Annals of Physical and Rehabilitation Medicine xxx (2016) xxx–xxx

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Original article

High-intensity stretch treatment for severe postoperative adhesive capsulitis of the shoulder

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ARTICLE INFO

Article history:
Received 13 November 2015
Accepted 27 April 2016

Keywords:
Adhesive capsulitis
Shoulder
Stretching
High intensity stretching
Physical therapy

ABSTRACT

Background: Some patients with postoperative adhesive capsulitis reach a plateau in their recovery with a standard protocol of physical therapy (PT), which puts them at risk for further surgical intervention.
Objectives: We aimed to evaluate therapy for postoperative adhesive capsulitis of the shoulder in 2 groups of patients: (1) those who used a high-intensity stretch (HIS) device after reaching a plateau in their recovery with a standard protocol of traditional PT (PT + HIS) and (2) those who showed no plateau in their recovery with a standard protocol of traditional PT alone (PT only).
Methods: We retrospectively reviewed the records for 60 patients (51 males; mean age 46.7 ± 12.6 years) with postoperative adhesive capsulitis who received treatment between March 2007 and May 2010. Forward elevation and combined internal/external rotation at the initial postoperative visit and final visit were measured. The measurements from group 2 patients were used as an observational benchmark.
Results: The PT + HIS ($n = 42$) and PT-only ($n = 18$) patients did not differ in total follow-up time. Initial elevation was worse for PT + HIS than PT-only patients (22.1° lower, $P = 0.02$), but the final elevation was equivalent. Initial rotation was worse for PT + HIS than PT-only patients (16.6° lower, $P = 0.04$), but the final rotation was higher for PT + HIS patients (10.6° higher, $P = 0.04$). Gains in elevation and rotation were greater for the PT + HIS than PT-only patients ($P = 0.04$ and $P = 0.01$).
Conclusions: Patients with postoperative adhesive capsulitis of the shoulder who are unable to reach their PT treatment goals with a standard protocol of PT may benefit from the addition of HIS to their treatment regimen. HIS could be a valuable adjunct to PT for treating postoperative adhesive capsulitis in appropriate patients.

1. Introduction

Adhesive capsulitis of the shoulder occurs in up to 5% of the population [1,2]. It can limit a patient's ability to perform activities of daily living due to pain and to loss of both active and passive range of motion (ROM). Two general categories of adhesive capsulitis have been described:

- primary, or idiopathic;
- and secondary [3–5].

Primary adhesive capsulitis develops gradually over time without a specific known cause. Secondary adhesive capsulitis generally results from trauma or immobilization and can be separated into 3 types:

- endocrine disorder-related;
- post-traumatic;
- and postoperative [6].

Up to 40% of patients with adhesive capsulitis experience symptoms for longer than 3 years and up to 15% have a persistent disability [7,8]. Recovery from primary adhesive capsulitis generally includes a return of motion and resolution of symptoms; however, secondary adhesive capsulitis can be more difficult to treat [9]. Postoperative adhesive capsulitis can follow a more protracted course, often requiring a surgical release procedure [5,9–15]. Postoperative adhesive capsulitis can occur in up to 13% of patients after rotator cuff repair [11]. Other aetiologies of postoperative adhesive capsulitis include labral repair, capsulorrhaphy, shoulder arthroplasty and humerus fracture fixation [15]. Adhesive capsulitis incurs significant costs: direct costs were reported to be $7 billion in the United States in 2000 (equivalent to more than $9 billion in 2016) [16].

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http://dx.doi.org/10.1016/j.rehab.2016.04.010
1877-0657/

The standard of care for postoperative adhesive capsulitis has included treatment with continuous passive motion (CPM) devices in the early postoperative period, followed by traditional physical therapy (PT). CPM devices are intended to prevent the formation of scar tissue and move the joint back and forth throughout the entire ROM of the joint. The use of CPM devices for treating frozen shoulder has had mixed results [17–19]. Other non-surgical interventions used as adjunct therapy to PT include glucocorticoid injections and arthrographic joint distension [1,20–23]. If motion loss persists after prolonged conservative treatment, surgical intervention including manipulation under anesthesia or lysis of adhesions is often the only recourse. An effective non-operative solution after surgery could provide significant savings in downstream healthcare costs by preventing a second surgical procedure along with the subsequent additional PT and doctor visits.

Mechanical therapy (performed at home) used as an adjunct to outpatient PT has been successful in treating adhesive capsulitis in the knee [24–26]. Mechanical therapy devices can be classified as low- or high-intensity stretch (HIS) devices [27]. HIS devices can apply torque to the joint similar to that applied by a physical therapist, whereas low-intensity devices apply lower torque to the joint and are usually used for longer treatment periods. Unlike CPM devices that are designed to prevent scar tissue formation, HIS devices are designed to stretch a joint at its end ROM to permanently elongate scar tissue that has already formed in the joint. In general, patients are given HIS devices when they are not meeting treatment milestones and have reached a plateau in their recovery with a standard protocol of PT. This plateau puts them at risk for further surgical intervention including manipulation under anesthesia or lysis of adhesions. A study of more than 60,000 patients with secondary adhesive capsulitis in the knee due to injury or surgery reported that patients receiving an HIS device were at significantly less risk of re-hospitalization or re-operation than those receiving a low-intensity device or PT alone [28]. To our knowledge, only one study has evaluated the use of an HIS device for treating shoulder stiffness [29]. That study dealt with frozen shoulder and is addressed in the discussion.

The purpose of this retrospective study of patients with postoperative adhesive capsulitis was to evaluate the efficacy of treatment for 2 groups of patients:

- patients who had reached a plateau in their recovery and failed to meet treatment goals with a standard protocol of traditional PT alone who were given an HIS device in addition to PT (PT + HIS);
- and patients with no evidence of reaching a plateau in their recovery and who met their treatment goals with PT alone (PT only).

We aimed to examine whether patients who had reached a plateau in their recovery with PT alone would benefit from the addition of HIS to their treatment protocol, so that they would recover to an equivalent level as compared to patients who reached all treatment goals with PT alone. The retrospective nature of this study and atypical study design precluded a direct comparison between group 1 and 2 patients. Results from group 2 patients were used as a benchmark to observe group 1 patients, for an observational study.

2. Materials and methods

2.1. Participants

This retrospective institutional research board-approved study was granted a waiver of informed consent. Clinical notes were examined for patients seen postoperatively between March 2007 and May 2010 after undergoing an arthroscopic shoulder procedure performed by one of the authors (PW). Within this time, 60 patients (51 males, mean age 46.7 ± 12.6 years, height 1.8 ± 0.1 m, weight 93.9 ± 18.1 kg) received treatment for postoperative adhesive capsulitis. Surgical procedures included rotator cuff repair, subacromial and nerve decompression, paracapsular release, biceps tenodesis, labral repair, repair of a superior labral tear from anterior to posterior, distal clavicle excision, capsulorrhaphy, and microfracture surgery (see Supplementary Table). Overall, 42/60 patients reached a plateau in their recovery after failing to achieve target treatment goals with a standard protocol of traditional PT. For these 42 patients, the addition of HIS mechanical therapy (High-Intensity Stretch Device, ERMI Shoulder Flexionater®) was considered the best treatment to avoid further surgical intervention (PT + HIS group). The other 18 patients showed no evidence of a plateau in their recovery and reached their treatment goals with a standard protocol of PT (PT-only group). For the 42 PT + HIS patients, the HIS device was introduced after a mean of 10.4 ± 4.0 weeks of treatment with a standard protocol of traditional PT. The 42 patients received the HIS device while continuing with PT for a mean of 15.8 ± 7.0 weeks, for a total mean of 26.2 ± 10.1 weeks treatment time (10.4 weeks of PT alone + 15.8 weeks of PT + HIS). The PT-only patients did not reach a plateau in their recovery and met all treatment goals with the standard protocol of traditional PT for a statistically equivalent duration (26.8 ± 10.3 weeks). Therefore, PT + HIS patients did not require more treatment time than PT-only patients. The groups did not differ in mean age (46.6 vs. 44.3; $P = 0.41$), height (1.8 m vs. 1.7 m; $P = 0.14$) or weight (96.2 kg vs. 78.0 kg; $P = 0.16$).

2.2. Intervention

The postoperative PT protocol for each patient was customized to the patient's pathology and the surgical procedure performed. All patients started with formal PT within 3 days after surgery. All patients except those who underwent a subscapularis tendon repair began with passive flexion, elevation and internal and external rotation on the scapular plane, in addition to selected active-assisted ROM exercises.

Interval target goals for ROM progress during PT were specified for each patient and were based on the contralateral shoulder ROM. ROM goals varied among patients and depended on the age and sex of the patient, preoperative ROM in the injured shoulder, injury and surgery type, and ROM in the contralateral arm. The 42 patients in the PT + HIS group were consistently unable to reach their ROM goals and were prescribed an HIS device; they also continued PT. All of these patients showed failure after at least 5 weeks of PT (mean 10.4 ± 4.0 weeks) before the introduction of the HIS device, with the exception of one patient who had limited pre-surgery ROM, reached a plateau early in treatment and received the device after 2.6 weeks (18 days) of PT. Because this project is retrospective, we are not able, at this stage, to give specific numbers that define a plateau in recovery. However, patients with $< 45^\circ$ in external rotation and 120° in forward elevation after 5 or more weeks of PT are generally considered at risk of a poor outcome without additional intervention.

The PT + HIS patients were given an HIS device to be used at home (Fig. 1). After the device was set up in the patient's home, the patient received clear demonstrations on how to use it. Patients were asked to perform six 10-min sessions of end-range stretching per day with the device.

The HIS device could be set to stretch in external rotation, abduction or a combination of the 2 movements (Fig. 1). The patient could increase the torque being applied to the shoulder by pumping the hydraulic actuator lever arm, which was controlled by the patient's unaffected arm. By pumping the lever arm, the patient moved the affected shoulder to its end ROM, and that static

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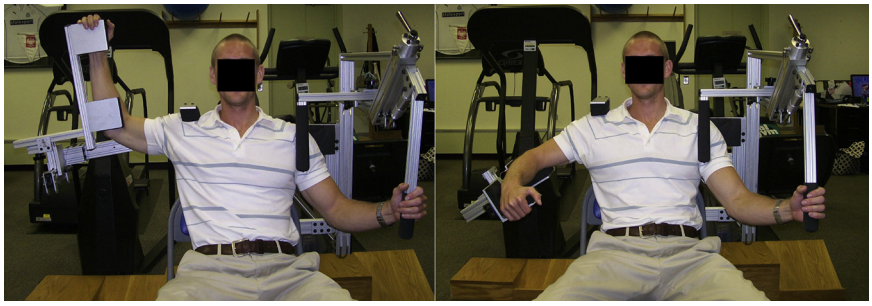

Fig. 1. A patient using the high-intensity stretch (HIS) mechanical therapy device to stretch the shoulder. The device is shown during stretching of the shoulder in external rotation at 90° of abduction (left) and in abduction (right). The device can also stretch external rotation at 0° of abduction (not pictured).

position was maintained for periods of up to 10 min. The level of torque could be adjusted as needed throughout the stretch period by using the actuator lever arm to increase torque or the quick-release valve to reduce torque. A common treatment protocol was to stretch for 10 min, rest for 10 min, then stretch for 10 min. This protocol was repeated 2 additional times per day to achieve the desired goal of 60 min of end-range stretching per day.

Passive arc of elevation was measured according to the American Shoulder and Elbow Surgeons (ASES) recommendations for standardized shoulder assessment [30]. This motion, also called "forward elevation," consists of the maximum arm–trunk angle viewed from any direction. The arc of elevation was performed with the patient standing, and internal and external rotation was measured with the patient supine and with the scapula stabilized by the examiner and the shoulder at 90° of abduction. The same clinician used a goniometer for measurement at each office visit during the treatment. However, intermediate measurements are not presented in this paper, because this study focused on the baseline measurement at the initial postoperative follow-up visit and the final recorded measurements. Because this study is retrospective, the duration of PT and the timing of office visits differed for each subject.

2.3. Statistical analyses

Passive shoulder arc of elevation (ELEV), external rotation (ER), internal rotation (IR), and total range of rotation (ER + IR) measurements were obtained from each patient's electronic medical records. Means (SD) and 95% confidence intervals were used to characterize measurements at each follow-up period. Two-sample equal variance t test was used to compare outcomes between groups. The F-test was used to ensure equal variances before applying t tests. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Follow-up period

The PT + HIS ($n = 42$) and PT-only ($n = 18$) patients did not differ in total treatment time. For PT + HIS patients, the HIS device was introduced after a mean of 10.4 ± 4.0 weeks of treatment with a standard protocol of traditional PT. Patients used the HIS device while continuing with PT for a mean of 15.8 ± 7.0 weeks, for a total mean treatment time of 26.2 ± 10.1 weeks (10.4 weeks of PT alone + 15.8 - weeks of PT + HIS). Patients in the PT-only group who did not reach a plateau in their recovery and met all treatment goals performed a standard protocol of traditional PT for the statistically equivalent duration of 26.8 ± 10.3 weeks.

3.2. Shoulder elevation

At baseline, during the first postoperative visit, mean ELEV was lower for PT + HIS than PT-only patients (114.8 ± 29.2° vs. 136.9 ± 38°; $P = 0.02$) (Table 1, Fig. 2). Final ELEV measurements did not differ between the groups (158.2 ± 21° vs. 160.5 ± 12°), but gains in ELEV were greater for PT + HIS than PT patients (43.3 ± 30.7° vs. 23.5 ± 39.2°; $P = 0.04$) (Figs. 2 and 3).

3.3. Shoulder rotation

The mean baseline total rotation (ER + IR) was lower for PT + HIS than PT-only patients (67.4 ± 23.6° vs. 85.3 ± 40.8°; $P = 0.04$) (Table 1, Fig. 4). The baseline ER rotation was lower for PT + HIS than PT-only patients (27.6 ± 11° vs. 35.0 ± 15.1°; $P = 0.04$) and baseline IR was lower (40.6 ± 17.4° vs. 50.3 ± 31.4°; $P = 0.13$). The mean final total rotation (ER + IR) was higher for PT + HIS than PT-only patients (115.0 ± 20.5° vs. 101.6 ± 26.1°; $P = 0.04$). Gain in total rotation was significantly higher for PT + HIS than PT-only patients (47.6 ± 28.5° vs. 16.3 ± 45.9°; $P < 0.01$) (Figs. 3 and 4). The ROM gains in ER and IR alone were higher (but not significantly) for PT + HIS than PT-only patients ($P = 0.06$ and $P = 0.08$, respectively).

4. Discussion

The most significant findings in this study are that:

- mean baseline elevation was significantly lower (22.1°) for PT + HIS than PT-only patients, but the final elevation was statistically equivalent to that for PT-only patients (within 2.3°);
- and the mean baseline total rotation was significantly lower (16.6°) for PT + HIS than PT-only patients, but the final total rotation was significantly higher (10.6°) than that for PT-only patients.

In addition, gains in ROM in forward elevation and total rotation were significantly greater for PT + HIS than PT-only patients.

Table 1
Shoulder range of motion measurements for patients with physical therapy and high-intensity stretching device (PT + HIS) and PT only.

Measurement, degrees	PT + HIS		PT only	
	Mean ± SD	95% CI	Mean ± SD	95% CI
Baseline ELEV	114.8 ± 29.2*	106.0–123.7	136.9 ± 38	119.4–154.5
Final ELEV	158.2 ± 21	151.8–164.5	160.5 ± 12	155.0–166.0
Gain in ELEV	43.3 ± 30.7*	34.0–52.6	23.6 ± 39.2	5.4–41.7
Baseline ER + IR	67.4 ± 23.6*	60.2–74.5	85.3 ± 40.8	66.4–104.1
Final ER + IR	115 ± 20.5*	108.8–121.2	101.6 ± 26.1	89.5–113.7
Gain in ER + IR	47.6 ± 28.5*	39.0–56.2	16.3 ± 45.9	−4.9–37.5
Baseline ER	27.6 ± 11*	24.3–31.0	35.0 ± 15.1	28.0–42.0
Final ER	38 ± 6.5	36.0–40.0	38.2 ± 13.6	31.9–44.5
Gain in ER	10.4 ± 12.5	6.6–14.2	3.2 ± 14.9	−3.65–10.1
Baseline IR	40.6 ± 17.4*	35.4–45.9	50.3 ± 31.4	35.8–64.8
Final IR	76.9 ± 18	71.4–82.3	72.9 ± 20.5	63.5–82.4
Gain in IR	36.2 ± 21	29.9–42.6	22.7 ± 38.7	4.8–40.5

ELEV: elevation; ER: external rotation; IR: internal rotation.
* $P < 0.05$ compared with PT only.

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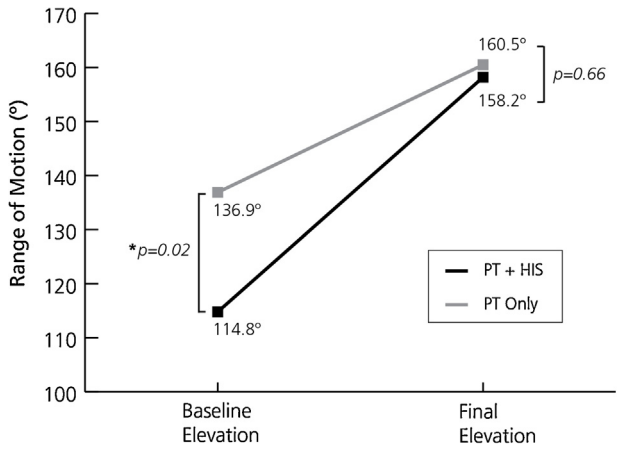

Fig. 2. Baseline and final elevation for patients with physical therapy + HIS (PT + HIS) and PT-only.

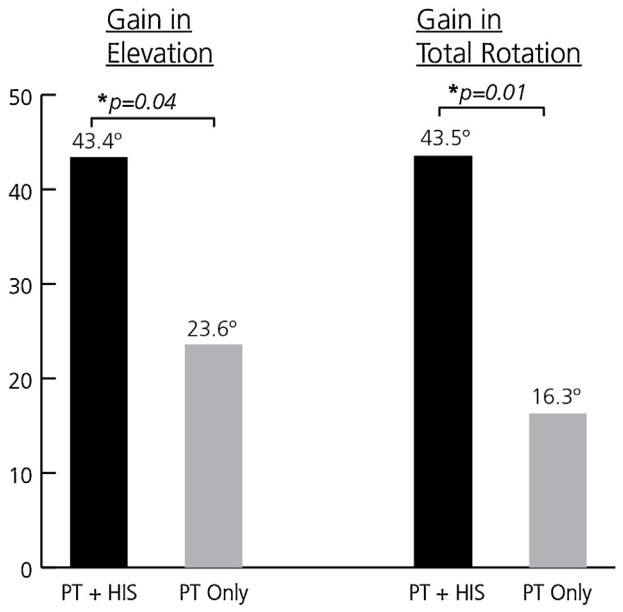

Fig. 3. Range of motion gains for PT + HIS and PT-only patients.

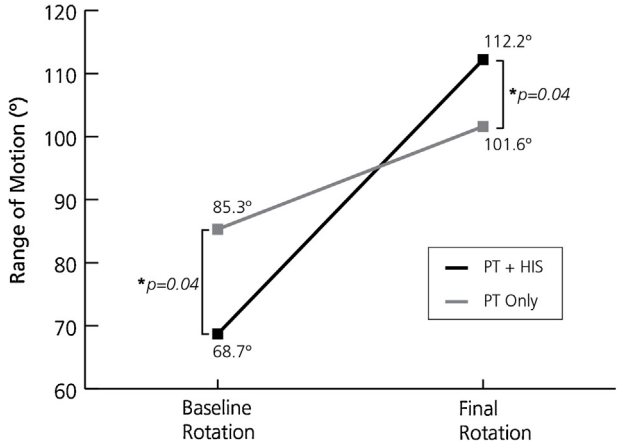

Fig. 4. Baseline and final total rotation for PT + HIS and PT-only patients.

Clearly, the 42 patients in the PT + HIS group benefited by the additional therapy provided by the HIS device. These patients likely had more severe adhesive capsulitis than PT-only patients, as shown by the significantly lower ROM at baseline. This observation may explain why PT alone was insufficient to allow for progressing past an early plateau. There may be a threshold in the severity of adhesive capsulitis that when exceeded, prevents recovery to a satisfactory level with PT alone. Continuing with the standard protocol of PT alone in the PT + HIS patients did not make sense; a plateau had been reached and no improvement was seen. The expense of PT was not warranted with the consistent lack of progress. The treatment plan needed to be adjusted because results were not being achieved, so HIS was added to the treatment regimen. Treatment of postoperative adhesive capsulitis regularly involves progressive stages of rehabilitation based on postoperative timing, so our finding is significant that patients in the PT + HIS group who were worse off at baseline were able to "catch up" to patients in the PT-only group and achieve equivalent or better results in the same overall treatment time [31]. This result is not surprising because patients in the PT + HIS group had the device at home and could therefore perform more therapy. The preferred treatment timeline includes an increase in self-management strategies (i.e., home program) by the patient and a decrease in the number of in-clinic therapy visits over time. Third-party insurers are unlikely to pay for prolonged PT, so an at-home adjunct to PT can be beneficial for continued progress because the number of PT visits may be restricted financially. This issue is important because of the prolonged time associated with recovery from adhesive capsulitis. Both groups in our study required 26 weeks of treatment.

The successful treatment with PT + HIS possibly prevented a cascade of costly negative morbidities such as a secondary surgical procedure [9,32]. Complications associated with capsular release surgery include postoperative instability of the glenohumeral joint, nerve injury and increased shoulder stiffness. Recurrence of severe shoulder stiffness after capsular release has been reported in 10% to 11% of patients. Earlier implementation of HIS in patients identified as being at a plateau would progress the recovery along the preferred treatment timeline and would likely lead to significant downstream savings. The expense of HIS devices in appropriate patients is much less than the cost of a second surgical procedure and the subsequent PT and physician visits.

In the PT + HIS group, the mean duration of PT before starting HIS treatment was 10.4 weeks. Symptoms of adhesive capsulitis are generally not resolved quickly and can last for prolonged periods even with therapy [7,8]. The 10.4-week average was skewed by several patients who underwent 5 or more months of PT before HIS treatment. With earlier identification of patients who have reached a plateau in recovery, this 10.4-week period could be reduced and the overall treatment time would likely be reduced as well, thereby decreasing downstream costs.

Treatment with HIS was effective for several reasons. First, the treatment protocol for HIS follows the concept of total end range time [33,34], in which gains in ROM in a stiff joint are directly proportional to the time spent stretching that joint at its end ROM. Second, the HIS device in this study was patient-controlled, manual, and hydraulically sensitive to allow for kinesthetic feedback and quick release. No motors or automation are used in the device, which eliminates the risk of injury associated with motors and ensures that the patient has full kinesthetic control. The patient can stretch the shoulder to the precise level of the end-range stretch and keep that stretch by using the patient-controlled adjustment. The variable control provided by the HIS device can apply torque equivalent to what a physical therapist can apply, so the device mimics the physical therapist's stretch. This end-range stretch is especially effective in that muscle guarding and pain are minimized because the patient controls the stretch. The patient is able to stretch the joint to a level by using an HIS device that would feel uncomfortable if performed by a therapist during manual stretching. Finally, the patient is able to stretch their shoulder

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Table 2
Criteria for the classification of irritability level as proposed by Kelley et al. [35].

High irritability	Moderate irritability	Low irritability
High pain (≥7/10)	Moderate pain (4–6/10)	Low pain (≤3/10)
Consistent night/resting pain	Intermittent night/resting pain	No night/resting pain
High patient-reported disability	Moderate patient-reported disability	Low patient-reported disability
Pain prior to end ROM	Pain at end ROM	Minimal pain at end ROM
AROM < PROM, secondary to pain	AROM similar to PROM	AROM same as PROM

ROM: range of motion; AROM: active range of motion; PROM: passive range of motion.

multiple times per day and is not limited to the 2 or 3 sessions of PT per week that are generally prescribed. Gains in ROM achieved during in-clinic therapy visits can be maintained at home with an HIS device, so each new visit can increase ROM rather than regaining motion lost since the previous visit. Use of an HIS device can advance the patient along the preferred treatment timeline of increased self-management strategies and decreased frequency of in-clinic therapy visits over time.

Similar results with the same HIS device used in this study have been reported with shoulder hypomobility [29]. In that study, patients with idiopathic or postoperative adhesive capsulitis who had reached a plateau in their recovery received outpatient PT plus the same adjunct HIS therapy as in the current study. Patients were classified by the irritability criteria suggested by Kelley et al. (Table 2) [35]. It was suggested that HIS could be disadvantageous for patients with high irritability, but in the study by Dempsey et al. [29], all patients showed significantly improved ASES scores and external rotation ROM and abduction ROM, regardless of irritability status.

Our study suggests that the use of HIS is warranted for patients with postoperative adhesive capsulitis who have reached a plateau in their recovery. These patients are outliers who may have a more severe form of adhesive capsulitis or biological reasons for the plateau. Other modalities such as PT alone [21,22,36–38], CPM devices [17–19] and traction-type devices [39] have generally not been as effective for these patients. Paul et al. reported improved ROM with use of a traction device to treat adhesive capsulitis [39]. However, only changes in flexion were recorded and no external/internal rotation measures were reported. Rotation is critical for performing both activities of daily living and industrial/athletic movements. Moreover, the study by Paul et al. excluded postoperative patients. The current study documents improvement in all planes of motion in postoperative patients.

Arthrographic joint distension and glucocorticoid injections alone or with PT have been reported to be more effective in treating adhesive capsulitis than PT alone or manual therapy plus exercise [1,21,22]. Home exercise has also been found an effective treatment [40]. However, whether these techniques are effective in patients with severe adhesive capsulitis was not known.

Limitations to our study include a lack of randomization and lack of standardization of the intervention timing and measurements. We had no standardized set of treatment goals because of the retrospective nature of the study. Criteria for group assignment were subjective. Furthermore, each therapy protocol was patient-specific, although we grouped these similar surgical procedures to estimate the typical progression of therapy for this population. These limitations preclude us from making conclusions based on a true group comparison because of multiple confounding factors due to the retrospective nature of the study and atypical study design.

5. Conclusions

Our retrospective observational study suggests that patients with postoperative adhesive capsulitis of the shoulder who were unable to reach their PT treatment goals during a standard protocol of PT benefited from the addition of HIS to their treatment regimen. HIS may be a valuable adjunct to PT in appropriate patients.

Authors' contributions

P.W. – participated in the study design, data collection, data analysis, manuscript preparation, and final approval.

A.I.-W. – participated in the study design, data collection, data analysis, manuscript preparation, and final approval.

C.M. – participated in the study design, data collection, data analysis, manuscript preparation, and final approval.

W.H. – participated in data analysis, manuscript preparation and final approval.

Disclosure of interest

The authors declare that they have no competing interest.

Acknowledgements

Support for this research was provided in part by ERMI, Inc. None of the authors received funding from ERMI. ERMI had no role in the study design, performance, analysis, writing of the manuscript or publication decision.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.rehab.2016.04.010.

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Please cite this article in press as: Wolin PM, et al. High-intensity stretch treatment for severe postoperative adhesive capsulitis of the shoulder. Ann Phys Rehabil Med (2016), http://dx.doi.org/10.1016/j.rehab.2016.04.010