Carpal Tunnel Syndrome: A Summary of Clinical Practice Guideline Recommendations

Using the Evidence to Guide Physical Therapist Practice

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Carpal tunnel syndrome (CTS) is the most common upper extremity nerve compression syndrome. Patients with CTS experience reduced sensation, dexterity, and function. Irreversible changes in nerve structure and function due to demyelination and axonal damage can occur in long-standing cases. Published in the May 2019 issue of *JOSPT*, clinical practice guidelines for CTS summarize the best available evidence on incidence and prevalence, pathophysiology, classification, risk factors, examination techniques, and interventions. These guidelines provide practical recommendations for physical therapy examination, diagnosis, and treatment.

WHAT WE KNEW

We knew there was significant evidence on physical therapy management of CTS, but it had not been used to create clinical practice guidelines on this subject.

WHAT WE DID

We conducted a systematic review for each of the areas presented in the guidelines, including articles published prior to November 2018. Articles that met the inclusion criteria were scored and assigned a level of evidence. Information was summarized and recommendations were made.

WHAT WE FOUND

The clinical exam should include a select battery of well-characterized diagnostic tests and outcome measures. The best available evidence supports use of a nighttime orthosis that places the wrist at or near a neutral, comfortable position. For some individuals with CTS, nonsurgical management is curative; however, more than 50% of patients undergoing nonsurgical management progress to surgery within 1 year.

Factors associated with failed nonsurgical management include (1) higher initial scores on the Boston Carpal Tunnel Questionnaire (CTQ)-symptom severity scale that do not improve, (2) duration of symptoms greater than or equal to 1 year, (3) a positive Phalen test, (4) greater intensity of nighttime symptoms, (5) thenar atrophy, and (6) more than 1 prior failed nonsurgical intervention.

BOTTOM LINE FOR PRACTICE

Examination for CTS should include a thorough history and symptom assessment, the Katz hand diagram, static 2-point discrimination, monofilament testing, the Phalen test, the Tinel sign, the carpal compression test, and the wrist ratio index, as well as the CTQ-symptom severity scale and CTQ-functional scale or the Disabilities of the Arm, Shoulder and Hand questionnaire. Dexterity may be assessed using the Purdue Pegboard or the Dellon-modified Moberg Pickup Test. Baseline grip and 3-point or tip pinch strength may also be assessed.

Individuals with severe CTS, as evidenced by thenar atrophy or electrodiagnostic findings, should be referred to a physician for surgical consultation. Individuals with CTS should be provided with a wrist orthosis, worn at night with the wrist situated comfortably at or near a neutral position. Clinicians should not use low-level laser therapy, iontophoresis, or magnet therapy.

After consideration of associated costs and contraindications, additional nonsurgical interventions may be added. These include modification of the orthosis design and prescription, ergonomic interventions, superficial heat, interferential current, phonophoresis, manual therapy, and exercise (lumbrical or general stretching). Patients who regress or do not improve should be referred to a hand surgeon. A flow chart summarizing key elements of diagnosis and treatment of CTS is provided on the next page.

This *JOSPT* Perspectives for Practice was written by a team of *JOSPT*'s Special Features Editors Alexander Scott, PhD, BSc(PT), and Kathryn Sibley, PhD, and staff, using material contributed by guidelines[1] author Mia Erickson, PT, EdD. The flow chart on the following page was produced by Kate Minick, PT, DPT, OCS, of Intermountain Healthcare, Rehabilitation Services, Salt Lake City, UT.

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1. Erickson M, Lawrence M, Stegink Jansen CW, Coker D, Amadio P, Cleary C. Hand pain and sensory deficits: carpal tunnel syndrome. *J Orthop Sports Phys Ther*. 2019;49:CPG1-CPG85. https://doi.org/10.2519/jospt.2019.0301

Hand Pain and Sensory Deficits: Carpal Tunnel Syndrome (CTS) Care Process Model

Component 1: Diagnosis/Classification of CTS: Evaluation of Clinical Findings

Diagnosis
- Detailed history, including duration, location, and severity of symptoms and history of prior interventions
- Perform upper-quarter screening and rule out cervical radiculopathy and thoracic outlet, pronator teres, ulnar, and radial tunnel syndromes
- Semmes-Weinstein monofilament testing (SWMT): use 2.83 (sensitivity, 98%) or 3.22 (specificity, 97%) monofilament to assess light touch sensation – A
- Static 2-point discrimination on middle finger (higher specificity versus sensitivity) – A
- Katz hand diagram (sensitivity, 75%; specificity, 72%), Phalen test (sensitivity, 68%; specificity, 73%), Tinel sign (sensitivity, 50%; specificity, 77%), carpal compression test (sensitivity, 64%; specificity, 83%) – B
- Age (>45 y), shaking hands to relieve symptoms, sensory loss in thumb, wrist ratio index (>0.67), scores from Boston Carpal Tunnel Questionnaire-symptom severity scale (CTQ-SSS; >1.9) – B
  - 3 positive: sensitivity, 0.98 and specificity, 0.54; 4 positive: positive likelihood ratio = 4.60; 5 positive: sensitivity, 0.18 and specificity, 0.99
- Baseline grip and 3-point or tip pinch strength – C

Mild
- Intermittent symptoms

Moderate
- Constant symptoms
- When suspecting moderate CTS, use SWMT with a 3.22 filament as normal on any radial finger; diagnostic accuracy, 90% – A

Severe
- Thenar muscle atrophy
- When suspecting severe CTS, use SWMT with a 3.22 filament as normal on any radial finger; diagnostic accuracy, 90% – A

Component 2: Outcome Assessment

Patient-Reported Outcome Measures – B
- CTQ-SSS: assess symptoms and change in individuals managed surgically or nonsurgically
- Boston Carpal Tunnel Questionnaire-functional scale: assess function and change following CTR surgery
- Disabilities of the Arm, Shoulder and Hand questionnaire: assess function and change following CTR surgery

Physical Impairment Measures
- Do NOT use lateral pinch as outcome – A
- Do NOT use grip strength for change less than 3 months following CTS surgery – B
- Do NOT use threshold or vibration testing to assess change – C
- Use Phalen test to assess long-term change following CTS surgery – C

Physical Performance Measures – C
- Purdue Pegboard: dexterity (compare with established norms)
- Dellon-modified Moberg pick-up test: dexterity (compare with established norms; can be used to assess change following CTS surgery)

Component 3: Intervention Strategies

Education
- Effects of mouse use and alternate strategies – C
- Use of keyboards with reduced strike force – C
- Pathology, risk identification, symptom self-management, aggravating postures/activities – C

Orthoses
- Neutral-positioned wrist orthosis worn at night for short-term relief and functional improvement – B
- If night-only use is ineffective, include daytime, symptomatic, or full-time use for mild to moderate CTS – C
- If no relief, add metacarpophalangeal joint immobilization or modify wrist joint position – C
- Recommended for women with CTS during pregnancy with postpartum follow-up – C

Superficial heat: short-term symptom relief – C

Microwave or shortwave diathermy: short-term pain and symptom relief for mild to moderate CTS – C

Interferential current: trial for short-term pain relief – C

Phonophoresis: clinical symptom relief for mild to moderate CTS – C

Manual therapy: short-term relief for mild to moderate CTS – C
- Can include soft tissue mobilization at sites of potential median nerve entrapment and cervical spine stretching and mobilization

Orthotic/stretching program: for short-term symptom relief for mild to moderate CTS in patients without thenar atrophy and with normal 2-point discrimination – C

Not Recommended
- Low-level laser therapy or other nonlaser light therapy – B
- Thermal ultrasound for mild to moderate CTS – C
- Iontophoresis for mild to moderate CTS – B
- Use of magnets – B

Based on the guidelines, the grades in this flow chart may be translated as follows: A, strong evidence; B, moderate evidence; C, weak evidence; D, conflicting evidence; F, expert opinion. Figure produced for *JOSPT* by Kate Minick, PT, DPT, OCS, of Intermountain Healthcare, Rehabilitation Services, Salt Lake City, UT.

Carpal Tunnel Syndrome
Treating Hand Pain and Numbness

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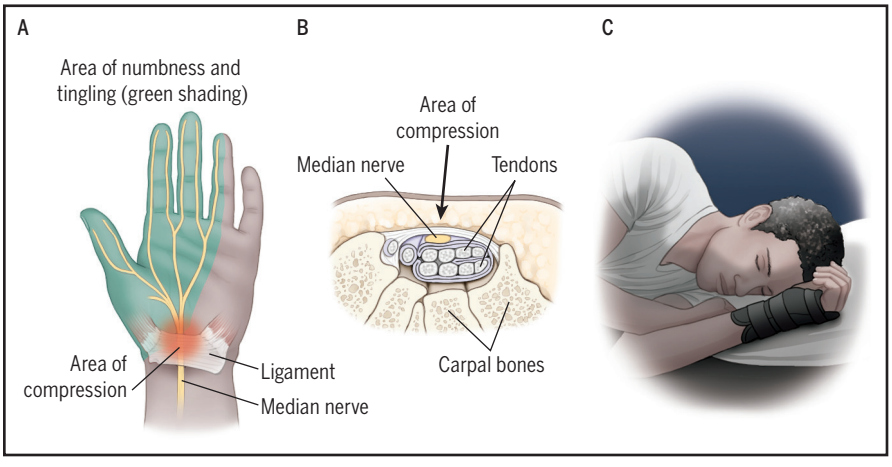
Numbness and tingling in your hand and fingers can be painful and limit your use of them. Pain and a loss of feeling in your thumb, index finger, middle finger, and part of your ring finger may be a sign of carpal tunnel syndrome (see illustration). Eight percent of people have carpal tunnel syndrome at some point in their lives. Women and those over 30 years of age tend to experience this condition more often.

This syndrome and the pain, numbness, tingling, and weakness in your hand that result from it are caused by pressure on the median nerve as it travels through the carpal tunnel. Guidelines published in the May 2019 issue of *JOSPT* make recommendations, based on best practices from the published literature, for evaluating, diagnosing, and treating carpal tunnel syndrome. For you as a patient, these guidelines outline the best rehabilitation treatment options based on the scientific research. Ultimately, the best care is a combination of the leading science, the clinical expertise of your health care provider, and your input as the patient. These guidelines help inform the first step in that process.



UNDERSTANDING CARPAL TUNNEL SYNDROME. The median nerve can be compressed in the carpal tunnel. This can cause numbness and tingling of the hand, shown here in the green-shaded area (A). If these symptoms progress, your hand can become weaker. This image of the carpal tunnel shows the median nerve (yellow) in the carpal tunnel (B). One of the best nonsurgical treatment options is to wear a night brace that keeps your wrist straight (in a neutral position) while you sleep (C).

This *JOSPT* Perspectives for Patients is based on clinical practice guidelines by Erickson et al titled "Hand Pain and Sensory Deficits: Carpal Tunnel Syndrome" (*J Orthop Sports Phys Ther. 2019;49(5):CPG1-CPG85. https://doi.org/10.2519/jospt.2019.0301*).

This Perspectives article was written by a team of *JOSPT*'s editorial board and staff. Deydre S. Teyhen, PT, PhD, Editor, and Jeanne Robertson, Illustrator.

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NEW INSIGHTS

To develop these guidelines, expert clinicians and researchers reviewed papers about carpal tunnel syndrome either published or accepted for publication before November 2018. These reviewers screened thousands of articles and closely examined hundreds of the best papers about the diagnosis, outcome measures, assistive technologies and braces, and nonsurgical treatment options for this condition.

PRACTICAL ADVICE

Physical therapists are well trained to assess and evaluate people with carpal tunnel syndrome. Although some patients (anywhere from 28% to 62%) recover without treatment, others (from 32% to 58%) get worse. A key to nonsurgical treatment shown to help those with carpal tunnel syndrome is the use of a night brace; a night brace should hold your wrist in a neutral position and only be worn for short-term symptom relief.

If you have mild to moderate carpal tunnel syndrome, stretching exercises and the night brace can help, as can manual therapy of your cervical spine and upper extremity performed by a therapist. Education on the proper setup of your computer, especially the mouse, and how hard you strike the keyboard may also help control your symptoms of pain and loss of feeling.

The literature review for these guidelines found that low-level laser therapy, thermal ultrasound, iontophoresis, and magnets provided no consistent benefit in treating carpal tunnel syndrome. If nonsurgical treatment does not help, you may need surgery. Your physical therapist can help guide your recovery, decreasing your symptoms.

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Short-term Effects of Manual Therapy in Patients After Surgical Fixation of Ankle and/or Hindfoot Fracture: A Randomized Clinical Trial

BACKGROUND: Patients with surgical fixation of ankle and/or hindfoot fractures often experience decreased range of motion and loss of function following surgery and postsurgical immobilization, yet there is minimal evidence to guide care for these patients.

OBJECTIVES: To assess whether manual therapy may provide short-term improvements in range of motion, muscle stiffness, gait, and balance in patients who undergo operative fixation of an ankle and/or hindfoot fracture.

METHODS: In this multisite, double-blind randomized clinical trial, 72 consecutive patients who underwent open reduction internal fixation of an ankle and/or hindfoot fracture and were receiving physical therapy treatment of exercise and gait training were randomized to receive either impairment-based manual therapy (manual therapy group) or a sham manual therapy treatment of light soft tissue mobilization and proximal tibiofibular joint mobilizations (control group). Participants in both groups received 3 treatment sessions over 7 to 10 days, and outcomes were assessed immediately post intervention. Outcomes included ankle joint range of motion, muscle stiffness, gait characteristics, and balance measures. Group-by-time effects were compared using linear mixed modeling.

RESULTS: There were no significant differences between the manual therapy and control groups for range of motion, gait, or balance outcomes. There was a significant difference from baseline to the final follow-up in resting gastrocnemius muscle stiffness between the manual therapy and control groups (−47.9 N/m; 95% confidence interval: −86.1, −9.8; $P = .01$). There was no change in muscle stiffness for the manual therapy group between baseline and final follow-up, whereas muscle stiffness increased in the control group by 6.4%.

CONCLUSION: A brief course of manual therapy consisting of 3 treatment sessions over 7 to 10 days did not lead to better short-term improvement than the application of sham manual therapy for most clinical outcomes in patients after ankle and/or hindfoot fracture who were already being treated with exercise and gait training. Our results, however, suggest that manual therapy might decrease aberrant resting muscle stiffness after ankle and/or hindfoot surgical fixation.

LEVEL OF EVIDENCE: Therapy, level 2.
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KEY WORDS: *ankle, balance, calcaneus, fracture, gait, manual therapy, talus*

Pilon fractures or fractures of the talus or calcaneus (hindfoot fractures) have an estimated annual societal cost of $28.5 to $40.5 million due to prolonged absence from work and frequent complications.[26,33] Fractures to the ankle and hindfoot frequently result in functional deficits, such as range-of-motion (ROM) impairments, alterations in gait patterns, and difficulties with balance and proprioception, leading to long-term limitations.[6,12,15,17,31,34,35,40] To date, there is no clear consensus on the best management of these complex fractures, as few physical therapy management studies have been done in individuals who sustain such fractures.

Individuals who incur these fractures often experience persistent ROM limitations, not only from the fracture itself but also from a prolonged immobilization post surgery. Individuals with talar or calcaneal fractures are often immobilized 12 to 16 weeks after operative fixation, which often results in decreased talocrural joint and subtalar joint (STJ) motion. Schulze et al[36] found that only approximately 20% of patients were able to regain full talocrural joint ROM after sustaining a talus fracture. Loss of STJ motion is also common, with an average median STJ motion between 25% and 50% of the unaffected side in patients who sustain calcaneal fractures.[32] Previous research has shown a significant association between decreased ankle dorsiflexion ROM and

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dynamic postural control in individuals with lower extremity injuries.[38] It is possible that a loss of ROM after complex fractures may inhibit the foot's ability to make corrections during balance activities, and restoring motion may lead to improvements in balance and gait. Research has also demonstrated that individuals with calcaneal fractures presenting with slower gait speeds report poorer functional outcomes as assessed by the American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot score.[12] These limitations in ROM, gait, and balance are likely factors responsible for substantial limitations of activities of daily living in this population.

Manual therapy has been shown to improve ROM outcomes in several lower extremity conditions. Improvements in ankle dorsiflexion ROM have been demonstrated following manual therapy treatments for individuals with both acute and chronic ankle sprains.[10,13,22,43,44] It has also been shown that manual therapy may improve pressure pain thresholds in patients with lateral ankle pain.[44] Manual therapy techniques, compared to electrophysical agents, provide improved outcomes for patients with plantar heel pain.[3] For individuals with inversion ankle sprains, manual therapy has been shown to impart immediate changes in load distributions of the foot.[22] Hoch and McKeon[13] demonstrated that manual therapy may have mechanical and functional benefits for sensorimotor function in patients with chronic ankle instability. Previous studies report significant changes after a single treatment session of manual therapy in patients with nonoperatively treated foot and ankle conditions.[13,22] However, despite the number of studies assessing the effects of manual therapy for lower extremity injuries managed nonoperatively, few studies have assessed the effects of manual therapy on patients with ankle/hindfoot fractures who have undergone operative fixation.[21,28]

Research investigating the efficacy of manual therapy in improving common impairments in patients undergoing surgical internal fixation post fracture to the ankle and/or hindfoot is necessary to prepare for larger clinical-effectiveness trials. The purpose of this study was to identify short-term effects of manual therapy on ROM, muscle stiffness, gait, and balance in patients who have sustained a fracture to the ankle and/or hindfoot. We hypothesized that, compared to a control group, manual therapy directed at specific impairments would improve ankle ROM, aid in normalizing muscle stiffness, improve temporal and spatial characteristics of gait, and improve balance.

METHODS

Participants

This multicenter randomized controlled trial included patients from 2 different health systems who had undergone open reduction internal fixation (ORIF) of an ankle or hindfoot fracture. Between January 2016 and April 2018, US Department of Defense beneficiaries (active-duty military and civilian dependents) were recruited from the physical therapy department of Womack Army Medical Center at Fort Bragg, NC. Additional participants were also recruited from Intermountain Healthcare in Salt Lake City, UT.

Eligible individuals underwent an ORIF of either an ankle or hindfoot fracture, were between 18 and 70 years of age, were able to fully weight bear on the operative leg, and had a limitation of weight-bearing dorsiflexion ROM as measured by the ankle lunge test. Additionally, to be eligible, participants had to demonstrate a between-limb difference of greater than 5.0 cm on the ankle lunge test, which is a deficit 3 times greater than the minimal detectable change (MDC) of 1.38 cm.[37]

Exclusion criteria were any prior foot/ankle surgery or deformity that would affect gait or balance; inability to attend follow-up visits; any previous manual therapy for the current ankle and/or hindfoot fracture; a known nonunion/malunion; avascular necrosis as demonstrated on radiographs; a syndesmotic screw that had not yet been removed; or additional fractures of the spine, hip, or lower extremity that would likely affect weight bearing. Though all potential participants had received previous physical therapy based on impairments in ROM, balance, and gait prior to enrollment in the study and were working on prescribed exercises, they were excluded from participation if they had received prior manual therapy. Individuals were advised to continue their home exercise program, but not to add any new exercise or activity during the study trial.

The study was approved by the Institutional Review Boards of both Intermountain Healthcare and Womack Army Medical Center, and all participants provided informed consent in accordance with the World Medical Association Declaration of Helsinki (ethical principles for medical research involving human subjects). This clinical trial was prospectively registered at ClinicalTrials.gov (NCT02609347).

Randomization

Participants were randomized to the manual therapy group or the control group based on a computer-generated randomization list, stratified by site and with randomly varying block sizes of 10, prepared prior to beginning enrollment by a coinvestigator uninvolved with data collection. Randomization was performed for each site, and the treatment allocation was placed in opaque sealed envelopes prior to enrollment. These envelopes were opened after all baseline procedures were completed. Both the participants and the assessors were blinded to group allocation. After completion of the study, participants were asked which group they believed they were allocated to.

Intervention

All patients received treatment based on their group allocation every 2 to 3 days, for a total of 3 treatment sessions within the 7- to 10-day study period. Patients

randomized to the manual therapy group received individualized impairment-based treatment according to fracture type. For example, if a participant presented with a talar neck fracture and was lacking dorsiflexion ROM, the therapist avoided an anterior-to-posterior talocrural joint mobilization, which may place increased stress through the talar neck, and instead may have elected to mobilize the talonavicular joint, STJ, or distal tibiofibular joint based on assessed perceived stiffness. The **APPENDIX** (available at www.jospt.org) provides a list of potential joint mobilization options based on fracture type.

Participants randomized to the control group received light soft tissue mobilization and grade I to II proximal tibiofibular joint mobilizations. The amount of time spent with each participant was documented. Treatments were provided by 3 physical therapists with 3 to 15 years of experience in manual therapy for patients with foot and ankle conditions.

Demographic and Outcome Measures

Participants completed the AOFAS ankle-hindfoot score, the Lower Extremity Functional Scale (LEFS), the numeric pain-rating scale (NPRS), and the Beck Anxiety Inventory at baseline, after their second visit, and at 7 to 10 days after their final visit. In addition, individuals completed the following assessments in random order at the same time points: the ankle lunge test for ankle dorsiflexion ROM, the foot assessment platform for midfoot mobility, the MyotonPRO device (Myoton AS, Tallinn, Estonia) for gastrocnemius muscle stiffness, gait analysis using an instrumented walkway (GAITRite; CIR Systems, Inc, Franklin, NJ), the single-limb stance (SLS) test for balance, and the Star Excursion Balance Test for balance and reach.

Demographic Measures

The AOFAS ankle-hindfoot score is the most frequently cited outcome score for patients who have sustained an intra-articular calcaneal fracture and consists of 9 patient- and physician-reported items regarding function and alignment of the ankle and hindfoot.[34] A perfect score of 100 points indicates no disability.[29] Forty points of the AOFAS ankle-hindfoot score are devoted to pain, 50 points to function, and 10 points to alignment.[32]

The LEFS is an outcome tool frequently used to assess functional outcomes in patients sustaining lower extremity injury. It is a 20-item questionnaire that rates a patient's difficulty with various activities, with a perfect score of 80 points indicating no disability.[24] The minimal clinically important difference for the LEFS is 9 points.[24]

The Beck Anxiety Inventory has been utilized in patients who have sustained foot and ankle trauma. It consists of 21 questions that assess how an individual has been feeling over the past week, with higher scores indicating increased anxiety. It is designed for individuals 17 to 80 years of age, and previous research has demonstrated links between psychosocial factors such as anxiety and foot trauma.[1,41]

Pain intensity was measured on an 11-point (0-10) NPRS.[7] Current, best, and worst pain intensities were collected at each assessment. The NPRS has been found to be a reliable and valid measure of pain intensity.[8]

Outcome Measures

The ankle lunge test is a simple linear measure of weight-bearing ankle dorsiflexion ROM that has been shown to be a valid and reliable tool to assess ROM in this patient population.[37] The intrarater reliability (intraclass correlation coefficient [ICC] = 0.99) and interrater reliability (ICC = 0.97) of this test are excellent.[37] The MDC was found to be 1.38 cm, and studies have demonstrated average changes of 7.8 ± 11.1 cm after manual therapy techniques.[28]

Midfoot mobility (mediolateral and vertical mobility) was measured with the foot assessment platform. Using both mediolateral mobility and vertical mobility, a composite score of the foot mobility magnitude was derived. The foot mobility magnitude was calculated as $\sqrt{(DiffAH)^2 + (DiffMFW)^2}$, where *DiffAH* is the difference in arch height from a weight-bearing to a non–weight-bearing position, and *DiffMFW* is the difference in midfoot width from a weight-bearing to a non–weight-bearing position. Reported interrater ICC values range from 0.83 to 0.99, and the standard error of the measurement ranges from 0.04 to 0.13 cm. Minimal detectable change values range from 0.10 to 0.37 cm.[25]

Muscle stiffness was assessed with the MyotonPRO (Myoton AS), which is a noninvasive tool used to characterize mechanical stiffness of skeletal muscle.[2,19] Tissue stiffness (elasticity) is most commonly quantified as Young's modulus, defined as the slope of the stress-strain curve of a material in the elastic deformation region of interest. The MyotonPRO operates by applying a mechanical impulse to the skin, which is then transmitted to the underlying soft tissue and muscle (0.58 N for 15 milliseconds). The external mechanical impulse causes the muscle to respond by a damped natural oscillation, which is recorded by an accelerometer in the form of an acceleration signal. This acceleration signal is used to calculate Young's modulus and other viscoelastic parameters. The gastrocnemius of each patient was assessed in both a relaxed (prone) and a contracted (performing a heel raise) position. The height of the heel raise was recorded for each patient, and the measurement was made at the same height each subsequent time. An average of 3 measures was utilized. The reliability of measurements using the MyotonPRO has been shown to be high (ICC>0.93).[16]

Gait analysis was performed on a GAITRite system (CIR Systems, Inc). The active measurement area of the 6-m mat is 61 cm wide and 488 cm long. Sensors are arranged in a grid pattern (48 × 384) and placed 1.27 cm apart, and the sampling rate of the system varies between 32.2 and 38.4 Hz. All data were automatically uploaded to a computer as the participant walked across the mat. Participants walked across the mat without

shoes, and an average of 3 trials was used for analysis. Spatial and temporal characteristics of gait included normalized gait velocity, percent of time spent in single-limb support, and stance time.[42]

The SLS test was used to assess postural control. Postural control was defined as controlling the body's position in space for the dual purposes of stability and orientation.[27] The SLS test was performed alternately on the affected and unaffected limb. The SLS test has been shown to be reliable for patients with ankle injuries.[5] Participants were asked to stand for 60 seconds, with hands on their hips, without shoes, and the average of 3 trials was recorded. The test was stopped when the patient's hands did not remain on the hips continuously or when the patient touched the contralateral limb to the ground or to the limb on which he or she was performing the test.

The Star Excursion Balance Test is used to assess dynamic balance and global ROM and strength, and has been shown to have high intrarater (ICC = 0.88-0.96) and interrater (ICC = 0.83-0.93) reliability.[14] The standardized mean difference ranges from 6.68 to 9.15 cm.[14] In bare feet, participants were asked to position their hands at their hips. They were instructed that the heel must remain in contact with the ground throughout the test and were asked to lightly touch the marker with the end of the big toe on the contralateral foot to the maximal distance while maintaining balance. The test was successful if the patient was able to return to the upright position without touching the contralateral limb to the ground upon return. For standardization, the distance reached was measured and divided by leg length, then multiplied by 100.[14] The average of 3 trials was used, and 3 directions—anterior, posteromedial, and posterolateral—were performed so as not to fatigue participants.[5,11,30]

Data Analysis

A priori power analysis was performed using G*Power 3,[9] with the ankle lunge test as the primary outcome. With power set to 80% and an alpha set to 5%, complete data on 68 patients would provide 81% power to detect an effect size of 0.70 between groups.[28] We planned to recruit up to 76 patients to allow for up to a 10% dropout rate. Because there was no loss to follow-up, recruitment was concluded after enrolling 72 individuals.

All analyses were performed using SPSS Version 23.0 statistical software (IBM Corporation, Armonk, NY). Baseline descriptive statistics were summarized and assessed for potentially important differences. Linear mixed modeling was used to compare changes in the manual therapy group to those in the control group across time. Group, time, and the group-by-time interaction were modeled as fixed effects. Treatment effects were estimated using separate, random-intercept, and slope linear mixed models for each outcome variable. For each model, a covariance structure (autoregressive, unstructured, scaled identity) was used, based on best model fit and ability of the model to reach convergence. The baseline score was used as a covariate in each model. The primary analysis of interest was the adjusted pairwise comparison of each outcome at the 2-week follow-up. All enrolled patients completed the study and received the treatment to which they were assigned.

RESULTS

Patients were recruited from Womack Army Medical Center (n = 13) and Intermountain Healthcare (n = 59) and randomized to the manual therapy group (n = 40) and the control group (n = 32). No patients were lost to follow-up. **FIGURE 1** provides a flow diagram of the study. The overall mean ± SD number of days from injury until surgical fixation was 12.9 ± 13.3, with a range of 0 to 76 days, and the number of days from surgery to enrollment was 113.2 ± 37.9. Baseline characteristics of the participants by group assignment are provided in **TABLE 1**. The manual therapy group had lower self-reported scores for both the AOFAS ankle-hindfoot score and the LEFS compared to the control group, and

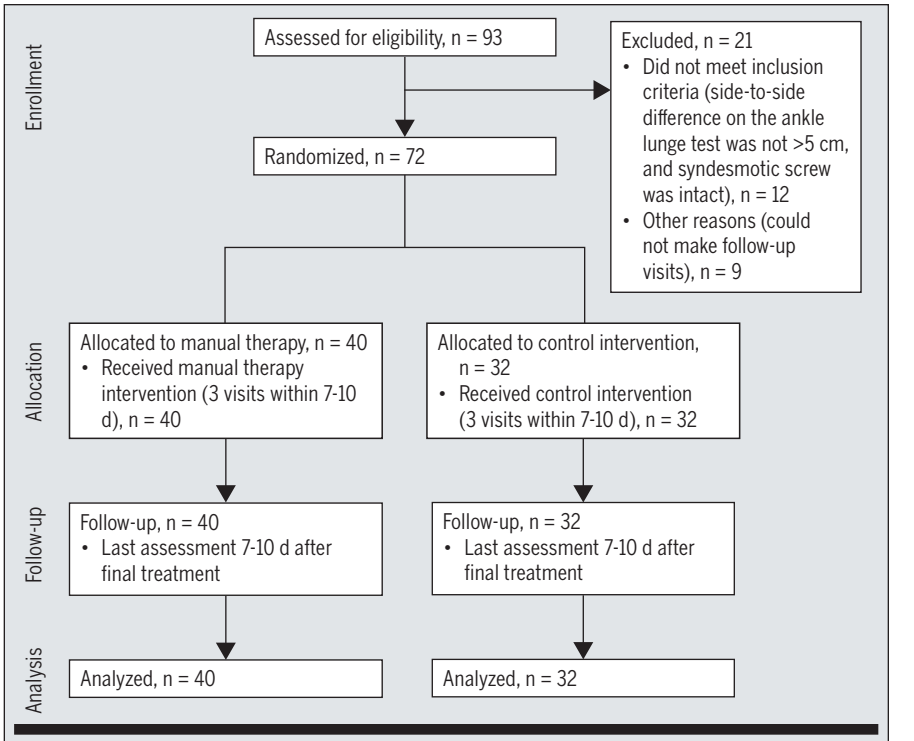

FIGURE 1. Flow diagram of the study.

higher reported initial pain; however, differences were lower than previously reported minimal clinically important difference values,[4,8,24] and therefore these variables were not used as covariates in the model.

The types of fractures and internal fixations performed are reported in **TABLE 2**. The manual therapy group had a total of 64 fractures and fixations, while the control group had a total of 43 fractures and fixations. The average ± SD number of minutes spent with hands-on treatment for all 3 sessions was similar between groups (control, 63.6 ± 11.3 minutes; manual therapy, 60.6 ± 14.8 minutes). The treatment techniques performed in the manual therapy group are reported in **FIGURE 2**. There were no significant differences between the 3 physical therapists providing treatment for any outcome measure. In addition, no adverse events were reported for either group.

There were no significant differences between the manual therapy and control groups in ROM, gait, or balance outcomes (**TABLES 3** through **5**). Resting gastrocnemius muscle stiffness was statistically different between the manual therapy group and control group at the final follow-up (adjusted mean difference, −47.9 N/m; 95% confidence interval [CI]: −86.1, −9.8; P = .01). Specifically, while there was essentially no change in muscle stiffness for the manual therapy group, the control group increased by 6.4%. Additionally, several outcomes changed statistically in both groups across the 2-week period (**TABLES 3** through **5**). The primary outcome, ankle lunge test, improved statistically in both groups from baseline to the final follow-up; however, only the manual therapy group demonstrated an improvement (1.8 cm; 95% CI: 1.3, 2.4) greater than the MDC of 1.38 cm.

To assess the level of blinding of study participants, patients were asked what group they thought they were randomized to at the completion of the study. Thirty-six of the 40 patients (90%) in the manual therapy group and 17 of the 32 patients (53%) in the control group thought they were randomized to the manual therapy group.

TABLE 1 Baseline Demographics*

Characteristic	Manual Therapy Group (n = 40)	Control Group (n = 32)
Age, y	42.7 ± 14.8	42.31 ± 13.8
Sex (male), n (%)	24 (60)	22 (69)
BMI, kg/m^2	26.7 ± 4.9	26.1 ± 5.6
Days from injury to surgical fixation	13.0 ± 14.4	12.8 ± 12.0
Days from surgical fixation to enrollment	111.6 ± 43.5	115.1 ± 29.7
Affected side (right), n (%)	25 (63)	13 (41)
LEFS (0-80)	49.5 ± 12.4	55.1 ± 8.4
AOFAS (0-100)	69.6 ± 13.6	76.4 ± 10.9
Pain (0-10)	3.0 ± 2.1	2.1 ± 1.6
Beck Anxiety Inventory (0-63)	4.7 ± 5.6	2.8 ± 2.7

Abbreviations: AOFAS, American Orthopaedic Foot and Ankle Society ankle-hindfoot score; BMI, body mass index; LEFS, Lower Extremity Functional Scale.
**Values are mean ± SD unless otherwise indicated.*

TABLE 2 Operative Fixation Type by Group*

Type of Fracture/Surgical Repair	Manual Therapy Group (n = 40)	Control Group (n = 32)
Pilon	4	4
Calcaneal	6	4
Talar	2	5
Trimalleolar	6	3
Bimalleolar	9	3
Lateral malleolar	13	10
Medial malleolar	3	2
Syndesmotic ORIF	13	10
Deltoid ligament repair	6	2
STJ dislocation	1	0
Partial TCJ dislocation	1	0
Total surgical procedures	64	43

Abbreviations: ORIF, open reduction internal fixation; STJ, subtalar joint; TCJ, talocrural joint.
**Values are n.*

DISCUSSION

Few high-quality studies have been conducted to guide the management of patients who sustain fractures of the ankle and/or hindfoot. This study assessed the short-term effects of manual therapy in individuals who underwent ORIF followed by prolonged immobilization, and who had already received treatment consisting of exercise and gait training. Results of this randomized controlled trial suggest that supplementing prior treatment with 3 sessions of impairment-based manual physical therapy did not result in greater improvement in ROM, gait, or balance compared to therapy consisting of soft tissue mobilization and proximal tibiofibular joint mobilization. The only between-group difference identified was in resting muscle stiffness, which increased in the control group but not in the manual therapy

group. This suggests that manual therapy may decrease short-term aberrant neuromotor effects after ankle and/or hindfoot surgical fixation.

The patients in the current study were immobilized between 10 and 16 weeks following ORIF surgery. It is possible that patients immobilized for 3 to 4 months may require more than 3 manual therapy treatment sessions to see significant changes in motion. Landrum et al[20] assessed dorsiflexion ROM in 10 individuals with lower extremity injuries. All patients were immobilized for 5 weeks or less, except for a single patient with a fifth metatarsal fracture, who was immobilized for 9 weeks and showed no change in ankle dorsiflexion

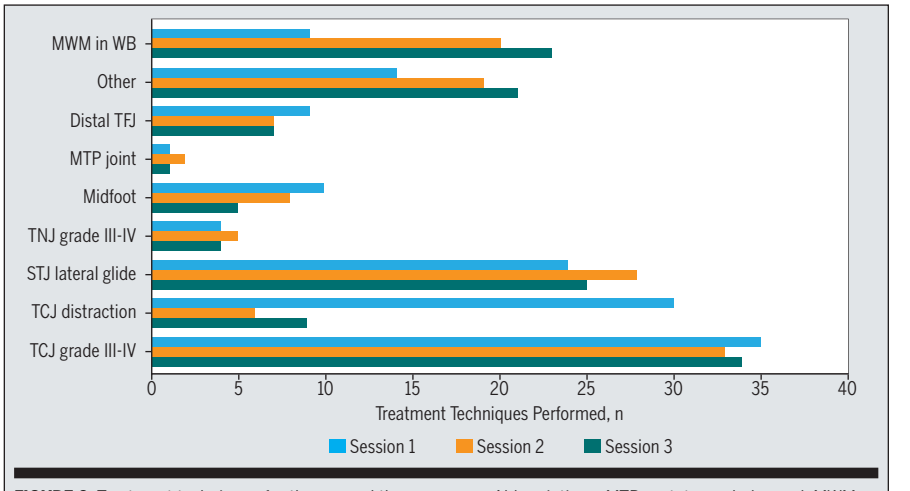

FIGURE 2. Treatment techniques for the manual therapy group. Abbreviations: MTP, metatarsophalangeal; MWM, mobilization with movement; STJ, subtalar joint; TCJ, talocrural joint; TFJ, tibiofibular joint; TNJ, talonavicular joint; WB, weight bearing.

TABLE 3 Outcome Measures of Motion and Muscle Stiffness for Each Group

Outcome/Visit	Manual Therapy Group*	Control Group*	Between-Group Difference†‡	*P* Value
Ankle lunge test, cm				
Baseline	1.6 ± 3.6	2.5 ± 3.7		
Assessment 1 (1 wk)	3.2 ± 3.8	2.8 ± 3.9	0.5 (−1.3, 2.2)	.62
Mean change from baseline†	1.7 (1.1, 2.2)	0.3 (0.0, 0.6)		
Assessment 2 (2 wk)	3.4 ± 3.5	3.5 ± 3.9	−0.1 (−1.9, 1.7)	.93
Mean change from baseline†	1.8 (1.3, 2.4)	1.0 (0.6, 1.4)		
Foot mobility magnitude, mm				
Baseline	10.4 ± 3.2	11.4 ± 3.6		
Assessment 1 (1 wk)	10.8 ± 3.1	11.9 ± 3.5	−1.0 (−2.9, 0.8)	.31
Mean change from baseline†	0.4 (−0.5, 1.3)	0.5 (−0.5, 1.6)		
Assessment 2 (2 wk)	11.3 ± 3.5	11.1 ± 4.3	0.2 (−1.7, 2.1)	.54
Mean change from baseline†	0.9 (−0.2, 1.9)	−0.3 (−1.2, 0.6)		
MyotonPRO (resting), N/m§				
Baseline	306.4 ± 69.9	330.9 ± 12.9		
Assessment 1 (1 wk)	307.4 ± 74.5	330.3 ± 72.1	−21.4 (−59.3, 16.4)	.26
Mean change from baseline†	1.0 (−12.5, 14.5)	−0.6 (−14.2, 12.9)		
Assessment 2 (2 wk)	307.5 ± 75.4	361.2 ± 99.8	−47.9 (−86.1, −9.8)	.01
Mean change from baseline†	0.7 (−11.9, 13.3)	21.2 (−6.1, 48.5)		
MyotonPRO (contracted), N/m§				
Baseline	419.2 ± 170.4	454.3 ± 166.0		
Assessment 1 (1 wk)	390.6 ± 133.8	463.2 ± 165.1	−71.4 (−143.1, −0.3)	.05
Mean change from baseline†	−28.6 (−51.5, −5.7)	8.9 (−18.5, 36.3)		
Assessment 2 (2 wk)	412.3 ± 149.9	475.6 ± 150.5	−63.0 (−135.4, 9.3)	.09
Mean change from baseline†	−8.1 (−31.5, 15.2)	12.6 (−37.1, 62.3)		

**Values are mean ± SD unless otherwise indicated.*
†Values in parentheses are 95% confidence interval.
‡Adjusted for baseline scores of outcome variable.
§The data do not always add up due to incomplete pretest-posttest data for a few patients who participated in the study. In the manual therapy group, 1 patient had missing data for the MyotonPRO. In the control group, 3 patients had 1 missing data point for the MyotonPRO.

ROM after manual therapy techniques.[20] Painter et al[28] reported on a case series of 11 patients who showed improved dorsiflexion motion after immobilization. These patients received an average of 6.6 (range, 3-10) treatment sessions.[28] Of the 11 patients, the 3 patients with a longer immobilization period (21-75 days) were considered more challenging to treat.[28] The patients in the current study were immobilized approximately 70 to 120 days and might have warranted an increase in the number of manual therapy treatment sessions.

In addition, the soft tissue mobilization received by the control group might have helped to stimulate the lymphatic system, which can aid in a decrease in posttraumatic edema.[39] In theory, a decrease in swelling of the talocrural joint could have helped facilitate improvements in talocrural joint dorsiflexion ROM.

The control group demonstrated a significant increase in muscle stiffness from baseline to the 1-week follow-up period of almost 10%. Kelly et al[16] assessed the reliability of measuring muscle stiffness of the gastrocnemius in both a resting and a contracted position in healthy individuals. Similar to the current study, Kelly et al[16] used a prone position to assess resting gastrocnemius muscle stiffness and obtained values equal to 326.2 N/m (95% CI: 299.3, 353.0). When compared to these healthy individuals, patients in the current study with ankle fractures who were in the manual therapy group remained within the 95% CI (307.5 N/m), whereas those in the control group increased to 361.2 N/m.[16]

In this study, muscle stiffness of the contracted gastrocnemius muscle was measured in standing; however, Kelly et al[16] measured muscle stiffness of the contracted gastrocnemius in prone at 40% and 80% of maximum voluntary isometric contraction (MVIC). They found mean stiffness of the gastrocnemius in resting to be 326.2 N/m (95% CI: 299.3, 353.0). At 40% MVIC, the stiffness increased to 588.93 N/m (95% CI: 491.68, 686.18), and at 80% MVIC, stiffness increased to 658.04 N/m (95% CI: 558.47, 757.60), for a difference of 331.84 (95% CI: 222.66, 441.07) between resting and 80% MVIC in healthy individuals.[16] In comparison, the mean difference in gastrocnemius stiffness in the current study between a relaxed and a contracted position was 119.52 N/m (95% CI: 89.16, 149.87). Previous studies have demonstrated that muscle stiffness is linearly related to muscle force during an isometric contraction.[18,23] It is possible that secondary muscles of plantar flexion (ie, tibialis posterior, flexor digitorum longus, flexor hallucis longus) were recruited more due to weakness of the primary plantar flexors as a result of prolonged immobilization.

Limitations and Directions for Future Research

The current study only assessed the short-term response to a limited number of manual therapy sessions. Although

TABLE 4 Results of Gait Parameters for Each Group

Outcome/Visit	Manual Therapy Group*	Control Group*	Between-Group Difference†‡	*P* Value
Normalized gait velocity, m/s				
Baseline	1.15 ± 0.28	1.18 ± 0.42		
Assessment 1 (1 wk)	1.30 ± 0.26	1.40 ± 0.36	−0.10 (−0.26, 0.06)	.21
Mean change from baseline†	0.15 (0.07, 0.20)	0.22 (0.04, 0.39)		
Assessment 2 (2 wk)	1.40 ± 0.26	1.49 ± 0.33	−0.09 (−0.25, 0.07)	.25
Mean change from baseline†	0.24 (0.19, 0.30)	0.31 (0.13, 0.49)		
Stance time, % of gait				
Baseline	67.79 ± 7.46	66.24 ± 6.11		
Assessment 1 (1 wk)	66.07 ± 7.59	66.72 ± 7.71	−0.65 (−4.44, 3.14)	.73
Mean change from baseline†	−1.72 (−3.83, 0.39)	0.48 (−3.68, 4.63)		
Assessment 2 (2 wk)	64.80 ± 5.57	68.01 ± 8.32	−3.20 (−6.99, 0.59)	.10
Mean change from baseline†	−2.98 (−6.42, 0.45)	1.76 (−2.58, 6.11)		
Stance time, s				
Baseline	0.97 ± 0.61	0.80 ± 0.29		
Assessment 1 (1 wk)	0.90 ± 0.52	0.87 ± 0.39	0.04 (−0.19, 0.26)	.75
Mean change from baseline†	−0.07 (−0.18, 0.04)	0.07 (−0.13, 0.27)		
Assessment 2 (2 wk)	0.77 ± 0.32	0.94 ± 99.8	−0.17 (−0.39, 0.06)	.15
Mean change from baseline†	−0.21 (−0.45, 0.04)	0.14 (−0.09, 0.37)		

**Values are mean ± SD unless otherwise indicated.*
†Values in parentheses are 95% confidence interval.
‡Adjusted for baseline scores of outcome variable.

this limited time frame and dosage might not be generalizable to clinical outcomes after clinically oriented rehabilitation that includes manual therapy, our intent was simply to evaluate the short-term efficacy of manual therapy on specific impairments in patients operatively treated for ankle/hindfoot fracture. The fact that only 53% of patients in the control group (versus 90% in the manual therapy group) thought that they received manual therapy suggests that participant blinding was only partially successful. This is consistent with the inherent difficulty of blinding patients to manual therapy intervention.

Another potential limitation of this study is that individuals were not randomized by fracture type. In this study, there were a greater number of individuals in the manual therapy group who had multiple fractures or ligamentous injuries that required operative fixation compared to the control group. It is possible that manual therapy may be more beneficial to individuals with fractures who require prolonged immobilization earlier in the rehabilitative process. However, this study only assessed initiating manual therapy after patients were able to fully bear weight (between 10 and 16 weeks) and included individuals who had been treated with exercise and gait training therapy for 4 to 8 weeks.

Future research should assess the effects of a greater number of manual

TABLE 5 Outcome Measures of Balance for Each Group

Outcome/Visit	Manual Therapy Group*	Control Group*	Between-Group Difference†‡	*P* Value
Normalized SEBT (anterior), cm				
Baseline	49.6 ± 6.7	49.2 ± 10.8		
Assessment 1 (1 wk)	53.0 ± 6.8	53.6 ± 6.6	−0.5 (−4.2, 3.2)	.78
Mean change from baseline†	3.4 (2.0, 4.8)	4.4 (0.4, 8.4)		
Assessment 2 (2 wk)	54.5 ± 6.8	57.2 ± 10.9	−2.7 (−6.4, 1.0)	.15
Mean change from baseline†	4.9 (2.9, 6.9)	8.1 (3.1, 13.0)		
Normalized SEBT (posteromedial), cm				
Baseline	85.5 ± 11.6	85.2 ± 18.8		
Assessment 1 (1 wk)	89.1 ± 11.1	91.0 ± 9.0	−3.1 (−8.1, 2.0)	.23
Mean change from baseline†	3.6 (1.2, 5.9)	5.8 (−0.2, 11.8)		
Assessment 2 (2 wk)	91.2 ± 11.1	93.8 ± 9.7	−2.6 (−7.6, 2.4)	.31
Mean change from baseline†	5.6 (2.9, 8.4)	8.6 (2.1, 15.1)		
Normalized SEBT (posterolateral), cm				
Baseline	75.0 ± 17.7	76.0 ± 17.2		
Assessment 1 (1 wk)	80.1 ± 15.4	82.4 ± 11.4	−2.3 (−8.7, 4.1)	.48
Mean change from baseline†	5.1 (2.6, 7.6)	6.4 (0.7, 12.1)		
Assessment 2 (2 wk)	84.1 ± 14.6	86.1 ± 11.7	−2.0 (−8.4, 4.4)	.54
Mean change from baseline†	9.1 (5.6, 12.2)	10.1 (5.0, 15.2)		
SLS (eyes open), s§				
Baseline	29.3 ± 21.8	35.2 ± 21.5		
Assessment 1 (1 wk)	33.1 ± 24.0	39.3 ± 20.6	−6.3 (−16.8, 4.3)	.24
Mean change from baseline†	3.8 (0.1, 7.5)	4.1 (0.3, 7.9)		
Assessment 2 (2 wk)	37.7 ± 22.4	43.2 ± 20.8	−5.6 (−16.1, 5.0)	.30
Mean change from baseline†	9.0 (5.0, 12.9)	8.1 (2.8, 13.4)		
SLS (eyes closed), s§				
Baseline	5.6 ± 9.4	7.2 ± 8.4		
Assessment 1 (1 wk)	8.4 ± 2.5	7.8 ± 10.0	0.4 (−6.2, 7.0)	.90
Mean change from baseline†	2.8 (0.2, 5.4)	0.6 (−2.1, 3.3)		
Assessment 2 (2 wk)	8.1 ± 14.7	9.7 ± 14.2	−1.6 (−8.2, 5.0)	.64
Mean change from baseline†	2.5 (0.4, 5.0)	2.5 (−0.3, 5.3)		

Abbreviations: SEBT, Star Excursion Balance Test; SLS, single-leg stance.
**Values are mean ± SD unless otherwise indicated.*
†Values in parentheses are 95% confidence interval.
‡Adjusted for baseline scores of outcome variable.
§The data do not always add up due to incomplete pretest-posttest data for 1 patient in the manual therapy group for the SLS test.

therapy treatment sessions for individuals with prolonged immobilization periods. In addition, high-quality trials of long-term outcomes for individuals who have undergone operative fixation of ankle/hindfoot fractures should include therapeutic exercise, as this may help to maximize the benefit of manual therapy.

CONCLUSION

Results of this randomized controlled trial suggest that 3 sessions of impairment-based manual physical therapy for patients with ORIF for an ankle and/or hindfoot fracture, who had already received physical therapy consisting of exercise and gait training, did not result in greater improvement of ROM, gait, or balance compared to therapy consisting of soft tissue mobilization and proximal tibiofibular joint mobilization. The only between-group difference identified was in resting muscle stiffness, which increased in the control group but not in the manual therapy group. This suggests that manual therapy may decrease short-term aberrant neuromotor effects after ankle and/or hindfoot surgical fixation. It is possible that this population of patients may benefit from manual therapy earlier in the postoperative phase or from a greater number of manual therapy treatments. ◉

KEY POINTS

FINDINGS: For patients who underwent an open reduction internal fixation surgery for an ankle and/or hindfoot fracture, and who were already receiving physical therapy consisting of exercise and gait training, 3 sessions of impairment-based manual therapy did not result in greater improvements in range of motion, gait, and balance compared to a control group receiving soft tissue mobilization and proximal tibiofibular joint mobilization.

IMPLICATIONS: Manual therapy may decrease short-term aberrant neuromotor effects after ankle and/or hindfoot fracture treated with open reduction internal fixation.

CAUTION: Due to the short-term follow-up and low frequency of manual therapy sessions utilized in this study, results of this trial regarding the role of manual therapy in the management of patients sustaining hindfoot and/or ankle fractures should be interpreted with caution.

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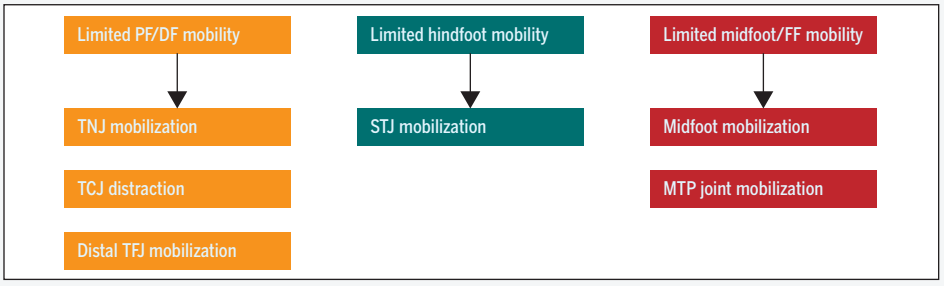
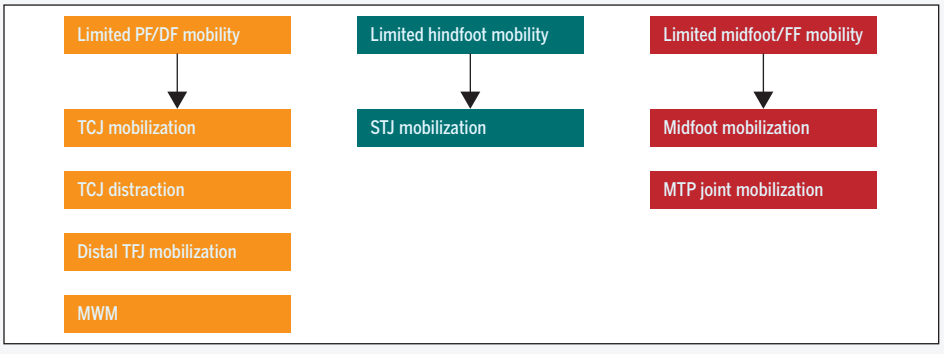
APPENDIX

MANUAL THERAPY TECHNIQUES FOR DIFFERENT TYPES OF SURGERY

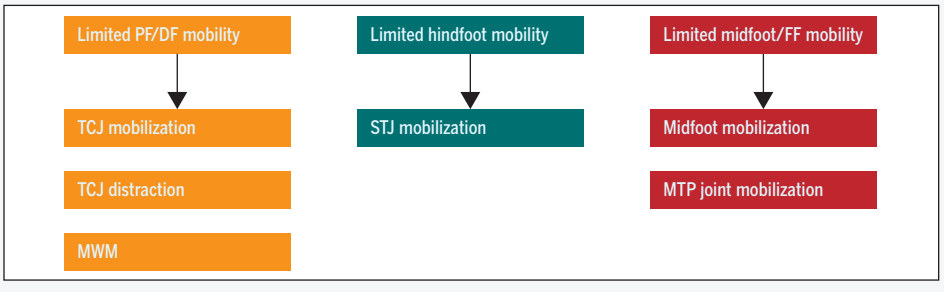
Talar Neck ORIF



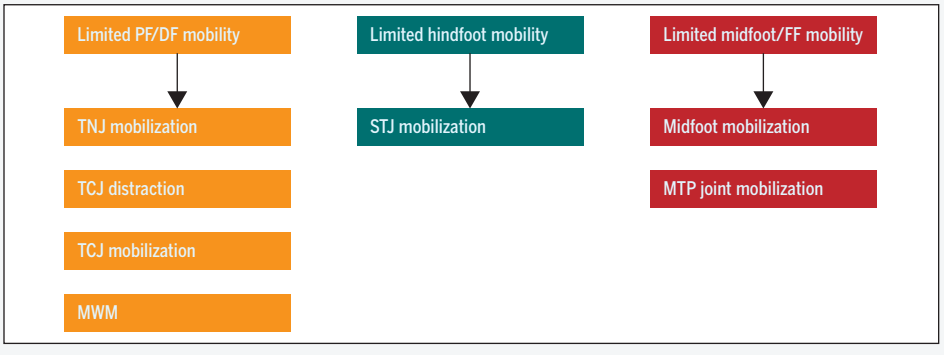
Calcaneal ORIF



Pilon ORIF



Bimalleolar/Trimalleolar/Lateral Malleolar or Medial Malleolar ORIF



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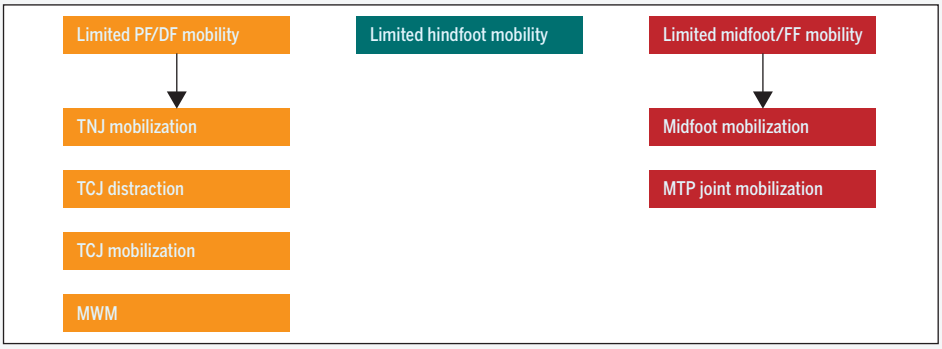
Maisonneuve ORIF



Abbreviations: DF, dorsiflexion; FF, forefoot; MTP, metatarsophalangeal; MWM, mobilization with movement; ORIF, open reduction internal fixation; PF, plantar flexion; TCJ, talocrural joint; TFJ, tibiofibular joint; TNJ, talonavicular joint; STJ, subtalar joint.

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Ultrasound-Guided Percutaneous Electrical Nerve Stimulation of the Radial Nerve for a Patient With Lateral Elbow Pain: A Case Report With a 2-Year Follow-up

BACKGROUND: Patients with lateral elbow pain are often diagnosed with lateral epicondylalgia. Lateral elbow pain is often associated with dysfunction of the wrist extensor muscles; however, in some cases, it can also mimic signs and symptoms of radial nerve dysfunction.

CASE DESCRIPTION: In this case report, a 43-year-old man, who was originally referred with a diagnosis of lateral epicondylalgia as a result of playing table tennis and who previously responded favorably to manual therapy and exercise, presented to the clinic for treatment. An exacerbation while participating in a table tennis match resulted in a return of his lateral epicondylalgia symptoms, which did not respond favorably to the same interventions used in his prior course of therapy. Further examination revealed sensitization of the radial nerve, which was treated with 2 sessions of ultrasound-guided percutaneous electrical nerve stimulation and 4 weeks of a low-load, concentric/eccentric exercise program for the wrist extensors.

OUTCOMES: Following this intervention, the patient experienced clinically meaningful improvement in pain intensity (numeric pain-rating scale), function (Patient-Rated Tennis Elbow Evaluation), and related disability (Disabilities of the Arm, Shoulder and Hand questionnaire). The patient progressively exhibited complete resolution of pain and function, which was maintained at 2 years.

DISCUSSION: This case report demonstrates the outcomes of a patient with lateral elbow pain who did not respond to manual therapy and exercise. Once radial nerve trunk sensitivity was identified and the intervention, consisting of ultrasound-guided percutaneous electrical nerve stimulation targeting the radial nerve combined with a low-load exercise program, was applied, a full resolution of pain and function occurred rapidly. Future clinical trials should examine the effect of percutaneous electrical nerve stimulation in the management of nerve-related symptoms associated with musculoskeletal pain conditions.

LEVEL OF EVIDENCE: Therapy, level 5.
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KEY WORDS: *elbow pain, nerve, percutaneous electrical nerve stimulation, sensitization*

Lateral epicondylalgia (LE) is a musculoskeletal condition associated with dysfunction of the wrist extensor tendons.[10,27] Approximately 1% to 3% of the general population will experience lateral elbow pain at some point in life.[33] Lateral epicondylalgia is more prevalent in women between the ages of 35 and 50 years and is often aggravated by repetitive motions or prolonged wrist positions associated with occupational activities[20] or physical activities/sports.[22] Histopathological studies have shown that microtrauma, potentially associated with repetitive motions, can result in tissue breakdown, with a tissue response of angiofibroplastic hyperplasia and subsequent release of pronociceptive substances in the tendon of the wrist extensor muscles, particularly the extensor carpi radialis brevis (ECRB).[1,26]

Conservative care, such as physical therapy, education, and activity modification, is often the initial management strategy for patients with LE; however, there is no consensus in the literature regarding the most effective intervention approach.[4] Several interventions, particularly manual therapy[28] and exercise,[7] are effective for the treatment of LE. Others have proposed the application of trigger point dry needling,[15] based on the presence of myofascial trigger points in this population.[12]

One relevant anatomical structure that may also be involved in elbow-related

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pain is the radial nerve. Fernández-de-las-Peñas et al[13] found greater mechanical pain hypersensitivity of the radial nerve in women with unilateral LE when compared to healthy women. A recent study observed that the cross-sectional area of the radial nerve was significantly larger on the affected side in individuals with unilateral refractory LE, suggesting the presence of swelling within the nerve sheath.[16] A potential reason for dysfunction of the radial nerve in individuals with LE may be the proximity of this nerve trunk to the tendon of the ECRB muscle. A cadaveric study found that the radial nerve lies within 4.5 mm of the ECRB muscle as it passes through the arcade of Frohse.[37] Interestingly, the compression of the radial nerve at the arcade of Frohse, which exhibits a similar clinical presentation to LE, is described as radial tunnel syndrome.[31]

This paper describes the outcomes of a patient with symptoms compatible with recalcitrant LE who did not respond to previous interventions, including manual therapy, exercise, and trigger point dry needling; however, he responded favorably to a novel approach of radial nerve electrical stimulation.

CASE DESCRIPTION

History

The patient was a 43-year-old man who presented to physical therapy with elbow pain and stiffness on the radial side of the right elbow-forearm (**FIGURE 1A**). He was employed as a teacher and participated in table tennis twice a week for exercise. He reported that his initial symptoms began insidiously about 3 years earlier. Pain was exacerbated with physical activity, particularly after a table tennis game. The patient was diagnosed with LE by a physician, based on the patient history, activities that aggravated his symptoms, palpation of the wrist extensor tendon, pain with contraction and stretching of wrist extensor muscles, and the location of the symptoms.[17]

According to a medical report provided by the patient, he initially underwent a full medical screen, including evaluation for potential red flags suggesting an underlying medical condition, which was found to be unremarkable. At that time, he was instructed to stop playing table tennis temporarily and was referred to a physical therapist, who applied an initial 3 sessions of soft tissue massage of the wrist extensor/flexor muscles, stretching of the wrist extensors, and a low-load eccentric exercise program of the wrist extensors approximately 1 month after the first onset of his symptoms. He reported that this previous management approach improved his symptoms by 70% to 80% and that the improvement was maintained for 2 years. There were slight exacerbations of his elbow pain after participating in table tennis games, which were moderately controlled with the stretching and exercise program of the wrist extensor muscles.

Six months before his first visit to the primary author's clinic, the patient hit the lateral part of his elbow against a wall during a tennis table match. After that event, his elbow pain was exacerbated and reached 8/10 points on a numeric pain-rating scale (NPRS). Two weeks after the traumatic event, the patient received 10 sessions (daily for 2 weeks) of multimodal physical therapy, including manual mobilizations directed at the elbow and wrist, soft tissue manual therapy of the wrist extensors, stretching of the wrist extensor/flexor muscles, and low-load concentric exercises (eccentric exercise was very painful). This intervention, applied by his initial physical therapist, did not relieve his symptoms or improve function. In fact, the patient perceived the eccentric part of the exercise program as very painful (9/10 points on the NPRS).

The patient presented for the first time to the primary author's clinic about 3 months following the trauma from hitting the wall and the onset of his exacerbated symptoms. He was taking nonsteroidal anti-inflammatory medication, but still reported constant and intense elbow pain. The patient described the mean intensity of his pain at rest as 7/10 points on the NPRS, which increased to 9/10 with repetitive movement involving contraction of the wrist muscles. The pain was described as deep and burning around the lateral epicondyle.

In addition, the patient also reported pain referral throughout the dorsal and radial aspect of the forearm and, sometimes, an "electrical shock-like" pain on the radial side of the right wrist (**FIGURE 1B**). This pain caused the patient to discontinue playing sports and occasionally required him to cease computer work for a few minutes. The patient provided written informed consent to participate in this case report.

Examination and Clinical Reasoning

On the first visit, an extensive clinical examination was performed by the primary author, a physical therapist with 15 years of experience in the management of musculoskeletal pain disorders. Prior to physical examination of the elbow, the patient underwent an upper-quarter examination. Examination of the cervical spine included active neck range-of-motion testing for flexion, extension, and

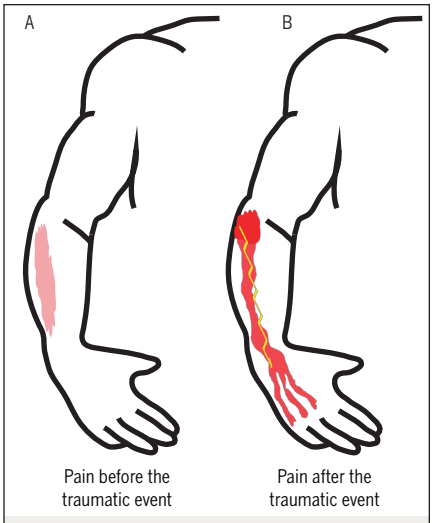

FIGURE 1. Pain pattern of the patient. (A) Symptoms before the traumatic event. (B) Symptoms after the traumatic event, leading to the proposed intervention. The yellow color represents "electrical shock-like" pain, whereas the red color represents deep and burning pain. The intensity of the red color was associated with the intensity of pain, mostly located around the lateral epicondyle.

bilateral sidebending and rotation with and without overpressure. Examination of the shoulder area involved active range-of-motion testing followed by overpressure of shoulder flexion, extension, abduction, and internal and external rotation to 90°. None of the movements altered or reproduced his symptoms. Varus and valgus stress tests with the elbow extended and supinated were also performed and found to be negative. Active motions assessed at the wrist included flexion, extension, and radial and ulnar deviation. All active ranges were followed by overpressure. None of these tests reproduced the patient's symptoms.

However, manual palpation of the wrist extensors revealed the presence of active trigger points in the ECRB muscle, with pain referral that reproduced the patient's symptoms.[34] Accordingly, the therapist first proposed the application of 2 sessions of trigger point dry needling,[8] combined with a concentric/eccentric exercise program for 4 weeks.[35] The patient perceived a slight improvement with this intervention, but viewed the exercise program as painful and not beneficial at this stage.

Based on the limited improvement, we conducted a thermography analysis of the patient's forearms and an examination of mechanical pain sensitivity of the radial nerve by applying the upper-limb nerve tension test with radial nerve trunk bias (ULNT2b) and manual palpation of the radial nerve trunk.[5] The thermography revealed an increased temperature, suggesting an altered sympathetic response,[36] in the areas of the patient's symptoms—the dorsal and radial aspect of the forearm and the radial side of the right wrist—that was not observed within the asymptomatic extremity (**FIGURE 2**). Palpation of the right nerve trunk was exquisitely painful at the spiral groove of the humerus and proximal to the lateral intermuscular septum between the brachialis and the triceps brachii, whereas the ULNT2b revealed an "increased tension" in the elbow and forearm; however, this procedure did not reproduce the patient's symptoms. The proximal sensitizing movements of shoulder abduction and contralateral cervical sidebending increased the perceived tension but, again, did not reproduce any symptoms.

A comparison with the asymptomatic side revealed similar tension in the forearm, without clear side-to-side differences. Data from the current clinical examination of this patient led us to believe that his symptoms were related to an increased sensitivity of the radial nerve with associated sympathetic responses, compatible with a neuritis of the radial nerve or a potential radial tunnel syndrome.

The dysfunction of the radial nerve trunk in individuals with lateral elbow pain is not new in the literature; however, data regarding treatment are limited to case reports. In a case series by Arumugam et al,[2] a single session of neural mobilization targeting the radial nerve resulted in a reduction of pain in computer users with lateral elbow pain. Ekstrom and Holden[9] described a case report of an individual who also experienced positive outcomes with neural mobilizations, ultrasound, strengthening exercises, and stretching. One common finding of these reports is that the individuals exhibited a positive ULNT2b,[2,9] which was not observed in our patient. Therefore, we decided to apply a different intervention.

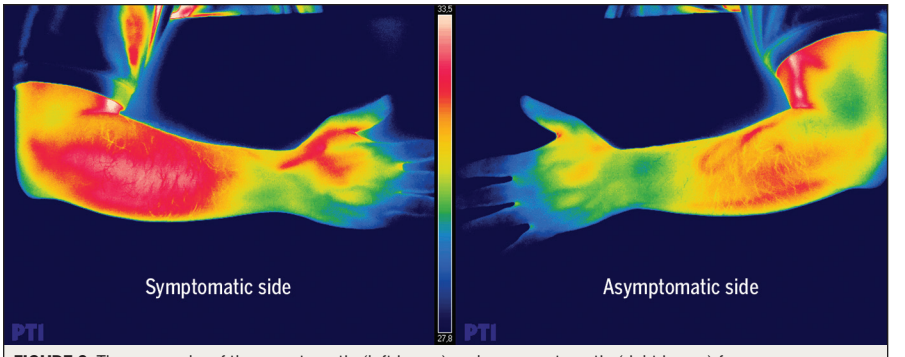

FIGURE 2. Thermography of the symptomatic (left image) and nonsymptomatic (right image) forearm.

Intervention

Based on the observations during the clinical-reasoning process, the therapist explained to the patient the findings obtained from the examination, the suspected condition, and the proposed treatment. The therapist explained to the patient that the intervention would consist of an ultrasound-guided percutaneous electrical nerve stimulation (PENS) of the radial nerve trunk, with the goal of decreasing the sensitivity of the radial nerve. The clinical reasoning for the application of this intervention was based on 2 premises: (1) the lack of effectiveness of manual therapy, trigger point dry needling, and the low-load exercise program; and (2) the presence of radial nerve trunk mechanical sensitivity and a negative ULNT2b. The application of PENS was based on reducing radial nerve sensitivity by altering nociceptive input and reducing neurogenic inflammation and ectopic discharge.

Our intervention was the application of an electrical current through needling filaments placed close to the nerve. This procedure is typically used for postsurgical regional anesthesia; however, the main difference is that the needle employed in postsurgical regional anesthesia is placed in situ during treatment, has a bevel, and is not solid.[24] In this case report, we used solid-filament needles similar to those used for trigger point dry needling.

It has been postulated that ultrasound imaging can be used to visualize peripheral nerves and thus increase the accuracy and specificity of invasive interventions such as neural blocks.[23] Therefore, in an effort to achieve this result, we used an M-MSK ultrasound system (FUJIFILM

SonoSite, Inc, Bothell, WA) with a linear-array transducer (HFL38x; FUJIFILM SonoSite) at 12 MHz. We imaged the patient's radial nerve trunk in transverse cross-sectional (short axis) and longitudinal (long axis) views at 2 points: (1) upper point, under the lateral intermuscular septum between the triceps brachii and brachialis, approximately 10 cm superior to the lateral epicondyle[23] (**FIGURE 3A**); and (2) lower point, at the upper third of the forearm on the posterior interosseous nerve after passing the arcade of Frohse (**FIGURE 3B**).

Once the radial nerve was identified, the skin was cleaned with an antiseptic before needle insertion. The first needle (0.30 × 25 mm; Agu-Punt, Barcelona, Spain) was ultrasound guided, with the needle tip placed close to the radial nerve at the upper point (**FIGURE 3A**, **ONLINE VIDEO 1**). Also ultrasound guided, the second needle (0.30 × 40 mm; Agu-Punt) tip was positioned close to the posterior interosseous nerve at the lower point (**FIGURE 3B**). We confirmed nerve stimulation by visible contraction of the innervated musculature in response to 2 to 3 electric impulses (10 Hz, 1.5 mA, 240 microseconds) with a Pointer Plus (Goldsberg International Enterprises Ltd, Kowloon, Hong Kong). The needles were left in situ at both points, connected to an electrostimulator (ES-160; ITO Co Ltd, Tokyo, Japan) applying a biphasic continuous waveform at low frequency (2 Hz)[19] and with a 250-microsecond pulse duration, for 30 minutes (**FIGURE 4**).[18] The current was increased at an intensity of visible motor response of the innervated musculature (around 5-6 mA)[38] (**ONLINE VIDEO 2**). The intervention was repeated for a total of 2 visits over 2 weeks. No specific recommendations were provided between sessions.

On the second visit, 1 week after the initial PENS intervention, the patient reported a marked improvement. During the session, the patient received another intervention of ultrasound-guided PENS of the radial nerve as described above, and was also instructed to perform a low-load exercise program targeting the wrist extensor muscles. The exercise program consisted of 5 strengthening exercises of the wrist extensors, combining the concentric and eccentric phases of each. The speed and amplitude of performance of the exercises were applied until exacerbation of symptoms was produced. The program was performed for 4 weeks, 3 times a day, for 10 repetitions each time. No further intervention was applied.

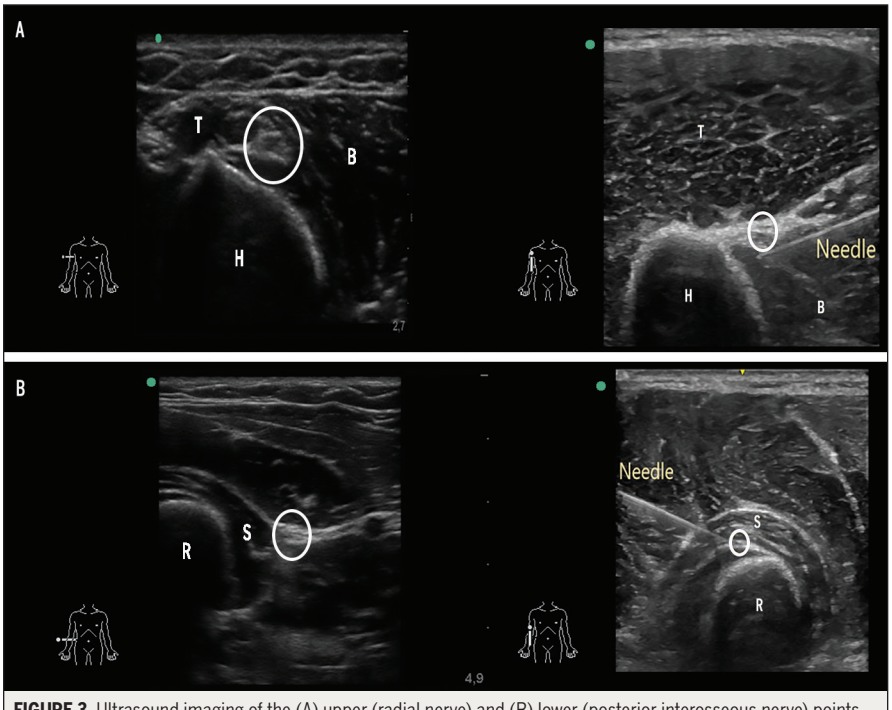

FIGURE 3. Ultrasound imaging of the (A) upper (radial nerve) and (B) lower (posterior interosseous nerve) points for application of ultrasound-guided percutaneous electrical nerve stimulation. The short-axis (left) view and the long-axis (right) view of the targeted areas are shown. The circle represents the radial nerve. Abbreviations: B, brachialis muscle; H, humerus; R, radius; S, supinator muscle; T, triceps brachii muscle.

OUTCOMES

The NPRS, Patient-Rated Tennis Elbow Evaluation, and Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) were assessed at baseline, 1 week post intervention (after the second PENS session), and at 1, 3, 6, 9, 12, 18, and 24 months post intervention.

An 11-point NPRS (0, no pain; 10, worst imaginable pain) was used to assess the intensity of pain at rest. The NPRS has been shown to possess strong reliability and validity.[25] It has been reported that the minimal clinically important difference (MCID) for the NPRS is 2 points.[11]

The Patient-Rated Tennis Elbow Evaluation has been found to be both reliable and valid for capturing function in individuals with LE.[29,32] The questionnaire consists of 2 parts, including both pain and function. The first part consists of 5 questions scored from 0 (no pain) to 10 (most severe pain). The scores for

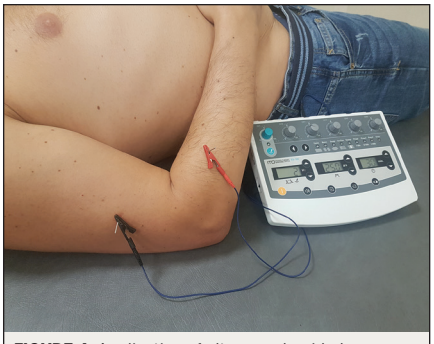

FIGURE 4. Application of ultrasound-guided percutaneous electrical nerve stimulation on the patient.

the 5 pain questions are summed, and a total score out of 50 is reported. The function part of the questionnaire comprises 10 questions, the scores of which are summed and divided by 2, for a total score out of 50. Scores on the pain and function subscales are summed for a total score out of 100. Lower scores indicate better function. The MCID for the Patient-Rated Tennis Elbow Evaluation has yet to be reported.

The DASH is an outcome of disability for patients with upper extremity musculoskeletal disorders.[21] It consists of a total of 30 questions about the degree of difficulty performing functional activities, the severity of symptoms, and the impact on social activities and work. Each question is scored on a 5-point Likert scale, with 1 being "no difficulty to perform, no symptom, or no impact" and 5 being "unable to do, very severe symptom, or high impact." The total score ranges from 0 to 100, where higher scores reflect greater disability. The MCID for the DASH has been reported as 10.83 points.[14]

The **TABLE** reports the outcomes throughout our patient's 2-year follow-up period. The patient experienced clinically important improvements in all outcomes immediately after the PENS sessions, including a decrease in pain of 3 points on the NPRS and 21.46 points on the DASH, surpassing the respective MCIDs.[11,14] The patient started playing table tennis around 4 to 5 months after the second PENS session, with lower levels of pain (1/10 NPRS), and achieved a full return to playing table tennis at 6 months after the intervention. The patient continued experiencing improvements over time, and at the 9-month follow-up reported being pain free and at full function as measured by the NPRS and PRTEE (**FIGURE 5**). These improvements were maintained 2 years after treatment, with no further intervention by any other medical provider.

DISCUSSION

This case report describes clinical reasoning and the physical therapy management of a patient with chronic lateral elbow pain exacerbated by trauma and not responding to manual therapy, dry needling, and exercise.

Because previous physical therapy modalities, including manual therapy, exercise, and trigger point dry needling, were not effective in this patient, we proposed the application of PENS in an attempt to decrease the sensitivity to mechanical stimulus of the peripheral nervous system, particularly the radial nerve. Within 2 visits, the patient noted changes in pain intensity and related disability that exceeded the MCID of 2 points and 10.83 points, respectively.[11,14] The patient achieved a rapid and clinically meaningful improvement in both pain and functional status. In fact, after 2 sessions of PENS combined with 4 weeks of a low-load exercise program (which was painful with previous interventions), there was a nearly complete resolution of his symptoms, and he returned to work and sport after 6 months of restrictions in physical activities. Although a case report of a single patient outcome does not allow us to infer a cause-and-effect relationship, a meaningful clinical change in the patient's status occurring within 2 intervention sessions in a chronic condition that was unaffected by previous interventions suggests that the intervention approach, based on the suspicion of radial nerve dysfunction, was helpful.

Of relevance in this case is the role of the neural component of LE and the need to consider this thoroughly in the diagnostic-reasoning process. The absence of data on the validity of tests for LE, the clinically observed lack of specificity for signs and symptoms, and the absence of a gold standard test for this condition certainly indicate the potential for misdiagnosis and inappropriate interventions in potential refractory cases. It is plausible that our patient developed LE during the initial stage of his symptoms, but it likely evolved into a more complex pain condition with a concomitant radial nerve dysfunction. It is important to consider that the clinical presentations of LE and radial tunnel syndrome are very similar, leading to potential confusion.

Based on the clinical examination in this case, we applied ultrasound-guided PENS, a novel intervention approach targeting the radial nerve. There is a lack of literature investigating the effects of this intervention, although a few case series have documented a positive effect of ultrasound-guided PENS in patients with subacromial pain syndrome[39] or postsurgical pain.[24] Nevertheless, several differences in methodology, particularly type of needle and time of retention of the needle, can be observed between previous studies[24,39] and this case report. For instance, Wilson et al[39] implanted permanent electrodes close to the vicinity of the nerve. The current case report provides preliminary evidence regarding the potential effect of PENS applied with solid-filament needles (dry needling needles), although future randomized clinical trials are needed to further examine the

TABLE Outcomes During the 2-Year Follow-up Period*

	Baseline	1 wk	1 mo	3 mo	6 mo	9 mo	12 mo	18 mo	24 mo
NPRS at rest†	7	4	2	1	0.5	0	0	0	0
PRTEE score‡	60	37	15	9	8	0	0	0	0
DASH score‡	35.74	14.28	10.82	1.7	0	0	0	0	0

Abbreviations: DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; NPRS, numeric pain-rating scale; PRTEE, Patient-Rated Tennis Elbow Evaluation.
**At 4 to 5 months post intervention, the patient started playing table tennis, with only 1/10 pain intensity.*
†Measured on a scale from 0 to 10.
‡Measured on a scale from 0 to 100.

clinical effectiveness of PENS. In fact, it is important to consider that the methodology of the PENS intervention used in this case clearly requires the use of ultrasound imaging for localization of targeted tissue and to reduce the risk of puncturing the nerve trunks.[23]

Several potential mechanisms could explain the effects of PENS on pain. For instance, large-diameter, myelinated, afferent peripheral nerve fibers are triggered with the use of electrical current and, therefore, may impede communication of nociceptive signals to the central nervous system from small-diameter pain fibers at the level of the spinal cord ("gate control theory").[6] Nerve trunk pain is often related to an increased activity in mechanically sensitized nociceptors within the nervi nervorum (nerves that innervate the connective tissue layers of the nerve itself). In a sensitized state (as in our patient), nerve endings of the nervi nervorum can lead to an increase in synthesis and release of algogenic substances, resulting in a neurogenic inflammation and spontaneous discharges within the nerve fibers.[40]

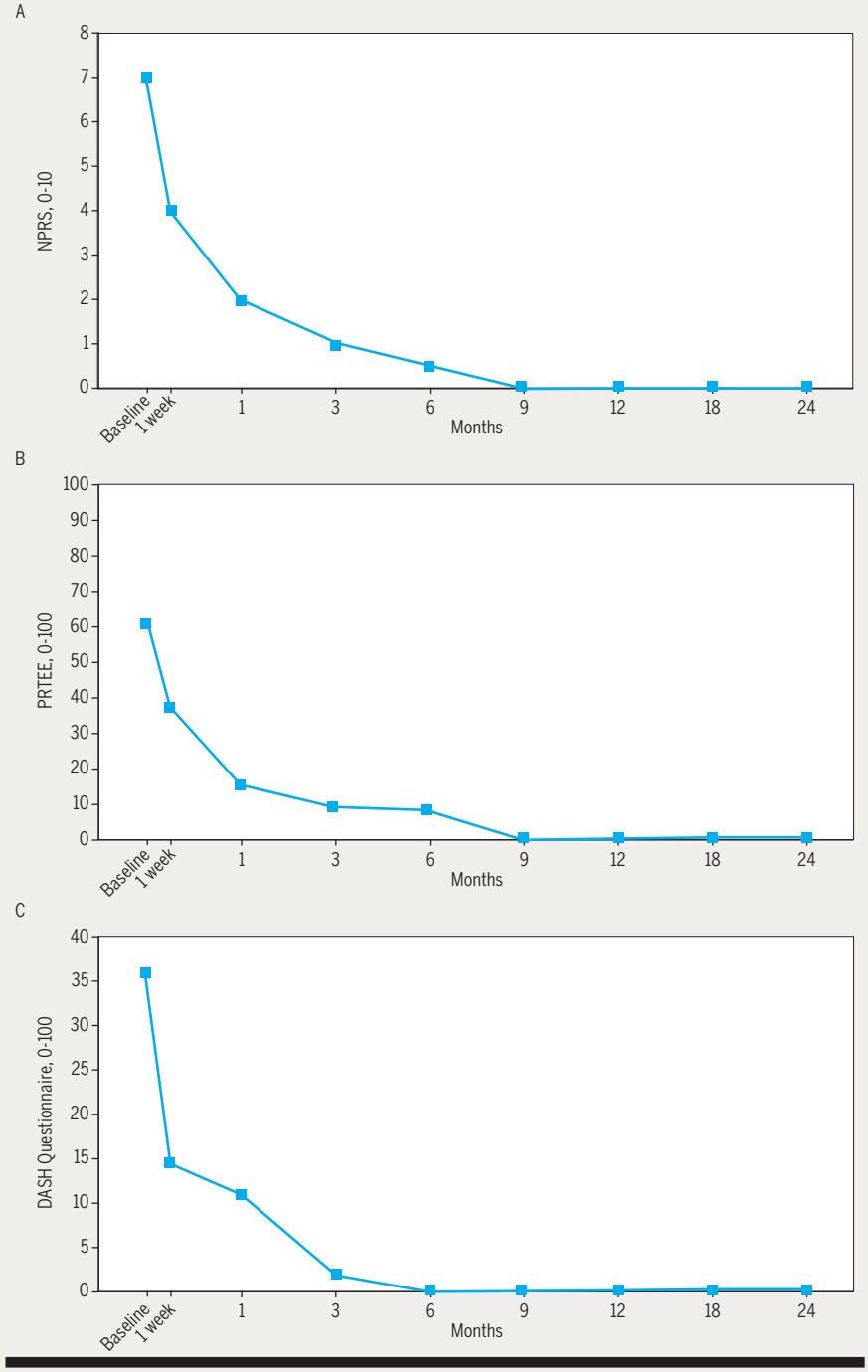

FIGURE 5. Evolution of (A) pain intensity (NPRS, 0-10), (B) function (PRTEE, 0-100), and related disability (DASH, 0-100) during the 2-year follow-up period. Abbreviations: DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; NPRS, numeric pain-rating scale; PRTEE, Patient-Rated Tennis Elbow Evaluation.

In this case, the PENS stimuli were placed over the radial nerve trunk and posterior interosseous nerve. As the lateral epicondyle receives innervation from the posterior cutaneous nerve of the forearm, a branch of the radial nerve,[30] and the ECRB muscle receives innervation from the radial nerve itself, it is possible that electrical stimulation of the nerve may lead to a decrease in algogenic substances and spontaneous neural discharges. It is interesting to note that the patient reported a rapid decrease in pain and a quick restoration of motor function after the first session, suggesting that PENS could exert a beneficial effect on both sensory and motor systems. It is also possible that different underlying mechanisms, including nonspecific effects on the central nervous system or patient expectation, could be involved in PENS effects, similar to other manual therapies.[3] Future studies should investigate these hypotheses.

We acknowledge multiple limitations to this case report. First, a case report does not allow us to infer a cause-and-effect relationship. Second, the patient received both PENS and a low-load exercise program, so it is not possible to determine whether the outcomes were associated with one or the other aspect of this intervention. Nevertheless, as the exercise program was unsuccessful previously, it

seems that the application of PENS before the program may lead to better outcomes. Third, the suspected diagnosis was based on a thermography analysis and an examination of mechanical sensitivity of the radial nerve, particularly an increased sensitivity to palpation—both procedures without psychometric properties (positive or negative likelihood ratio, sensitivity or specificity data) for diagnosis. To further determine the effectiveness of PENS in chronic pain conditions, randomized controlled trials are needed.

CONCLUSION

This case report describes the management of a patient with chronic and recalcitrant lateral elbow pain previously diagnosed as LE of muscle origin. Clinical examination led to a plausible concomitant diagnosis of an increased sensitivity (neuritis) of the radial nerve compatible with radial tunnel syndrome. Physical therapy intervention consisted of ultrasound-guided PENS over the radial nerve and posterior interosseous nerve, combined with a low-load, concentric/eccentric exercise program for the wrist extensor muscles for 4 weeks. The patient experienced clinically meaningful changes in pain intensity and functional status, with a complete resolution of symptoms and full return to work and physical activity 5 to 6 months after treatment, which lasted for 2 years. ◉

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Ultrasound-Guided Percutaneous Electrical Nerve Stimulation of the Radial Nerve for a Patient With Lateral Elbow Pain: A Case Report With a 2-Year Follow-up

BACKGROUND: Patients with lateral elbow pain are often diagnosed with lateral epicondylalgia. Lateral elbow pain is often associated with dysfunction of the wrist extensor muscles; however, in some cases, it can also mimic signs and symptoms of radial nerve dysfunction.

CASE DESCRIPTION: In this case report, a 43-year-old man, who was originally referred with a diagnosis of lateral epicondylalgia as a result of playing table tennis and who previously responded favorably to manual therapy and exercise, presented to the clinic for treatment. An exacerbation while participating in a table tennis match resulted in a return of his lateral epicondylalgia symptoms, which did not respond favorably to the same interventions used in his prior course of therapy. Further examination revealed sensitization of the radial nerve, which was treated with 2 sessions of ultrasound-guided percutaneous electrical nerve stimulation and 4 weeks of a low-load, concentric/eccentric exercise program for the wrist extensors.

OUTCOMES: Following this intervention, the patient experienced clinically meaningful improvement in pain intensity (numeric pain-rating scale), function (Patient-Rated Tennis Elbow Evaluation), and related disability (Disabilities of the Arm, Shoulder and Hand questionnaire). The patient progressively exhibited complete resolution of pain and function, which was maintained at 2 years.

DISCUSSION: This case report demonstrates the outcomes of a patient with lateral elbow pain who did not respond to manual therapy and exercise. Once radial nerve trunk sensitivity was identified and the intervention, consisting of ultrasound-guided percutaneous electrical nerve stimulation targeting the radial nerve combined with a low-load exercise program, was applied, a full resolution of pain and function occurred rapidly. Future clinical trials should examine the effect of percutaneous electrical nerve stimulation in the management of nerve-related symptoms associated with musculoskeletal pain conditions.

LEVEL OF EVIDENCE: Therapy, level 5.
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KEY WORDS: *elbow pain, nerve, percutaneous electrical nerve stimulation, sensitization*

Lateral epicondylalgia (LE) is a musculoskeletal condition associated with dysfunction of the wrist extensor tendons.[10,27] Approximately 1% to 3% of the general population will experience lateral elbow pain at some point in life.[33] Lateral epicondylalgia is more prevalent in women between the ages of 35 and 50 years and is often aggravated by repetitive motions or prolonged wrist positions associated with occupational activities[20] or physical activities/sports.[22] Histopathological studies have shown that microtrauma, potentially associated with repetitive motions, can result in tissue breakdown, with a tissue response of angiofibroplastic hyperplasia and subsequent release of pronociceptive substances in the tendon of the wrist extensor muscles, particularly the extensor carpi radialis brevis (ECRB).[1,26]

Conservative care, such as physical therapy, education, and activity modification, is often the initial management strategy for patients with LE; however, there is no consensus in the literature regarding the most effective intervention approach.[4] Several interventions, particularly manual therapy[28] and exercise,[7] are effective for the treatment of LE. Others have proposed the application of trigger point dry needling,[15] based on the presence of myofascial trigger points in this population.[12]

One relevant anatomical structure that may also be involved in elbow-related

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pain is the radial nerve. Fernández-de-las-Peñas et al[13] found greater mechanical pain hypersensitivity of the radial nerve in women with unilateral LE when compared to healthy women. A recent study observed that the cross-sectional area of the radial nerve was significantly larger on the affected side in individuals with unilateral refractory LE, suggesting the presence of swelling within the nerve sheath.[16] A potential reason for dysfunction of the radial nerve in individuals with LE may be the proximity of this nerve trunk to the tendon of the ECRB muscle. A cadaveric study found that the radial nerve lies within 4.5 mm of the ECRB muscle as it passes through the arcade of Frohse.[37] Interestingly, the compression of the radial nerve at the arcade of Frohse, which exhibits a similar clinical presentation to LE, is described as radial tunnel syndrome.[31]

This paper describes the outcomes of a patient with symptoms compatible with recalcitrant LE who did not respond to previous interventions, including manual therapy, exercise, and trigger point dry needling; however, he responded favorably to a novel approach of radial nerve electrical stimulation.

CASE DESCRIPTION

History

The patient was a 43-year-old man who presented to physical therapy with elbow pain and stiffness on the radial side of the right elbow-forearm (**FIGURE 1A**). He was employed as a teacher and participated in table tennis twice a week for exercise. He reported that his initial symptoms began insidiously about 3 years earlier. Pain was exacerbated with physical activity, particularly after a table tennis game. The patient was diagnosed with LE by a physician, based on the patient history, activities that aggravated his symptoms, palpation of the wrist extensor tendon, pain with contraction and stretching of wrist extensor muscles, and the location of the symptoms.[17]

According to a medical report provided by the patient, he initially underwent a full medical screen, including evaluation for potential red flags suggesting an underlying medical condition, which was found to be unremarkable. At that time, he was instructed to stop playing table tennis temporarily and was referred to a physical therapist, who applied an initial 3 sessions of soft tissue massage of the wrist extensor/flexor muscles, stretching of the wrist extensors, and a low-load eccentric exercise program of the wrist extensors approximately 1 month after the first onset of his symptoms. He reported that this previous management approach improved his symptoms by 70% to 80% and that the improvement was maintained for 2 years. There were slight exacerbations of his elbow pain after participating in table tennis games, which were moderately controlled with the stretching and exercise program of the wrist extensor muscles.

Six months before his first visit to the primary author's clinic, the patient hit the lateral part of his elbow against a wall during a tennis table match. After that event, his elbow pain was exacerbated and reached 8/10 points on a numeric pain-rating scale (NPRS). Two weeks after the traumatic event, the patient received 10 sessions (daily for 2 weeks) of multimodal physical therapy, including manual mobilizations directed at the elbow and wrist, soft tissue manual therapy of the wrist extensors, stretching of the wrist extensor/flexor muscles, and low-load concentric exercises (eccentric exercise was very painful). This intervention, applied by his initial physical therapist, did not relieve his symptoms or improve function. In fact, the patient perceived the eccentric part of the exercise program as very painful (9/10 points on the NPRS).

The patient presented for the first time to the primary author's clinic about 3 months following the trauma from hitting the wall and the onset of his exacerbated symptoms. He was taking nonsteroidal anti-inflammatory medication, but still reported constant and intense elbow pain. The patient described the mean intensity of his pain at rest as 7/10 points on the NPRS, which increased to 9/10 with repetitive movement involving contraction of the wrist muscles. The pain was described as deep and burning around the lateral epicondyle.

In addition, the patient also reported pain referral throughout the dorsal and radial aspect of the forearm and, sometimes, an "electrical shock-like" pain on the radial side of the right wrist (**FIGURE 1B**). This pain caused the patient to discontinue playing sports and occasionally required him to cease computer work for a few minutes. The patient provided written informed consent to participate in this case report.

Examination and Clinical Reasoning

On the first visit, an extensive clinical examination was performed by the primary author, a physical therapist with 15 years of experience in the management of musculoskeletal pain disorders. Prior to physical examination of the elbow, the patient underwent an upper-quarter examination. Examination of the cervical spine included active neck range-of-motion testing for flexion, extension, and

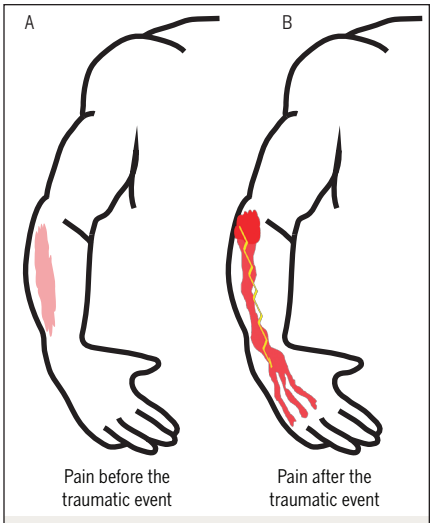

FIGURE 1. Pain pattern of the patient. (A) Symptoms before the traumatic event. (B) Symptoms after the traumatic event, leading to the proposed intervention. The yellow color represents "electrical shock-like" pain, whereas the red color represents deep and burning pain. The intensity of the red color was associated with the intensity of pain, mostly located around the lateral epicondyle.

bilateral sidebending and rotation with and without overpressure. Examination of the shoulder area involved active range-of-motion testing followed by overpressure of shoulder flexion, extension, abduction, and internal and external rotation to 90°. None of the movements altered or reproduced his symptoms. Varus and valgus stress tests with the elbow extended and supinated were also performed and found to be negative. Active motions assessed at the wrist included flexion, extension, and radial and ulnar deviation. All active ranges were followed by overpressure. None of these tests reproduced the patient's symptoms.

However, manual palpation of the wrist extensors revealed the presence of active trigger points in the ECRB muscle, with pain referral that reproduced the patient's symptoms.[34] Accordingly, the therapist first proposed the application of 2 sessions of trigger point dry needling,[8] combined with a concentric/eccentric exercise program for 4 weeks.[35] The patient perceived a slight improvement with this intervention, but viewed the exercise program as painful and not beneficial at this stage.

Based on the limited improvement, we conducted a thermography analysis of the patient's forearms and an examination of mechanical pain sensitivity of the radial nerve by applying the upper-limb nerve tension test with radial nerve trunk bias (ULNT2b) and manual palpation of the radial nerve trunk.[5] The thermography revealed an increased temperature, suggesting an altered sympathetic response,[36] in the areas of the patient's symptoms—the dorsal and radial aspect of the forearm and the radial side of the right wrist—that was not observed within the asymptomatic extremity (**FIGURE 2**). Palpation of the right nerve trunk was exquisitely painful at the spiral groove of the humerus and proximal to the lateral intermuscular septum between the brachialis and the triceps brachii, whereas the ULNT2b revealed an "increased tension" in the elbow and forearm; however, this procedure did not reproduce the patient's symptoms. The proximal sensitizing movements of shoulder abduction and contralateral cervical sidebending increased the perceived tension but, again, did not reproduce any symptoms.

A comparison with the asymptomatic side revealed similar tension in the forearm, without clear side-to-side differences. Data from the current clinical examination of this patient led us to believe that his symptoms were related to an increased sensitivity of the radial nerve with associated sympathetic responses, compatible with a neuritis of the radial nerve or a potential radial tunnel syndrome.

The dysfunction of the radial nerve trunk in individuals with lateral elbow pain is not new in the literature; however, data regarding treatment are limited to case reports. In a case series by Arumugam et al,[2] a single session of neural mobilization targeting the radial nerve resulted in a reduction of pain in computer users with lateral elbow pain. Ekstrom and Holden[9] described a case report of an individual who also experienced positive outcomes with neural mobilizations, ultrasound, strengthening exercises, and stretching. One common finding of these reports is that the individuals exhibited a positive ULNT2b,[2,9] which was not observed in our patient. Therefore, we decided to apply a different intervention.

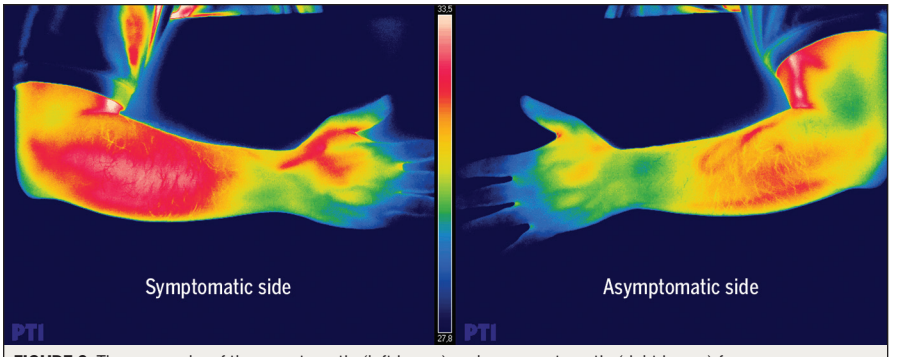

FIGURE 2. Thermography of the symptomatic (left image) and nonsymptomatic (right image) forearm.

Intervention

Based on the observations during the clinical-reasoning process, the therapist explained to the patient the findings obtained from the examination, the suspected condition, and the proposed treatment. The therapist explained to the patient that the intervention would consist of an ultrasound-guided percutaneous electrical nerve stimulation (PENS) of the radial nerve trunk, with the goal of decreasing the sensitivity of the radial nerve. The clinical reasoning for the application of this intervention was based on 2 premises: (1) the lack of effectiveness of manual therapy, trigger point dry needling, and the low-load exercise program; and (2) the presence of radial nerve trunk mechanical sensitivity and a negative ULNT2b. The application of PENS was based on reducing radial nerve sensitivity by altering nociceptive input and reducing neurogenic inflammation and ectopic discharge.

Our intervention was the application of an electrical current through needling filaments placed close to the nerve. This procedure is typically used for postsurgical regional anesthesia; however, the main difference is that the needle employed in postsurgical regional anesthesia is placed in situ during treatment, has a bevel, and is not solid.[24] In this case report, we used solid-filament needles similar to those used for trigger point dry needling.

It has been postulated that ultrasound imaging can be used to visualize peripheral nerves and thus increase the accuracy and specificity of invasive interventions such as neural blocks.[23] Therefore, in an effort to achieve this result, we used an M-MSK ultrasound system (FUJIFILM

SonoSite, Inc, Bothell, WA) with a linear-array transducer (HFL38x; FUJIFILM SonoSite) at 12 MHz. We imaged the patient's radial nerve trunk in transverse cross-sectional (short axis) and longitudinal (long axis) views at 2 points: (1) upper point, under the lateral intermuscular septum between the triceps brachii and brachialis, approximately 10 cm superior to the lateral epicondyle[23] (**FIGURE 3A**); and (2) lower point, at the upper third of the forearm on the posterior interosseous nerve after passing the arcade of Frohse (**FIGURE 3B**).

Once the radial nerve was identified, the skin was cleaned with an antiseptic before needle insertion. The first needle (0.30 × 25 mm; Agu-Punt, Barcelona, Spain) was ultrasound guided, with the needle tip placed close to the radial nerve at the upper point (**FIGURE 3A**, **ONLINE VIDEO 1**). Also ultrasound guided, the second needle (0.30 × 40 mm; Agu-Punt) tip was positioned close to the posterior interosseous nerve at the lower point (**FIGURE 3B**). We confirmed nerve stimulation by visible contraction of the innervated musculature in response to 2 to 3 electric impulses (10 Hz, 1.5 mA, 240 microseconds) with a Pointer Plus (Goldsberg International Enterprises Ltd, Kowloon, Hong Kong). The needles were left in situ at both points, connected to an electrostimulator (ES-160; ITO Co Ltd, Tokyo, Japan) applying a biphasic continuous waveform at low frequency (2 Hz)[19] and with a 250-microsecond pulse duration, for 30 minutes (**FIGURE 4**).[18] The current was increased at an intensity of visible motor response of the innervated musculature (around 5-6 mA)[38] (**ONLINE VIDEO 2**). The intervention was repeated for a total of 2 visits over 2 weeks. No specific recommendations were provided between sessions.

On the second visit, 1 week after the initial PENS intervention, the patient reported a marked improvement. During the session, the patient received another intervention of ultrasound-guided PENS of the radial nerve as described above, and was also instructed to perform a low-load exercise program targeting the wrist extensor muscles. The exercise program consisted of 5 strengthening exercises of the wrist extensors, combining the concentric and eccentric phases of each. The speed and amplitude of performance of the exercises were applied until exacerbation of symptoms was produced. The program was performed for 4 weeks, 3 times a day, for 10 repetitions each time. No further intervention was applied.

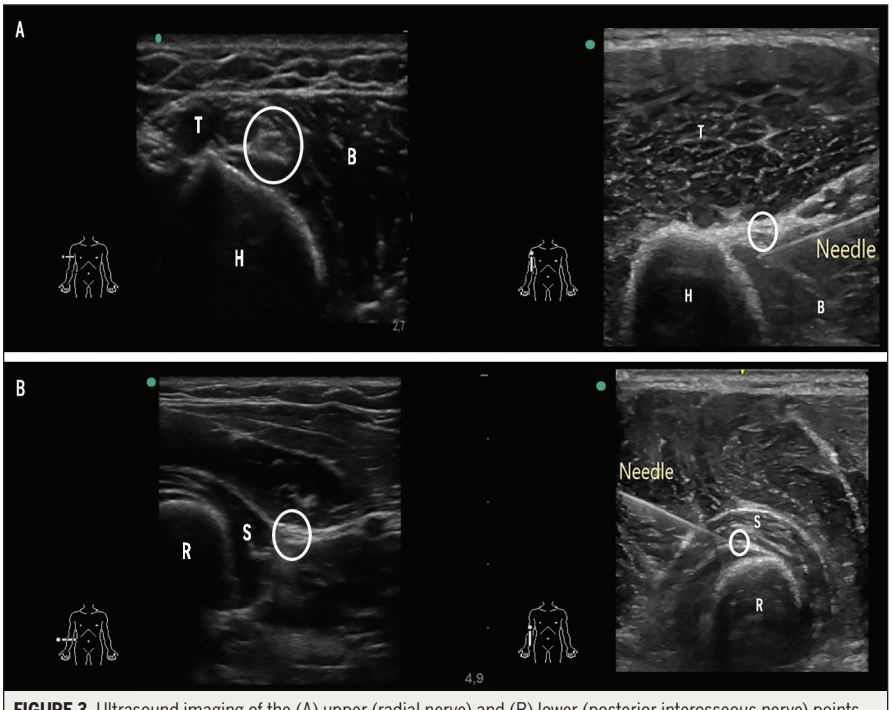

FIGURE 3. Ultrasound imaging of the (A) upper (radial nerve) and (B) lower (posterior interosseous nerve) points for application of ultrasound-guided percutaneous electrical nerve stimulation. The short-axis (left) view and the long-axis (right) view of the targeted areas are shown. The circle represents the radial nerve. Abbreviations: B, brachialis muscle; H, humerus; R, radius; S, supinator muscle; T, triceps brachii muscle.

OUTCOMES

The NPRS, Patient-Rated Tennis Elbow Evaluation, and Disabilities of the Arm, Shoulder and Hand questionnaire (DASH) were assessed at baseline, 1 week post intervention (after the second PENS session), and at 1, 3, 6, 9, 12, 18, and 24 months post intervention.

An 11-point NPRS (0, no pain; 10, worst imaginable pain) was used to assess the intensity of pain at rest. The NPRS has been shown to possess strong reliability and validity.[25] It has been reported that the minimal clinically important difference (MCID) for the NPRS is 2 points.[11]

The Patient-Rated Tennis Elbow Evaluation has been found to be both reliable and valid for capturing function in individuals with LE.[29,32] The questionnaire consists of 2 parts, including both pain and function. The first part consists of 5 questions scored from 0 (no pain) to 10 (most severe pain). The scores for

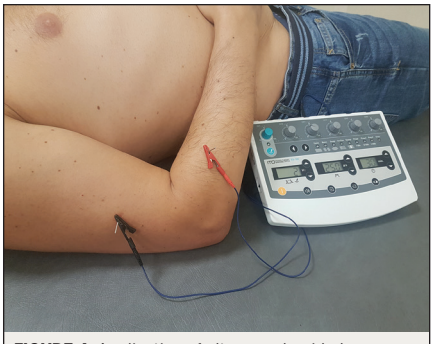

FIGURE 4. Application of ultrasound-guided percutaneous electrical nerve stimulation on the patient.

the 5 pain questions are summed, and a total score out of 50 is reported. The function part of the questionnaire comprises 10 questions, the scores of which are summed and divided by 2, for a total score out of 50. Scores on the pain and function subscales are summed for a total score out of 100. Lower scores indicate better function. The MCID for the Patient-Rated Tennis Elbow Evaluation has yet to be reported.

The DASH is an outcome of disability for patients with upper extremity musculoskeletal disorders.[21] It consists of a total of 30 questions about the degree of difficulty performing functional activities, the severity of symptoms, and the impact on social activities and work. Each question is scored on a 5-point Likert scale, with 1 being "no difficulty to perform, no symptom, or no impact" and 5 being "unable to do, very severe symptom, or high impact." The total score ranges from 0 to 100, where higher scores reflect greater disability. The MCID for the DASH has been reported as 10.83 points.[14]

The **TABLE** reports the outcomes throughout our patient's 2-year follow-up period. The patient experienced clinically important improvements in all outcomes immediately after the PENS sessions, including a decrease in pain of 3 points on the NPRS and 21.46 points on the DASH, surpassing the respective MCIDs.[11,14] The patient started playing table tennis around 4 to 5 months after the second PENS session, with lower levels of pain (1/10 NPRS), and achieved a full return to playing table tennis at 6 months after the intervention. The patient continued experiencing improvements over time, and at the 9-month follow-up reported being pain free and at full function as measured by the NPRS and PRTEE (**FIGURE 5**). These improvements were maintained 2 years after treatment, with no further intervention by any other medical provider.

DISCUSSION

This case report describes clinical reasoning and the physical therapy management of a patient with chronic lateral elbow pain exacerbated by trauma and not responding to manual therapy, dry needling, and exercise.

Because previous physical therapy modalities, including manual therapy, exercise, and trigger point dry needling, were not effective in this patient, we proposed the application of PENS in an attempt to decrease the sensitivity to mechanical stimulus of the peripheral nervous system, particularly the radial nerve. Within 2 visits, the patient noted changes in pain intensity and related disability that exceeded the MCID of 2 points and 10.83 points, respectively.[11,14] The patient achieved a rapid and clinically meaningful improvement in both pain and functional status. In fact, after 2 sessions of PENS combined with 4 weeks of a low-load exercise program (which was painful with previous interventions), there was a nearly complete resolution of his symptoms, and he returned to work and sport after 6 months of restrictions in physical activities. Although a case report of a single patient outcome does not allow us to infer a cause-and-effect relationship, a meaningful clinical change in the patient's status occurring within 2 intervention sessions in a chronic condition that was unaffected by previous interventions suggests that the intervention approach, based on the suspicion of radial nerve dysfunction, was helpful.

Of relevance in this case is the role of the neural component of LE and the need to consider this thoroughly in the diagnostic-reasoning process. The absence of data on the validity of tests for LE, the clinically observed lack of specificity for signs and symptoms, and the absence of a gold standard test for this condition certainly indicate the potential for misdiagnosis and inappropriate interventions in potential refractory cases. It is plausible that our patient developed LE during the initial stage of his symptoms, but it likely evolved into a more complex pain condition with a concomitant radial nerve dysfunction. It is important to consider that the clinical presentations of LE and radial tunnel syndrome are very similar, leading to potential confusion.

Based on the clinical examination in this case, we applied ultrasound-guided PENS, a novel intervention approach targeting the radial nerve. There is a lack of literature investigating the effects of this intervention, although a few case series have documented a positive effect of ultrasound-guided PENS in patients with subacromial pain syndrome[39] or postsurgical pain.[24] Nevertheless, several differences in methodology, particularly type of needle and time of retention of the needle, can be observed between previous studies[24,39] and this case report. For instance, Wilson et al[39] implanted permanent electrodes close to the vicinity of the nerve. The current case report provides preliminary evidence regarding the potential effect of PENS applied with solid-filament needles (dry needling needles), although future randomized clinical trials are needed to further examine the

TABLE Outcomes During the 2-Year Follow-up Period*

	Baseline	1 wk	1 mo	3 mo	6 mo	9 mo	12 mo	18 mo	24 mo
NPRS at rest†	7	4	2	1	0.5	0	0	0	0
PRTEE score‡	60	37	15	9	8	0	0	0	0
DASH score‡	35.74	14.28	10.82	1.7	0	0	0	0	0

Abbreviations: DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; NPRS, numeric pain-rating scale; PRTEE, Patient-Rated Tennis Elbow Evaluation.
**At 4 to 5 months post intervention, the patient started playing table tennis, with only 1/10 pain intensity.*
†Measured on a scale from 0 to 10.
‡Measured on a scale from 0 to 100.

clinical effectiveness of PENS. In fact, it is important to consider that the methodology of the PENS intervention used in this case clearly requires the use of ultrasound imaging for localization of targeted tissue and to reduce the risk of puncturing the nerve trunks.[23]

Several potential mechanisms could explain the effects of PENS on pain. For instance, large-diameter, myelinated, afferent peripheral nerve fibers are triggered with the use of electrical current and, therefore, may impede communication of nociceptive signals to the central nervous system from small-diameter pain fibers at the level of the spinal cord ("gate control theory").[6] Nerve trunk pain is often related to an increased activity in mechanically sensitized nociceptors within the nervi nervorum (nerves that innervate the connective tissue layers of the nerve itself). In a sensitized state (as in our patient), nerve endings of the nervi nervorum can lead to an increase in synthesis and release of algogenic substances, resulting in a neurogenic inflammation and spontaneous discharges within the nerve fibers.[40]

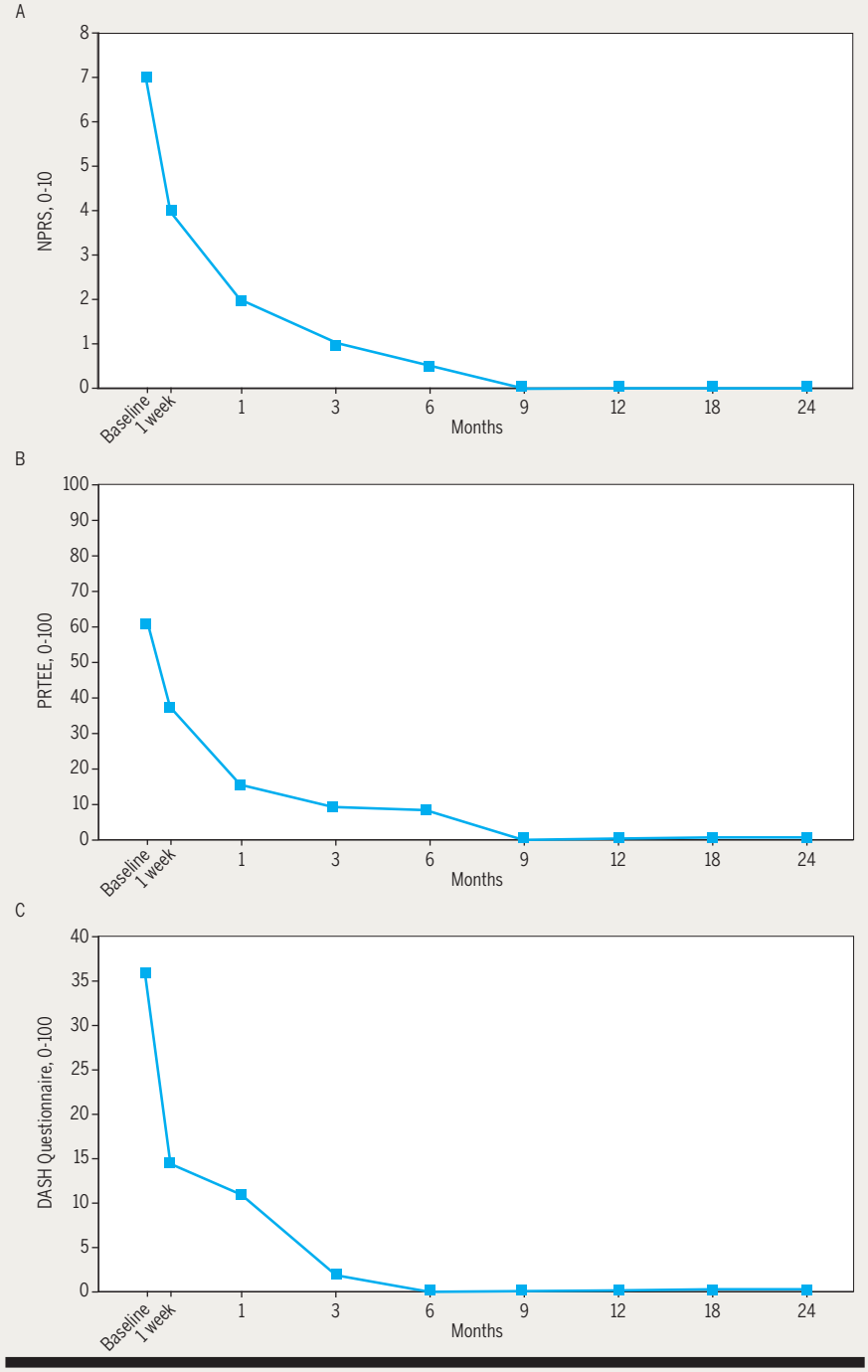

FIGURE 5. Evolution of (A) pain intensity (NPRS, 0-10), (B) function (PRTEE, 0-100), and related disability (DASH, 0-100) during the 2-year follow-up period. Abbreviations: DASH, Disabilities of the Arm, Shoulder and Hand questionnaire; NPRS, numeric pain-rating scale; PRTEE, Patient-Rated Tennis Elbow Evaluation.

In this case, the PENS stimuli were placed over the radial nerve trunk and posterior interosseous nerve. As the lateral epicondyle receives innervation from the posterior cutaneous nerve of the forearm, a branch of the radial nerve,[30] and the ECRB muscle receives innervation from the radial nerve itself, it is possible that electrical stimulation of the nerve may lead to a decrease in algogenic substances and spontaneous neural discharges. It is interesting to note that the patient reported a rapid decrease in pain and a quick restoration of motor function after the first session, suggesting that PENS could exert a beneficial effect on both sensory and motor systems. It is also possible that different underlying mechanisms, including nonspecific effects on the central nervous system or patient expectation, could be involved in PENS effects, similar to other manual therapies.[3] Future studies should investigate these hypotheses.

We acknowledge multiple limitations to this case report. First, a case report does not allow us to infer a cause-and-effect relationship. Second, the patient received both PENS and a low-load exercise program, so it is not possible to determine whether the outcomes were associated with one or the other aspect of this intervention. Nevertheless, as the exercise program was unsuccessful previously, it

seems that the application of PENS before the program may lead to better outcomes. Third, the suspected diagnosis was based on a thermography analysis and an examination of mechanical sensitivity of the radial nerve, particularly an increased sensitivity to palpation—both procedures without psychometric properties (positive or negative likelihood ratio, sensitivity or specificity data) for diagnosis. To further determine the effectiveness of PENS in chronic pain conditions, randomized controlled trials are needed.

CONCLUSION

This case report describes the management of a patient with chronic and recalcitrant lateral elbow pain previously diagnosed as LE of muscle origin. Clinical examination led to a plausible concomitant diagnosis of an increased sensitivity (neuritis) of the radial nerve compatible with radial tunnel syndrome. Physical therapy intervention consisted of ultrasound-guided PENS over the radial nerve and posterior interosseous nerve, combined with a low-load, concentric/eccentric exercise program for the wrist extensor muscles for 4 weeks. The patient experienced clinically meaningful changes in pain intensity and functional status, with a complete resolution of symptoms and full return to work and physical activity 5 to 6 months after treatment, which lasted for 2 years. ◉

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A Systematic Review of Proposed Rehabilitation Guidelines Following Anatomic and Reverse Shoulder Arthroplasty

BACKGROUND: Total shoulder arthroplasty (TSA) is indicated for patients with glenohumeral arthritis. In this procedure, the humeral head and glenoid surface are replaced with prosthetic components. Reverse total shoulder arthroplasty (RTSA) is indicated for patients with glenohumeral arthritis and a poorly functioning rotator cuff. In this procedure, a glenosphere articulates with a humerosocket. While those surgeries are commonly performed, a thorough review of the literature is required to determine the areas of agreement and variations in postoperative rehabilitation.

OBJECTIVES: To describe the literature on rehabilitation protocols following anatomic TSA and RTSA.

METHODS: For this systematic review, a computerized search was conducted in medical databases from inception to May 21, 2018 for relevant descriptive studies on TSA and RTSA rehabilitation protocols. The methodological index for nonrandomized studies tool and the modified Downs and Black tool for randomized controlled trials were used for assessment of the individual studies.

RESULTS: Sixteen studies met the inclusion criteria, of which 1 provided level I evidence, 1 provided level III evidence, 2 provided level IV evidence, and 12 provided level V evidence. Ten of the studies described rehabilitation guidelines for TSA and 6 described those for RTSA. Following TSA, the use of a sling was recommended for a duration that varied from 3 to 8 weeks, and 4 of the 10 published protocols included resisted exercise during the initial stage of healing (the first 6 weeks after surgery). Seven of 10 published protocols recommended limiting shoulder external rotation to 30° and that passive range of motion be fully restored by 12 weeks post surgery. Suggested use of a sling post RTSA varied from "for comfort only" to 6 weeks, motion parameters varied from no passive range of motion to precautionary range limits, and all protocols agreed on performing deltoid isometric exercises early post surgery. There was a high level of heterogeneity for the rehabilitation guidelines and associated precautions for both TSA and RTSA.

CONCLUSION: The majority of published protocols were descriptive in nature. Published rehabilitation strategies following TSA and RTSA are based on biomechanical principles, healing time frames, and exercise loading principles, with little consistency among protocols. There is a need to determine optimal rehabilitation approaches post TSA and RTSA based on clinical outcomes.

LEVEL OF EVIDENCE: Therapy, level 5.
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KEY WORDS: *arthroplasty, protocol, rehabilitation, replacement, shoulder*

Shoulder arthroplasty procedures have more than doubled in the last decade to as many as 70 000 surgeries performed each year in the United States alone.[17,35,47] Anatomic total shoulder arthroplasty (TSA) is indicated for end-stage arthritic shoulder conditions in individuals with an intact rotator cuff and sufficient glenoid bone stock to allow for stable glenoid component implantation.[31] This includes primary glenohumeral osteoarthritis,[32] avascular necrosis with glenoid chondral wear,[49,50] inflammatory arthritis with an intact rotator cuff,[30] and arthritis after instability or postcapsulorrhaphy.[12] The TSA procedure involves replacing the humeral head and glenoid with similarly shaped prosthetic components.[12,32]

A reverse total shoulder arthroplasty (RTSA) is indicated for patients with massive rotator cuff tears.[7,15] The fixed-fulcrum kinematics of the RTSA, with the glenoid as the convex articular surface, allows the deltoid to be the dominant musculature for arm elevation or abduction.[2,6] Though RTSA was initially designed to manage arthritis in the rotator cuff–deficient shoulder,[6] the indications have expanded to include management of massive irreparable rotator cuff tears without osteoarthritis,[51] primary osteoarthritis with excessive posterior glenoid erosion,[25] and proximal humerus fractures.[6] This expanded list of pathologies to be treated by RTSA has led to an increase in shoulder arthroplasty, with approximately one third of all shoulder

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arthroplasties in the United States being RTSAs, and greater than 90% in some European countries.[17,47] Due to the increasing frequency of both TSA and RTSA, there is a need for evidence-based postsurgical rehabilitation guidelines.

Dating back to the work of Hughes and Neer,[32] rehabilitation post TSA included the principle of early range of motion (ROM) in a protected and graduated manner to avoid stiffness and minimize muscle atrophy, while protecting healing tissues and minimizing risks of instability or stress fractures.[7,32,59,60] Since publication of this initial TSA rehabilitation protocol,[32] the surgical procedure and related rehabilitation principles have progressed, specifically with respect to the management of the subscapularis takedown,[19,37,40] which is needed for humeral-head exposure to initiate dislocation during surgery.[14] Surgical options, based on surgeon preference and training, include detaching the subscapularis at its bony insertion on the humerus,[38] performing a tenotomy approximately 1 cm proximal to its insertion, or performing a lesser tuberosity osteotomy.[14,40]

The authors of a narrative review[52] based on lower-quality studies concluded that all surgical methods resulted in similar tendon integrity and functional outcomes. In a prospective comparison of lesser tuberosity osteotomy to subscapularis tenotomy, there was no difference in tendon healing rates, American Shoulder and Elbow Surgeons patient-reported shoulder outcome scores, or strength.[38] In a systematic review by Levy et al,[39] the weighted mean subscapularis retear rate was 3.0% ± 13.6% following TSA. Subscapularis failure following TSA is associated with anterior shoulder instability, pain, lower patient-reported outcomes, and weakness in shoulder internal rotation.[39,52] Differences in subscapularis surgical methods complicate comparison among rehabilitation protocols following TSA.[34] However, the majority of TSA rehabilitation protocols are still based on Hughes and Neer's[32] original work, with no specificity regarding subscapularis management and a paucity of clinical data to support a preferred rehabilitative strategy.[59]

While TSA and RTSA have some similarities, there are key differences in surgical indications and postoperative precautions.[10,32,36,60] Unlike TSA, which is critically dependent on the function of the subscapularis,[10,19,37,40] postoperative subscapularis integrity is not as critical to successful outcomes post RTSA.[26] This lesser need for protection of healing tissues post RTSA has been used as a justification for a faster, more aggressive rehabilitation protocol.[60] However, the complication rate post RTSA is significantly higher than for TSA, including dislocation and acromial stress fracture, which may create a rationale for a slower rehabilitation approach.[58] There is, therefore, substantial disagreement about RTSA rehabilitation guidelines.[36]

While there are multiple published rehabilitation protocols, including some based on thorough biomechanical rationales, for both TSA and RTSA,[7,32,60] there is no consensus for the types and timelines of physical therapy interventions following shoulder arthroplasty.[17,35,48] Given the prevalence of both surgical procedures within the health care setting, there is a need to perform a systematic review of the literature to determine the extent of consensus and level of evidence for postsurgical rehabilitation.

METHODS

Study Design

A systematic review was performed of the published rehabilitation protocols, precautions, and clinical outcomes post TSA and RTSA. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines were followed.[42] This review was prospectively registered with PROSPERO (CRD42018095551).

Search Strategy

A comprehensive search was conducted, with the assistance of a medical librarian (L.L.), in 6 online databases (MEDLINE, CINAHL, Cochrane Library, Embase, PsycINFO, and ClinicalTrials.gov) from inception to May 21, 2018. Controlled vocabulary (eg, Medical Subject Headings in PubMed) and key words were incorporated for "anatomic total shoulder arthroplasty," "reverse total shoulder arthroplasty," "rehabilitation," and "rehabilitation precautions." See the **APPENDIX**, available at www.jospt.org, for the full search strategy. References were tracked in Covidence systematic review software (Veritas Health Innovation Ltd, Melbourne, Australia).

Eligibility Criteria

Inclusion criteria consisted of (1) patients treated with TSA or RTSA, (2) description of rehabilitation protocols following TSA or RTSA, (3) comparison between home-based therapy and physical therapy provided in clinical settings, (4) studies that analyzed biomechanical and tissue physiology rehabilitation precautions and protocols, (5) publication in a peer-reviewed journal, and (6) full-text articles written in English.

Exclusion criteria consisted of (1) case reports or cadaveric studies, (2) surgical revision of TSA or RTSA, (3) patients who incurred a fracture or osteonecrosis, (4) studies that reported on management of hemiarthroplasty, (5) articles that included individuals with chronic dislocation or rheumatoid arthritis, (6) studies that did not thoroughly report rehabilitation protocols, (7) surgical technical reports, (8) articles that reported only surgical complications, (9) studies that reported only non–shoulder-related comorbidities, and (10) papers written in a language other than English.

Study Selection

Two authors (J.K. and G.B.) independently assessed studies identified by the search criteria. Titles and abstracts were initially screened. Following title and abstract screening, the 2 authors independently performed full-text review. If any conflicts arose and agreement on full-text inclusion could not be reached, a third author (G.G.)

served as arbiter for final study eligibility. Following full-text screening, a hand search was performed by 2 authors (J.K. and G.B.) for any additional manuscripts.

Data Extraction

Two authors (J.K. and G.B.) collected and recorded data in a customized database using Microsoft Excel, Version 2013 (Microsoft Corporation, Redmond, WA). Data regarding study design, sample size, age, sex, follow-up time, surgical procedure, rehabilitation timing, rehabilitation precautions, rehabilitation venue, and complications (ROM, strength, patient-reported outcomes, etc) were recorded.

TABLE 1 Inclusion and Exclusion Criteria

Key Concept	Inclusion Criteria	Exclusion Criteria
Population	• Glenohumeral joint osteoarthritis • Rotator cuff arthropathy • Rotator cuff deficiency	• Humeral fracture • Osteonecrosis • Rheumatoid arthritis • Chronic dislocation
Exposure	• Primary TSA • Primary RTSA	• TSA revision • RTSA revision • Shoulder hemiarthroplasty
Outcomes	• Thoroughly reported rehabilitation protocols • Home-based therapy versus physical therapy • Biomechanical and tissue physiology rehabilitation concepts	• In situ or cadaveric studies • Biomechanical studies • Reported only complication • Reported only outcomes

Abbreviations: RTSA, reverse total shoulder arthroplasty; TSA, total shoulder arthroplasty.

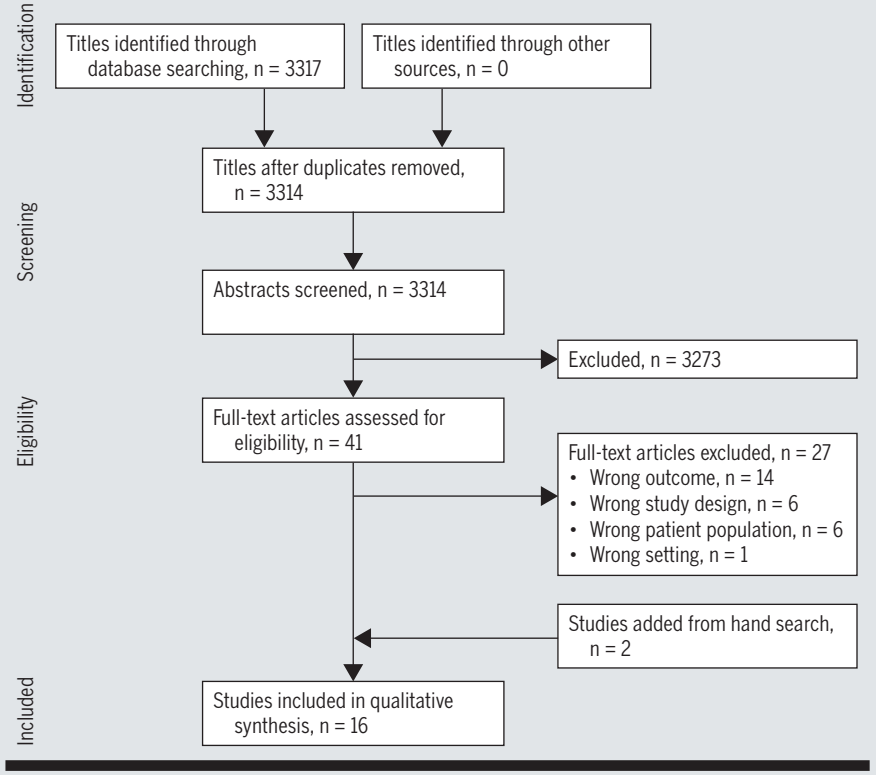

FIGURE. PRISMA flow diagram.

Risk-of-Bias Assessment

Methodological risk of bias was assessed by 2 authors (J.K. and G.B.) independently. If consensus could not be reached, a third author (G.G.) arbitrated the final decision. The Oxford Centre for Evidence-Based Medicine levels of evidence (levels I-V)[45] were utilized to ascertain study design. The methodological index for nonrandomized studies (MINORS) checklist was used as well to assess the risk of bias of the included studies.[53] On the MINORS checklist, comparative studies are rated with a maximum score of 24, whereas noncomparative studies are rated with a maximum score of 16.

The modified Downs and Black[22] tool was used to assess the risk of bias for randomized controlled studies. The modified Downs and Black[22] tool uses a scale ranging from 0 to 15, with studies scoring 12 to 15 being regarded as high quality, those scoring 10 or 11 regarded as moderate quality, and those scoring 9 or lower regarded as low quality.[43]

Statistical Analysis

Due to the heterogeneity and nonuniformity of the data in the included studies, the results are summarized in a descriptive manner.

RESULTS

Search Results

A total of 3317 references were imported for screening. After duplicates were removed (n = 3), 3314 publications underwent title and abstract screening. After 3273 publications were excluded, 41 underwent full-text review. An additional 2 papers were added through a hand search of included manuscripts. After exclusion, 16 papers were included in quality assessment and analysis (**TABLE 1**, **FIGURE**).[3,4,7-9,11,12,20,23,27,36,44,46,54,59,60]

Risk of Bias

A total of 15 publications were assessed using the MINORS tool (**TABLE 2**), with 1 rated as level III,[44] 2 rated as level IV,[4,46] and 12 rated as level V evidence.[3,7-9,11,12,23,27,36,54,59,60]

The median MINORS score for the 13 noncomparative studies was 2 of 16.[3,4,7-9,11,12,23,27,36,54,59,60] The median MINORS score for the 2 comparative studies was 14 of 24.[44,46] No studies performed a prospective collection of data or had an unbiased evaluation of end points. Three studies had an appropriate follow-up time.[4,44,46]

The single randomized controlled trial (level I)[20] scored 11 of 15 on the modified Downs and Black[22] scale (**TABLE 2**). The study did not adequately control for potential confounders.

Rehabilitation

Ten manuscripts reported on rehabilitation post TSA,[4,8,9,11,12,20,23,27,44,59] with 9 delineating rehabilitation strategies by phases of recovery (**TABLE 3**). Five papers[4,8,12,23,27] included 3 rehabilitation phases (time frame: 10+ weeks to 6 months), 4 papers[9,11,20,44] described 4 rehabilitation phases (time frame: 12+ weeks to 6 months), and 1 paper[59] reported rehabilitation for different shoulder pathologies without delineation of phases of recovery. Of 10 studies, 7 utilized a shoulder sling for a duration ranging from 3 to 8 weeks post surgery.[4,9,11,12,20,27,44] Three studies allowed resisted exercise in the first 3 weeks,[8,23,27] with 2 of 3 initiating deltoid isometrics[8,23] and 1 aquatic exercise.[27] Seven of 10 studies progressed to full shoulder ROM by week 8.[4,8,9,12,20,23,27] Only 1 study[20] did not recommend shoulder strengthening by the second rehabilitation phase, with the other 9 studies[4,8,9,11,12,23,27,44,59] including deltoid isometrics, 3 starting closed-chain exercises at 4 to 6 weeks[11,23,44] and 2 specifically beginning scapular strengthening exercises in that phase.[9,11] All 10 studies recommended full shoulder ROM and beginning shoulder strengthening by week 12,[4,8,9,11,12,20,23,27,44,59] and only 2 studies recommended specific lifelong activity modification.[20,44]

Six publications reported on rehabilitation post RTSA (**TABLE 4**).[3,7,36,46,54,60] Five publications[3,7,46,54,60] described the rehabilitation protocol post RTSA and 1 used a questionnaire to gather expert opinions.[36] One study had 4 rehabilitation phases in a time frame of 4-plus months,[7] 2 studies had 3 rehabilitation phases in a time frame of 12 to 6 months,[3,54] and 2 studies had 2 rehabilitation phases in a time frame of 6 to 12 weeks.[46,60] Four of 6 studies[7,46,54,60] required sling use after surgery, with time frames ranging from 2 to 6 weeks. Two studies[3,60] did not allow passive ROM in the first 6 weeks, while the other 4 studies did.[7,36,46,54] Three studies[7,46,54] recommended resisted exercise within the first 6 weeks post surgery, focusing on deltoid and scapular isometrics. All 6 studies[3,7,36,46,54,60] initiated shoulder passive ROM and resisted exercise by week 6. Resisted exercise consisted of deltoid and scapular strengthening[3,7,36,46,54,60] and push-ups and rows,[54] and 1 study recommended exercise when supine active shoulder flexion is well controlled.[3] All 6 studies[3,7,36,46,54,60] recommended full passive and active ROM by week 12. Two studies[7,60] prescribed lifelong activity modification of lifting no more than 6.8 kg.

TABLE 2 Descriptors of Manuscripts Included in the Review

Study	Level of Evidence (Design)	Risk of Bias*	Surgical Procedure
Blacknall and Neumann[3]	V (expert opinion)	2/16	RTSA
Boardman et al[4]	IV (case series)	7/16	TSA
Boudreau et al[7]	V (expert opinion)	2/16	RTSA
Brander et al[8]	V (expert opinion)	2/16	TSA
Brown and Friedman[9]	V (expert opinion)	2/16	TSA
Cahill et al[11]	V (expert opinion)	2/16	TSA
Cameron et al[12]	V (expert opinion)	2/16	TSA
Denard and Lädermann[20]	I (RCT)	11/15†	TSA
Etier et al[23]	V (expert opinion)	2/16	TSA
Fusaro et al[27]	V (expert opinion)	2/16	TSA
Kwaees and Charalambous[36]	V (expert opinion)	4/16	RTSA
Mulieri et al[44]	III (case-control)	16/24	TSA
Romano et al[46]	IV (case series)	12/24	RTSA
St Pierre and Frankle[54]	V (expert opinion)	2/16	RTSA
Wilcox et al[59]	V (expert opinion)	2/16	TSA
Wolff and Rosenzweig[60]	V (expert opinion)	2/16	RTSA

Abbreviations: RCT, randomized controlled trial; RTSA, reverse total shoulder arthroplasty; TSA, total shoulder arthroplasty.
**Rated using the methodological index for nonrandomized studies for noncomparative (0-16 points) and comparative (0-24 points) studies unless otherwise indicated.*
†Rated using the Downs and Black[22] scale (0-15 points).

Precautions

Seven studies[8,11,12,20,23,27,44] provided precautions for the first 6 weeks post TSA. In 5 studies,[8,11,12,23,44] shoulder flexion or scapular abduction was limited to values ranging from 90° to 130°. In all 7 studies,[8,11,12,20,23,27,44] shoulder external rotation was limited to values ranging from 15° to 30°, while in 1 study[8] shoulder internal rotation was limited to 45°. For the period of 6 to 12 weeks post surgery, only 2 studies[11,44] still required ROM precautions, with shoulder flexion or scapular abduction limited to 135° to 150° and shoulder external rotation limited to 35° to 45°. Two studies recommended lifelong precautions,[20,44] with Denard and Lädermann[20] limiting patients to lift no more than 11.3 kg with the surgical arm and Mulieri et al[44] limiting patient shoulder ROM to 55° of external rotation and 30° of extension.

For RTSA, 4 studies[3,7,46,60] provided precautions for the first 6 weeks post surgery. Of these, 3 studies[3,7,60] recommended

avoiding shoulder internal rotation, adduction, and extension, and 1 study[46] required that individuals with a subscapularis repair limit shoulder external rotation for 4 weeks and perform no active shoulder internal rotation for 8 weeks. For weeks 6 through 12 post surgery, 2 studies[7,60] required precautions, with both continuing to limit shoulder internal rotation, shoulder adduction, and extension. Past week 12, only Boudreau et al[7] stipulated precautions, prohibiting patients from lifting more than 1.4 kg. Two studies had lifelong precautions,[7,60] limiting patients to lifting no more than 6.8 kg with the surgical arm.

DISCUSSION

Rehabilitation following TSA and RTSA is important for patients to have the best possible outcomes with minimal complications.[3,7,20,32] Currently, there is significant diversity in postsurgical rehabilitation programs, specifically regarding when exercises are initiated, the amount of allowed shoulder motion, the timing and extent of resisted exercises, and short- and long-term precautions.[14,20,36,44] Current rehabilitation guidelines post TSA and RTSA are based on low-quality evidence, with only 1[20] of 16 studies being a randomized controlled trial and 12 studies being based on expert opinion.[3,7-9,11,12,23,27,36,54,59,60] Thus, there is a need for further high-quality randomized controlled trials investigating rehabilitation protocols post TSA and RTSA. Currently, even well-done case-control trials and other retrospective designs could add substantially to this area.

Anatomic TSA

Preventing stiffness during the early recovery phase, while protecting healing tissue impacted by surgery, requires a balance of rest and exercise.[32] Following TSA, regardless of the subscapularis tendon takedown procedure, the sub-

TABLE 3 Rehabilitation Guidelines Following Anatomic Total Shoulder Arthroplasty

Study	Sling	PROM	AAROM	AROM	Resisted Exercise	Precaution
Boardman et al[4]	0-6 wk	0-3 wk: shoulder stretching at home	3-5 wk: pulley exercises 5-10 wk: ER and IR at 0° and 90° of abduction	0-4 wk: elbow, wrist, and hand 10+ wk: gradual return to shoulder function	5-10 wk: shoulder isometrics 10+ wk: exercises with elastic bands	None
Brander et al[8]	0-4 wk	0-3 wk: 90° of flexion and abduction, 45° of IR, 15° of ER 4-12 wk: greater than 90° of flexion and abduction	3-4 wk: wall walking 6-12 wk: greater than 90°	0-6 wk: ADL with nonsurgical side 6-12 wk: past 90°, 2-handed ADL 12+ wk: AROM without resistance in all planes and full-ROM body-weight exercise in all planes	0-3 wk: deltoid isometrics 3-6 wk: deltoid vigorous isometrics 6-12 wk: progress to isotonics as tolerated 12+ wk: progressive resistance	None
Brown and Friedman[9]	0-4 wk	0-4 wk: ER, IR, flexion 4-6 wk: continue with ER, IR, flexion	4-6 wk: horizontal adduction, ER at 90° of abduction	4-6 wk: flexion in supine 6-10 wk: flexion and abduction in sitting	4-6 wk: shoulder isometrics, scapular and distal arm musculature 6-10 wk: ER and IR 10 wk to 6 mo: add weights to active ROM exercise, wall push-ups, functional specificity	None
Cahill et al[11]	0-6 wk	0-4 wk: 120° of flexion, 30° of ER 4-6 wk: horizontal adduction, 90° of ER	0-4 wk: pendulums 4-10 wk: ER and pulleys	0-4 wk: elbow, wrist, and hand 4-10 wk: shoulder, all planes	4-10 wk: deltoid isometrics, closed-chain exercises, scapular retraction 10-16 wk: isometrics, scapular strengthening, resistance exercises 16-22 wk: functional strength through full ROM, gym program	4-10 wk: 150° of flexion, 45° of ER
Cameron et al[12]	0-4 wk	0-6 wk: 120° of flexion, 30° of ER 6-10 wk: full ROM	0-6 wk: pendulums 6-10 wk: pendulums	0-6 wk: elbow, wrist, and hand 6-10 wk: shoulder flexion and abduction 11+ wk: full activities as tolerated	6-10 wk: ER and IR exercises with elastic bands 11+ wk: free-weight exercises	0-6 wk: protect subscapularis

Table continues on page 342.

TABLE 3 Rehabilitation Guidelines Following Anatomic Total Shoulder Arthroplasty (continued)

Study	Sling	PROM	AAROM	AROM	Resisted Exercise	Precaution
Denard and Lädermann[20] (immediate)	0-4 wk	Flexion as tolerated, 30° of ER 4-8 wk: ER as tolerated	0-4 wk: pulleys 4-8 wk: flexion	0-4 wk: elbow, wrist, and hand 4-8 wk: flexion 8-12 wk: full ROM as tolerated	8-12 wk: strength as tolerated 12+ wk: activity as tolerated	12+ wk: 11.3 kg
Denard and Lädermann[20] (delayed)	0-4 wk	0-4 wk: none 4-8 wk: flexion and ER	8-12 wk: begin AAROM	0-4 wk: elbow, wrist, and hand 8-12 wk: ROM as tolerated	8-16 wk: strength as tolerated 16+ wk: activity as tolerated	16+ wk: 11.3 kg
Etier et al[23]	0-6 wk	0-6 wk: 130° of flexion, 25° of ER 6-12 wk: movement as tolerated in all planes	0-6 wk: pendulum 6-12 wk: movement as tolerated in all planes	0-6 wk: elbow, wrist, and hand 6-12 wk: flexion 12+ wk: full ROM as tolerated	0-6 wk: deltoid isometrics 6-12 wk: closed-kinetic-chain exercises, light resistance exercises 12+ wk: isometrics and resistive exercises	None
Fusaro et al[27]	0-6 wk	0-6 wk: PROM device 6 wk to 3 mo: full ROM	0-6 wk: pendulums and pulleys 6 wk to 3 mo: full ROM	0-6 wk: elbow, wrist, and hand 6 wk to 3 mo: nonpainful ROM	0-6 wk: aquatic PT 6 wk to 3 mo: proprioception isometrics 3+ mo: return to driving and work 6+ mo: moderate sports	None
Mulieri et al[44] (PT group)	0-6 wk	0-3 wk: 20° of ER, 120° of scapular abduction, sling use except during therapy 4-6 wk: ER to 35°, sling use except during therapy 6-12 wk: 55° of ER	4-6 wk: scapular abduction to 135° with wand	0-3 wk: elbow, wrist, and hand 4-6 wk: elbow, wrist, and hand 7-9 wk: flexion, ER, extension, diagonals	4-6 wk: closed-kinetic-chain exercises; isometrics for IR, ER, extension, abduction, and depression 7-9 wk: isometrics at various angles, biceps and triceps isometrics, closed-kinetic-chain exercise 9-12 wk: elastic band and isometrics	None
Mulieri et al[44] (home group)	0-8 wk	0-8 wk: pendulum 9 wk: discontinue sling use 9+ wk: 55° of ER	None	0-8 wk: elbow, wrist, and hand	14+ wk: elastic-band exercises and isometrics	14+ wk: 55° of ER

Abbreviations: AAROM, active-assisted range of motion; ADL, activities of daily living; AROM, active range of motion; ER, external rotation; IR, internal rotation; PROM, passive range of motion; PT, physical therapy; ROM, range of motion.

scapularis repair requires the most protection.[10,13,41] Subscapularis failure after TSA can result in anterior shoulder instability, pain, weakness in internal rotation, early glenoid loosening, and lower patient-reported outcome scores.[5,10,13]

Overall, there was no consensus on subscapularis protection post surgery. Denard and Lädermann[20] published the only TSA rehabilitation randomized controlled trial, contrasting immediate rehabilitation versus rehabilitation after 4 weeks (delayed physical therapy). They found a greater subscapularis healing rate in the delayed group (96% versus 81%), which was associated with improved patient-reported outcomes and shoulder flexion ROM. Some studies[4,20] recommended utilizing pulleys for active-assisted ROM after surgery. Cadaveric studies suggest that shoulder elevation can be unrestricted following subscapularis repair.[61] However, electromyographic studies have shown that seated pulley exercises are not truly passive and, therefore, potentially place increased stress on the subscapularis.[21,28]

In contrast, there was good agreement that the amount of shoulder external rotation ROM following subscapularis takedown should be limited to prevent passive tension on the repaired tendon, and active and resisted internal rotation exercises should be limited to prevent active tension across the repair.[8,11,20] Some authors[13,29] have suggested limiting shoulder external rotation to neutral when performed with the arm along the trunk, having observed better subscapularis function with this approach. This contrasts other postoperative initial external rotation precautions of 30° to 40°, which have shown higher rates of subscapularis complications.[41] Multiple studies[4,9,27] in this review did not have external rotation ROM precautions in the first rehabilitation phase. Furthermore, 3 studies[11,23,44] initiated subscapularis isometrics and quadruped closed-kinetic-chain exercises beginning at 4 weeks. These guidelines incur increased subscapularis injury risk.[8,11,20,23,44]

TABLE 4 Rehabilitation Guidelines Post Reverse Total Shoulder Arthroplasty

Study	Sling	PROM	AROM	Resisted Exercise	Precaution
Boudreau et al[7]	0-4 wk	0-6 wk: elevation, 90°-120°; ER, 30° 6-12 wk: flexion and ER as tolerated 12-16 wk: all movements as tolerated	0-6 wk: elbow, wrist, and hand 6-12 wk: shoulder as tolerated	0-6 wk: submaximal deltoid and scapular isometrics 6-12 wk: deltoid isometrics 12-16 wk: slow strength progression for deltoid and scapula 4+ mo: stretch and strengthen with maintenance programs	0-6 wk: avoid IR, adduction, and extension 6-12 wk: no adduction, IR, or extension 12-16 wk: do not exceed 1.4 kg, enforce good mechanics for elevation 4+ mo: 6.8 kg
Blacknall and Neumann[3]*	Comfort only	None	0-6 wk: assisted elevation to 90° and ER to 30° 6-12 wk: 0°-90° of active short level-arm flexion, inclined surface; progress to straight-arm flexion 12-16 wk: ROM as tolerated	0-3 wk: deltoid isometrics 3-6 wk: vigorous isometrics 6-12 wk: progress to isotonics as tolerated 12+ wk: progressive resistance	0-6 wk: avoid ER, IR, abduction, and extension
St Pierre and Frankle[54]	0-4 wk	0-6 wk: pendulums (supports for 2 wk, then unsupported) 6-12 wk: as tolerated 12-16 wk: as tolerated; add sleeper stretch	0-6 wk: elbow, wrist, and hand table slides for supported elevation and wand-assisted elevation in supine 12-16 wk: as tolerated	4-6 wk: shoulder isometrics, scapular musculature, and distal arm 6-10 wk: ER and IR 10 wk to 6 mo: weights to active exercise, wall push-ups, functional specificity	None
Romano et al[46] (group A)†	0-2 wk	0-12 wk: as tolerated	0-6 wk: flexion to 60°-120°, ER to 20°-30° 6+ wk: as tolerated	0-6 wk: deltoid and scapular isometrics 6-12 wk: deltoid and scapular musculature using elastic band	0-6 wk: if subscapularis repaired, then no ER PROM for 4 wk and no resisted IR for 2 mo
Romano et al[46] (group C)†	0-4 wk	0-12 wk: as tolerated	0-6 wk: flexion to 60°-120°, ER to 20°-30° 6+ wk: as tolerated	0-6 wk: deltoid and scapular isometrics 4 wk: begin AROM exercises 8 wk: deltoid and scapular musculature using elastic band	0-6 wk: if subscapularis repaired, then no ER PROM for 4 wk and no resisted IR for 2 mo
Wolff and Rosenzweig[60]	2-6 wk	0-6 wk: no PROM 6+ wk: as tolerated	Not reported	6-12 wk: deltoid and scapular strength progression: isometric to isotonic	0-6 wk: avoid IR, adduction, and extension 6-12 wk: continue avoiding adduction, IR, and extension 4+ mo: 6.8 kg

Abbreviations: AROM, active range of motion; ER, external rotation; IR, internal rotation; PROM, passive range of motion; ROM, range of motion.
**Time frames do not apply; progression is strictly criterion dependent.*
†Differentiated progression into group A (cuff tear arthropathy, primary osteoarthritis cuff deficiency with pseudoparalysis), group B (all others not in A or C), and group C (rheumatoid arthritis, fracture).

Early postoperative rehabilitation precautions are critical to allowing tendon healing and preventing subscapularis failure following TSA.[13,29] There is a great need to carefully study the role of formal physical therapy following this surgical procedure, with specific attention given to the different subscapularis takedown methods and how exercise selection and progression impact subscapularis healing. Specifically, investigations need to focus on the impact of early passive external rotation and resisted internal rotation.[5,29,39] Recent research has found that immobilization following rotator cuff surgery can increase rotator cuff tendon healing,[57] while other studies recommend conservative ROM and loading following rotator cuff surgery.[14,56] There is a need to determine the best timetable and strategies to protect the subscapularis while improving shoulder ROM and function post TSA.

Reverse Total Shoulder Arthroplasty

There were 6 reports[3,7,36,46,54,60] on rehabilitation guidelines following RTSA. All these publications were written by experts, and the guidelines were based on knowledge of anatomy,[3,7,46,60] biomechanics,[7,60] and surgical procedures.[3,7,46,54,60] However, none systematically and prospectively

evaluated patient-reported and clinical outcomes and complication incidence. Additionally, the results of a survey of 30 surgeons with publications on RTSA indicated great variability in duration of use of a sling and the timing to begin shoulder motion post surgery.[36]

Reverse total shoulder arthroplasty is often recommended as an end-stage procedure to reduce pain and improve functional elevation in patients with massive rotator cuff tear, with or without arthritis.[7] Blacknall and Neumann[3] and St Pierre and Frankle[54] both stress the benefit of a prehabilitation session with a physical therapist to review expectations and practice exercises prior to surgery.[3,54] If these expectations for recovery can be clearly explained to patients prior to the operation, then outcomes may be more favorable, as patient expectation has been linked to successful outcomes following shoulder arthroplasty.[55] All of the rehabilitation progressions post RTSA emphasized protection from combined movement of shoulder extension, adduction, and internal rotation (hand-behind-the-back posture) due to risk of instability and to allow scar formation around the reverse articulation; however, each protocol differed regarding when to integrate this motion into recovery.[3,7,36,46,54,60] While some authors promote rehabilitation differentiation based on other concomitant procedures, such as rotator cuff repair or tendon transfers,[7,46,60] others do not highlight this as an important consideration.[8,38]

Previous authors[16,18] have reported that patients with or without repair of the subscapularis had no difference in complication rates or outcomes postoperatively; however, an intact subscapularis may provide improved shoulder internal rotation ROM.[18] Therefore, if repaired, consideration should be given to protecting the healing tendon. Post surgery, immediate concerns for rehabilitation include prosthesis protection from dislocation and acromial overload from deltoid tension, which can increase risk for stress reaction or stress fracture.[1,16,24]

Despite these known concerns, there was substantial disagreement between authors on proper protection time frames and progression of rehabilitation and activity. Boudreau et al[7] published rehabilitation guidelines dividing recovery into 4 phases that emphasized initial joint protection followed by gradual tissue loading. These authors[7] recommended sling use for 3 to 4 weeks following surgery, early deltoid and scapular isometric exercises, and a gradual restoration of passive ROM in the first 6 weeks of recovery. When passive ROM is restored, active-assisted and then active ROM progression, as described by Jackins,[33] is recommended to provide gradual deltoid load to the acromion. Similarly, Romano et al[46] employed sling use for 2 to 4 weeks, with immediate deltoid and scapular isometrics. In contrast, Blacknall and Neumann[3] proposed a less restrictive criterion-based rehabilitation progression. These authors[3] did not promote use of a sling and allowed rehabilitation progression based on demonstration of good deltoid and pain control and no instability signs.

A final rehabilitation method proposed by St Pierre and Frankle[54] promoted surgeon-directed rehabilitation for patients with exercises performed at home using web-based videos. A sling was worn for 4 weeks, during which time deltoid and scapular isometrics were performed. Supported elevation was allowed without motion limitation at 3 weeks, and strengthening with elastic-band exercises and shoulder extension ensued at 5 to 7 weeks. Pain was used as the main criterion to advance exercise, and a unique feature of this rehabilitation plan was the integration of core stability exercises. Referral for formal physical therapy was reserved for patients who were not progressing well, or who had higher-level rehabilitation goals.[54] Other authors[60] suggested a more conservative approach, promoting 2 to 6 weeks of full immobilization, depending on patient factors, deferral of deltoid and scapular strengthening for 6 weeks, and formal rehabilitation continuing for 4 to 6 months. Even with reported stress fracture and deltoid overload risk,[1,16,24] healing and protective time frames did not have expert agreement.[3,7,36,46,54,60]

Limitations

This systematic review limited the search to articles with full text published in the English language, which might have resulted in a loss of literature and a potential bias. The body of evidence was primarily based on level V evidence, which had low methodological quality. The MINORS tool is specifically designed for nonrandomized observational studies.[53] Therefore, with most studies being clinical commentaries or expert opinions, there is an inherent bias in this study's quality assessment.

CONCLUSION

Currently, there is low consensus among published rehabilitation guidelines post TSA and RTSA, precluding specific clinical best practice suggestions. The only consensus is that therapy is believed to play an important role in optimizing patient outcomes, and that there is a need for high-quality prospective research.[3,20,54,60] Objective scientifically based information is essential in determining best practice to optimize outcomes for patients post TSA or RTSA. ◉

KEY POINTS

FINDINGS: Most published rehabilitation guidelines post total shoulder arthroplasty and reverse total shoulder arthroplasty are clinical commentaries, with little consensus on timelines for initiation and progression of exercises.

IMPLICATIONS: There is a need for prospective randomized controlled trials comparing rehabilitation methodologies after total shoulder arthroplasty and reverse total shoulder arthroplasty to determine best practice.

CAUTION: Due to heterogeneous findings and paucity of substantial data, the evidence was not sufficient to create spe-

cific clinical best-practice suggestions regarding total shoulder arthroplasty and reverse total shoulder arthroplasty rehabilitation.

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APPENDIX

SEARCH STRATEGY

(((((((“Shoulder Joint”[Mesh] OR “Shoulder”[Mesh] OR shoulder[tiab])) AND (“Arthroplasty, Replacement”[mesh] OR arthroplasty[tiab] OR arthroplastic[tiab] OR “total joint”[tiab] OR “replacement”[tiab] OR Periprosthetic[tiab] OR “peri-implant”[tiab] OR “Shoulder Prosthesis”[Mesh] OR “Arthroplasty, Replacement, Shoulder”[Mesh] OR hemiarthroplasty[tiab] OR prosthesis[tiab] OR prosthetic[tiab] OR endoprosthe*[tiab] OR implant[tiab] OR implants[tiab])) AND (Physical Therapy Modalities[MeSH] OR “physical therapy” [tiab] OR “physical therapies” [tiab] OR Physiotherapy[tiab] OR physiotherapies[tiab] OR Exercise[MeSH] OR Exercise[tiab] OR Exercises[tiab] OR “Exercise Therapy”[tiab] OR “Resistance Training” [tiab] OR Rehabilitation[MeSH] OR Rehabilitation[subheading] OR Rehabilitation[tiab] OR Rehabilitate[tiab] OR Rehabilitating[tiab] OR Rehabilitates[tiab] OR Rehabilitated[tiab] OR “therapy”[Subheading])) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR randomization[tiab] OR randomisation[tiab] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR Clinical trial[pt] OR “clinical trial”[tiab] OR “clinical trials”[tiab] OR “evaluation studies”[Publication Type] OR “evaluation studies as topic”[MeSH Terms] OR “evaluation study”[tiab] OR evaluation studies[tiab] OR “intervention studies” [tiab] OR “intervention study”[tiab] OR “intervention studies”[tiab] OR “case-control studies”[MeSH Terms] OR “case-control”[tiab] OR “cohort studies”[MeSH Terms] OR cohort[tiab] OR “longitudinal studies”[MeSH Terms] OR “longitudinal”[tiab] OR longitudinally[tiab] OR “prospective”[tiab] OR prospectively[tiab] OR “retrospective studies”[MeSH Terms] OR “retrospective”[tiab] OR “follow up”[tiab] OR “comparative study”[Publication Type] OR “comparative study”[tiab] OR systematic[subset] OR “meta-analysis”[Publication Type] OR “meta-analysis as topic”[MeSH Terms] OR “meta-analysis”[tiab] OR “meta-analyses”[tiab]))) NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR case report[tiab] OR Comment[ptyp])) AND English[lang]) NOT (animals[mesh terms] NOT humans[mesh terms])

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A Systematic Review of Proposed Rehabilitation Guidelines Following Anatomic and Reverse Shoulder Arthroplasty

BACKGROUND: Total shoulder arthroplasty (TSA) is indicated for patients with glenohumeral arthritis. In this procedure, the humeral head and glenoid surface are replaced with prosthetic components. Reverse total shoulder arthroplasty (RTSA) is indicated for patients with glenohumeral arthritis and a poorly functioning rotator cuff. In this procedure, a glenosphere articulates with a humerosocket. While those surgeries are commonly performed, a thorough review of the literature is required to determine the areas of agreement and variations in postoperative rehabilitation.

OBJECTIVES: To describe the literature on rehabilitation protocols following anatomic TSA and RTSA.

METHODS: For this systematic review, a computerized search was conducted in medical databases from inception to May 21, 2018 for relevant descriptive studies on TSA and RTSA rehabilitation protocols. The methodological index for nonrandomized studies tool and the modified Downs and Black tool for randomized controlled trials were used for assessment of the individual studies.

RESULTS: Sixteen studies met the inclusion criteria, of which 1 provided level I evidence, 1 provided level III evidence, 2 provided level IV evidence, and 12 provided level V evidence. Ten of the studies described rehabilitation guidelines for TSA and 6 described those for RTSA. Following TSA, the use of a sling was recommended for a duration that varied from 3 to 8 weeks, and 4 of the 10 published protocols included resisted exercise during the initial stage of healing (the first 6 weeks after surgery). Seven of 10 published protocols recommended limiting shoulder external rotation to 30° and that passive range of motion be fully restored by 12 weeks post surgery. Suggested use of a sling post RTSA varied from "for comfort only" to 6 weeks, motion parameters varied from no passive range of motion to precautionary range limits, and all protocols agreed on performing deltoid isometric exercises early post surgery. There was a high level of heterogeneity for the rehabilitation guidelines and associated precautions for both TSA and RTSA.

CONCLUSION: The majority of published protocols were descriptive in nature. Published rehabilitation strategies following TSA and RTSA are based on biomechanical principles, healing time frames, and exercise loading principles, with little consistency among protocols. There is a need to determine optimal rehabilitation approaches post TSA and RTSA based on clinical outcomes.

LEVEL OF EVIDENCE: Therapy, level 5.
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KEY WORDS: *arthroplasty, protocol, rehabilitation, replacement, shoulder*

Shoulder arthroplasty procedures have more than doubled in the last decade to as many as 70 000 surgeries performed each year in the United States alone.[17,35,47] Anatomic total shoulder arthroplasty (TSA) is indicated for end-stage arthritic shoulder conditions in individuals with an intact rotator cuff and sufficient glenoid bone stock to allow for stable glenoid component implantation.[31] This includes primary glenohumeral osteoarthritis,[32] avascular necrosis with glenoid chondral wear,[49,50] inflammatory arthritis with an intact rotator cuff,[30] and arthritis after instability or postcapsulorrhaphy.[12] The TSA procedure involves replacing the humeral head and glenoid with similarly shaped prosthetic components.[12,32]

A reverse total shoulder arthroplasty (RTSA) is indicated for patients with massive rotator cuff tears.[7,15] The fixed-fulcrum kinematics of the RTSA, with the glenoid as the convex articular surface, allows the deltoid to be the dominant musculature for arm elevation or abduction.[2,6] Though RTSA was initially designed to manage arthritis in the rotator cuff–deficient shoulder,[6] the indications have expanded to include management of massive irreparable rotator cuff tears without osteoarthritis,[51] primary osteoarthritis with excessive posterior glenoid erosion,[25] and proximal humerus fractures.[6] This expanded list of pathologies to be treated by RTSA has led to an increase in shoulder arthroplasty, with approximately one third of all shoulder

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arthroplasties in the United States being RTSAs, and greater than 90% in some European countries.[17,47] Due to the increasing frequency of both TSA and RTSA, there is a need for evidence-based postsurgical rehabilitation guidelines.

Dating back to the work of Hughes and Neer,[32] rehabilitation post TSA included the principle of early range of motion (ROM) in a protected and graduated manner to avoid stiffness and minimize muscle atrophy, while protecting healing tissues and minimizing risks of instability or stress fractures.[7,32,59,60] Since publication of this initial TSA rehabilitation protocol,[32] the surgical procedure and related rehabilitation principles have progressed, specifically with respect to the management of the subscapularis takedown,[19,37,40] which is needed for humeral-head exposure to initiate dislocation during surgery.[14] Surgical options, based on surgeon preference and training, include detaching the subscapularis at its bony insertion on the humerus,[38] performing a tenotomy approximately 1 cm proximal to its insertion, or performing a lesser tuberosity osteotomy.[14,40]

The authors of a narrative review[52] based on lower-quality studies concluded that all surgical methods resulted in similar tendon integrity and functional outcomes. In a prospective comparison of lesser tuberosity osteotomy to subscapularis tenotomy, there was no difference in tendon healing rates, American Shoulder and Elbow Surgeons patient-reported shoulder outcome scores, or strength.[38] In a systematic review by Levy et al,[39] the weighted mean subscapularis retear rate was 3.0% ± 13.6% following TSA. Subscapularis failure following TSA is associated with anterior shoulder instability, pain, lower patient-reported outcomes, and weakness in shoulder internal rotation.[39,52] Differences in subscapularis surgical methods complicate comparison among rehabilitation protocols following TSA.[34] However, the majority of TSA rehabilitation protocols are still based on Hughes and Neer's[32] original work, with no specificity regarding subscapularis management and a paucity of clinical data to support a preferred rehabilitative strategy.[59]

While TSA and RTSA have some similarities, there are key differences in surgical indications and postoperative precautions.[10,32,36,60] Unlike TSA, which is critically dependent on the function of the subscapularis,[10,19,37,40] postoperative subscapularis integrity is not as critical to successful outcomes post RTSA.[26] This lesser need for protection of healing tissues post RTSA has been used as a justification for a faster, more aggressive rehabilitation protocol.[60] However, the complication rate post RTSA is significantly higher than for TSA, including dislocation and acromial stress fracture, which may create a rationale for a slower rehabilitation approach.[58] There is, therefore, substantial disagreement about RTSA rehabilitation guidelines.[36]

While there are multiple published rehabilitation protocols, including some based on thorough biomechanical rationales, for both TSA and RTSA,[7,32,60] there is no consensus for the types and timelines of physical therapy interventions following shoulder arthroplasty.[17,35,48] Given the prevalence of both surgical procedures within the health care setting, there is a need to perform a systematic review of the literature to determine the extent of consensus and level of evidence for postsurgical rehabilitation.

METHODS

Study Design

A systematic review was performed of the published rehabilitation protocols, precautions, and clinical outcomes post TSA and RTSA. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines were followed.[42] This review was prospectively registered with PROSPERO (CRD42018095551).

Search Strategy

A comprehensive search was conducted, with the assistance of a medical librarian (L.L.), in 6 online databases (MEDLINE, CINAHL, Cochrane Library, Embase, PsycINFO, and ClinicalTrials.gov) from inception to May 21, 2018. Controlled vocabulary (eg, Medical Subject Headings in PubMed) and key words were incorporated for "anatomic total shoulder arthroplasty," "reverse total shoulder arthroplasty," "rehabilitation," and "rehabilitation precautions." See the **APPENDIX**, available at www.jospt.org, for the full search strategy. References were tracked in Covidence systematic review software (Veritas Health Innovation Ltd, Melbourne, Australia).

Eligibility Criteria

Inclusion criteria consisted of (1) patients treated with TSA or RTSA, (2) description of rehabilitation protocols following TSA or RTSA, (3) comparison between home-based therapy and physical therapy provided in clinical settings, (4) studies that analyzed biomechanical and tissue physiology rehabilitation precautions and protocols, (5) publication in a peer-reviewed journal, and (6) full-text articles written in English.

Exclusion criteria consisted of (1) case reports or cadaveric studies, (2) surgical revision of TSA or RTSA, (3) patients who incurred a fracture or osteonecrosis, (4) studies that reported on management of hemiarthroplasty, (5) articles that included individuals with chronic dislocation or rheumatoid arthritis, (6) studies that did not thoroughly report rehabilitation protocols, (7) surgical technical reports, (8) articles that reported only surgical complications, (9) studies that reported only non–shoulder-related comorbidities, and (10) papers written in a language other than English.

Study Selection

Two authors (J.K. and G.B.) independently assessed studies identified by the search criteria. Titles and abstracts were initially screened. Following title and abstract screening, the 2 authors independently performed full-text review. If any conflicts arose and agreement on full-text inclusion could not be reached, a third author (G.G.)

served as arbiter for final study eligibility. Following full-text screening, a hand search was performed by 2 authors (J.K. and G.B.) for any additional manuscripts.

Data Extraction

Two authors (J.K. and G.B.) collected and recorded data in a customized database using Microsoft Excel, Version 2013 (Microsoft Corporation, Redmond, WA). Data regarding study design, sample size, age, sex, follow-up time, surgical procedure, rehabilitation timing, rehabilitation precautions, rehabilitation venue, and complications (ROM, strength, patient-reported outcomes, etc) were recorded.

TABLE 1 Inclusion and Exclusion Criteria

Key Concept	Inclusion Criteria	Exclusion Criteria
Population	• Glenohumeral joint osteoarthritis • Rotator cuff arthropathy • Rotator cuff deficiency	• Humeral fracture • Osteonecrosis • Rheumatoid arthritis • Chronic dislocation
Exposure	• Primary TSA • Primary RTSA	• TSA revision • RTSA revision • Shoulder hemiarthroplasty
Outcomes	• Thoroughly reported rehabilitation protocols • Home-based therapy versus physical therapy • Biomechanical and tissue physiology rehabilitation concepts	• In situ or cadaveric studies • Biomechanical studies • Reported only complication • Reported only outcomes

Abbreviations: RTSA, reverse total shoulder arthroplasty; TSA, total shoulder arthroplasty.

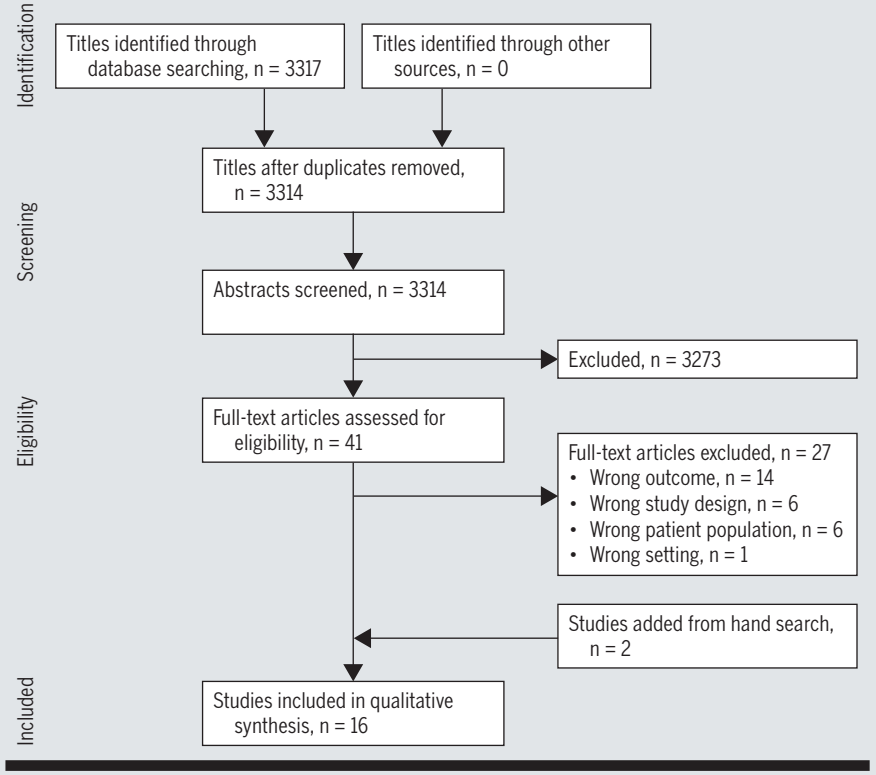

FIGURE. PRISMA flow diagram.

Risk-of-Bias Assessment

Methodological risk of bias was assessed by 2 authors (J.K. and G.B.) independently. If consensus could not be reached, a third author (G.G.) arbitrated the final decision. The Oxford Centre for Evidence-Based Medicine levels of evidence (levels I-V)[45] were utilized to ascertain study design. The methodological index for nonrandomized studies (MINORS) checklist was used as well to assess the risk of bias of the included studies.[53] On the MINORS checklist, comparative studies are rated with a maximum score of 24, whereas noncomparative studies are rated with a maximum score of 16.

The modified Downs and Black[22] tool was used to assess the risk of bias for randomized controlled studies. The modified Downs and Black[22] tool uses a scale ranging from 0 to 15, with studies scoring 12 to 15 being regarded as high quality, those scoring 10 or 11 regarded as moderate quality, and those scoring 9 or lower regarded as low quality.[43]

Statistical Analysis

Due to the heterogeneity and nonuniformity of the data in the included studies, the results are summarized in a descriptive manner.

RESULTS

Search Results

A total of 3317 references were imported for screening. After duplicates were removed (n = 3), 3314 publications underwent title and abstract screening. After 3273 publications were excluded, 41 underwent full-text review. An additional 2 papers were added through a hand search of included manuscripts. After exclusion, 16 papers were included in quality assessment and analysis (**TABLE 1**, **FIGURE**).[3,4,7-9,11,12,20,23,27,36,44,46,54,59,60]

Risk of Bias

A total of 15 publications were assessed using the MINORS tool (**TABLE 2**), with 1 rated as level III,[44] 2 rated as level IV,[4,46] and 12 rated as level V evidence.[3,7-9,11,12,23,27,36,54,59,60]

The median MINORS score for the 13 noncomparative studies was 2 of 16.[3,4,7-9,11,12,23,27,36,54,59,60] The median MINORS score for the 2 comparative studies was 14 of 24.[44,46] No studies performed a prospective collection of data or had an unbiased evaluation of end points. Three studies had an appropriate follow-up time.[4,44,46]

The single randomized controlled trial (level I)[20] scored 11 of 15 on the modified Downs and Black[22] scale (**TABLE 2**). The study did not adequately control for potential confounders.

Rehabilitation

Ten manuscripts reported on rehabilitation post TSA,[4,8,9,11,12,20,23,27,44,59] with 9 delineating rehabilitation strategies by phases of recovery (**TABLE 3**). Five papers[4,8,12,23,27] included 3 rehabilitation phases (time frame: 10+ weeks to 6 months), 4 papers[9,11,20,44] described 4 rehabilitation phases (time frame: 12+ weeks to 6 months), and 1 paper[59] reported rehabilitation for different shoulder pathologies without delineation of phases of recovery. Of 10 studies, 7 utilized a shoulder sling for a duration ranging from 3 to 8 weeks post surgery.[4,9,11,12,20,27,44] Three studies allowed resisted exercise in the first 3 weeks,[8,23,27] with 2 of 3 initiating deltoid isometrics[8,23] and 1 aquatic exercise.[27] Seven of 10 studies progressed to full shoulder ROM by week 8.[4,8,9,12,20,23,27] Only 1 study[20] did not recommend shoulder strengthening by the second rehabilitation phase, with the other 9 studies[4,8,9,11,12,23,27,44,59] including deltoid isometrics, 3 starting closed-chain exercises at 4 to 6 weeks[11,23,44] and 2 specifically beginning scapular strengthening exercises in that phase.[9,11] All 10 studies recommended full shoulder ROM and beginning shoulder strengthening by week 12,[4,8,9,11,12,20,23,27,44,59] and only 2 studies recommended specific lifelong activity modification.[20,44]

Six publications reported on rehabilitation post RTSA (**TABLE 4**).[3,7,36,46,54,60] Five publications[3,7,46,54,60] described the rehabilitation protocol post RTSA and 1 used a questionnaire to gather expert opinions.[36] One study had 4 rehabilitation phases in a time frame of 4-plus months,[7] 2 studies had 3 rehabilitation phases in a time frame of 12 to 6 months,[3,54] and 2 studies had 2 rehabilitation phases in a time frame of 6 to 12 weeks.[46,60] Four of 6 studies[7,46,54,60] required sling use after surgery, with time frames ranging from 2 to 6 weeks. Two studies[3,60] did not allow passive ROM in the first 6 weeks, while the other 4 studies did.[7,36,46,54] Three studies[7,46,54] recommended resisted exercise within the first 6 weeks post surgery, focusing on deltoid and scapular isometrics. All 6 studies[3,7,36,46,54,60] initiated shoulder passive ROM and resisted exercise by week 6. Resisted exercise consisted of deltoid and scapular strengthening[3,7,36,46,54,60] and push-ups and rows,[54] and 1 study recommended exercise when supine active shoulder flexion is well controlled.[3] All 6 studies[3,7,36,46,54,60] recommended full passive and active ROM by week 12. Two studies[7,60] prescribed lifelong activity modification of lifting no more than 6.8 kg.

TABLE 2 Descriptors of Manuscripts Included in the Review

Study	Level of Evidence (Design)	Risk of Bias*	Surgical Procedure
Blacknall and Neumann[3]	V (expert opinion)	2/16	RTSA
Boardman et al[4]	IV (case series)	7/16	TSA
Boudreau et al[7]	V (expert opinion)	2/16	RTSA
Brander et al[8]	V (expert opinion)	2/16	TSA
Brown and Friedman[9]	V (expert opinion)	2/16	TSA
Cahill et al[11]	V (expert opinion)	2/16	TSA
Cameron et al[12]	V (expert opinion)	2/16	TSA
Denard and Lädermann[20]	I (RCT)	11/15†	TSA
Etier et al[23]	V (expert opinion)	2/16	TSA
Fusaro et al[27]	V (expert opinion)	2/16	TSA
Kwaees and Charalambous[36]	V (expert opinion)	4/16	RTSA
Mulieri et al[44]	III (case-control)	16/24	TSA
Romano et al[46]	IV (case series)	12/24	RTSA
St Pierre and Frankle[54]	V (expert opinion)	2/16	RTSA
Wilcox et al[59]	V (expert opinion)	2/16	TSA
Wolff and Rosenzweig[60]	V (expert opinion)	2/16	RTSA

Abbreviations: RCT, randomized controlled trial; RTSA, reverse total shoulder arthroplasty; TSA, total shoulder arthroplasty.
**Rated using the methodological index for nonrandomized studies for noncomparative (0-16 points) and comparative (0-24 points) studies unless otherwise indicated.*
†Rated using the Downs and Black[22] scale (0-15 points).

Precautions

Seven studies[8,11,12,20,23,27,44] provided precautions for the first 6 weeks post TSA. In 5 studies,[8,11,12,23,44] shoulder flexion or scapular abduction was limited to values ranging from 90° to 130°. In all 7 studies,[8,11,12,20,23,27,44] shoulder external rotation was limited to values ranging from 15° to 30°, while in 1 study[8] shoulder internal rotation was limited to 45°. For the period of 6 to 12 weeks post surgery, only 2 studies[11,44] still required ROM precautions, with shoulder flexion or scapular abduction limited to 135° to 150° and shoulder external rotation limited to 35° to 45°. Two studies recommended lifelong precautions,[20,44] with Denard and Lädermann[20] limiting patients to lift no more than 11.3 kg with the surgical arm and Mulieri et al[44] limiting patient shoulder ROM to 55° of external rotation and 30° of extension.

For RTSA, 4 studies[3,7,46,60] provided precautions for the first 6 weeks post surgery. Of these, 3 studies[3,7,60] recommended

avoiding shoulder internal rotation, adduction, and extension, and 1 study[46] required that individuals with a subscapularis repair limit shoulder external rotation for 4 weeks and perform no active shoulder internal rotation for 8 weeks. For weeks 6 through 12 post surgery, 2 studies[7,60] required precautions, with both continuing to limit shoulder internal rotation, shoulder adduction, and extension. Past week 12, only Boudreau et al[7] stipulated precautions, prohibiting patients from lifting more than 1.4 kg. Two studies had lifelong precautions,[7,60] limiting patients to lifting no more than 6.8 kg with the surgical arm.

DISCUSSION

Rehabilitation following TSA and RTSA is important for patients to have the best possible outcomes with minimal complications.[3,7,20,32] Currently, there is significant diversity in postsurgical rehabilitation programs, specifically regarding when exercises are initiated, the amount of allowed shoulder motion, the timing and extent of resisted exercises, and short- and long-term precautions.[14,20,36,44] Current rehabilitation guidelines post TSA and RTSA are based on low-quality evidence, with only 1[20] of 16 studies being a randomized controlled trial and 12 studies being based on expert opinion.[3,7-9,11,12,23,27,36,54,59,60] Thus, there is a need for further high-quality randomized controlled trials investigating rehabilitation protocols post TSA and RTSA. Currently, even well-done case-control trials and other retrospective designs could add substantially to this area.

Anatomic TSA

Preventing stiffness during the early recovery phase, while protecting healing tissue impacted by surgery, requires a balance of rest and exercise.[32] Following TSA, regardless of the subscapularis tendon takedown procedure, the sub-

TABLE 3 Rehabilitation Guidelines Following Anatomic Total Shoulder Arthroplasty

Study	Sling	PROM	AAROM	AROM	Resisted Exercise	Precaution
Boardman et al[4]	0-6 wk	0-3 wk: shoulder stretching at home	3-5 wk: pulley exercises 5-10 wk: ER and IR at 0° and 90° of abduction	0-4 wk: elbow, wrist, and hand 10+ wk: gradual return to shoulder function	5-10 wk: shoulder isometrics 10+ wk: exercises with elastic bands	None
Brander et al[8]	0-4 wk	0-3 wk: 90° of flexion and abduction, 45° of IR, 15° of ER 4-12 wk: greater than 90° of flexion and abduction	3-4 wk: wall walking 6-12 wk: greater than 90°	0-6 wk: ADL with nonsurgical side 6-12 wk: past 90°, 2-handed ADL 12+ wk: AROM without resistance in all planes and full-ROM body-weight exercise in all planes	0-3 wk: deltoid isometrics 3-6 wk: deltoid vigorous isometrics 6-12 wk: progress to isotonics as tolerated 12+ wk: progressive resistance	None
Brown and Friedman[9]	0-4 wk	0-4 wk: ER, IR, flexion 4-6 wk: continue with ER, IR, flexion	4-6 wk: horizontal adduction, ER at 90° of abduction	4-6 wk: flexion in supine 6-10 wk: flexion and abduction in sitting	4-6 wk: shoulder isometrics, scapular and distal arm musculature 6-10 wk: ER and IR 10 wk to 6 mo: add weights to active ROM exercise, wall push-ups, functional specificity	None
Cahill et al[11]	0-6 wk	0-4 wk: 120° of flexion, 30° of ER 4-6 wk: horizontal adduction, 90° of ER	0-4 wk: pendulums 4-10 wk: ER and pulleys	0-4 wk: elbow, wrist, and hand 4-10 wk: shoulder, all planes	4-10 wk: deltoid isometrics, closed-chain exercises, scapular retraction 10-16 wk: isometrics, scapular strengthening, resistance exercises 16-22 wk: functional strength through full ROM, gym program	4-10 wk: 150° of flexion, 45° of ER
Cameron et al[12]	0-4 wk	0-6 wk: 120° of flexion, 30° of ER 6-10 wk: full ROM	0-6 wk: pendulums 6-10 wk: pendulums	0-6 wk: elbow, wrist, and hand 6-10 wk: shoulder flexion and abduction 11+ wk: full activities as tolerated	6-10 wk: ER and IR exercises with elastic bands 11+ wk: free-weight exercises	0-6 wk: protect subscapularis

Table continues on page 342.

TABLE 3 Rehabilitation Guidelines Following Anatomic Total Shoulder Arthroplasty (continued)

Study	Sling	PROM	AAROM	AROM	Resisted Exercise	Precaution
Denard and Lädermann[20] (immediate)	0-4 wk	Flexion as tolerated, 30° of ER 4-8 wk: ER as tolerated	0-4 wk: pulleys 4-8 wk: flexion	0-4 wk: elbow, wrist, and hand 4-8 wk: flexion 8-12 wk: full ROM as tolerated	8-12 wk: strength as tolerated 12+ wk: activity as tolerated	12+ wk: 11.3 kg
Denard and Lädermann[20] (delayed)	0-4 wk	0-4 wk: none 4-8 wk: flexion and ER	8-12 wk: begin AAROM	0-4 wk: elbow, wrist, and hand 8-12 wk: ROM as tolerated	8-16 wk: strength as tolerated 16+ wk: activity as tolerated	16+ wk: 11.3 kg
Etier et al[23]	0-6 wk	0-6 wk: 130° of flexion, 25° of ER 6-12 wk: movement as tolerated in all planes	0-6 wk: pendulum 6-12 wk: movement as tolerated in all planes	0-6 wk: elbow, wrist, and hand 6-12 wk: flexion 12+ wk: full ROM as tolerated	0-6 wk: deltoid isometrics 6-12 wk: closed-kinetic-chain exercises, light resistance exercises 12+ wk: isometrics and resistive exercises	None
Fusaro et al[27]	0-6 wk	0-6 wk: PROM device 6 wk to 3 mo: full ROM	0-6 wk: pendulums and pulleys 6 wk to 3 mo: full ROM	0-6 wk: elbow, wrist, and hand 6 wk to 3 mo: nonpainful ROM	0-6 wk: aquatic PT 6 wk to 3 mo: proprioception isometrics 3+ mo: return to driving and work 6+ mo: moderate sports	None
Mulieri et al[44] (PT group)	0-6 wk	0-3 wk: 20° of ER, 120° of scapular abduction, sling use except during therapy 4-6 wk: ER to 35°, sling use except during therapy 6-12 wk: 55° of ER	4-6 wk: scapular abduction to 135° with wand	0-3 wk: elbow, wrist, and hand 4-6 wk: elbow, wrist, and hand 7-9 wk: flexion, ER, extension, diagonals	4-6 wk: closed-kinetic-chain exercises; isometrics for IR, ER, extension, abduction, and depression 7-9 wk: isometrics at various angles, biceps and triceps isometrics, closed-kinetic-chain exercise 9-12 wk: elastic band and isometrics	None
Mulieri et al[44] (home group)	0-8 wk	0-8 wk: pendulum 9 wk: discontinue sling use 9+ wk: 55° of ER	None	0-8 wk: elbow, wrist, and hand	14+ wk: elastic-band exercises and isometrics	14+ wk: 55° of ER

Abbreviations: AAROM, active-assisted range of motion; ADL, activities of daily living; AROM, active range of motion; ER, external rotation; IR, internal rotation; PROM, passive range of motion; PT, physical therapy; ROM, range of motion.

scapularis repair requires the most protection.[10,13,41] Subscapularis failure after TSA can result in anterior shoulder instability, pain, weakness in internal rotation, early glenoid loosening, and lower patient-reported outcome scores.[5,10,13]

Overall, there was no consensus on subscapularis protection post surgery. Denard and Lädermann[20] published the only TSA rehabilitation randomized controlled trial, contrasting immediate rehabilitation versus rehabilitation after 4 weeks (delayed physical therapy). They found a greater subscapularis healing rate in the delayed group (96% versus 81%), which was associated with improved patient-reported outcomes and shoulder flexion ROM. Some studies[4,20] recommended utilizing pulleys for active-assisted ROM after surgery. Cadaveric studies suggest that shoulder elevation can be unrestricted following subscapularis repair.[61] However, electromyographic studies have shown that seated pulley exercises are not truly passive and, therefore, potentially place increased stress on the subscapularis.[21,28]

In contrast, there was good agreement that the amount of shoulder external rotation ROM following subscapularis takedown should be limited to prevent passive tension on the repaired tendon, and active and resisted internal rotation exercises should be limited to prevent active tension across the repair.[8,11,20] Some authors[13,29] have suggested limiting shoulder external rotation to neutral when performed with the arm along the trunk, having observed better subscapularis function with this approach. This contrasts other postoperative initial external rotation precautions of 30° to 40°, which have shown higher rates of subscapularis complications.[41] Multiple studies[4,9,27] in this review did not have external rotation ROM precautions in the first rehabilitation phase. Furthermore, 3 studies[11,23,44] initiated subscapularis isometrics and quadruped closed-kinetic-chain exercises beginning at 4 weeks. These guidelines incur increased subscapularis injury risk.[8,11,20,23,44]

TABLE 4 Rehabilitation Guidelines Post Reverse Total Shoulder Arthroplasty

Study	Sling	PROM	AROM	Resisted Exercise	Precaution
Boudreau et al[7]	0-4 wk	0-6 wk: elevation, 90°-120°; ER, 30° 6-12 wk: flexion and ER as tolerated 12-16 wk: all movements as tolerated	0-6 wk: elbow, wrist, and hand 6-12 wk: shoulder as tolerated	0-6 wk: submaximal deltoid and scapular isometrics 6-12 wk: deltoid isometrics 12-16 wk: slow strength progression for deltoid and scapula 4+ mo: stretch and strengthen with maintenance programs	0-6 wk: avoid IR, adduction, and extension 6-12 wk: no adduction, IR, or extension 12-16 wk: do not exceed 1.4 kg, enforce good mechanics for elevation 4+ mo: 6.8 kg
Blacknall and Neumann[3]*	Comfort only	None	0-6 wk: assisted elevation to 90° and ER to 30° 6-12 wk: 0°-90° of active short level-arm flexion, inclined surface; progress to straight-arm flexion 12-16 wk: ROM as tolerated	0-3 wk: deltoid isometrics 3-6 wk: vigorous isometrics 6-12 wk: progress to isotonics as tolerated 12+ wk: progressive resistance	0-6 wk: avoid ER, IR, abduction, and extension
St Pierre and Frankle[54]	0-4 wk	0-6 wk: pendulums (supports for 2 wk, then unsupported) 6-12 wk: as tolerated 12-16 wk: as tolerated; add sleeper stretch	0-6 wk: elbow, wrist, and hand table slides for supported elevation and wand-assisted elevation in supine 12-16 wk: as tolerated	4-6 wk: shoulder isometrics, scapular musculature, and distal arm 6-10 wk: ER and IR 10 wk to 6 mo: weights to active exercise, wall push-ups, functional specificity	None
Romano et al[46] (group A)†	0-2 wk	0-12 wk: as tolerated	0-6 wk: flexion to 60°-120°, ER to 20°-30° 6+ wk: as tolerated	0-6 wk: deltoid and scapular isometrics 6-12 wk: deltoid and scapular musculature using elastic band	0-6 wk: if subscapularis repaired, then no ER PROM for 4 wk and no resisted IR for 2 mo
Romano et al[46] (group C)†	0-4 wk	0-12 wk: as tolerated	0-6 wk: flexion to 60°-120°, ER to 20°-30° 6+ wk: as tolerated	0-6 wk: deltoid and scapular isometrics 4 wk: begin AROM exercises 8 wk: deltoid and scapular musculature using elastic band	0-6 wk: if subscapularis repaired, then no ER PROM for 4 wk and no resisted IR for 2 mo
Wolff and Rosenzweig[60]	2-6 wk	0-6 wk: no PROM 6+ wk: as tolerated	Not reported	6-12 wk: deltoid and scapular strength progression: isometric to isotonic	0-6 wk: avoid IR, adduction, and extension 6-12 wk: continue avoiding adduction, IR, and extension 4+ mo: 6.8 kg

Abbreviations: AROM, active range of motion; ER, external rotation; IR, internal rotation; PROM, passive range of motion; ROM, range of motion.
**Time frames do not apply; progression is strictly criterion dependent.*
†Differentiated progression into group A (cuff tear arthropathy, primary osteoarthritis cuff deficiency with pseudoparalysis), group B (all others not in A or C), and group C (rheumatoid arthritis, fracture).

Early postoperative rehabilitation precautions are critical to allowing tendon healing and preventing subscapularis failure following TSA.[13,29] There is a great need to carefully study the role of formal physical therapy following this surgical procedure, with specific attention given to the different subscapularis takedown methods and how exercise selection and progression impact subscapularis healing. Specifically, investigations need to focus on the impact of early passive external rotation and resisted internal rotation.[5,29,39] Recent research has found that immobilization following rotator cuff surgery can increase rotator cuff tendon healing,[57] while other studies recommend conservative ROM and loading following rotator cuff surgery.[14,56] There is a need to determine the best timetable and strategies to protect the subscapularis while improving shoulder ROM and function post TSA.

Reverse Total Shoulder Arthroplasty

There were 6 reports[3,7,36,46,54,60] on rehabilitation guidelines following RTSA. All these publications were written by experts, and the guidelines were based on knowledge of anatomy,[3,7,46,60] biomechanics,[7,60] and surgical procedures.[3,7,46,54,60] However, none systematically and prospectively

evaluated patient-reported and clinical outcomes and complication incidence. Additionally, the results of a survey of 30 surgeons with publications on RTSA indicated great variability in duration of use of a sling and the timing to begin shoulder motion post surgery.[36]

Reverse total shoulder arthroplasty is often recommended as an end-stage procedure to reduce pain and improve functional elevation in patients with massive rotator cuff tear, with or without arthritis.[7] Blacknall and Neumann[3] and St Pierre and Frankle[54] both stress the benefit of a prehabilitation session with a physical therapist to review expectations and practice exercises prior to surgery.[3,54] If these expectations for recovery can be clearly explained to patients prior to the operation, then outcomes may be more favorable, as patient expectation has been linked to successful outcomes following shoulder arthroplasty.[55] All of the rehabilitation progressions post RTSA emphasized protection from combined movement of shoulder extension, adduction, and internal rotation (hand-behind-the-back posture) due to risk of instability and to allow scar formation around the reverse articulation; however, each protocol differed regarding when to integrate this motion into recovery.[3,7,36,46,54,60] While some authors promote rehabilitation differentiation based on other concomitant procedures, such as rotator cuff repair or tendon transfers,[7,46,60] others do not highlight this as an important consideration.[8,38]

Previous authors[16,18] have reported that patients with or without repair of the subscapularis had no difference in complication rates or outcomes postoperatively; however, an intact subscapularis may provide improved shoulder internal rotation ROM.[18] Therefore, if repaired, consideration should be given to protecting the healing tendon. Post surgery, immediate concerns for rehabilitation include prosthesis protection from dislocation and acromial overload from deltoid tension, which can increase risk for stress reaction or stress fracture.[1,16,24]

Despite these known concerns, there was substantial disagreement between authors on proper protection time frames and progression of rehabilitation and activity. Boudreau et al[7] published rehabilitation guidelines dividing recovery into 4 phases that emphasized initial joint protection followed by gradual tissue loading. These authors[7] recommended sling use for 3 to 4 weeks following surgery, early deltoid and scapular isometric exercises, and a gradual restoration of passive ROM in the first 6 weeks of recovery. When passive ROM is restored, active-assisted and then active ROM progression, as described by Jackins,[33] is recommended to provide gradual deltoid load to the acromion. Similarly, Romano et al[46] employed sling use for 2 to 4 weeks, with immediate deltoid and scapular isometrics. In contrast, Blacknall and Neumann[3] proposed a less restrictive criterion-based rehabilitation progression. These authors[3] did not promote use of a sling and allowed rehabilitation progression based on demonstration of good deltoid and pain control and no instability signs.

A final rehabilitation method proposed by St Pierre and Frankle[54] promoted surgeon-directed rehabilitation for patients with exercises performed at home using web-based videos. A sling was worn for 4 weeks, during which time deltoid and scapular isometrics were performed. Supported elevation was allowed without motion limitation at 3 weeks, and strengthening with elastic-band exercises and shoulder extension ensued at 5 to 7 weeks. Pain was used as the main criterion to advance exercise, and a unique feature of this rehabilitation plan was the integration of core stability exercises. Referral for formal physical therapy was reserved for patients who were not progressing well, or who had higher-level rehabilitation goals.[54] Other authors[60] suggested a more conservative approach, promoting 2 to 6 weeks of full immobilization, depending on patient factors, deferral of deltoid and scapular strengthening for 6 weeks, and formal rehabilitation continuing for 4 to 6 months. Even with reported stress fracture and deltoid overload risk,[1,16,24] healing and protective time frames did not have expert agreement.[3,7,36,46,54,60]

Limitations

This systematic review limited the search to articles with full text published in the English language, which might have resulted in a loss of literature and a potential bias. The body of evidence was primarily based on level V evidence, which had low methodological quality. The MINORS tool is specifically designed for nonrandomized observational studies.[53] Therefore, with most studies being clinical commentaries or expert opinions, there is an inherent bias in this study's quality assessment.

CONCLUSION

Currently, there is low consensus among published rehabilitation guidelines post TSA and RTSA, precluding specific clinical best practice suggestions. The only consensus is that therapy is believed to play an important role in optimizing patient outcomes, and that there is a need for high-quality prospective research.[3,20,54,60] Objective scientifically based information is essential in determining best practice to optimize outcomes for patients post TSA or RTSA. ◉

KEY POINTS

FINDINGS: Most published rehabilitation guidelines post total shoulder arthroplasty and reverse total shoulder arthroplasty are clinical commentaries, with little consensus on timelines for initiation and progression of exercises.

IMPLICATIONS: There is a need for prospective randomized controlled trials comparing rehabilitation methodologies after total shoulder arthroplasty and reverse total shoulder arthroplasty to determine best practice.

CAUTION: Due to heterogeneous findings and paucity of substantial data, the evidence was not sufficient to create spe-

cific clinical best-practice suggestions regarding total shoulder arthroplasty and reverse total shoulder arthroplasty rehabilitation.

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APPENDIX

SEARCH STRATEGY

(((((((“Shoulder Joint”[Mesh] OR “Shoulder”[Mesh] OR shoulder[tiab])) AND (“Arthroplasty, Replacement”[mesh] OR arthroplasty[tiab] OR arthroplastic[tiab] OR “total joint”[tiab] OR “replacement”[tiab] OR Periprosthetic[tiab] OR “peri-implant”[tiab] OR “Shoulder Prosthesis”[Mesh] OR “Arthroplasty, Replacement, Shoulder”[Mesh] OR hemiarthroplasty[tiab] OR prosthesis[tiab] OR prosthetic[tiab] OR endoprosthe*[tiab] OR implant[tiab] OR implants[tiab])) AND (Physical Therapy Modalities[MeSH] OR “physical therapy” [tiab] OR “physical therapies” [tiab] OR Physiotherapy[tiab] OR physiotherapies[tiab] OR Exercise[MeSH] OR Exercise[tiab] OR Exercises[tiab] OR “Exercise Therapy”[tiab] OR “Resistance Training” [tiab] OR Rehabilitation[MeSH] OR Rehabilitation[subheading] OR Rehabilitation[tiab] OR Rehabilitate[tiab] OR Rehabilitating[tiab] OR Rehabilitates[tiab] OR Rehabilitated[tiab] OR “therapy”[Subheading])) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR randomization[tiab] OR randomisation[tiab] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR Clinical trial[pt] OR “clinical trial”[tiab] OR “clinical trials”[tiab] OR “evaluation studies”[Publication Type] OR “evaluation studies as topic”[MeSH Terms] OR “evaluation study”[tiab] OR evaluation studies[tiab] OR “intervention studies” [tiab] OR “intervention study”[tiab] OR “intervention studies”[tiab] OR “case-control studies”[MeSH Terms] OR “case-control”[tiab] OR “cohort studies”[MeSH Terms] OR cohort[tiab] OR “longitudinal studies”[MeSH Terms] OR “longitudinal”[tiab] OR longitudinally[tiab] OR “prospective”[tiab] OR prospectively[tiab] OR “retrospective studies”[MeSH Terms] OR “retrospective”[tiab] OR “follow up”[tiab] OR “comparative study”[Publication Type] OR “comparative study”[tiab] OR systematic[subset] OR “meta-analysis”[Publication Type] OR “meta-analysis as topic”[MeSH Terms] OR “meta-analysis”[tiab] OR “meta-analyses”[tiab]))) NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR case report[tiab] OR Comment[ptyp])) AND English[lang]) NOT (animals[mesh terms] NOT humans[mesh terms])

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Rotator Cuff–Related Shoulder Pain: To Inject or Not to Inject?

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The shoulder is the third most common site of musculoskeletal pain, and each year approximately 1% of adults over the age of 45 years present to their primary care provider with a new episode of shoulder pain.[4,9] The most common source of shoulder pain is thought to involve the tendons of the rotator cuff and associated structures around the subacromial space.[30,59] Clinically, the ability to accurately differentiate between the rotator cuff tendons and other related tissues is limited.[22,26] As with other musculoskeletal conditions of no specific structural cause, a more generic diagnostic term has been suggested, *rotator cuff–related shoulder pain* (RCRSP),[34] which is an overarching clinical term that includes a number of conditions, such as subacromial impingement syndrome,[42] subacromial pain syndrome,[13] and rotator cuff tendinopathy.[35,36]

The management of RCRSP may include exercise, surgery,[40] or injection therapy (commonly involving corticosteroids).[59] Up to 96% of musculoskeletal clinicians consider subacromial corticosteroid injection an efficacious treatment for RCRSP.[29] Approximately 22% of those who report shoulder pain to their general practitioner receive an injection during the initial consultation.[59] Furthermore, it has been suggested that diagnostic injections have a potential role in helping diagnosis by way of determining whether symptoms arise from a specific structure.[8] A wide range of health professionals across various disciplines, including physical therapists, perform injections in the management of musculoskeletal conditions. Those who perform or recommend injection therapy for RCRSP have a duty of care to provide advice on the expected benefits and outcomes, as well as the potential risks and associated harms. Clinicians also need to consider what medication to inject, where to inject it, and how to inject it. The aim of this Viewpoint is to discuss these issues.

What to Inject?

Corticosteroid and Local Anesthetic Injections Corticosteroid medications (alone and in combination with local anesthetic) have been used in the management of various musculoskeletal disorders for the last 60 years and are the most common form of drug used for injection therapy.[52] A recently published meta-analysis assessed short-term outcomes and concluded that corticosteroid injections provide, at best, minimal pain relief in a small number of patients with RCRSP, with a number needed to treat of 5.[38] These findings are consistent with those of previous reviews suggesting that the benefits of corticosteroid injections for RCRSP are inconsistent[14] and short lasting (up to 8 weeks).[2,7,12,14,20] Furthermore, there is equivocal evidence for the use of corticosteroid injections for RCRSP in the medium term and long term.[2,7,12,14,20] This is due, in part, to a limited number of well-designed studies assessing outcomes at medium- and long-term follow-up.[12]

There are also concerns about the safety of corticosteroid injections. Although adverse events are rare,[6,14] there is evidence of corticosteroid injections having potentially negative effects on rotator cuff tissue.[15,16,43,44] One prospective study[44] reported a 17% incidence of full-thickness

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rotator cuff tears at 12-week follow-up in patients who received a corticosteroid injection. Because this study did not include a group that did not receive an injection, it could not identify a causal relationship between the injury and the injection. In addition, the findings of this study were not replicated in a similar case-control study.[4] Despite concerns, there is no definitive consensus on the possible negative effects of corticosteroid injection therapy on rotator cuff tissue.

Local Anesthetic Injections Alone In light of the potentially deleterious effects of corticosteroids on tendon tissue, it has been suggested that local anesthetic injections alone (albeit not without risk) may be a safer alternative.[12,34] Local anesthetics such as lidocaine and bupivacaine may have a therapeutic effect by reducing tenocyte numbers[9,53] and altering collagen organization in tendons.[28] Increased cellularity has been associated with tendinopathy,[54] and, if elevated, reducing tenocyte numbers may be a possible mechanism by which local anesthetic injections contribute to the restoration of tendon homeostasis.

To date, there have been no randomized controlled trials comparing local anesthetic injections with an established sham injection in the treatment of RCRSP. There is evidence that local anesthetic injections have less favorable outcomes in comparison to corticosteroid injections (in combination or alone) in the short term.[12] However, there is no evidence to suggest that local anesthetic injections are any less or more effective than corticosteroids (in combination or alone) in the mid to long term.[12]

Sodium Chloride (Saline) Injections There is a paucity of research comparing saline to other forms of injection for the treatment of RCRSP.[12] It appears that only 2 previous studies have been conducted that compare corticosteroid with saline-only injections.[47,61] Neither study reported a significant difference in pain outcomes between groups in the short term. Due to methodological limitations, both of these studies appear to have a high risk of bias, and conclusions must be interpreted with caution. There is clearly a need for future high-quality research to establish whether saline injections are an efficacious treatment option in the management of RCRSP.

Platelet-Rich Plasma Injections There are conflicting opinions regarding the use of platelet-rich plasma for various musculoskeletal pathologies.[17,19] A recent systematic review[37] identified 3 studies that met inclusion criteria for RCRSP.[32,46,56] All 3 studies included small sample sizes and were thus underpowered, meaning the researchers were unable to detect clinically meaningful effects.[37] The reviewers concluded that for the treatment of RCRSP, platelet-rich plasma injections demonstrate negligible to small mean effect sizes across the 3 included studies (0.32).[37] This finding is not surprising, as it is documented that pain is often poorly correlated with tissue pathology.[21,48] The decision to use a treatment designed specifically to target tissue healing, such as platelet-rich plasma, may be based on flawed reasoning. In summary, there is a lack of evidence to make any clear suggestions of any benefit of platelet-rich plasma for the treatment of RCRSP.

Prolotherapy Prolotherapy involves injecting specific concentrations of hypertonic dextrose solution around pathological tissue in an attempt to encourage collagen synthesis and tissue healing. Although prolotherapy is used by some clinicians in the management of RCRSP, the exact mechanism of supposed therapeutic action has not been clearly identified.[55] One recent randomized clinical trial, in which patients and evaluators were blinded to treatment selection, reported favorable outcomes for prolotherapy compared to saline injections at 9-month follow-up.[3] Interestingly, this benefit could not be attributed to the treatment's proposed regenerative effects on tendinopathic tissue. Further research suggests favorable outcomes when compared with nonsurgical management[33] and exercise[55] at 1-year follow-up. The conclusions of these latter 2 studies need to be considered cautiously, as neither study included a sham control group, and thus favorable results may be attributed to contextual (placebo) effects. It is clear that further high-quality research comparing prolotherapy with other types of injection therapy is needed, as well as a better understanding of its mechanisms of action.

Where to Inject?

Research investigating the importance of the location of the injection has solely focused on corticosteroid injections. It is established that intratendon corticosteroid injection may lead to significant structural disorganization and even necrosis of tendon tissue.[25,31,60] Evidence suggests superior outcomes for subacromial corticosteroid injection over a combined approach of subacromial and intratendon injections.[27] Therefore, the preferred location of injection for RCRSP is into the subacromial-subdeltoid bursa or subacromial space.[39]

Studies investigating the systemic effects of corticosteroid injections have suggested no significant difference in outcomes for RCRSP between subacromial and intramuscular (buttock) injections. Both injection locations provided significantly better outcomes compared to an intramuscular saline injection designed as a placebo.[58] A more recent study compared a treatment group that received both subacromial corticosteroid and intramuscular (buttock) local anesthetic injections, with a control group that received subacromial local anesthetic and intramuscular corticosteroid injections. The study reported no significant difference between local and systemic corticosteroid injections.[18] This conclusion needs to be considered cautiously, as the benefits reported in this study's[18] control group may be a result of the possible aforementioned effects of the subacromial local anesthetic injection. Future research is needed to explore this area.

How to Inject?

Historically, musculoskeletal injection therapy has relied on clinical knowledge

of specific anatomical landmarks to guide needle placement. Researchers have previously attributed poor outcomes of injection therapy to inaccurate needle placement, assuming that an accurate needle placement should improve clinical outcomes.[27,50] Evidence is contradictory as to the accuracy of landmark-guided injections into the subacromial space, with a previous systematic review and meta-analysis suggesting that landmark- and ultrasound-guided injections are equally accurate.[1] In contrast, other evidence suggests accuracy ranging between 30% and 80% for landmark-guided injections.[24] Despite this uncertainty, the use of musculoskeletal ultrasound to guide needle placement continues to gain popularity.[18,23,41]

To date, 5 systematic reviews have compared the efficacy of landmark- and ultrasound-guided injections for the treatment of RCRSP. Despite the inclusion of the same trials within several reviews, conclusions are somewhat contradictory.[1,5,51,57,62] The lack of consensus within the literature has led to a degree of confusion as to the role of ultrasound to guide injections. However, researchers are in agreement that there is a paucity of well-designed studies comparing these injection methods. In general, studies mostly assess short-term outcomes in smaller samples, and are often nonrandomized and therefore subject to selection bias. Furthermore, studies are at risk of performance bias, as participants have often not been blinded to their treatment group. This raises the question of whether any observed advantages of ultrasound-guided injections are related to contextual effects, perhaps highlighting the clinical importance of the "treatment act" as opposed to the treatment itself. For these reasons, conclusions from this body of research should be interpreted with caution.

Future Research

Recent advances in the understanding of tendon-related disorders like RCRSP have focused on the assessment and treatment of load capacity.[10] Critics of injection therapy may argue that it seems contradictory to treat a condition that is defined by a lack of tolerance to load (capacity) with a treatment that is known to cause structural changes that may reduce tissue capacity. Perhaps it is of no surprise that the role of injectable substances such as corticosteroid (known both for potent anti-inflammatory and potentially deleterious structural effects) and their mechanism of action remain uncertain. Our understanding of what causes tendon-related conditions to be associated with the experience of pain is still limited,[48] as is our understanding of the relationship between tendon pain and structure.[21,48] Furthermore, the importance and role of inflammation in tendon pain are still debated,[11,45] and these are all areas of much-needed future research.

In relation to injection therapy research, future studies should aim to reduce performance bias by including validated sham control groups, thus ensuring sufficient participant blinding. To evaluate the success of blinding, researchers should ask participants whether they believe they received the active treatment. There must also be transparency within the reporting of participants' perceptions of the different treatment options and whether these perceptions affected their outcomes. Once these factors have been controlled for, the various injection types and techniques can be more accurately compared. As with other fields of musculoskeletal medicine, comparisons should also be made with other conventional treatment options, for example, the "wait and see" approach or exercise therapy. Long-term follow-up should be used, and researchers should assess baseline and follow-up psychosocial and pain-related measurements to identify patient characteristics that may help predict outcome.

The conclusions of this Viewpoint are in agreement with a recent systematic review that compared treatments for multiple musculoskeletal pain presentations that may be treated with pharmacological injections.[2] This Viewpoint argues that current evidence is equivocal with respect to the optimal procedure, frequency, dose, and active component of the injection, and that injections may be no more effective than nonpharmacological interventions such as exercise.[2] The continued use of injection therapy in the treatment of RCRSP has been attributed by some to force of habit and an underappreciation of the placebo effect.[38] Furthermore, its cost-effectiveness has also been questioned.[12] Currently, clinicians and those considering undergoing a shoulder injection for RCRSP should remain cautious due to the poor quality of research evidence.

Key Points

- As a result of a paucity of high-quality research in this area, it is not possible to make strong recommendations regarding the type, location, and technique of injection therapy in the management of RCRSP.
- There is no clear consensus on the possible negative effects of corticosteroid injections on rotator cuff tissue.
- When compared to local anesthetic injections alone, corticosteroid injections may provide mild short-term pain relief for some patients with RCRSP. There is no evidence to suggest a difference between injection types in the mid to long term. ◉

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Rotator Cuff–Related Shoulder Pain: To Inject or Not to Inject?

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The shoulder is the third most common site of musculoskeletal pain, and each year approximately 1% of adults over the age of 45 years present to their primary care provider with a new episode of shoulder pain.[4,9] The most common source of shoulder pain is thought to involve the tendons of the rotator cuff and associated structures around the subacromial space.[30,59] Clinically, the ability to accurately differentiate between the rotator cuff tendons and other related tissues is limited.[22,26] As with other musculoskeletal conditions of no specific structural cause, a more generic diagnostic term has been suggested, *rotator cuff–related shoulder pain* (RCRSP),[34] which is an overarching clinical term that includes a number of conditions, such as subacromial impingement syndrome,[42] subacromial pain syndrome,[13] and rotator cuff tendinopathy.[35,36]

The management of RCRSP may include exercise, surgery,[40] or injection therapy (commonly involving corticosteroids).[59] Up to 96% of musculoskeletal clinicians consider subacromial corticosteroid injection an efficacious treatment for RCRSP.[29] Approximately 22% of those who report shoulder pain to their general practitioner receive an injection during the initial consultation.[59] Furthermore, it has been suggested that diagnostic injections have a potential role in helping diagnosis by way of determining whether symptoms arise from a specific structure.[8] A wide range of health professionals across various disciplines, including physical therapists, perform injections in the management of musculoskeletal conditions. Those who perform or recommend injection therapy for RCRSP have a duty of care to provide advice on the expected benefits and outcomes, as well as the potential risks and associated harms. Clinicians also need to consider what medication to inject, where to inject it, and how to inject it. The aim of this Viewpoint is to discuss these issues.

What to Inject?

Corticosteroid and Local Anesthetic Injections Corticosteroid medications (alone and in combination with local anesthetic) have been used in the management of various musculoskeletal disorders for the last 60 years and are the most common form of drug used for injection therapy.[52] A recently published meta-analysis assessed short-term outcomes and concluded that corticosteroid injections provide, at best, minimal pain relief in a small number of patients with RCRSP, with a number needed to treat of 5.[38] These findings are consistent with those of previous reviews suggesting that the benefits of corticosteroid injections for RCRSP are inconsistent[14] and short lasting (up to 8 weeks).[2,7,12,14,20] Furthermore, there is equivocal evidence for the use of corticosteroid injections for RCRSP in the medium term and long term.[2,7,12,14,20] This is due, in part, to a limited number of well-designed studies assessing outcomes at medium- and long-term follow-up.[12]

There are also concerns about the safety of corticosteroid injections. Although adverse events are rare,[6,14] there is evidence of corticosteroid injections having potentially negative effects on rotator cuff tissue.[15,16,43,44] One prospective study[44] reported a 17% incidence of full-thickness

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rotator cuff tears at 12-week follow-up in patients who received a corticosteroid injection. Because this study did not include a group that did not receive an injection, it could not identify a causal relationship between the injury and the injection. In addition, the findings of this study were not replicated in a similar case-control study.[4] Despite concerns, there is no definitive consensus on the possible negative effects of corticosteroid injection therapy on rotator cuff tissue.

Local Anesthetic Injections Alone In light of the potentially deleterious effects of corticosteroids on tendon tissue, it has been suggested that local anesthetic injections alone (albeit not without risk) may be a safer alternative.[12,34] Local anesthetics such as lidocaine and bupivacaine may have a therapeutic effect by reducing tenocyte numbers[9,53] and altering collagen organization in tendons.[28] Increased cellularity has been associated with tendinopathy,[54] and, if elevated, reducing tenocyte numbers may be a possible mechanism by which local anesthetic injections contribute to the restoration of tendon homeostasis.

To date, there have been no randomized controlled trials comparing local anesthetic injections with an established sham injection in the treatment of RCRSP. There is evidence that local anesthetic injections have less favorable outcomes in comparison to corticosteroid injections (in combination or alone) in the short term.[12] However, there is no evidence to suggest that local anesthetic injections are any less or more effective than corticosteroids (in combination or alone) in the mid to long term.[12]

Sodium Chloride (Saline) Injections There is a paucity of research comparing saline to other forms of injection for the treatment of RCRSP.[12] It appears that only 2 previous studies have been conducted that compare corticosteroid with saline-only injections.[47,61] Neither study reported a significant difference in pain outcomes between groups in the short term. Due to methodological limitations, both of these studies appear to have a high risk of bias, and conclusions must be interpreted with caution. There is clearly a need for future high-quality research to establish whether saline injections are an efficacious treatment option in the management of RCRSP.

Platelet-Rich Plasma Injections There are conflicting opinions regarding the use of platelet-rich plasma for various musculoskeletal pathologies.[17,19] A recent systematic review[37] identified 3 studies that met inclusion criteria for RCRSP.[32,46,56] All 3 studies included small sample sizes and were thus underpowered, meaning the researchers were unable to detect clinically meaningful effects.[37] The reviewers concluded that for the treatment of RCRSP, platelet-rich plasma injections demonstrate negligible to small mean effect sizes across the 3 included studies (0.32).[37] This finding is not surprising, as it is documented that pain is often poorly correlated with tissue pathology.[21,48] The decision to use a treatment designed specifically to target tissue healing, such as platelet-rich plasma, may be based on flawed reasoning. In summary, there is a lack of evidence to make any clear suggestions of any benefit of platelet-rich plasma for the treatment of RCRSP.

Prolotherapy Prolotherapy involves injecting specific concentrations of hypertonic dextrose solution around pathological tissue in an attempt to encourage collagen synthesis and tissue healing. Although prolotherapy is used by some clinicians in the management of RCRSP, the exact mechanism of supposed therapeutic action has not been clearly identified.[55] One recent randomized clinical trial, in which patients and evaluators were blinded to treatment selection, reported favorable outcomes for prolotherapy compared to saline injections at 9-month follow-up.[3] Interestingly, this benefit could not be attributed to the treatment's proposed regenerative effects on tendinopathic tissue. Further research suggests favorable outcomes when compared with nonsurgical management[33] and exercise[55] at 1-year follow-up. The conclusions of these latter 2 studies need to be considered cautiously, as neither study included a sham control group, and thus favorable results may be attributed to contextual (placebo) effects. It is clear that further high-quality research comparing prolotherapy with other types of injection therapy is needed, as well as a better understanding of its mechanisms of action.

Where to Inject?

Research investigating the importance of the location of the injection has solely focused on corticosteroid injections. It is established that intratendon corticosteroid injection may lead to significant structural disorganization and even necrosis of tendon tissue.[25,31,60] Evidence suggests superior outcomes for subacromial corticosteroid injection over a combined approach of subacromial and intratendon injections.[27] Therefore, the preferred location of injection for RCRSP is into the subacromial-subdeltoid bursa or subacromial space.[39]

Studies investigating the systemic effects of corticosteroid injections have suggested no significant difference in outcomes for RCRSP between subacromial and intramuscular (buttock) injections. Both injection locations provided significantly better outcomes compared to an intramuscular saline injection designed as a placebo.[58] A more recent study compared a treatment group that received both subacromial corticosteroid and intramuscular (buttock) local anesthetic injections, with a control group that received subacromial local anesthetic and intramuscular corticosteroid injections. The study reported no significant difference between local and systemic corticosteroid injections.[18] This conclusion needs to be considered cautiously, as the benefits reported in this study's[18] control group may be a result of the possible aforementioned effects of the subacromial local anesthetic injection. Future research is needed to explore this area.

How to Inject?

Historically, musculoskeletal injection therapy has relied on clinical knowledge

of specific anatomical landmarks to guide needle placement. Researchers have previously attributed poor outcomes of injection therapy to inaccurate needle placement, assuming that an accurate needle placement should improve clinical outcomes.[27,50] Evidence is contradictory as to the accuracy of landmark-guided injections into the subacromial space, with a previous systematic review and meta-analysis suggesting that landmark- and ultrasound-guided injections are equally accurate.[1] In contrast, other evidence suggests accuracy ranging between 30% and 80% for landmark-guided injections.[24] Despite this uncertainty, the use of musculoskeletal ultrasound to guide needle placement continues to gain popularity.[18,23,41]

To date, 5 systematic reviews have compared the efficacy of landmark- and ultrasound-guided injections for the treatment of RCRSP. Despite the inclusion of the same trials within several reviews, conclusions are somewhat contradictory.[1,5,51,57,62] The lack of consensus within the literature has led to a degree of confusion as to the role of ultrasound to guide injections. However, researchers are in agreement that there is a paucity of well-designed studies comparing these injection methods. In general, studies mostly assess short-term outcomes in smaller samples, and are often nonrandomized and therefore subject to selection bias. Furthermore, studies are at risk of performance bias, as participants have often not been blinded to their treatment group. This raises the question of whether any observed advantages of ultrasound-guided injections are related to contextual effects, perhaps highlighting the clinical importance of the "treatment act" as opposed to the treatment itself. For these reasons, conclusions from this body of research should be interpreted with caution.

Future Research

Recent advances in the understanding of tendon-related disorders like RCRSP have focused on the assessment and treatment of load capacity.[10] Critics of injection therapy may argue that it seems contradictory to treat a condition that is defined by a lack of tolerance to load (capacity) with a treatment that is known to cause structural changes that may reduce tissue capacity. Perhaps it is of no surprise that the role of injectable substances such as corticosteroid (known both for potent anti-inflammatory and potentially deleterious structural effects) and their mechanism of action remain uncertain. Our understanding of what causes tendon-related conditions to be associated with the experience of pain is still limited,[48] as is our understanding of the relationship between tendon pain and structure.[21,48] Furthermore, the importance and role of inflammation in tendon pain are still debated,[11,45] and these are all areas of much-needed future research.

In relation to injection therapy research, future studies should aim to reduce performance bias by including validated sham control groups, thus ensuring sufficient participant blinding. To evaluate the success of blinding, researchers should ask participants whether they believe they received the active treatment. There must also be transparency within the reporting of participants' perceptions of the different treatment options and whether these perceptions affected their outcomes. Once these factors have been controlled for, the various injection types and techniques can be more accurately compared. As with other fields of musculoskeletal medicine, comparisons should also be made with other conventional treatment options, for example, the "wait and see" approach or exercise therapy. Long-term follow-up should be used, and researchers should assess baseline and follow-up psychosocial and pain-related measurements to identify patient characteristics that may help predict outcome.

The conclusions of this Viewpoint are in agreement with a recent systematic review that compared treatments for multiple musculoskeletal pain presentations that may be treated with pharmacological injections.[2] This Viewpoint argues that current evidence is equivocal with respect to the optimal procedure, frequency, dose, and active component of the injection, and that injections may be no more effective than nonpharmacological interventions such as exercise.[2] The continued use of injection therapy in the treatment of RCRSP has been attributed by some to force of habit and an underappreciation of the placebo effect.[38] Furthermore, its cost-effectiveness has also been questioned.[12] Currently, clinicians and those considering undergoing a shoulder injection for RCRSP should remain cautious due to the poor quality of research evidence.

Key Points

- As a result of a paucity of high-quality research in this area, it is not possible to make strong recommendations regarding the type, location, and technique of injection therapy in the management of RCRSP.
- There is no clear consensus on the possible negative effects of corticosteroid injections on rotator cuff tissue.
- When compared to local anesthetic injections alone, corticosteroid injections may provide mild short-term pain relief for some patients with RCRSP. There is no evidence to suggest a difference between injection types in the mid to long term. ◉

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Cervical Muscular Endurance Performance in Women With and Without Migraine

An increasing number of studies have reported that individuals with migraine are more likely to present with neck pain[2,4,5,8,16,24-26,36] and cervical dysfunction.[10-12,30] The coexistence of migraine and neck pain is also associated with a greater frequency of migraine attacks,[10,13] a greater susceptibility to chronification,[24,38] and more severe self-reported migraine-related disability.[13] Accordingly, the primary role of physical therapists in the management of migraine may be to recognize, treat, and prevent potential disorders of the musculoskeletal system that may be associated with these patients' headaches.[14]

Strength, endurance, and coordination deficits of the neck musculature are expected findings in patients with neck pain and headache.[3] Although this applies directly to individuals with cervicogenic headache, these deficits may also be present in patients with migraine. A number of studies have reported weakness and altered coordination of the neck musculature in individuals with migraine,[9,11,12,30,32] yet only 2 studies, to our knowledge, have investigated neck flexor endurance.[31,40] Oksanen et al[31] reported no differences in neck flexion holding time between adolescents with migraine and healthy adolescents. This finding seems consistent with the results from Wanderley et al,[40] who reported no increased fatigability of the sternocleidomastoid in adults when compared to healthy controls when performing a 20-second neck flexion isometric contraction.

However, no study has reported on neck muscle endurance in women with migraine, which represents the most prevalent sex and age group affected by migraine.[1] Moreover, there is a lack of information regarding endurance of the neck extensors, the only muscle group with reported weakness in patients with migraine.[11] Therefore, the aim of this study was to compare the endurance of the neck flexors and extensors between women with and without migraine. We hypothesized that women with migraine would present with lower endurance. As a secondary and exploratory objective, we sought to determine the potential influence of neck pain on the tests used in this study; thus, muscle endurance results

BACKGROUND: Despite previous evidence, the association between migraines and cervical muscular performance is unclear.

OBJECTIVE: To compare the differences in neck flexor and extensor muscle endurance between women with and without migraine.

METHODS: In this cross-sectional, controlled laboratory study, 26 women with migraine and 26 age-matched women without migraine or headache were assessed using clinical tests of neck flexor and extensor muscle endurance. Holding times were compared between groups using the Mann-Whitney *U* test for independent samples.

RESULTS: Patients with migraine exhibited a lower holding time for both neck extensor endurance ($P = .001$) and neck flexor endurance ($P<.001$) than did the controls. The median neck flexor holding time was 35.0 seconds for the migraine group and 60.5 seconds for the control group. The migraine group held the neck extensor endurance test position for a median of 166.5 seconds compared to 290.5 seconds held by the control group. Both groups reported a similar level of neck pain during the endurance tests ($P>.05$); however, only individuals in the migraine group reported pain referred to the head during testing.

CONCLUSION: Women with migraine demonstrated decreased neck flexor and extensor endurance compared to women without migraine, which may indicate an association between migraine and reduced performance of the neck muscles.
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KEY WORDS: *cervical spine, headache, migraine disorders, neck*

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are described using stratification by both self-reported history of neck pain and neck pain during these tests.

METHODS

Participants

Women between 18 and 55 years of age with a history of migraine were recruited from the headache clinic at a university-based hospital from September 2016 to February 2018. The inclusion criteria were (1) a diagnosis of migraine by a neurologist with 13 years of experience in headaches, (2) diagnosis made according to the beta version of the third edition of the *International Classification of Headache Disorders*,[20] and (3) a frequency of at least 3 migraine attacks per month for the past 3 months. Age-matched (within 5 years) women with no history of headache, were recruited from the local community and by social media advertisements to participate in the control group.

The exclusion criteria for all participants were (1) other primary or secondary headache diagnoses, (2) a history of overuse of headache medication, according to *International Classification of Headache Disorders* recommendations,[20] (3) a history of head and/or neck trauma, (4) current pregnancy, (5) history of cancer, (6) the use of an anesthetic block within the past 3 months, (7) a history of cervical disc herniation, and (8) spinal articular degenerative disease, as confirmed by the medical records from the hospital and/or by the participant's report. All participants gave written informed consent, according to the Ethics Committee of the Ribeirão Preto Medical School (process number 1100/2017), and their rights were protected.

The sample-size estimation was based on data from a pilot study with 15 female participants in each group. Using data for the neck extensors, 26 participants in each group were required, based on the following parameters: effect size of 0.71, derived from the mean ± SD holding times of 313.5 ± 124.2 seconds for controls and 221.6 ± 135.4 seconds for the migraine group; a power of 80%; and a level of significance of .05. Sample calculations were performed using G*Power Version 3.1.9.2 (Heinrich-Heine Universität, Düsseldorf, Germany).

Procedures

Participants' demographics included data on age, weight, and height. They were asked to report the characteristics of their migraines, such as their frequency (number of days with migraine per month), years suffering from migraine, and the intensity of migraines on an 11-point numeric pain-rating scale.[22] The same questions were asked regarding the characteristics of neck pain.

Muscle endurance tests for the neck flexors and extensors were performed by an examiner blinded to the participant's group allocation. Testing was performed consistent with the protocol proposed by Edmondston et al.[6,7] Reported intrarater reliability for testing of the neck flexors and extensors varied from 0.71 to 0.93 and from 0.73 to 0.85, respectively.[7,28] Tests were only performed once to prevent pain exacerbation. The holding time for each test was measured in seconds using a manual stopwatch.

The neck extensor endurance test was performed with participants in a prone position, with their head over the removable support of the plinth and their arms alongside their body. Nonelastic straps at the level of the sixth thoracic vertebra and posterior superior iliac spines were used to stabilize the participant's trunk. A separate strap was used around the participant's head to suspend a 2-kg weight approximately 30 cm above the floor (**FIGURE 1**). The participant's head was positioned in a neutral horizontal plane, with a gentle chin tuck, and the test was started when the examiner removed the support from the participant's head. The participants were instructed to keep their head in the same position, with eyes looking at the floor. The test was concluded when (1) the participant was no longer able to sustain the head position, (2) the head/neck position changed more than 5° for more than 3 seconds, as registered by the CROM device (Performance

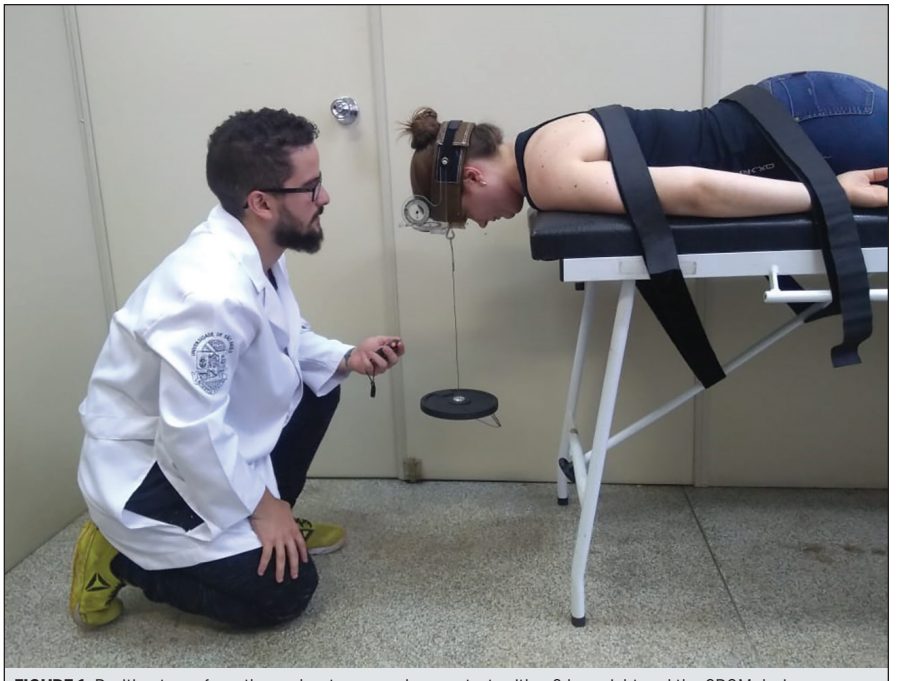

FIGURE 1. Position to perform the neck extensor endurance test, with a 2-kg weight and the CROM device (Performance Attainment Associates) to monitor head displacement.

Attainment Associates, Lindstrom, MN), or (3) the participant decided to terminate the test due to neck pain or fatigue. The examiner provided verbal encouragement, such as "Try to maintain your head position" or "Keep up this position," throughout the test.[6,7]

The neck flexor endurance test was performed with participants in a hook-lying position. Nonelastic straps were positioned at the sternum and the anterior superior iliac spines to stabilize the participant's trunk. The examiner placed his hand behind the occiput and instructed the participant to perform craniocervical neck flexion, followed by a gentle lift of the head off the plinth (**FIGURE 2**). The desired position to start the test was a combination of slight head and neck flexion, so as to test both superficial and deep neck flexors, and a distance between the participant's head and the examiner's hand of about 3 cm. Verbal instructions, such as "Tuck your chin in," "Hold your head up," or "Try to keep this position," were given to encourage the participant to maintain the test position. The test was concluded when (1) the participant was unable to maintain the unsupported head position, or (2) the participant decided to terminate the test due to neck pain or fatigue.[6,7]

FIGURE 2. Position to perform the neck flexor endurance test, with the patient in a hook-lying position while performing a combination of upper and lower cervical spine flexion.

Statistical Analysis

Statistical analyses were performed using SPSS Statistics Version 20 (IBM Corporation, Armonk, NY), with the significance level set at $P<.05$. Descriptive statistics were used to characterize the sample and to summarize the results. Data that were normally distributed were presented as mean, SD, and 95% confidence interval. Data without normal distribution were descriptively presented as median and interquartile range. The distribution of dependent variables was verified by histograms and by comparison between residual and theoretical quartiles of a standard normal distribution, and confirmed by the Shapiro-Wilk test.

Demographics were compared between groups using the Student t test for independent samples. The proportional distributions of self-reported neck pain and neck pain during the test between groups were compared using the chi-square test or Fisher exact test. However, as no normal distribution could be confirmed for them, holding times for both endurance tests were compared between groups using the Mann-Whitney U test.

To determine the potential influence of neck pain on holding time for both tests, the migraine and control groups were stratified by self-reported history of neck pain (the subgroup with a "history of neck pain"). Additionally, a second and independent stratification was performed based on the presence of neck pain during the endurance tests (the subgroup reporting "neck pain during the test"). Based on the low sample sizes, only descriptive data were provided for the above subgroups.

RESULTS

Potential participants with migraine (n = 92) were recruited from the headache center. Sixty-six (72%) were excluded due to a concomitant headache diagnosis, analgesic overuse, or because they had fewer than 3 migraine attacks over the past 3 months. Therefore, 26 participants with migraine (mean ± SD age, 29.8 ± 7.5 years) and 26 controls (age, 28.6 ± 3.7 years) were included in the study. Descriptive data on migraine intensity and frequency are provided in **TABLE 1**. A history of neck pain was reported by 18 individuals (69%) in the migraine group and by 3 individuals (12%) in the control group ($\chi^2 = 17.972$, $P<.001$) (**TABLE 1**).

The migraine group demonstrated a shorter holding time than the control group for both the cervical flexor ($U = 132.0$, $z = -3.771$, $P<.001$) and extensor ($U = 149.5$, $z = -3.450$, $P = .001$) muscles (**FIGURE 3**). The median holding times for neck flexion were 35.0 seconds and 60.5 seconds for the migraine and control groups, respectively. The median holding

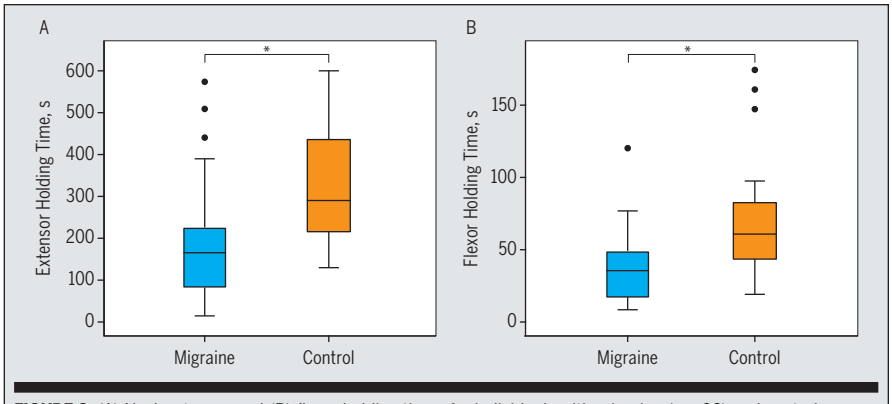

FIGURE 3. (A) Neck extensor and (B) flexor holding times for individuals with migraine (n = 26) and controls (n = 26). In the box plot, horizontal bold lines show the medians, and the box limits indicate the 25th and 75th percentiles. Whiskers represent the upper and lower limits and dots represent the outliers. *$P\leq.001$, obtained from the Mann-Whitney U test for independent samples.

times for neck extension were 166.5 seconds and 290.5 seconds for the migraine and control groups, respectively (**FIGURE 3**, **TABLE 2**).

When the data were stratified based on a history of neck pain, muscle endurance was higher in the control group, regardless of a history of neck pain. Those in the control group with a history of neck pain showed lower endurance in both muscle groups (**TABLE 2**). In the group of individuals with migraine, those with a history of neck pain had lower endurance for the neck extensors but, in contrast, slightly higher endurance for the neck flexors (**TABLE 2**).

The proportion of participants who reported neck pain during both endurance tests was similar between the migraine and control groups (flexion test, $P = .55$; extension test, $P = 1.00$) (**TABLE 1**). Twenty-seven percent of patients in the control group reported neck pain during neck flexion and 46% reported neck pain during neck extension. Within the migraine group, 39% of patients reported neck pain during neck flexion and 46% during neck extension. In the control group, participants who reported neck pain during the test had a greater holding time for both the extensor and flexor endurance tests than those without neck pain (**TABLE 2**). This contrasts the findings in those with migraine, which indicate a greater holding time for both tests for those who did not report neck pain during the tests (**TABLE 2**). Only individuals in the migraine group reported pain referred to the head during the endurance tests: 27% during neck flexion and 23% during neck extension (**TABLE 1**).

DISCUSSION

The results of this study suggest that migraine may be associated with reduced cervical muscle endurance for both the neck flexors and extensors. Neck pain during testing did not appear to affect the results, as similar rates of neck pain and mean neck pain intensity during both endurance tests were reported for both the migraine and control groups.

The current study is, to our knowledge, the first to investigate cervical muscle endurance in women with migraine

TABLE 1 Demographics and Pain Data*

	Migraine Group (n = 26)	Control Group (n = 26)	Mean Difference†	*P* Value
Age, y	29.8 ± 7.5	28.6 ± 3.7	1.2 (−2.0, 4.5)	.45
BMI, kg/m^2	24.3 ± 4.2	22.7 ± 3.5	1.7 (−0.5, 3.8)	.13
Migraine				
Years with the symptoms	15.9 ± 8.1			
Frequency of attacks, d/mo	9.3 ± 7.9			
Duration, h	31.0 ± 29.3			
Intensity (0-10 NPRS)	8.9 ± 1.1			
History of neck pain‡				
Presence, n (%)	18 (69)	3 (12)		<.001
Years with the symptoms	4.2 ± 3.8	1.7 ± 0.6		
Frequency, d/mo	10.6 ± 6.3	10.0 ± 4.4		
Intensity (0-10 NPRS)	4.7 ± 1.6	6.0 ± 2.0		
Neck flexor test				
Neck pain during the test, n (%)§	10 (39)	7 (27)		.55
Neck pain intensity (0-10 NPRS)‖	3.7 ± 2.3	4.9 ± 2.8		
Pain referred to the head, n (%)‖	7 (27)	0 (0)		
Intensity of pain referred to the head (0-10 NPRS)‖	4.3 ± 2.8	...		
Neck extensor test				
Neck pain during the test, n (%)§	12 (46)	12 (46)		1.00
Neck pain intensity (0-10 NPRS)‖	4.0 ± 2.1	4.6 ± 2.6		
Pain referred to the head, n (%)‖	6 (23)	0 (0)		
Intensity of pain referred to the head (0-10 NPRS)‖	4.3 ± 2.2	....		

Abbreviations: BMI, body mass index; NPRS, numeric pain-rating scale.
**Values are mean ± SD unless otherwise indicated.*
†Values in parentheses are 95% confidence interval.
‡Neck pain characteristics were not compared statistically due to the low number of controls with neck pain (n = 3).
§P value obtained from a chi-square test.
‖Pain characteristics during the test were not compared statistically due to the low number in both groups.

and adds to existing knowledge about the profile of cervical spine muscle impairments in this population. The assessment protocol used in the current study is reliable,[7] easily reproduced in clinical practice, and does not require specific or expensive instruments.[39] Considering that most daily activities are related to sustained posture of the cervical spine, this reduced muscle endurance would likely contribute to neck-related disability and pain.[10]

Our results differ from those reported in previous studies. The median holding time for the neck flexors in our control group (60.5 seconds) was lower than the mean holding time previously reported for healthy girls (70.3 seconds).[31] Similarly, in the migraine group, the median holding time found in the current study (35.0 seconds) was lower than the previously reported mean holding time for girls with migraine (54.1 seconds).[31] This lower holding time was likely due, in part, to the different methods used to assess neck flexor endurance, as Oksanen et al[31] tested endurance with participants performing cervical spine forward flexion while jutting out the chin.

Differences between studies may also reflect age-related differences,[18] the mean ages being 17 and 29 years for the previous[31] and current studies, respectively. However, the most notable difference is that Oksanen et al[31] reported no difference in neck flexor endurance between adolescents with and without migraine, which is in direct contrast to our findings. The age difference between the participants in both studies suggests that migraine may be associated with reduced neck muscle endurance only in individuals who have had the condition over a longer time. Given that there have been no previous reports describing the mean holding time for the extensors in patients with migraine, comparison data are restricted to the flexors.

When comparing our findings with previously published normative data for women, based on studies that used the same test position used in the current study, the median hold time (60.5 seconds) for our control group is similar to the normative cutoff value of 60 seconds reported by Ylinen et al,[41] but higher than the 37 seconds reported by Peolsson et al.[34] In fact, the median hold time (35.0 seconds) for those with migraine in our study compares favorably with the normative values published by Peolsson et al.[34]

The only previously published study, to our knowledge, that has reported normative data for the neck extensor test in healthy women did not use excessive head displacement as a criterion to interrupt the test,[34] which may explain why the mean holding time (507 seconds) reported by that study is much higher than the median scores reported in our study (healthy controls, 290.5 seconds; migraine, 166.5 seconds).

Based on the findings of this study, it should be considered that the presence of migraine is associated with a lower endurance of the cervical spine musculature; however, the higher prevalence of neck pain reported by those with migraine could have also influenced muscle endurance. In fact, the lower median endurance scores of individuals with a history of neck pain in both groups suggest that lower performance in the group with migraine could be attributed, in part, to the much larger proportion of individuals with a history of neck pain in that group. However, patients with migraine demonstrated lower holding times than the control group, even when considering the subgroups of those with and without a history of neck pain. Similarly, the relationship between lower neck flexor and/or extensor muscular endurance and neck pain is unclear, as some studies have reported a difference between patients and controls[17,23,27,35,37] and others have not.[6,15,28,33,37]

Another interesting result of the present study is the difference in the median holding times for those with or without neck pain reported during the test. When we considered the frequency of neck pain during the test, we observed similar rates between those with or without migraine. However, participants with migraine and neck pain had a shorter median holding time in contrast to a longer median holding time in controls. Therefore, it seems that, for controls, the report of neck pain during the test might be related to a longer period of sustained muscle contrac-

TABLE 2 Hold Time for Neck Flexor and Extensor Muscle Endurance Tests*

	Neck Flexor Test		Neck Extensor Test	
	Migraine Group	Control Group	Migraine Group	Control Group
All participants§	35.0 (30.0)	60.5 (36.3)†	166.5 (135.3)	290.5 (213.3)‡
History of neck pain‖	37.0 (36.3)	56.0 (39.0)	153.0 (101.3)	203.0 (63.5)
No history of neck pain¶	33.0 (13.8)	62.0 (33.5)	228.5 (185.3)	322.0 (214.5)
Neck pain during the test#	24.5 (31.3)	71.0 (52.5)	149.0 (175.8)	365.5 (233.0)
No neck pain during the test**	35.5 (28.0)	53.0 (32.5)	177.5 (104.25)	256.0 (142.3)

Values are median (interquartile range) seconds.
†P<.001, between-group difference obtained from the Mann-Whitney U test.
‡P = .001, between-group difference obtained from the Mann-Whitney U test.
§Migraine group, n = 26; control group, n = 26.
‖Migraine group, n = 18; control group, n = 3. These data were not analyzed statistically due to the low sample size of the control group.
¶Migraine group, n = 8; control group, n = 23. These data were not analyzed statistically due to the low sample size of the migraine group.
#For the neck flexor test: migraine group, n = 10; control group, n = 7 and for the neck extensor test: migraine group, n = 12; control group, n = 12. These data were not analyzed statistically due to the low sample size of each group.
***For the neck flexor test: migraine group, n = 16; control group, n = 19 and for the neck extensor test: migraine group, n = 14; control group, n = 14. These data were not analyzed statistically due to the low sample size of each group.*

tions, whereas for patients with migraine, neck pain may have contributed to lower muscular endurance values. Additionally, the occurrence of pain referred to the head during the endurance test was only observed within the migraine group and potentially also contributed, in part, to lower endurance.

The assessment of cervical muscle performance in patients with migraine is not common practice in physical therapy. In a recent international Delphi study including physical therapists,[29] muscular endurance tests did not rank among the list of useful examination tests for the evaluation of musculoskeletal impairments in that patient population. Additionally, more than 50% of physical therapists believed cervical muscle strength to be either probably or definitely not a useful parameter to assess in individuals with migraine, and approximately 50% had the same opinion for the assessment of individuals with cervicogenic and tension-type headaches.[29] However, findings of the present study, along with other recent reports, suggest that decreased cervical spine muscle performance may be associated with migraine and often coexisting neck pain, particularly for the neck extensors.[11,12,21]

Nevertheless, some potential limitations of this study should be recognized. First, the absolute data should be interpreted with caution, given that there are several variations of cervical muscle endurance tests in the literature. Considering the high variability of the endurance scores, better knowledge of measurement errors (minimum detectable change and minimal clinically important difference) would also be helpful in the interpretation of the data within and between studies.[28] In our study, for the flexor endurance test, the between-group difference was greater than the standard error of measurement reported for healthy controls (8-13 seconds)[19,28,41] and for individuals with neck pain (6-7 seconds).[7,28] Similarly, for the extensor endurance test, the observed difference was greater than the standard error of measurement reported for asymptomatic individuals (50 seconds)[28] and those with neck pain (26-44 seconds).[7,28] Yet, the interpretation of data among studies is still tenuous.

Second, the higher prevalence of individuals with a history of neck pain within the migraine group could be considered a confounding factor. However, this may reflect clinical practice, with population-based research studies reporting an approximately 80% prevalence of neck pain in individuals with migraine.[2] Third, the participants of the pilot study were included in the current sample, which might have influenced the results. Finally, the cross-sectional design does not allow determination of whether cervical muscle dysfunction is a cause or an effect of migraine and often-associated neck pain.

CONCLUSION

Women with migraine had a lower holding time for cervical spine flexor and extensor musculature compared to that of a matched control group. These results suggest that cervical spine muscle endurance may be an important and potentially overlooked aspect of cervical spine muscle function in this population. This impairment may be a modifiable characteristic that may assist in the management of patients with migraine. ◉

KEY POINTS

FINDINGS: Women with migraine have reduced neck muscle endurance.

IMPLICATIONS: Addressing impairments of the neck musculature in women with migraine may assist in the management of this patient population, which also often presents with neck pain.

CAUTION: Despite the pragmatic approach of this study, the results are restricted to women with migraine and may have been influenced by the high rates of associated neck pain. The cross-sectional nature of the study also precludes a conclusion of a direct cause-and-effect relationship between migraine, a history of neck pain, and limited neck musculature endurance.

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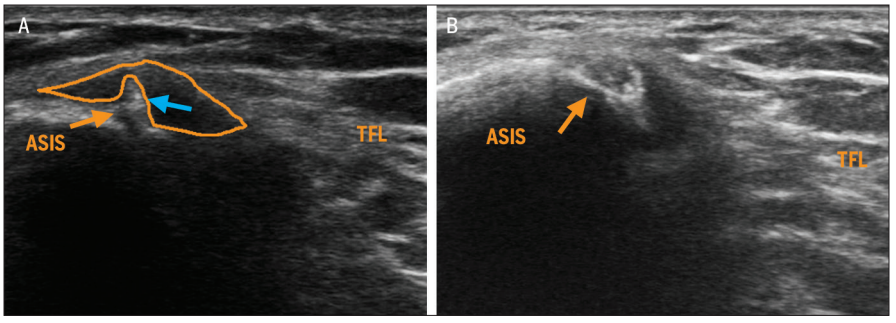

FIGURE 2. (A) The longitudinal section of left-hip sonography revealed an incomplete fracture of the ASIS. The orange arrow indicates the fracture line and the blue arrow indicates a periosteal avulsion from the TFL. The outlined region indicates edema superficial to the fractured site. (B) After 7 weeks, the longitudinal section of left-hip sonography showed evidence of callus formation (arrow) at the fractured site of the ASIS. Abbreviations: ASIS, anterior superior iliac spine; TFL, tensor fascia latae.

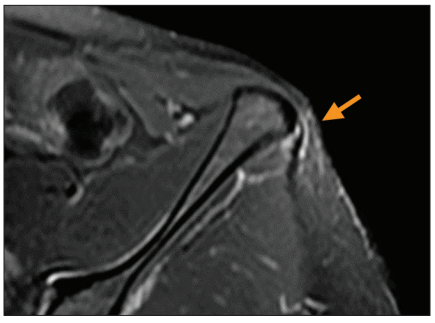

FIGURE 3. Axial, fat-saturated, T2-weighted, fast spin echo magnetic resonance imaging revealed an incomplete periosteal avulsion of the origin of the tensor fascia latae at the anterior superior iliac spine. The low signal intensity of the avulsed segment (arrow) is surrounded by the high signal intensity of the edema.

Incomplete Fracture of the Anterior Superior Iliac Spine

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A 32-year-old woman with a 2.5-year history of high-intensity interval training (2-4 times per week) presented to physical therapy with left anterior superior iliac spine (ASIS) pain that began during running 2 weeks prior. The patient was initially diagnosed with a tensor fascia latae (TFL) strain due to painful resisted hip abduction at 45° of flexion, a positive Ober test, and tenderness over the TFL. For 4 weeks, the patient performed TFL stretching and refrained from her routine training, but the improvement was minimal. Additionally, her pain became constant, aching, and sharp after playing a few minutes of soccer. She sought treatment from a sports medicine physician and was referred for radiographs to rule out a possible pelvic fracture. Radiographs were noncontributory (**FIGURE 1**, available at www.jospt.org). She was referred to another physical therapist, who diagnosed her with a gluteus medius muscle strain. Following 3 weeks (7 sessions) of soft tissue mobilization and therapeutic exercises with no change in her condition, she was referred for further imaging.

The sports medicine physician performed sonography approximately 4 months after the initial onset of pain to screen for a potential pelvic fracture.[1,2] A 15- to 6-MHz linear-array transducer was placed longitudinally, overlying the left ASIS and TFL.[3] The sonography revealed an approximately 2-mm fracture line on the posterior ASIS. Additionally, hypoechoic edema was noted adjacent to the fractured site (**FIGURE 2A**). The findings were later confirmed by magnetic resonance imaging, indicating an incomplete ASIS avulsion fracture and edema of the TFL (**FIGURE 3**). Management was then focused on relative rest and activity modification (pain-free sagittal plane motion only). Seven weeks after the diagnosis, the fractured ASIS demonstrated healing with callus formation (**FIGURE 2B**), and the patient reported minimal pain/disability during daily activities. The patient returned to moderate-intensity interval training without pain 14 weeks after her diagnosis. ◉ *J Orthop Sports Phys Ther 2019;49(5):355. doi:10.2519/jospt.2019.8504*

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Interpreting Outcomes 1—Change and Difference: Linking Evidence to Practice

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Scientific writing is by nature technical, so getting terminology and wording right is important. When there is inconsistency in definitions, or misuse of words, problems follow. Inconsistency can come about when there is no universally accepted definition for a concept or simply due to sloppiness on the author's part. But this is more than just a problem of semantics; when the same words are used to describe different concepts, study results can be easily and unknowingly misinterpreted.

Inconsistency is common when describing outcomes. Outcomes, whether assessed at baseline, during or post treatment, or at follow-up, can be measured in various ways.[2] But there is a critical division that is always relevant, and interpreting the findings of a study is not possible unless the reader understands which side of a metaphorical fence the numbers are on. The 2 sides of this fence can be called *change* and *difference*.

The distinction between change and difference is critical with respect to interpreting the results of studies of treatment effectiveness. The 2 types of findings give the reader different kinds of information.

Change

Put simply, change is the score on an outcome measure (eg, at follow-up) minus the score on the same measure at an earlier time point (eg, at baseline). This is change within a person, or mean change within a group of people over time. The problem comes when within-group mean change is called the "treatment effect" or the "response to treatment."

As mentioned in a previous Evidence in Practice article,[1] change from baseline to follow-up includes changes due to the natural history of the condition, regression to the mean, nonspecific effects, and the effect of treatment. This isn't the place to go into the intricacies of all these, but suffice it to say that all are relevant, regardless of the condition and the treatment; that is, this applies to every study! Within-group change over time is not the same as the treatment effect. Often, a person with a large change in outcome is called a *responder* to treatment A, but this language is misleading, too, because it is very likely that the same person would also be a responder to treatment B. This is basic stuff, but it is extremely tempting to attribute all the observed change to the treatment, and terms such as *treatment effect*, *treatment response*, and *responder* feed the temptation. This is not to say that change scores do not provide useful information. They are an estimate of what is likely to happen when a patient gets the study treatment, but they are different from the treatment effect and are not the treatment response.

Difference

Difference requires data from 2 groups of people. The between-group difference is the mean score on an outcome measure in treatment group A minus the mean score in group B. Typically, it is either the difference between scores at follow-up or the difference in change between the 2 groups. The difference can reasonably be called the *treatment effect* or *treatment response*, because (assuming the study is well designed) the size of the difference does not include natural history, regression to the mean, and nonspecific effects. Critically, the "treatment effect" is a comparative effect. It is what can be expected if a patient got treatment A compared to what can be expected if that patient got treatment B. So, the "effectiveness" of (or response to) treatment A, as reported in a particular study, is interpreted in the light of what treatment B involved. The difference in outcome scores between groups quantifies the treatment effect (**FIGURE**).

Things become tricky here for readers of research because authors sometimes report conclusions based on within-group changes in randomized controlled trials (RCTs). This usually happens when there is no difference between the groups. For example, they might conclude that

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treatment A is effective, or that both treatment A and treatment B are effective, based on within-group improvements. Stating that both treatments are effective is almost never a valid conclusion from an RCT, except in some very special circumstances. Within-group change in an RCT is no more the "treatment effect" than are the results from a single-group (uncontrolled) study: it still includes natural history, regression to the mean, and nonspecific effects. Interpreting the findings of an RCT in this way defeats the purpose of randomization and having a comparison group.

In Sum

When reading the results of a study, you need to be able to answer the question of whether the authors are talking about a within-group change or a between-group difference. The former includes natural recovery, regression to the mean, nonspecific effects, and treatment effects. The latter is the treatment effect.

Most of the time, the information necessary to answer the question is in the study methods and requires a working knowledge of how the study was performed, and what different methods and analyses can tell us. The important thing for someone reading an article is not so much identifying whether an author is using "correct" language but determining the true meaning behind the words used.

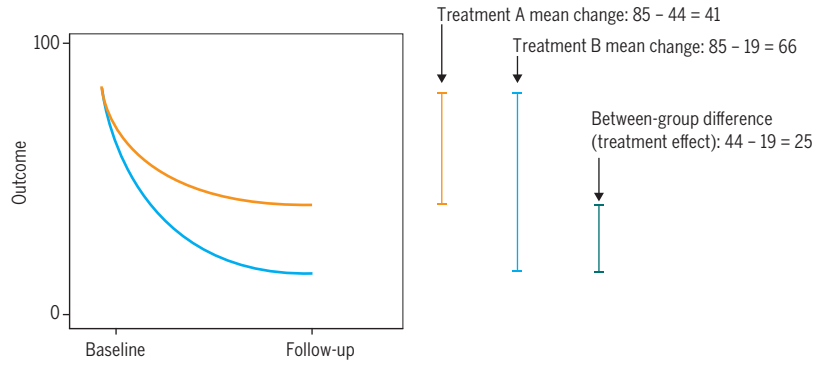

FIGURE. Change and difference.

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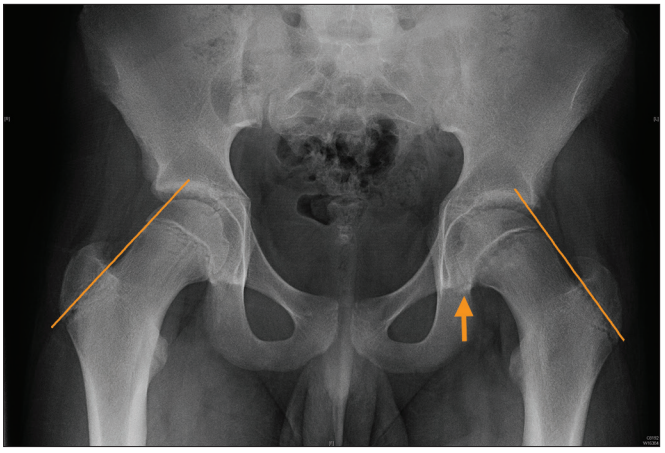

FIGURE 1. Anteroposterior radiograph of the pelvis, showing mild asymmetric widening of the left femoral-head epiphysis (arrow), indicating a Salter-Harris type I injury or early slipped capital femoral epiphysis. The diagonal lines show the line of Klein, which is a line drawn on the long-axis superior aspect of the femoral neck.[2] The lack of intersection between this line and the epiphysis confirms slipped capital femoral epiphysis.[2]

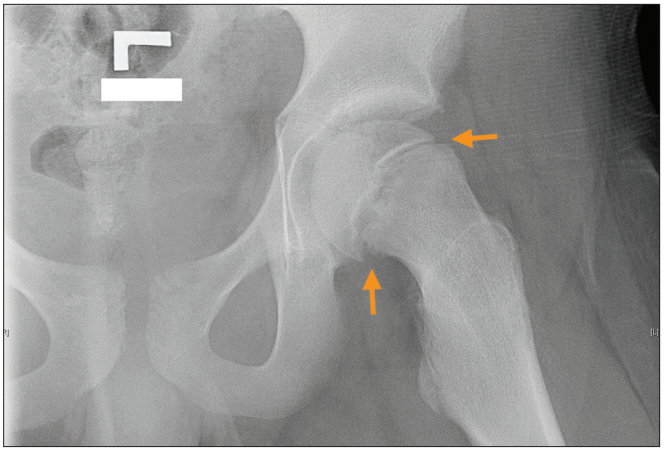

FIGURE 2. Frog-leg radiograph of the left hip revealing early slipped capital femoral epiphysis, which is evidenced by inferior slippage of the femoral head (arrows).

Slipped Capital Femoral Epiphysis Presenting as Quadriceps Strain

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An active 14-year-old adolescent boy with left hip pain of 3 weeks in duration was referred for physical therapy consultation by his pediatrician, with a diagnosis of left quadriceps strain. His chief complaint was pain of insidious onset in his left groin and lateral hip that was exacerbated by standing and sitting. His body mass index was in the 91st percentile for his age (overweight[1]), and he had recently started weight training for football. His past medical history was otherwise unremarkable.

On examination, his gait was found to be antalgic, with reduced stance time on his left leg. His passive left hip internal rotation range of motion and abduction range of motion elicited pain and were limited to 10° and 0°, respectively. Passive flexion range of motion and external rotation range of motion were pain free and comparable to his passive right hip range of motion. He exhibited significant weakness in left hip abduction and flexion.

Due to these findings, the physical therapist suspected slipped capital femoral epiphysis and immediately contacted the pediatrician to request radiographs. Slipped capital femoral epiphysis was confirmed by radiographs (**FIGURES 1** and **2**), and in situ pinning was performed by a pediatric orthopaedic surgeon the next day.

Slipped capital femoral epiphysis is most prevalent in children between 8 and 15 years of age, with many cases being undiagnosed.[2] Slipped capital femoral epiphysis should be considered in this patient population in the presence of antalgic gait, limited internal rotation, and poorly localized pain at the hip, groin, thigh, or knee.[3] Effective screening and timely referral for imaging are crucial, given the strong correlation between time of diagnosis and successful treatment.[3] Delayed diagnosis increases risk of complications, including avascular necrosis and chondrolysis.[3] *J Orthop Sports Phys Ther 2019;49(5):356. doi:10.2519/jospt.2019.8772*

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Blood Flow Restriction Training in Rehabilitation: A Useful Adjunct or Lucy's Latest Trick?

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In the American cartoonist Charles M. Schulz's comic series *Peanuts*, Lucy first pulled the ball away from Charlie Brown in 1951. Then she continued to torture him for the next 48 years, using variations on the theme. As a physical therapist of a certain age, every time I hear of some new approach promising more for less, I become Charlie Brown: "This has never worked in the past, so why should I believe it will this time? But wouldn't it be great if it were true?" Ever the optimist, my eternally misguided enthusiasm leaves me lying on my back, embarrassed, and vowing, "They won't fool me next time."

Then along comes an intervention claiming that some low-intensity exercise performed while wearing a blood pressure cuff will result in strength gains, improved performance, shorter postexercise recovery, and maybe even pain reduction. "Good grief," indeed. Or will it work this time?

Blood Flow Restriction Training: Early Origins

In the 1960s, scientists noticed improved walking tolerance in people with intermittent claudication after a physical training program.[29] The changes were not explained by increased collateral circulation. Perhaps alternate mechanisms were in play (other than improved blood flow), somehow enhancing muscle function?[11]

This much was the result of scientific investigation. Now we enter the realm of retrospective self-report from an individual whose business depended on the results—your "Spidey-sense" should already be tingling.

Coincidentally and independently, a Japanese high school student noticed that after a period of sustained sitting while attending a religious ceremony, he experienced a feeling of discomfort and swelling similar to that experienced after performing "strenuous calf-raise exercises."[48] For the next 5 years, he self-experimented with variations of occlusion and exercise during weight training. This period included a stint in hospital after a pulmonary embolism induced by self-described reckless tourniquet application.

Later, after opening his own fitness club, the Japanese now former high school student was injured while skiing. He reported that he had fractured both ankles and injured "cartilage and the medial ligament" of his knee. He refused the recommended surgery and hospitalization because of the demands of his business. Instead, he opted for occlusion training combined with isometrics of his casted limb for 2 months. He claimed he had hypertrophy, rather than atrophy, of his casted leg and good functional outcomes.[48] Commercial application of his approach over the ensuing decade saw growing popularity, along with patent applications for equipment and techniques in a number of countries, and "certifications" for practitioners adding to the business model.

By now, the alarm bells should be deafening to those looking for a science-based intervention, free of commercial influence.

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Usually, the story would end here. However, some independent research gives us pause for thought.

Hypertrophy Through Low Load: Plausible Evidence of a Floor Effect

An otherwise healthy, relatively untrained adult can expect muscle hypertrophy with loads as low as 15% to 30% of the 1-repetition maximum when performing exercises to volitional failure (exercise to fatigue),[5,13] although the effects of hypertrophy are more consistently achieved with higher loads and lower repetitions, especially when matching total work (eg, 70% of 1-repetition maximum).[2,13,46]

The patient in pain may present a conundrum: you may not be able to prescribe sufficiently high absolute load to ensure hypertrophy. If you conclude the pain is caused by inadequate muscle strength, then the conundrum is difficult to resolve and might even be intractable. You might also face a similar challenge where strengthening is indicated but loading the joint is not (eg, post surgery or resolving osteochondral defects).

"I really want to start strengthening as soon as possible. Do I really have to wait until the pain settles down? What if pain prevents the patient from loading? What if the pain doesn't settle down?"

Hypertrophy Is Possible With Low Loads and High Repetitions: Enter Blood Flow Restriction Training

Low-load resistance training with the addition of blood flow restriction can achieve equivalent hypertrophy to that of high-load resistance training.[6,17,34] Plausible mechanisms of action, each with some evidence in humans, include locally induced swelling in the muscle cells, improved local neural function (increased fiber recruitment), improved central neural function (increased cortical motor excitability), and increased muscle protein synthesis.[10,19,28]

Blood flow restriction training may also have additional hypertrophy benefits in muscles not directly affected by the blood flow restriction. Measurable improvements in the pectorals (bench press) and gluteus maximus (squatting) are possible with blood flow restriction to the upper[54,55] and lower[1] limbs, respectively. Increased recruitment of the more proximal synergists late in the set, when the occluded muscles are failing, is the most likely mechanism.[12]

Effects on muscle strength are lower with low-load resistance training combined with blood flow restriction than with heavy resistance training, despite similar objective muscle mass gains.[17] This might be due to enhanced fiber recruitment in heavy resistance training.[19] Early research in this area used arbitrary training occlusion pressures for all participants, typically not accounting for exercise position or individual variability.

Limb occlusion pressure will vary depending on the girth of the limb,[33] the cuff used,[40] and body position[16] (eg, lying compared to sitting or standing).[50,52] Limb occlusion pressure is different for different individuals, and even the same individual at different times of the day[18,21,25] (eg, morning versus afternoon, before or after recent exercise or coffee consumption).

Measuring and Adjusting Occlusion Pressure

Failing to individualize limb occlusion pressure might explain inferior strength gains compared with standard heavy resistance training.[16] However, while this is biologically plausible, research in this area is sparse. Cuff width is an important determinant of limb occlusion pressure, and the wider the cuff, the lower the required pressure to occlude the limb.[49] A wider cuff also has the benefit of less local discomfort[24,37] and lower chance of bruising.[38,39]

Clinicians should individually tailor occlusion pressure for safety and best outcomes.[16,32] They should measure limb occlusion pressure in the position in which the exercise will be performed and conduct the exercise as a percentage of this pressure. In the lower limb, 40% to 80% of limb occlusion pressure is effective.[32] Higher occlusion pressure might be desirable, although it is associated with more local discomfort. In the upper limb, lower occlusion pressures (up to 60% of occlusion pressure) can achieve similar results.

Measure limb occlusion pressure by auscultating distal arteries or with a relatively inexpensive handheld Doppler probe, which are valid compared to Doppler ultrasound.[30] More expensive commercially available systems allow for automatic measurement and application of a prescribed limb occlusion pressure, and can be adjusted during the exercise.[39,56]

Blood Flow Restriction Training's Performance and Recovery Enhancement Cousin: Ischemic Preconditioning

In a likely apocryphal story, native South Americans applied tourniquets to their legs immediately before important long-distance runs for performance enhancement.[36] In experiments in the middle of the 20th century, there was a dose-response relationship between measures such as time to exhaustion and the duration and intensity of application of a tourniquet to completely occlude limb perfusion prior to exercise.[41,44] A flurry of investigation followed, which failed to replicate these findings. This field lay fallow for years.[36]

In the mid 1980s, animal experiments documented reductions in cardiac infarction following bouts of ischemic preconditioning.[14,42] Meaningful, albeit conflicting and objectively small, improvements in sporting performance after local (eg, leg during leg exercise) and remote (eg, arm during leg exercise) ischemic preconditioning[20,36,47] prior to cycling,[14] swimming,[23] and running[3] may be possible. Modest gains are acquired with cycles of 3 or 4 bouts of 5 minutes of occlusion and 5 minutes of reperfusion performed a few hours prior to the event.[9,31,47] There is less research examining any benefit of ischemia as an intervention to improve recovery post exercise, and the results are mixed at best.[4]

Routine postexercise application of 3 or 4 bouts of 5-minute occlusion/reperfusion (30-40 minutes in total)[45] is likely not feasible in a team setting. The

time can probably be better spent, even with compliant athletes and available equipment.

But Wait, There's More! Have I Told You About Pain Relief?

Researchers noticed that patients with anterior knee pain that was present during single-leg squatting (a reassessment sign often used in people with this condition) had substantially reduced pain immediately after a session of low-load resistance training with the addition of blood flow restriction. Further, this benefit was retained for the duration of their session.[26] There may be a pain-reducing effect in excess of that seen through matched placebo-controlled exercise.[15,27] However, this research is preliminary and must be replicated before one can confidently conclude that it is a true effect.

It Can't All Be Sunshine and Daisies? What's the Risk?

"Reckless" tourniquet application is associated with potentially disastrous side effects, embolism being chief among them.[48] No one should die as a result of strength training. With appropriate patient screening and sensible individualized application, there are remarkably few reported side effects of blood flow restriction training.[17,35,49]

Anecdotally, blood flow restriction training is very common.[53] Likely, many tens of thousands of patients have participated in blood flow restriction training, yet there are very few reports of serious adverse events when precautions have been followed.[8,35,43,51,53] Local discomfort during the exercise (almost ubiquitous) and bruising (unusual, but not rare)[43] are the main adverse effects, although adverse events have been poorly reported.[17]

Far less common, but potentially very serious, are vascular problems. A medical history of vascular compromise or risk of embolism is an absolute contraindication to blood flow restriction training. Three reported cases of rhabdomyolysis[7,22,51] suggest that compromised renal function should be a contraindication.[57] Patients should always be monitored following exercise for excessive muscle soreness.[7]

TABLE Suggested Clinical Reasoning for the Application of Low-Load Blood Flow Restriction Training*

Parameters	• Description
Indications	• Hypertrophy required and heavy resistance training not clinically indicated
Contraindications	• Vascular compromise, clotting disorders or other elevated risk of embolism, renal compromise, hypertension (systolic blood pressure of 140 mmHg or greater)
Warnings	• Bruising is relatively common (in the upper limb especially). The exercise is very uncomfortable
Applications	• Measure limb occlusion pressure in the body position in which the exercise will be undertaken • Set training pressure (40% to 80% of limb occlusion pressure for leg, 30% to 60% for upper limb). Note that higher pressures are associated with more discomfort but likely superior clinical outcomes • First set: aim for voluntary failure at 30 repetitions at a rate of approximately 1 repetition every 2 to 4 seconds • Second to fourth sets: same weight as first set, 15 repetitions, 30 seconds of recovery between sets. Adjust weight up or down depending on performance in first set: harder if failure wasn't achieved, easier if patient could not reach 30 repetitions • Initially, alternate days; training can ultimately be performed twice daily • Expect to see meaningful results after at least 4 weeks of training • When clinically appropriate, shift to regular resistance training

**The contraindications and warnings are those peculiar to blood flow restriction training, and are in addition to usual care and precautions taken when prescribing resistance training. The exercise parameters suggested are based on the most frequently reported regimens.[17]*

Good Grief, Charlie Brown! Maybe It Is the Miracle We've Been Promised All This Time?

Well, maybe, partially. There are similar muscle mass gains with low-load resistance training plus individually tailored blood flow restriction compared to a similar period of high-intensity strength training. Apply up to 80% of limb occlusion pressure, and prescribe about 75 repetitions in total. Aim for fatigue failure after the first 30 repetitions, followed by 3 more sets of 15 repetitions at the same load (likely around 15% to 30% of 1-repetition maximum). Exercises can be performed on alternate days, and, after a while, even twice daily. Expect hypertrophy changes after at least 4 weeks, but probably closer to 8 weeks (**TABLE**).

Progression to heavy-load resistance training should continue to be your goal—blood flow restriction training is only an interim step. There is less compelling evidence that you can be confident of performance, postexercise recovery, and pain improvements, although this is an area to watch.

It took more than 30 years in practice, but we eventually got a clinical "cheat" that at least works for some select patients. Will there be another one in my lifetime? I seriously doubt it, but I'll try to keep an open mind, if not an empty head.

Key Points

- In patients who cannot tolerate high loads, blood flow restriction training using low loads is associated with similar hypertrophy effects to those of conventional high-load training.
- Training pressures need to be at least 40% of limb occlusion pressure, and can be up to 80% (lower in the arm than in the leg).
- Wider cuffs require lower pressures to occlude and are better tolerated.
- Safe application requires attention to contraindications and tailoring of the pressure to the individual patient, the exercise, and the cuff.

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Immediate and Short-term Effects of Thoracic Spine Manipulation in Patients With Cervical Radiculopathy: A Randomized Controlled Trial

BACKGROUND: Thoracic spine thrust manipulation has been shown to improve patient-rated outcomes for individuals with neck pain. However, there is limited evidence of its effectiveness in patients with cervical radiculopathy.

OBJECTIVES: To compare the immediate and short-term effects of thoracic manipulation to those of a sham thoracic manipulation in patients with cervical radiculopathy.

METHODS: In this multicenter randomized controlled trial, participants with cervical radiculopathy were randomized to receive either manipulation (n = 22) or sham manipulation (n = 21) of the thoracic spine. Outcomes were measured at baseline, immediately after treatment, and at a follow-up 48 to 72 hours after manipulation. A repeated-measures analysis of variance was used to analyze neck and upper extremity pain (numeric pain-rating scale), disability (Neck Disability Index), cervical range of motion (ROM), and endurance (deep neck flexor endurance test). The chi-square test was used to analyze changes in neck and upper extremity pain, centralization of symptoms, and beliefs about receiving the active manipulation treatment using a global rating of change scale.

RESULTS: Neck and upper extremity pain, cervical ROM, disability, and deep neck flexor endurance all showed significant interactions between group and time (P<.01). Immediately after treatment and at the 48-to-72-hour follow-up, the manipulation group had lower neck pain (P<.01), better cervical ROM (P<.01), lower disability (P<.01), and better deep neck flexor endurance (P = .02) compared to the sham manipulation group. The manipulation group had moderate to large effect-size changes over time. No between-group differences for upper extremity pain were found immediately following the intervention (P = .34) and at 48 to 72 hours after the intervention (P = .18). At 48 to 72 hours after treatment, a greater proportion of participants in the manipulation group reported improvement (global rating of change scale score of 4 or greater) in neck and upper extremity symptoms (P<.01), centralization of symptoms (P<.01), and beliefs about receiving an active manipulation (P = .01) compared to the sham manipulation group.

CONCLUSION: One session of thoracic manipulation resulted in improvements in pain, disability, cervical ROM, and deep neck flexor endurance in patients with cervical radiculopathy. Patients treated with manipulation were more likely to report at least moderate change in their neck and upper extremity symptoms up to 48 to 72 hours following treatment.

LEVEL OF EVIDENCE: Therapy, level 2.
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KEY WORDS: *clinical trial, neck pain, radiculopathy, thoracic spine, thrust manipulation*

Recent evidence supports the use of high-velocity, low-amplitude thrust manipulation to the thoracic spine in patients with neck pain.[3,6,8,11,20,42,43] Immediate and short-term improvements in pain and cervical spine range of motion (ROM) have been reported following manipulation of the thoracic spine.[11] Moreover, thoracic manipulation has demonstrated better outcomes compared to mobilization (nonthrust) in patients with neck pain.[8,32] Current evidence supports the use of thoracic manipulation in patients with neck pain, but there is a paucity of evidence for its use in patients with neck and arm pain related to cervical radiculopathy. A single case report has suggested that thoracic manipulation may be useful in the treatment of cervical radiculopathy, noting a decrease in upper extremity radicular symptoms following a single dose of thoracic manipulation.[12] Thoracic manipulation may be a viable treatment option in the early phases of treatment, when cervical manual interventions may not be tolerated well by patients with cervical radiculopathy.[12]

Cervical radiculopathy is most commonly associated with a cervical disc derangement or other space-occupying lesion, resulting in nerve root inflammation, impingement, or both.[30] Patients can present with or without neck pain and with a multitude of upper extremity symptoms. Physical therapy management of cervical radiculopathy includes manual therapy, exercise, and cervical traction.[3,7,9,30,39,42] Manual therapy may

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consist of mobilization/manipulation to the cervical and thoracic spine, neurodynamic techniques, and soft tissue mobilization.[12,27,42] Exercise involves strengthening the deep neck flexor muscles and scapular-thoracic region.[9,42] Traction includes manual, mechanical, and home traction options.[4,17,42] Studies indicate that a multimodal approach using these interventions has resulted in improved outcomes[4,8,9,31,42] and can be predictive of a successful outcome in this patient population.[7] The use of a standardized multimodal treatment of manual therapy and exercise has resulted in improvements in pain and disability.[42]

Unfortunately, multimodal treatment studies are unable to establish the isolated intervention effects of thoracic manipulation on symptoms, impairments, and function. Moreover, a 2016 systematic review[35] reported a lack of evidence for the effectiveness of thoracic manipulation as a single-mode intervention in patients with cervical radiculopathy. This same systematic review[35] suggests a need for more evidence to support the use of thoracic manipulation as a treatment option in this patient population. Further research is needed to justify the use of thoracic manipulation and to understand its short-term effects on related impairments and outcomes in patients with cervical radiculopathy.

The primary purpose of this study was to assess the immediate and short-term effects of 1 session of thoracic manipulation in patients with cervical radiculopathy, compared to those of a sham thoracic manipulation, on the primary outcomes of neck and upper extremity pain and patient-perceived changes in neck and upper extremity symptoms. Secondary outcomes included neck disability, active cervical spine motion, deep neck flexor muscle endurance, upper extremity numbness and tingling, and symptom distribution. We hypothesized that participants randomized to receive thoracic manipulation would have greater improvements in pain, disability, cervical ROM, and deep neck flexor muscle endurance compared to those receiving sham manipulation. Further, we hypothesized that a greater proportion of participants in the manipulation group would report at least moderate improvement in neck and upper extremity symptoms, as well as centralization of symptoms, compared to those in the sham manipulation group.

METHODS

Participants

Consecutive patients with unilateral upper extremity pain, paresthesia, or numbness, with or without neck pain, were recruited for this multicenter randomized controlled trial at 6 orthopaedic physical therapy clinics in Georgia, Virginia, and California between September 2011 and July 2014. Inclusion criteria were being 18 to 65 years of age, having a Neck Disability Index (NDI) score of 10/50 points or greater, and having a clinical diagnosis of cervical radiculopathy, as defined by Wainner and Gill[38] (positive scores on 3 of 4 clinical tests: Spurling's test, upper-limb neurodynamic test/median nerve bias, cervical distraction test, and cervical rotation toward the symptomatic side of less than 60°). When 3 of these 4 tests are positive, the diagnostic accuracy has a specificity of 0.94 (95% confidence interval [CI]: 0.88, 1.00) and a positive likelihood ratio of 6.1 (95% CI: 2.0, 18.6).[38] The inclusion criterion of an NDI score of 10 points or greater was selected to capture a meaningful clinical change of at least 8.5 points.[41] Exclusion criteria included history of previous cervical or thoracic spine surgery, bilateral upper extremity symptoms, signs or symptoms of upper motor neuron disorder, medical red flags (eg, tumor, fracture, rheumatoid arthritis, osteoporosis, prolonged steroid use), and cervical steroidal injection or medication within the past 2 weeks. Patients who satisfied the eligibility criteria were invited to participate in the study. Participants were queried about prior thoracic or cervical thrust manipulation for their current condition, and none reported having received these manipulations for their current episode of cervical radiculopathy.

Procedures

Before participating in the study, all participants signed an informed-consent form, and the rights of participants were protected. The study protocol was approved by the Institutional Review Board at Virginia Commonwealth University Office of Research (HM13804). The protocol was registered on ClinicalTrials.gov (NCT01495728). Each participant underwent standardized data collection, which included patient-reported outcomes and impairment measures. The data-collection procedures were performed at baseline, immediately after treatment, and 48 to 72 hours after treatment. The evaluating physical therapist collected baseline outcomes and performed the manipulation and sham manipulation, while another clinician blinded to group allocation collected all follow-up outcomes.

Randomization Following the baseline examination, participants were randomly assigned to receive manipulation or sham manipulation to the upper and mid thoracic spine. Numbered, sequential, sealed opaque envelopes containing group allocation for each clinic were opened by the evaluating physical therapist after the baseline examination. To decrease the potential effect of the clinic on treatment outcomes, randomization was stratified in blocks of 2 and 4 by clinic. Participants were blinded to group assignment. Blinding was assessed at the second follow-up time point (48-72 hours) by asking participants to indicate which group they believed they were assigned to (active or placebo look-alike treatment).

Intervention

Six physical therapists, 1 at each of the 6 outpatient clinics, recruited participants and performed the intervention. The physical therapists were 83% men (n = 5) and had an average of 8 years (range, 2-15 years) of orthopaedic physical ther-

apy experience. All clinicians were given on-site training and were provided with a standardized instruction manual for all examination, treatment, blinding, and data-collection procedures.

Manipulation Group Participants in the manipulation group received a supine high-velocity, low-amplitude thrust manipulation technique directed bilaterally to the upper thoracic (C7-T3) and mid-thoracic (T4-T9) spine (**FIGURE 1**; **APPENDIX A**, available at www.jospt.org). This specific technique has been described and used in clinical trials as a component for successful treatment of mechanical neck pain and cervicogenic headaches.[14,15] If there was no audible cavitation, a second attempt was performed. An audible cavitation was expected for each manipulation to be considered a success. Audible cavitations were recorded for each group.

Sham Manipulation Group Participants in the sham manipulation group were placed in a position identical to that used in the manipulation group, except that the hand over the inferior vertebrae of the motion segment was open (fingers extended). Participants were then asked to inhale and then exhale, but no thrust manipulation was delivered during exhalation. This open-hand sham manipulation procedure has been described in detail in a previous clinical trial (**APPENDIX A**).[6]

FIGURE 1. Upper thoracic manipulation.

Immediately after treatment and at the 48-to-72-hour follow-up, the physical therapist assessed for any adverse effects of manipulation, including an increase in neck, shoulder, arm, and/or hand symptoms. Participants in both groups were instructed to resume normal daily activities until the next scheduled visit, with no home exercise or advice. Participants were instructed to contact the investigator if they experienced any soreness lasting more than 3 hours.

Outcomes

The primary outcomes included self-reported pain of the neck and upper extremity on a numeric pain-rating scale (NPRS)[22] and changes in perceived improvement on the global rating of change scale (GROC).[21] The primary outcomes were selected to assess the immediate and short-term effects of thoracic manipulation on perceived benefits and common symptoms in participants with cervical radiculopathy. The secondary outcomes were disability on the NDI,[36] cervical ROM,[5] deep neck flexor muscle endurance,[19] and numbness, tingling, and distribution of symptoms, which were used to assess the effects of thoracic manipulation on disability, cervical spine impairments, and centralization of the distal symptoms. The NPRS, cervical ROM, and deep neck flexor muscle endurance data were collected at baseline, immediately following the manipulation procedure, and at 48 to 72 hours after the procedure. The GROC was collected at both follow-up time points, and the NDI at baseline and 48 to 72 hours after the intervention.

The NPRS[22] was administered by asking patients to rate the intensity of their current pain level on an 11-point scale ranging from 0 (no pain) to 10 (worst pain imaginable). Neck pain and upper extremity pain were separately assessed on the NPRS. Use of the NPRS for neck pain has been found to be reliable in patients with cervical radiculopathy,[41] with a minimal clinically important difference (MCID) of 2.2 points.[41] Clinically meaningful score cutoffs for the NPRS for pain in the upper extremity have not been established for patients with cervical radiculopathy. The MCID is 1.1 points in patients with shoulder-related pain.[25]

The GROC is a 15-point scale[21] on which respondents rate their perception of change after treatment. The scale ranges from −7 (a very great deal worse) to 0 (about the same) to +7 (a very great deal better). A score of +4 has been used to indicate moderate positive improvement in patient status.[21] Participants rated their neck symptoms and upper extremity symptoms separately on the GROC.

The NDI[36] is a 10-item questionnaire that measures the impact of neck symptoms on functional activities. Each item is scored from 0 to 5, with a total score that ranges from 0 to 50 points and higher scores representing higher disability. The NDI has acceptable reliability in the assessment of self-perceived disability and an MCID of 8.5 points in patients with cervical radiculopathy.[41]

Active cervical ROM (flexion, extension, rotation, sidebending) was assessed using a goniometer, as described by Cleland et al.[5] Rotation and sidebending were assessed on both the symptomatic and asymptomatic sides. The reliability of active cervical ROM measurements has been established in patients with mechanical neck pain.[5] The minimal detectable change (MDC) of cervical ROM ranges from 9.6° to 18.8° for flexion, 7.0° to 13.0° for extension, 5.9° to 10.0° for right sidebending, 9.1° to 19.0° for left sidebending, 7.6° to 13.9° for right rotation, and 6.4° to 6.7° for left rotation.[5,16]

The deep neck flexor muscle endurance test was performed as described by Harris et al.[19] This test has been found to have moderate reliability, with an MDC of 16.2 seconds in patients with neck pain.[19]

The distribution of tingling, numbness, and symptoms associated with cervical radiculopathy was assessed before and after

treatment. Prior to treatment, patients were educated about their symptoms and centralization using a body diagram and written instructions (**APPENDIX B**, available at www.jospt.org)[13,40] and confirmed that they understood the centralization phenomenon. A change in symptoms related to centralization was recorded as "yes" or "no" during both follow-up time points by the clinician blinded to group allocation.

Sample-Size Calculation

Effect sizes (0.62-0.66) for changes in neck pain treated with a multimodal approach and thoracic manipulation in patients with chronic neck pain have been estimated in prior randomized trials.[6,8,29] To generate a conservative sample-size estimate, we used an effect size of 0.40, alpha of .05, and power of 80%. A sample size of 22 participants per treatment group was indicated to detect a group-by-time interaction. Anticipating a 15% loss to follow-up, we aimed to recruit 25 participants per group, for a total of 50. Recruitment was stopped before achieving the recruitment goal for 2 reasons: (1) a very low dropout rate, and (2) an interim analysis showing that the effect size for neck pain (0.80) exceeded both the conservative estimate (0.40) and the estimates from previous trials (0.62-0.66).[6,8,29]

Data Analysis

All analyses were performed using SPSS Version 22 (IBM Corporation, Armonk, NY). Descriptive statistics were reported for the demographic characteristics of each group (**TABLE 1**). To determine whether covariates should be used in the analysis, baseline data for all outcome variables were inspected. No between-group differences greater than the MDC for each outcome variable were identified; therefore, the analyses did not include baseline variables as covariates.

The primary analysis included separate 2-by-3, repeated-measures analysis of variance (ANOVA) models to assess the effect of thoracic manipulation on neck and upper extremity pain as measured by the NPRS. Given a significant interaction, independent *t* tests (1-tailed) were used to determine whether the manipulation group had lower scores on the NPRS at the 2 follow-up time points compared to the sham manipulation group.

For each group, the average changes in NPRS score (both neck and upper extremity pain) from baseline to immediately after treatment and from baseline to 48 to 72 hours after treatment were calculated. The average between-group differences for the changes in NPRS score from baseline to immediate follow-up and from baseline to follow-up after 48 to 72 hours were also calculated. The 95% CI and effect size (Cohen *d*) for all variables were calculated.

The GROC score was dichotomized for the analysis. Participants who reported a GROC score of at least +4 (moderately better) were classified as having a moderate to large change in neck and/or upper extremity symptoms.[21] The proportion of participants with a +4 GROC score or greater was compared between groups using a chi-square test at both follow-up time points. We calculated the odds ratio and 95% CI for those who scored at least +4 on the GROCs for both neck and upper extremity symptoms at the immediate and 48-to-72-hour follow-ups. The number needed to treat and 95% CI to achieve a score of at least +4 on the GROCs for both neck and upper extremity symptoms were calculated at the 48-to-72-hour follow-up.

Independent 2-by-3, repeated-measures ANOVAs were used to assess between-group differences at each time point for each cervical ROM variable

TABLE 1 Baseline Demographic and Self-reported Variables

Variable	Manipulation Group (n = 22)	Sham Manipulation Group (n = 21)
Age, y*	48.8 ± 11.5	43.1 ± 10.8
Sex (female), n (%)	17 (77.3)	12 (57.1)
Height, m*	1.64 ± 0.1	1.67 ± 0.1
Weight, kg*	70.6 ± 19.6	83.9 ± 18.4
Dominant hand (right), n (%)	21 (95.5)	20 (95.2)
Symptomatic side (right), n (%)	12 (54.5)	10 (47.6)
Most troublesome symptom, n (%)		
Pain	19 (86.4)	17 (81.0)
Numbness and tingling	3 (13.6)	3 (14.3)
Unknown	...	1 (4.8)
Previous treatment, n (%)		
Rest	8 (36.4)	4 (19.0)
Cervical collar	1 (4.5)	0 (0)
Medication	11 (50)	16 (76.2)
Injection	4 (18.2)	7 (33.3)
Cervical traction	2 (9.1)	4 (19.0)
Currently employed, n (%)	12 (54.5)	15 (71.4)
Fear of movement (yes), n (%)	12 (54.5)	17 (81.0)
Onset, n (%)		
<1 mo	3 (13.6)	3 (14.3)
1-3 mo	6 (27.3)	4 (19.0)
3-6 mo	5 (22.7)	2 (9.5)
>6 mo	8 (36.4)	11 (52.4)
Unknown	...	1 (4.8)

**Values are mean ± SD.*

and the deep neck flexor endurance test. A 2-by-2, repeated-measures ANOVA was used to assess differences between groups at baseline and the 48-to-72-hour follow-up for NDI score. For both analyses, given a significant interaction, an independent *t* test (1-tailed) was used to assess whether the manipulation group had greater ROM, longer duration on the deep neck flexor endurance test, and lower NDI score compared to the sham manipulation group.

For each group, the average between-group difference for the change in cervical ROM and the deep neck flexor endurance test from baseline to immediate follow-up and from baseline to follow-up after 48 to 72 hours was calculated. The average between-group difference in change over time for the NDI was calculated between baseline and the 48-to-72-hour follow-up. The 95% CI and effect size (Cohen *d*) for all variables were calculated.

The proportion of participants reporting centralization of symptoms was compared between groups using a chi-square test. A chi-square test was also used to determine whether the proportion of participants who believed they were receiving an active versus an inactive intervention in each group differed. For all analyses, the alpha level was set at .05 a priori. Bonferroni correction was used to adjust the alpha level to .025 for all post hoc analyses of the significant ANOVAs.

RESULTS

Consecutive patients (n = 71) were screened for study eligibility, and participants (n = 43) who met the criteria and agreed to participate were enrolled in the study (**FIGURE 2**) and randomized to receive either thoracic manipulation (n = 22) or sham manipulation (n = 21). In each of the 6 clinics there were 5, 8, 7, 7, 8, and 8 participants, respectively.

Recording of adverse events indicated that no increases in neck, arm, or hand symptoms were reported immediately after treatment or at the 48-to-72-hour follow-up. Moreover, no participants reported soreness lasting more than 3 hours after the treatment. Audible cavitations were recorded in 100% of the manipulation group, while none were recorded in the sham manipulation group. A greater proportion of participants in the manipulation group (90%) believed they received the active treatment compared to those in the sham manipulation group (57%, $P = .01$).

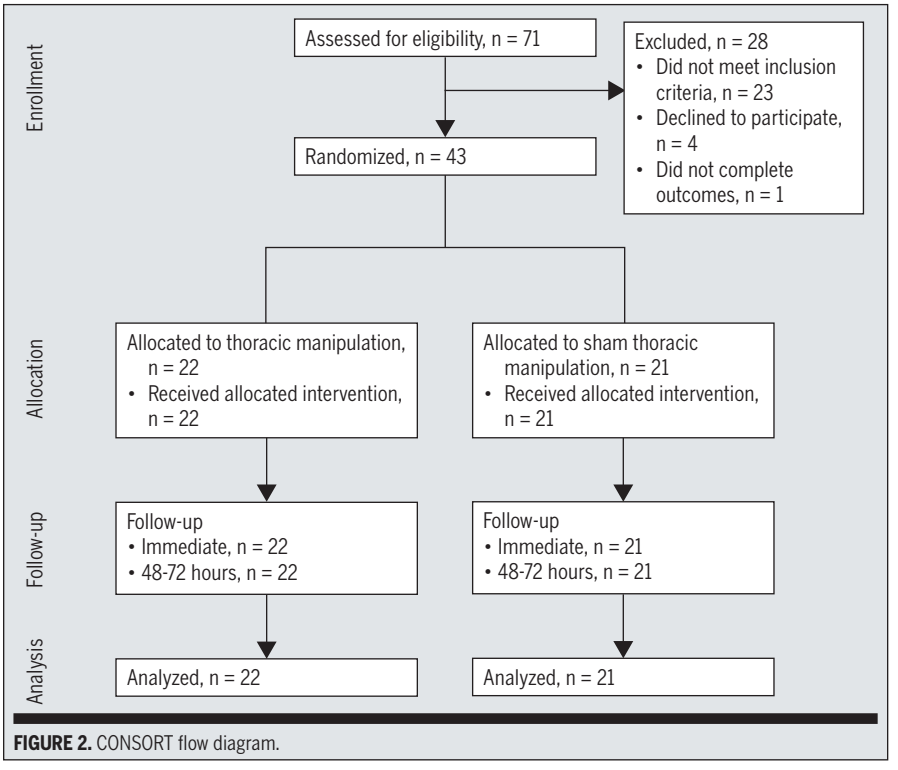

FIGURE 2. CONSORT flow diagram.

Primary Outcomes

A significant group-by-time interaction was found for both neck and upper extremity pain ($P<.01$). The subsequent independent *t* tests indicated that the manipulation group reported significantly less neck pain at both follow-up time points compared to the sham group (**TABLE 2**). There was no significant between-group difference for upper extremity pain at the 2 follow-up time points. At both follow-up time points, the manipulation group had a greater decrease in both neck and upper extremity pain compared to the sham group, and these changes were associated with large effect sizes (**TABLE 2**).

A significantly greater proportion of participants randomized to the manipulation group reported at least moderate improvement, with a GROC score of +4 or greater, in both neck and upper extremity symptoms compared to the sham manipulation group at both follow-up time points (**TABLE 2**). Similarly, the odds ratio values indicate that patients randomized to the manipulation group were more likely to report at least moderate improvements in their neck and upper extremity symptoms compared to the sham manipulation group at both follow-up time points (**TABLE 2**). At the 48-to-72-hour follow-up, the number needed to treat was 2.2 (95% CI: 1.5, 4.5) for the GROC for neck symptoms, and 3.1 (95% CI: 2.0, 8.1) for the GROC for upper extremity symptoms.

Secondary Outcomes

Significant group-by-time interactions were found for the NDI ($P<.01$) (**FIGURE 3**), deep neck flexor endurance test ($P<.01$) (**FIGURE 4**), and active cervical ROM in flex-

ion ($P<.01$), extension ($P<.01$), rotation to the symptomatic ($P<.01$) and asymptomatic sides ($P<.01$), and sidebending to the symptomatic side ($P<.01$) (**FIGURE 5**). Immediately after treatment, the manipulation group had greater active cervical flexion (mean difference, 10.8°; 95% CI: 4.2°, 17.6°; $P<.01$), extension (mean difference, 10.0°; 95% CI: 3.1°, 17.0°; $P<.01$), and rotation to the symptomatic (mean difference, 14.2°; 95% CI: 7.1°, 21.3°; $P<.01$) and asymptomatic sides (mean difference, 9.2°; 95% CI: 1.8°, 16.7°; $P = .02$) compared to the sham manipulation group. At 48 to 72 hours after treatment, the manipulation group demonstrated greater active cervical flexion (mean difference, 13.7°; 95% CI: 7.1°, 20.3°; $P<.01$), extension (mean difference, 11.1°; 95% CI: 4.5°, 17.8°; $P<.01$), rotation to the symptomatic (mean difference, 13.9°; 95% CI: 7.4°, 20.5°; $P<.01$) and asymptomatic sides (mean difference, 11.4°; 95% CI: 5.0°, 17.9°; $P<.01$), sidebending on the symptomatic side (mean difference, 8.6°; 95% CI: 3.2°, 14.1°; $P<.01$), and deep neck flexor endurance (mean difference, 6.3 seconds; 95% CI: 0.5, 12.2; $P = .02$) compared to the sham manipulation group. Figure captions provide the between-group differences for changes in deep neck flexor endurance (**FIGURE 4**) and cervical AROM (**FIGURE 5**) between baseline and follow-up time points. The NDI score was lower in the manipulation group at 48 to 72 hours after the intervention compared to the sham manipulation group (mean difference, −7.8 points; 95% CI: −13.3, −2.4; $P<.01$). The caption of **FIGURE 3** provides the between-group differences for changes in the NDI between baseline and follow-up time points.

A significantly greater proportion in the manipulation group versus the sham manipulation group reported centralization of symptoms immediately (55% versus 5%, $P<.01$) and at 48 to 72 hours (64% versus 5%, $P<.01$) after treatment.

DISCUSSION

This randomized clinical trial assessed the effects of a single session of upper thoracic and mid-thoracic thrust manipulation in individuals with cervical radiculopathy. Patients randomized to receive thoracic manipula-

TABLE 2 Primary Outcomes at Each Data-Collection Time Point

Outcome/Time Point	Manipulation Group (n = 22)*	Sham Manipulation Group (n = 21)*	Between-Group Differences†‡	Odds Ratio†	*P* Value
NPRS for neck pain§					<.01‖
Baseline	6.8 ± 2.0	7.5 ± 1.9	…	…	…
Immediate	5.0 ± 2.4	7.4 ± 1.7	−2.4 (−3.7, −1.2)	…	<.01¶
Change from baseline to immediate†	1.9 (0.9, 2.8), *d* = 0.9	0.1 (−0.2, 0.5), *d* = 0.2	1.8 (0.7, 2.7), *d* = 1.1	…	…
48-72 h	4.4 ± 2.5	7.5 ± 2.0	−3.1 (−4.5, −1.7)	…	<.01¶
Change from baseline to 48-72 h†	2.4 (1.3, 3.5), *d* = 1.0	0.1 (−0.4, 0.5), *d* = 0.1	2.3 (1.2, 3.5), *d* = 1.3	…	…
NPRS for upper extremity pain§					<.01‖
Baseline	7.4 ± 2.2	6.6 ± 2.0	…	…	…
Immediate	5.1 ± 2.4	5.9 ± 2.8	−0.8 (−2.4, 0.8)	…	.34¶
Change from baseline to immediate†	2.2 (1.2, 3.2), *d* = 1.0	0.7 (−0.2, 1.6), *d* = 0.4	1.5 (0.2, 2.8), *d* = 0.7	…	…
48-72 h	5.1 ± 2.0	6.0 ± 2.6	−1.0 (−2.4, 0.5)	…	.18¶
Change from baseline to 48-72 h†	2.3 (1.5, 3.2), *d* = 1.2	0.6 (−0.3, 1.5), *d* = 0.3	1.7 (0.5, 2.9), *d* = 0.9	…	…
GROC for neck symptoms, n (% improved)#					
Immediate	11 (50.0)	2 (9.5)	…	9.5 (1.8, 50.7)	<.01**
48-72 h	11 (50.0)	1 (4.8)	…	20.0 (2.3, 176.1)	<.01**
GROC for upper extremity symptoms, n (% improved)#					
Immediate	9 (40.9)	2 (9.5)	…	6.6 (1.2, 35.5)	.02**
48-72 h	7 (31.8)	0 (0.0)	…	Infinity	<.01**

Abbreviations: GROC, global rating of change; NPRS, numeric pain-rating scale.
**Values are mean ± SD unless otherwise indicated.*
†Values in parentheses are 95% confidence interval.
‡Calculated as manipulation group minus sham group at each time point.
§A 0-to-10 scale, where 0 is no pain.
‖Interaction effect.
¶Between-group post hoc comparison (independent-samples t test).
#Those who reported at least +4 ("moderately better") were categorized as "improved."
***Between-group comparison (chi-square test).*

tion as compared to sham manipulation had greater improvements in neck pain, neck-related patient-rated disability, and cervical impairments (ROM and deep neck flexor endurance) immediately and up to 48 to 72 hours after treatment. At both follow-up time points, a greater proportion of patients in the manipulation group reported at least a moderate change in their neck and upper extremity symptoms and centralization of their symptoms compared to patients in the sham manipulation group.

Primary Outcomes

NPRS (Neck Pain) and GROC (Neck Symptoms) Immediately after manipulation, the average reduction in NPRS for neck pain was 1.9 points in the manipulation group, compared to 0.1 points in the sham manipulation group, for a between-group mean change of 1.8 points. These changes over time and associated large effect sizes may indicate a large treatment effect for thoracic manipulation in patients with cervical radiculopathy.

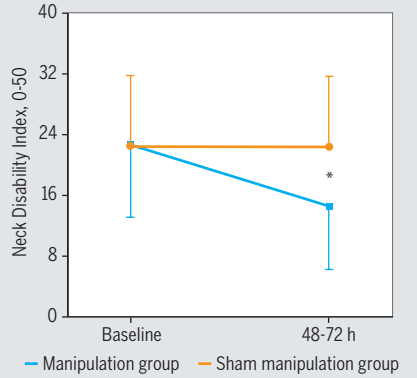

FIGURE 3. Mean Neck Disability Index score for the manipulation group (blue line) and the sham manipulation group (orange line). Error bars represent 1 SD. There was a significant group-by-time interaction (P<.01). *Significant between-group difference at 48-to-72-hour follow-up (independent t test P<.025). Mean between-group difference for the change in Neck and Disability Index score was calculated as mean change in the manipulation group minus mean change in the sham manipulation group, and reported with 95% confidence interval (CI) and effect size. From baseline to 48 to 72 hours, the mean between-group difference of the change in Neck Disability Index score was 8.0 points (95% CI: 4.5, 11.6 points) and the effect size was 1.4.

However, it should be noted that the lower-bound CI (0.7) does not meet the MCID (**TABLE 2**).

Similar results were found at the 48-to-72-hour follow-up (**TABLE 2**). Cleland et al[6] reported an immediate reduction of 15.4 mm on a 0-to-100-mm visual analog scale for neck pain when patients with neck pain were treated with thoracic manipulation. Direct comparison to the study by Cleland et al[6] is cautioned, as the study included patients with mechanical neck pain and used a different pain scale. Further, the specific manipulation techniques used in these studies differed. Cleland et al[6] used a flexion-based technique that more likely targeted the mid-thoracic spine, whereas the current study used an extension-based technique, which enabled a closer fulcrum contact to the cervicothoracic junction during the upper thoracic manipulation. In the current study, the average reduction in NPRS score for neck pain (2.4 points) in the manipulation group exceeded the MCID at the 48-to-72-hour follow-up.

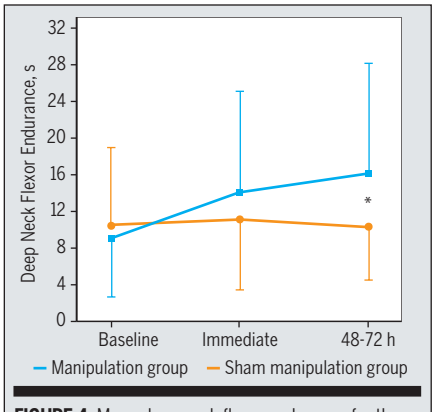

FIGURE 4. Mean deep neck flexor endurance for the manipulation group (blue line) and sham manipulation group (orange line). Error bars represent 1 SD. There was a significant group-by-time interaction (P<.01). *Significant between-group difference at 48-to-72-hour follow-up (independent t test P<.025). Mean between-group difference for the change in deep neck flexor endurance was calculated as mean change in the manipulation group minus mean change in the sham manipulation group, and reported with 95% confidence interval (CI) and effect size. From baseline to immediately after treatment, the mean between-group difference of the change in deep neck flexor endurance was 4.5 seconds (95% CI: 0.9, 8.0 seconds) and the effect size was 0.8. From baseline to 48 to 72 hours, the mean between-group difference of the change in deep neck flexor endurance was 7.8 seconds (95% CI: 3.7, 11.9 seconds) and the effect size was 1.2.

When evaluated using the GROC, 50% of patients who received thoracic manipulation reported at least a moderate positive change in their neck symptoms compared to those who received the sham manipulation at both time points. This is a proportion nearly as high as that reported by Young et al[42] (68%) in patients with cervical radiculopathy who were treated with a 4-week multimodal intervention of manual therapy and exercise, with or without traction. The low number needed to treat associated with immediate and short-term moderate improvements in neck symptoms may indicate that thoracic manipulation should be considered as an intervention in patients with cervical radiculopathy.

NPRS (Upper Extremity Pain) and GROC (Upper Extremity Symptoms) Post hoc testing indicated no between-group differences for the upper extremity NPRS at either time point. However, the between-group difference for the change in upper extremity NPRS score indicated greater reduction in arm pain of 1.5 points at the immediate follow-up and 1.7 points at the 48-to-72-hour follow-up, favoring the manipulation group. Although these changes were associated with moderate to large effect sizes, respectively, it should be noted that the lower-bound CIs at both follow-up points did not meet the MCID (**TABLE 2**).

However, these changes in arm pain after manipulation may still be clinically meaningful, as those patients in the manipulation group were significantly more likely to report at least a moderate change in the GROC score for upper extremity symptoms compared to patients in the sham manipulation group. The distal symptoms of patients with cervical radiculopathy are often treated with a comprehensive multimodal approach, which primarily targets both the cervical spine and neurodynamic system.[7,9,39,42] Therefore, larger between-group differences

in upper extremity pain might have been less likely to occur, as the participants received only a single session of manipulation to the thoracic spine.

Secondary Outcomes

Neck Disability Index At the 48-to-72-hour follow-up, the NDI score was lower in the manipulation group compared to the sham manipulation group, but the between-group difference for the change in NDI score (8.0 points) did not exceed the MCID of 8.5 points.[41] Cleland et al[8] examined the effect of thoracic manipulation in patients with neck pain, and reported that the manipulation group had a 6-point greater reduction in NDI score compared to the mobilization group at 48-to-96-hour follow-up. Unfortunately, the isolated effects of thoracic manipulation cannot be estimated, as additional cervical ROM exercise was included in the treatment of both groups. Although between-group differences of this magnitude generated with a single treatment technique may be clinically important, these effects may wash out at longer-term follow-up, as demonstrated by a recent study that pragmatically applied thoracic thrust and nonthrust manipulation in patients with mechanical neck pain.[18]

Active Cervical ROM From baseline to 48 to 72 hours after treatment, greater increases in cervical ROM flexion, extension, rotation on the symptomatic and asymptomatic sides, and sidebending on the symptomatic side were measured in the manipulation group compared to the sham manipulation group. These findings are consistent with the results of previous studies of thoracic manipulation for neck pain.[11,43]

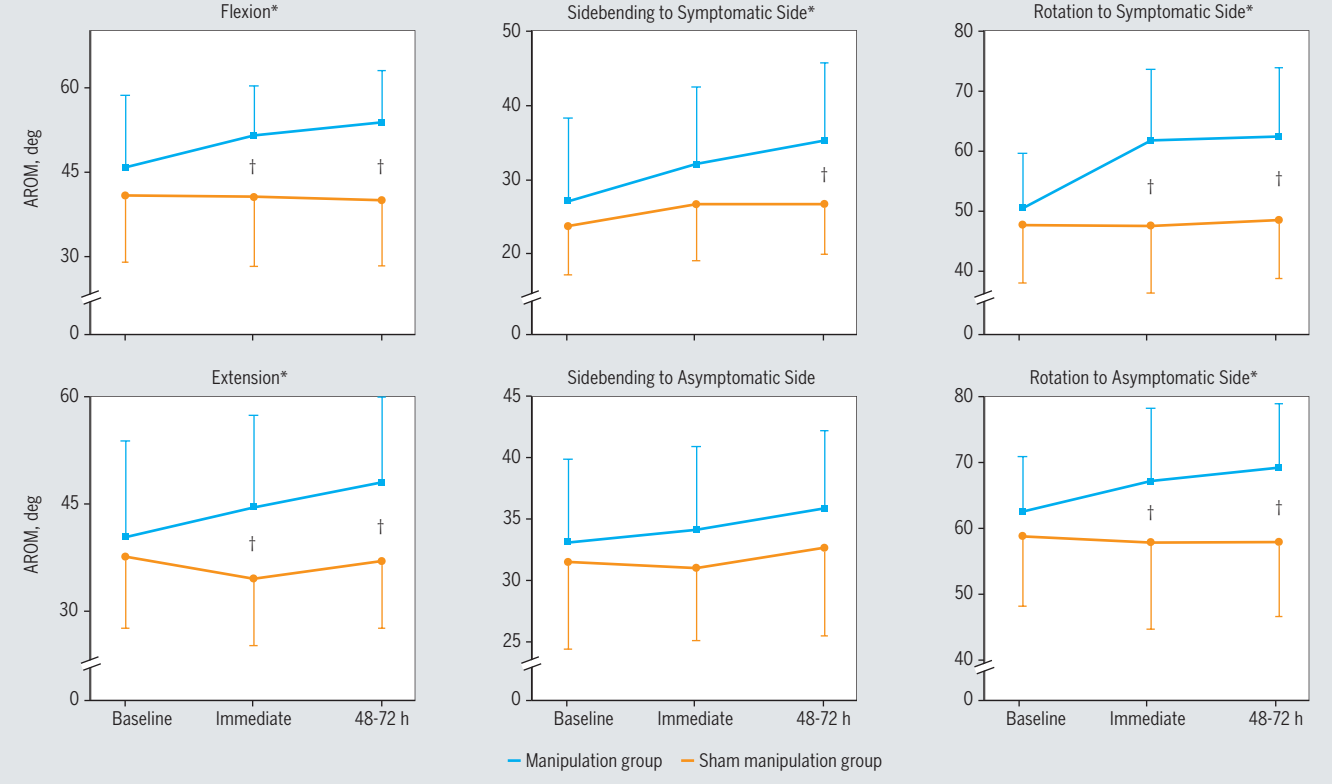

FIGURE 5. Mean cervical AROM for the manipulation (blue line) and sham manipulation (orange line) groups. Error bars represent 1 SD. *Significant group-by-time interaction ($P<.01$). †Significant between-group difference at designated follow-up time point (independent t test $P<.025$). Mean between-group difference was calculated as mean change in the manipulation group minus mean change in the sham manipulation group, and reported with 95% CI and effect size. For flexion, the mean between-group difference for the change from baseline to immediately after treatment was 5.7° (95% CI: 0.7°, 10.8°) and the effect size was 0.7; from baseline to 48 to 72 hours it was 8.6° (95% CI: 2.3°, 14.8°) and the effect size was 0.8. For extension, the mean between-group difference for the change from baseline to immediately after treatment was 7.2° (95% CI: 1.9°, 12.5°) and the effect size was 0.8; from baseline to 48 to 72 hours it was 8.4° (95% CI: 3.0°, 13.7°) and the effect size was 1.0. For sidebending on the symptomatic side, the mean between-group difference for the change from baseline to immediately after treatment was 2.2° (95% CI: –2.5°, 6.9°) and the effect size was 0.3; from baseline to 48 to 72 hours it was 5.3° (95% CI: 1.7°, 8.8°) and the effect size was 0.9. For sidebending on the asymptomatic side, the mean between-group difference for the change from baseline to immediately after treatment was 1.3° (95% CI: –2.3°, 4.9°) and the effect size was 0.2; from baseline to 48 to 72 hours, it was 1.5° (95% CI: –2.6°, 5.6°) and the effect size was 0.2. For rotation on the symptomatic side, the mean between-group difference for the change from baseline to the immediate time point was 11.5° (95% CI: 6.1°, 16.9°) and the effect size was 1.3; from baseline to 48 to 72 hours it was 11.2° (95% CI: 6.3°, 16.2°) and the effect size was 1.4. For rotation on the asymptomatic side, the mean between-group difference for the change from baseline to immediately after treatment was 5.6° (95% CI: 0.7°, 10.5°) and the effect size was 0.7; from baseline to 48 to 72 hours it was 7.8° (95% CI: 2.1°, 13.5°) and the effect size was 0.8. Abbreviations: AROM, active range of motion; CI, confidence interval.

The measures of rotation and sidebending toward the symptomatic side are particularly interesting, as the diagnostic criteria for cervical radiculopathy[37] include a positive Spurling A test (sidebending on the symptomatic side with overpressure) and restricted rotation on the symptomatic side (less than 60°). Greater mobility in these specific, and often provocative, measures may have had a clinical effect, as suggested by the between-group differences in pain/disability found in this study. In contrast, a recent systematic review questioned the clinical utility of using cervical ROM as an outcome measure following manipulation in patients with neck pain.[34] The authors suggest that there is conflicting evidence as to whether cervical ROM increases or decreases following mobilization/manipulation, and caution clinicians in making clinical judgments primarily based on cervical ROM.[34]

Deep Neck Flexor Muscle Endurance Test A greater increase in endurance of the deep neck flexors was measured in the manipulation group from baseline to the 48-to-72-hour follow-up compared to that measured in the sham manipulation group. The average between-group difference for the change in deep neck flexor endurance hold time was 7.8 seconds. However, this difference may not be meaningful, as it does not exceed the MDC measured in patients with neck pain (16.2 seconds).

These results should be interpreted with caution because patients with cervical radiculopathy may have shorter average times on the deep neck flexor endurance test compared to both patients with neck pain and controls.[19] In a prior study, patients with neck pain treated with a single session of thoracic thrust manipulation demonstrated greater deep neck flexor endurance compared to those receiving nonthrust mobilization.[15] The very short-term follow-up for reassessment may reduce the likelihood of muscle endurance changes, as these would be expected with a longer period of muscle training.[23] The improvement in deep neck flexor muscle performance in participants with cervical radiculopathy may be due to pain inhibition, as the participants in the manipulation group had greater reductions in pain at follow-up. In summary, it is likely that manipulation does not have a direct effect on muscle endurance but promotes changes in pain/symptoms/disability.

Tingling and Numbness and Distribution of Symptoms (Centralization) Fourteen (64%) of the participants in the manipulation group and 1 (5%) of the participants in the sham manipulation group reported centralization of symptoms at 48 to 72 hours. This phenomenon was originally associated with performance of repeated movements in patients with low back pain.[13,40] Although centralization has not specifically been assessed in prior studies of participants with cervical radiculopathy, multiple studies have reported reductions in upper extremity symptoms and symptom distribution following mobilization/manipulation, neurodynamic techniques, exercise, and traction.[1,10,12,17,26,27,42] The repeated motion of cervical retraction has been reported to help reduce nerve root compression and upper extremity pain in patients with C7 radiculopathy.[1] The movement of retraction involves upper cervical flexion and, more importantly, lower cervical extension. Interestingly, the upper thoracic manipulation performed in this study promotes translatory extension of the lower cervical and upper thoracic spinal segments while the upper cervical spine is resting in neutral/slight flexion (similar to end-range retraction).

Further, it has been proposed that restoration of normal biomechanics to the cervicothoracic motion segment may have a role in lowering mechanical stresses and improving distribution of joint forces in the cervical spine.[28] In light of these mechanical constructs, it is interesting to note that the manipulation group had greater active cervical extension compared to the sham manipulation group at both follow-up time points (**FIGURE 5**). The reduction in local and distal symptoms of the manipulation group may have been a result of a mechanical effect on the lower cervical spinal joints, disc derangements, or nerve root impingement.

Limitations

One limitation of this study is the very short-term follow-up. There has been some speculation on the limited importance of the immediate effects of a treatment intervention, as longer-term follow-up is ideal. However, for daily clinical practice, the investigation of immediate/short-term effects of an isolated technique can be useful. Moreover, this trial provides a foundation for future studies with longer follow-up.

Further, the sham manipulation procedure utilized in this study may not have been an adequate control. A greater proportion of participants in the manipulation group believed they received the intervention compared to those in the sham manipulation group. This might have influenced the outcomes between groups through different patient expectations.[2,24,33] Future research should ensure the believability of sham procedures for use in clinical trials.

CONCLUSION

In this study, 1 session of thoracic manipulation to patients with cervical radiculopathy resulted in improved pain, disability, cervical ROM, and deep neck flexor endurance compared to those patients treated with sham manipulation. Patients treated with manipulation were also more likely to report at least moderate change in their neck and upper extremity symptoms up to 48 to 72 hours following treatment. The findings of this study aid clinician decision making in treatment selection for immediate and short-term benefits for patients with cervical radiculopathy.

KEY POINTS

FINDINGS: One session of upper thoracic and mid-thoracic thrust manipulation

provided immediate and short-term benefits in perceived recovery, pain, disability, and neck impairments in patients with symptoms of cervical radiculopathy.

IMPLICATIONS: The results suggest that thoracic manipulation in patients with cervical radiculopathy is an effective early treatment option.

CAUTION: The results should not be generalized to a comprehensive multimodal treatment strategy or longer-term follow-up. Patients' beliefs of treatment received may have influenced the outcomes.

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APPENDIX A

DESCRIPTION OF HIGH-VELOCITY, LOW-AMPLITUDE THRUST AND SHAM PROCEDURES

High-Velocity, Low-Amplitude Thrust Manipulation

Manipulation technique directed bilaterally to the upper thoracic (C7-T3) and mid-thoracic (T4-T9) spine. Participants were positioned supine with their arms and forearms flexed across the chest, with the elbows aligned in a superoinferior direction (**FIGURE 1**). The therapist contacted the transverse processes of the lower vertebrae of the target motion segment with the thenar eminence and middle phalanx of the third digit. The upper lever was targeted by adding the secondary levers of rotation away from and sidebending toward the therapist. The lower lever, or underside hand, used pronation and radial deviation to achieve rotation (toward) and sidebending (away) moments. Participants were instructed to deeply inhale and exhale. During the exhalation phase, the space inferior to the xiphoid process and costochondral margin was used as the contact point against the patient's elbows to deliver a high-velocity, low-amplitude thrust manipulation in an anterior-to-posterior direction. If there was no audible cavitation with the manipulation, a second attempt was performed to further isolate the motion segments. An audible cavitation was expected for each manipulation to be considered a success.

Sham Manipulation

Participants were placed in the identical setup position as that for participants included in the active manipulation group, except for hand positioning. An open hand (extended fingers) was placed over the inferior vertebrae of the motion segment. Once the "premanipulative position" was achieved, the patient was instructed to take a deep inhalation and then exhale. No high-velocity, low-amplitude thrust manipulation was performed during the exhalation phase in the sham manipulation group.

APPENDIX B

DESCRIPTION OF CENTRALIZATION

Patient #___

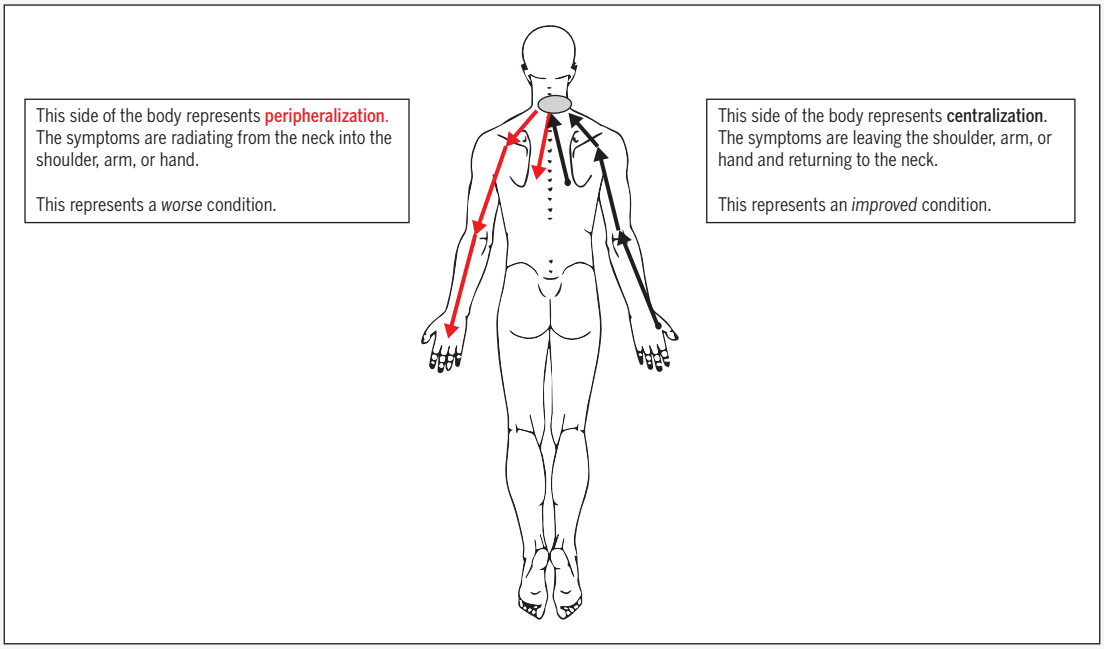
Please read carefully

The symptoms (pain/tingling/numbness) you have in your shoulder/arm or hand are likely a result of a problem in your neck. Although you may not have neck pain at this time, the test the physical therapist has performed on you today helped him or her identify your neck as the cause of your symptoms in the shoulder/arm/hand area.

Centralization

Joints, nerves, and disc material in your neck can send symptoms (pain/tingling/numbness) into the shoulder, arm, or hand. This process is called *peripheralization*. When pressure is relieved in the neck, the shoulder, arm, or hand symptoms may disappear or move toward the area that produced them (the neck). This concept is called *centralization*.

For example, let's say you have pain or numbness in the arm or hand that is coming from the neck. You then receive treatment to try and relieve the pressure in the neck area. Following treatment, you notice that the pain and numbness in the arm/hand is gone, but your neck feels a bit worse. This is the centralization process. It is very important to understand that this treatment is considered a success, and the therapist would consider you "better" even though your neck pain may be somewhat worse. We consider the symptoms away from your neck the more severe symptoms with your injury, and we want to eliminate them or get them closer to the neck.



*I have read and understand the information above. (1) Yes (2) No