Control/Strengthening**

*2-3 sets of 10 repetitions, progressing from yellow> red> green> blue band*

| Intervention Phase 1 | Details | Figures |
|---|---|---|
| **7. Chin tuck with scapular retraction (postural exercise)** | 7. Sitting or standing, tuck your chin and pull shoulder blades down and back. Avoid tilting of the head back or looking at the ceiling. |  |

**Motor Control/Strengthening**

*2-3 sets of 10 repetitions, progressing from yellow> red> green> blue band*

| Intervention Phase 2 | Details | Figures |
|---|---|---|
| **1. Shoulder abduction "scaption" (0°-90°)** | 1. Stand on band and grasp other side, thumb pointing up. Lift band to shoulder level staying in a plane of movement midway between front and side, then slowly lower. |  |
| **2. Shoulder flexion (0°-90°)** | 2. Stand on band and grasp other side, thumb pointing up. Lift band forward to shoulder level and slowly release. |  |
| **3. Shoulder external rotation with abduction (45°-90°)** | 3. Standing facing doorway with arm at or below shoulder level and elbow bent 90°. Pull band away from the door, keeping your elbow bent and slowly release. |  |
| **4. Shoulder internal rotation with abduction (45°-90°)** | 4. Stand facing away from the doorway with arm at or below shoulder level and elbow bent to 90°. Grasp band and pull palms down toward the floor. Slowly release. |  |
| **5. Quadruped push-up plus "camel"** | 5. Begin on hands and knees with arms shoulder width apart. Push downward causing your upper back to round then slowly release. |  |

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## APPENDIX (CONTINUED)

**Motor Control/Strengthening**

*2-3 sets of 10 repetitions, progressing from yellow> red> green> blue band*

| Intervention<br>Phase 2 | Details | Figures |
|---|---|---|
| **6. Prone shoulder horizontal abduction with scapular retraction "T"** | 6. Thumb turn up and lift arm up toward ceiling while squeezing shoulder blades toward spine. Slowly lower. |  |
| **7. Prone scapular retraction and shoulder elevation "Y"** | 7. Turn thumb up and lift arm diagonally above shoulder toward the ceiling while squeezing shoulder blades toward spine. Slowly lower. |  |

**Motor Control/Strengthening**

*2-3 sets of 10 repetitions, progressing from yellow> red> green> blue band*

| Intervention<br>Phase 3 | Details | Figures |
|---|---|---|
| **Continue all exercises from Phase 2 and add the following:** | | |
| **1. Bodyblade *below* 60°** | 1. Standing, hold the Bodyblade in the scapular plane *below* 60°. Perform exercise on both vertical and horizontal planes. Progress to "above 60°" when able to perform exercise pain free and with good scapular control. |  |
| **2. Bodyblade *above* 60°** | 2. Standing, hold the Bodyblade in the scapular plane *above* 60°. Perform exercise on both vertical and horizontal planes. |  |

*(Table continues on next page.)*

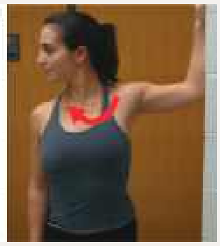
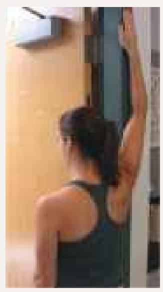
## APPENDIX (CONTINUED)

| Motor Control/Strengthening<br>*2-3 sets of 10 repetitions, progressing from yellow> red> green> blue band* | | |
|---|---|---|
| Intervention<br>Phase 3 | Details | Figures |
| **3. Lawn mower pull** | 3. Anchor band around a leg of bed or couch. Begin grasping band from across your body with hips and knees bent. Pull diagonal overhead while straightening legs and trunk. Slowly control return to start position. |  |
| **4. Forearm push-up plus "protraction plank"** | 4. Begin in forearm plank position with upper back sagged. Push downward through your forearm causing your upper back to round then slowly release. |  |

| Stretching<br>*30 seconds × 3 repetitions; performed in all phases* | | |
|---|---|---|
| Intervention | Details | Figures |
| **1. Thoracic extension towel stretch supine** | 1. Lie on top of a towel roll placed vertically under thoracic spine. Arms out to the side with palms up. |  |

*(Table continues on next page.)*

## APPENDIX (CONTINUED)

| Intervention | Details | Figures |
|---|---|---|
| | **Stretching**<br>*30 seconds × 3 repetitions; performed in all phases* | |
| **2. Doorway pectoral stretch** | 2. Bring arm across your body and use other hand to apply overpressure, pulling the elbow. |   |
| **3. Cross-body posterior shoulder stretching** | 3. Grasp towel behind your back with affected hand below. Use unaffected arm to lift affected arm until you feel a stretch. |  |
| **4. Shoulder external rotation cane stretch** | 4. Grasp cane with affected elbow bent. Use unaffected arm to push hand back toward plinth. |  |
| **5. Shoulder internal rotation "towel" stretch** | 5. Bring arm out to the side with elbow bent, forearm contacting wall. Turn your body away from the wall until you feel a stretch. |  |
| **6. Shoulder flexion stretch**<br>**Phase 1: supine cane flexion**<br>**Phases 2 and 3: standing wall stretch** | 6. Phase 1: Grasp cane with elbows straight and lift up until you feel a stretch.<br>Phases 2 and 3: Stand facing wall with arm reaching as high as possible. Slowly walk closer to the wall to increase your stretch. |  |

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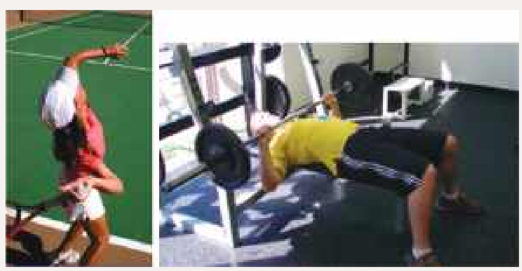
## APPENDIX (CONTINUED)

| Patient Education | | |
|---|---|---|
| **Intervention** | Details | Figures |
| **1. Sleeping** | - If you sleep well and wake up without pain, do not change anything.<br>- If you have trouble sleeping because of your shoulder, avoid resting your arm over your head, letting your arm rest across your body (may decrease blood flow).<br>- Also try propping your arm on a pillow to keep the arm slightly away from your side |  |
| **2. Daily activities** | - Avoid working with arms near or above horizontal, keep your elbows near your body for any prolonged work.<br>- Keep objects close to body when lifting, especially repetitive activities.<br>- Use a stool when a high reach is required. |  |
| **3. Strenuous work/sports** | - Incorporate the spine and hips for extreme and overhead movements.<br>- Be sure your fitness level matches the task you are doing, do not go beyond your capacity.<br>- Avoid excessive fatigue, take breaks when needed.<br>- Use assistive devices whenever possible (eg, carts, lift trucks) |  |

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## APPENDIX (CONTINUED)

| Manual Therapy<br>*10-15 minutes total duration, at least 1 thoracic, posterior, and inferior technique required* | | |
|---|---|---|
| Intervention (Thoracic Spine) | Details | Figures |
| **1. Thoracic PA glides in prone** | 1. PT assumes prone position. Use pisiform to apply posterior to anterior glide in spinous process. Hook fifth digit of top hand with index of bottom hand OR use pisiform of both hand on either side of spinous process to apply PA glide. |  |
| **2. Thoracic PA glides seated** | 2. Seated, PT grasp hands behind neck. Clinician makes a "V" with thumb and index fingers or use pisiform to apply posterior to anterior glide while extending PT's thoracic spine. |  |
| **3. Thoracic thrust in prone (max 2 reps)** | 3. PT assumes prone position. Target area is mid to low thoracic spine. Place pisiforms over transverse processes of single vertebra, then rotate hands so they are parallel to the spine to improve traction on the skin. Take up slack then ask patient to exhale. Perform a low amplitude high velocity trust at end range in a posterior to anterior direction. |  |
| **4. Thoracic thrust in supine (max 2 reps)** | 4. The target area is the mid to upper thoracic spine. Ask PT to clasp hands at the base of the neck. Stabilize segment using the "pistol" grip then use PT's arms to adjust spinal position over selected segment. Clasp PT's elbow and use body weight to apply high velocity, low amplitude trust through PT's arms |  |
| **5. Distraction thrust (max 2 reps)** | 5. Target are upper thoracic and lower cervical area. PT seated with hands clasped at base of neck. Clinician feeds hands through the PT's UEs to lie on top of PT's hands. Take up slack then apply high velocity, low amplitude distraction trust. |  |

*Abbreviations: PA, posterior-anterior; PT, patient; UE, upper extremity.*

*(Table continues on next page.)*

## APPENDIX (CONTINUED)

**Manual Therapy**
*10-15 minutes total duration, at least 1 thoracic, posterior, and inferior technique required*

| Intervention (Posterior Shoulder) | Details | Figures |
|---|---|---|
| **1. Posterior glide glenohumeral mobilization** | 1. PT is positioned supine with towel under scapula. Apply a posterior glide to the head of the humerus. Humeral position can vary. |  |
| **2. Mulligan MWM (posterior glide w/ elevation)** | 2. PT assumes seated position. Wrap one arm around PT on head of the humerus. The other hand stabilizes the scapula. Apply posterior glide with frontal hand. Apply constant force as PT actively elevates and lowers the arm. |   |
| **3. Posterior shoulder stretch (cross-body)** | 3. With patient supine, stabilize the scapula medially using thenar eminence of one hand. Use the other hand to apply a medially directed force. Hold for 30 seconds and repeat 3 times. |   |
| **4. Passive stretching into internal rotation** | 4. PT on side-lying or supine position. Place shoulder in IR end range and use one of the following techniques: sustained stretch, contract-relax, or oscillations at the end range. |   |

*Abbreviations: IR, internal rotation; MWM, mobilization with movement; PT, patient.*

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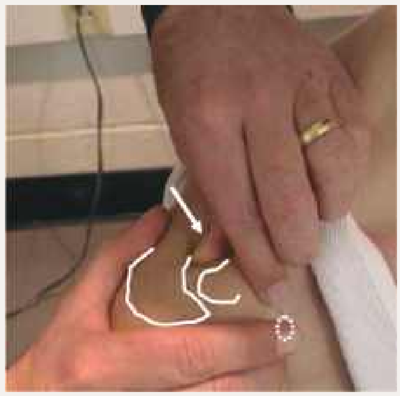
## APPENDIX (CONTINUED)

Manual Therapy

*10-15 minutes total duration, at least 1 thoracic, posterior, and inferior technique required*

| Intervention (Inferior Shoulder and AC Joint) | Details | Figures |
|---|---|---|
| **1. Inferior glenohumeral glides** | 1. Place PT in supine. Technique can be applied throughout the range. Stabilize scapula if performing glide in neutral. If in abducted position, be lateral to the acromion. |  |
| **2. PA glide on clavicle** | 2. PT assumes seated position. Head is at neutral or turned away from shoulder to allow upper trap to relax. One of clinician's hand is wrapped around PT's lateral shoulder, and the other pinches the distal clavicle. Anterior mobilization is applied to PT's distal clavicle. |  |
| **3. Inferior glide of clavicle on acromion** | 3. PT assumes supine position. Head is in neutral position or turned away from shoulder to allow upper traps to relax. Clinician has one hand stabilizing the PT's scapula and the other hand on the superior aspect of the distal clavicle. An inferior mobilization force is applied to the distal clavicle via thenar eminence. |  |

*Abbreviations: AC, acromioclavicular; PA, posterior-anterior; PT, patient.*