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ORIGINAL RESEARCH ARTICLE

Maximizing Total End Range Time is Safe and Effective for the Conservative Treatment of Frozen Shoulder Patients

ABSTRACT

Dempsey AL, Mills T, Karsch RM, Branch TP: Maximizing total end range time is safe and effective for the conservative treatment of frozen shoulder patients. Am J Phys Med Rehabil 2011;90:738–745.

Objective: The purpose of this retrospective cohort study was to compare range of motion, subjective outcomes, and the prevalence of reoperation in groups of frozen shoulder patients with either low or moderate/high irritability treated with the same total end range time–maximizing protocol.

Design: A total of 36 patients were treated with the total end range time-maximizing protocol (12 patients with low irritability and 24 patients with moderate/high irritability). American Shoulder and Elbow Society Standardized Shoulder Assessment Form (ASES) scores and external rotation and abduction were recorded before and after the rehabilitation protocol and were compared between the two groups.

Results: For both groups, external rotation and abduction of the involved shoulder significantly increased from pretreatment to posttreatment, and the posttreatment external rotation and abduction of the involved shoulder did not differ from those of the uninvolved shoulder. There were no differences between the groups in either external rotation ($P = 0.71$) or abduction ($P = 0.46$). ASES scores were significantly lower and pain scores were significantly higher for the moderate/high irritability group both before and after treatment than for the low irritability group; however, the moderate/high irritability group demonstrated significantly greater gains in both ASES and pain scores. One patient in the low irritability group underwent a lysis of adhesions.

Conclusions: We conclude that a total end range time–maximizing rehabilitation protocol is a safe, effective treatment option for patients with frozen shoulder.

Key Words: Shoulder, Range of Motion, Adhesive Capsulitis, Rehabilitation Outcome

Frozen shoulder, whether the result of primary adhesive capsulitis or secondary factors, is associated with a painful, restricted range of motion. Fibrosis and contracture of the capsuloligamentous complex and rotator cuff interval occur, resulting in restricted range of glenohumeral external rotation.[1–3] Because of the role of these contractures in limiting range of motion, previous authors have suggested that treatment protocols attempting to increase external rotation target the capsuloligamentous complex and rotator cuff intervals.

Kelley et al.[4] recently proposed that rehabilitation protocols for frozen shoulder patients should be based on the patient's irritability classification. The authors suggested that patients be classified with low, moderate, or high irritability based on patient-reported level of pain and disability, the presence of night pain, the degree of active and passive motion restriction, and where pain is noted in the available arc of motion.[4] One basic premise of the proposed rehabilitation guidelines was that the amount of total stress being applied to the joint be varied according to the patient's level of irritability. Patients classified with high irritability would be treated with low-intensity, short-duration stretches lasting no more than 5 secs and would be asked to repeat these exercises two to three times per day. As a patient's irritability decreased, patients would then perform higher-intensity stretching exercises and would be asked to increase both the duration and the frequency of the stretches to maximize the total end range time (TERT). TERT is a function of the intensity, duration, and frequency that stretching exercises are performed,[5,6] and Kelley et al.[4] further stated that TERT can be maximized through the use of home mechanical therapy devices. However, it was also stated that low-load, prolonged stretch devices are typically not tolerated by patients with moderate or high irritability.[4]

Although this was suggested to be true of low-load, prolonged stretch devices, it is unclear whether high-intensity stretch (HIS) mechanical therapy devices may be more easily tolerated by frozen shoulder patients. High-intensity mechanical therapy devices apply forces to the joint that more closely replicate the forces applied by physical therapists.[7] By applying a higher intensity, the duration and frequency use may be reduced while still maximizing TERT. Furthermore, by allowing patients to increase the intensity of stretch as tolerated, it is also unclear whether a TERT-maximizing treatment protocol including both outpatient physical therapy (PT) and adjunctive HIS home mechanical therapy may be effective not only with low irritability (LI) patients but also with moderate and high irritability patients. The purpose of this retrospective study was to compare range of motion, subjective outcomes, and the prevalence of reoperation in groups of frozen shoulder patients with either LI or moderate/high irritability (MHI) treated with the same TERT-maximizing protocol.

MATERIALS AND METHODS

As part of this institutional review board–approved retrospective protocol, we reviewed the medical records of a single, board-certified orthopedic surgeon, reviewing all frozen shoulder patients who were treated with the TERT-maximizing protocol. All patients were initially treated with a customized PT program specific to his/her pathology and/or surgical procedure. Patients who had undergone either distal clavicle resection, open reduction with internal fixation, or a rotator cuff repair for a tear less than 1 cm immediately began postoperative PT three times weekly, focusing on passive and active range of motion exercises. Patients who required repair of a tear bigger than 1 cm used a sling and focused solely on passive motion during the first four postoperative weeks. Patients with massive cuff tears used a sling for 6 wks, followed by slow progressive range of motion and outpatient PT. Capsular reconstruction patients were allowed to begin motion between 2 and 4 wks after the procedure. Patients with idiopathic primary frozen shoulder immediately began outpatient PT three times per week, focusing on both active and passive range of motion exercises.

Patients who failed at least 6 wks of supervised PT with three sessions per week were then treated with the TERT-maximizing protocol. Patients were considered to have failed supervised PT if they did not achieve glenohumeral abduction and glenohumeral external rotation equal to those of the opposite, uninvolved limb. The TERT-maximizing protocol did not include a corticosteroid injection and consisted of continued outpatient PT, nonsteroidal anti-inflammatory drugs, and home use of a HIS home mechanical therapy device (ERMI Shoulder Flexionater; ERMI, Inc, Atlanta, GA; Fig. 1). The HIS device was used in the patients' homes as an adjunct to outpatient PT, and patients were instructed to perform six 10-min bouts of end-range stretching per day with the HIS device per the manufacturer's instructions. Patients used the hydraulic pump to move the joint to the end range of motion, and the device's quick-release mechanism gave

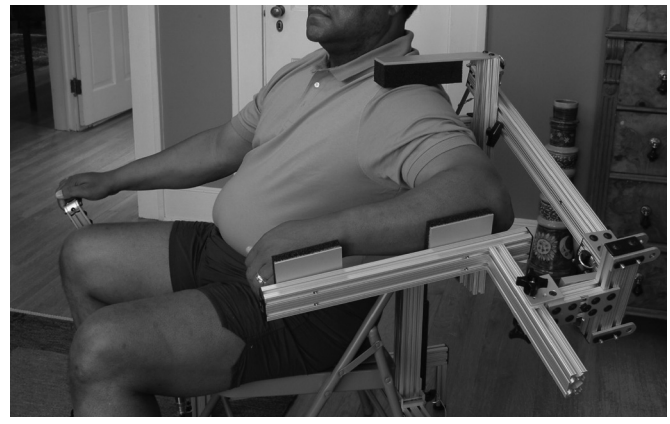

FIGURE 1 *High-intensity stretch home mechanical therapy device used to maximize total end range time. Patients initially used the device to stretch in external rotation and were then progressed to using the device to stretch in abduction, as shown.*

patients complete control of the intensity of stretch provided. The two separate stretches achieved by the device were glenohumeral external rotation and glenohumeral abduction. Torque was applied to the shoulder via the humerus and elbow, and the torque applied was dependent upon the force generated at the actuator lever arm, which was controlled by the patient's unaffected arm. Patients were instructed to move the joint to the end range of motion, using an intensity that was uncomfortable but beneath the pain threshold. Patients were given the same instructions, regardless of their classification of irritability. All patients were treated with the TERT-maximizing protocol until the motion of the involved limb equaled that of the opposite limb, the physician intervened, or the patient chose to discontinue the protocol.

During this time, range of motion of the involved and the uninvolved shoulder was measured and recorded in a standardized fashion by a single evaluator. This evaluator is a physician and was blinded to the patient's irritability classification. A 7-in goniometer was used for all measurements. Abduction was measured with the patient seated on an examination table with the examiner standing behind the patient. The examiner placed one hand on the top of the acromion to stabilize the scapula. The humerus was then passively abducted until motion was felt under the stabilizing hand. Pressure from the stabilizing hand minimized scapulothoracic movement isolating glenohumeral motion of the shoulder. The center of axis of the goniometer was located on the midpoint of the scapular spine. One stationary arm of the goniometer was placed parallel to the vertebral column. The other arm of the goniometer was placed parallel to the shaft of the abducted humerus and the measurement was taken.

External rotation was measured with the patient seated on an examination table and the examiner standing behind the patient. The examiner placed one hand on the top of the acromion to stabilize the scapula. The shoulder was placed in 0 degrees of glenohumeral abduction, the elbow was flexed at 90 degrees, and the forearm was placed in neutral pronation/supination. The glenohumeral joint was passively externally rotated until the examiner palpated resistance. Elbow and forearm positions were maintained throughout shoulder external rotation. The axis of the goniometer was aligned with the olecranon process. The stationary arm of the goniometer was placed perpendicular to the plane of the torso. The moveable arm of the goniometer was aligned with the ulnar styloid.

In addition, frozen shoulder patients routinely completed the American Shoulder and Elbow Society Standardized Shoulder Assessment Form (ASES).[8] A patient's ASES score was derived from a visual analog scale of pain and the ability to complete daily living exercises such as brushing one's hair or reaching a high shelf. The ASES is based on a point system ranging from 0 to 100, with 100 as the best score.

Patients were classified as having LI or MHI based on the scheme developed by Kelley et al.[4] Patients with LI were those who self-reported pain of less than or equal to 3 of 10, with 0 being "no pain at all" and 10 being "pain as bad as it can be." LI was also characterized by no rest pain or pain at night, low disability on the ASES score, minimal pain at the end range of motion, and active motion that equaled passive range of motion.[4] Patients with pain greater than 3 of 10, painful range of motion, moderate to severe disability on the ASES score, and either intermittent or consistent pain at rest or at night were considered to be in the MHI group. To

TABLE 1 Patient demographics and treatment characteristics (mean ± SD) for frozen shoulder patients with LI and with MHI

	LI	MHI	*P*
Subjects (men/women)	12 (6/6)	24 (11/13)	>0.99
Age, years	48.1 ± 6.5	50.2 ± 9.0	0.41
Height, cm	174.2 ± 8.4	172.4 ± 10.9	0.62
Weight, kg	85.0 ± 15.7	82.0 ± 19.6	0.65
Weeks of physical therapy	19.2 ± 9.4	13.3 ± 11.2	0.13
Weeks of HIS mechanical therapy	13.4 ± 8.2	10.8 ± 5.6	0.26
Weeks of follow-up	31.8 ± 31.7	41.3 ± 35.6	0.42

LI, low irritability; MHI, moderate/high irritability; HIS, high-intensity stretch.

compare the efficacy of this TERT-maximizing protocol among patients having either LI or MHI, we compiled range of motion and ASES scores from the date when the TERT-maximizing protocol was initiated and when the patient completed the protocol. Passive external rotation and abduction range of motion were compared between groups using separate 2 × 3 mixed-model analyses of variance. Range of motion was compared between the LI and MHI groups and between the pretreatment measurements of the involved shoulder, posttreatment measurements of the involved shoulder, and the measurements of the unaffected contralateral shoulder. Pretreatment and posttreatment ASES scores, pain ratings, and the activity of daily living subcomponent of the ASES score were compared using a 2 × 2 analysis of variance. Two-tailed independent *t* tests were used to compare patient age, height, weight, number of weeks of PT, number of weeks of HIS mechanical therapy, and duration of follow-up between groups. Between-group differences in sex and the prevalence of reoperation were evaluated with Fisher's exact tests. An α level of $P \leq 0.05$ was considered significant for all *t* tests and Fisher's exact tests. For the 2 × 3 range of motion–related analyses of variance, a Bonferroni correction was made for multiple comparisons and determined that an α level of $P \leq 0.006$ was considered significant. For the 2 × 2 ASES-related analyses of variance, a Bonferroni correction was made for multiple comparisons and determined that an α level of $P \leq 0.0125$ was considered significant. All analyses were performed using Statistics v 17.0 (SPSS, Inc, Chicago, IL).

RESULTS

Over a 15-mo period, 36 patients with complete medical records were treated with this TERT-maximizing protocol. Of these 36 patients, 10 (28%)

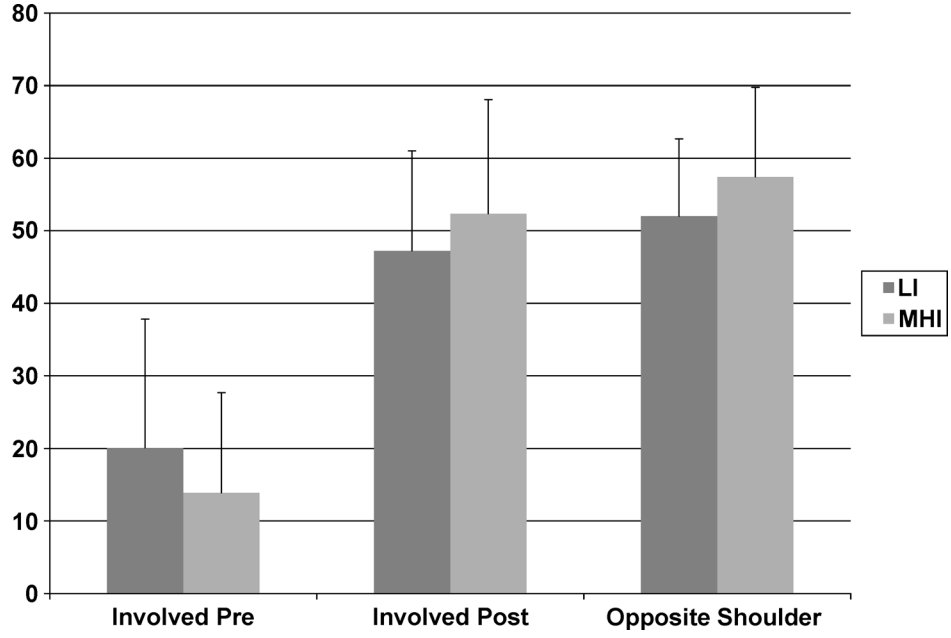

FIGURE 2 *Comparison of glenohumeral external rotation before and after treatment between the low irritability (LI) and moderate/high irritability (MHI) groups.*

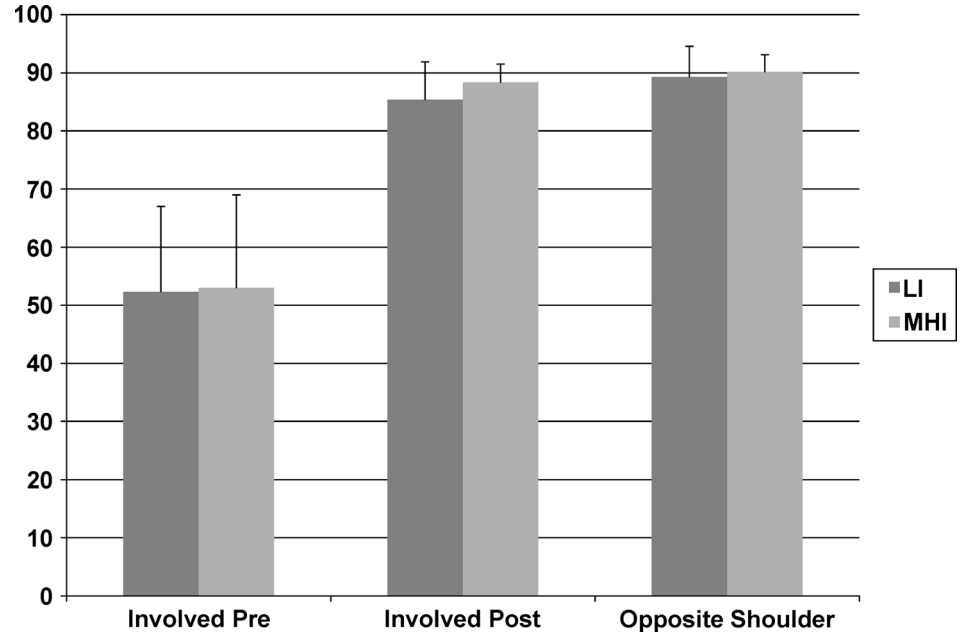

FIGURE 3 *Comparison of glenohumeral abduction before and after treatment between the low irritability (LI) and moderate/high irritability (MHI) groups.*

were treated as part of a worker's compensation claim. Twelve patients were classified with LI and 24 were classified with MHI. The two groups did not differ in age, sex, height, weight, number of weeks of PT, number of weeks of HIS mechanical therapy, or duration of follow-up (Table 1).

For both groups, passive external rotation and abduction of the involved shoulder significantly increased from pretreatment to posttreatment, and the posttreatment external rotation and abduction of the involved shoulder did not differ from those of the uninvolved shoulder (Figs. 2 and 3). There were no differences noted between the groups in either external rotation ($P = 0.71$) or abduction ($P = 0.46$).

ASES, pain, and activity of daily living scores all significantly improved from pretreatment to posttreatment (Table 2). ASES scores were significantly lower and pain scores were significantly higher for the MHI group both before and after treatment than for the LI group; however, the MHI group demonstrated significantly greater gains in both ASES and pain scores than the LI group did. There were no group differences in activity of daily living scores ($P = 0.46$).

No patients in this series underwent manipulation under anesthesia (MUA). One 46-yr-old male patient in the LI group required reoperation, resulting in an overall reoperation rate of 2.8% (1/36) for

TABLE 2 Comparison of ASES score (scale of 100, with 100 being the best possible score), pain subcomponent score (scale of 10, with 0 being the best possible score), and ADL subcomponent score (scale of 30, with 30 being the best possible score) between the LI and MHI groups

	LI	MHI	Group Comparison (P)
Pretreatment			
ASES score	60.0 ± 12.4	20.1 ± 11.6	<0.001
Pain subcomponent score	0.6 ± 1.2	7.7 ± 1.8	<0.001
ADL subcomponent score	5.1 ± 3.9	7.8 ± 6.7	0.22
Posttreatment			
ASES score	81.5 ± 14.7[a,b]	70.0 ± 18.2[a,b]	0.02
Pain subcomponent score	0.4 ± 0.9[a,b]	2.7 ± 1.9[a,b]	0.009
ADL subcomponent score	20.2 ± 7.4[a]	20.1 ± 7.9[a]	0.86

[a]Significant improvement over pretreatment score ($P < 0.05$).

[b]Significant test × group interaction ($P < 0.05$); the MHI group demonstrated significantly greater changes between the pretreatment and posttreatment tests.

ASES, American Shoulder and Elbow Society Standardized Shoulder Assessment Form; ADL, activity of daily living; LI, low irritability; MHI, moderate/high irritability.

patients treated with this TERT-maximizing protocol. He had initially undergone anterior capsule reconstruction, distal clavicle resection, and subacromial decompression as part of a worker's compensation claim. After failing 12 wks of PT, he was subsequently treated with the TERT-maximizing protocol. After 10 wks of the TERT-maximizing protocol, his ranges of external rotation and abduction improved to 60° and 90°, respectively. At that time, there was radiographic evidence of acromioclavicular osteoarthritis. The patient was given a corticosteroid injection and scheduled to undergo revision distal clavicle resection. During the procedure, a significant amount of scar tissue was noted in the area of the coracohumeral ligament, and a lysis of adhesions was performed.

DISCUSSION

The purpose of this retrospective study was to compare range of motion, subjective outcomes, and the prevalence of reoperation in groups of LI or MHI frozen shoulder patients treated with the same TERT-maximizing treatment protocol. Both the LI and MHI groups demonstrated significant gains in glenohumeral external rotation and abductions and significantly improved ASES, pain, and activity of daily living scores. In addition to being equally effective in both groups of frozen shoulder patients, the two groups did not differ in either the number of weeks of PT or HIS mechanical therapy.

One key aspect of this TERT-maximizing treatment protocol was that patients were asked to stretch multiple times per day at an intensity that was near, but not above, the pain threshold. Inferior clinical results have been reported by Diercks and Stevens[9] when treating frozen shoulder patients with aggressive end range of motion stretching performed above the pain threshold. In addition, the authors stated that aggressive stretching beyond the pain threshold was especially detrimental in the early phases of frozen shoulder syndrome,[9] when patients were most likely to have increased levels of irritability. Patients in the current study, regardless of irritability classification, were asked to stretch multiple times per day near, but not above, the pain threshold. Maximizing TERT within each patient's tolerance level while avoiding potential exacerbation of symptoms and/or inflammation seemed to result in safe, effective, and timely return of range of motion.

Proper patient selection is another factor that seems to be vital to the clinical success of this regimen. All patients in the current study had previously failed a minimum of 6 wks of outpatient PT before initiating the TERT-maximizing protocol. Overpressure stretching applied by a physical therapist at the patient's end range of motion often results in improved range of motion; however, these gains have been reported to be temporary.[5,6,10–12] These transient gains in motion may be related to the findings of Griggs et al.,[13] who reported that frozen shoulder patients who were previously treated with PT were at greater risk of requiring MUA to address their motion restrictions. With this in mind, it is noteworthy that only 1 (2.8%) of the 36 patients treated with the TERT-maximizing protocol required motion-restoring surgery.

Multiple nonoperative treatment options have been reported for the treatment of frozen shoulder patients. Other successful protocols have included PT and nonsteroidal anti-inflammatory drugs[14] and corticosteroid injections in conjunction with either outpatient PT and/or a home exercise program,[15] MUA,[16] and arthroscopic capsular release.[17] All protocols have reported improved range of motion or a decrease in pain and/or functional limitation; however, all of these protocols have significant drawbacks that limited their use in our clinical practices. Intra-articular corticosteroid injections have been reported not only to be a successful treatment option[15,18] but also to be associated with a high rate of adverse reactions.[18] van der Windt et al.[18] reported that 53% of patients treated with an intra-articular injection of 40 mg triamcinolone acetonide had an adverse reaction, which included pain, facial flushing, fever, skin irritation, sweating, fatigue, dry mouth, dizziness, and headache. Furthermore, a recent systematic review by Blanchard et al.[19] demonstrated that corticosteroid injections may provide a short-term benefit over other nonoperative treatment options, but that there is no clear long-term benefit. To minimize the risk of adverse reactions while still promoting both short- and long-term gains in range of motion and reduction of pain and disability, we opt not to treat our frozen shoulder patients with corticosteroid injections.

Surgical treatment options are available for frozen shoulder patients who fail to respond to conservative measures. Both MUA and arthroscopic capsular release have documented histories of success[17,20] but have been reported to be more successful in patients who have failed 6 mos or more of previous treatment.[17,21] MUA allows for noninvasive release of capsuloligamentous adhesions; however, it does so in an uncontrolled manner. Loew et al.[22] arthroscopically evaluated patients who had

undergone closed MUA and reported that 80% demonstrated tearing the anterior joint capsule, resulting in significant bleeding into the joint. Neither the short- nor long-term effects of this tearing and inflammatory response are well understood. In theory, the inflammatory response and increased intra-articular bleeding result in the proliferation of fibroblasts and an increased risk of arthrofibrosis.[23] This uncontrolled capsular tearing and associated inflammatory response may then be related to why 20% of frozen shoulder patients who have undergone a MUA report persistent pain and limited motion 2 yrs after the procedure.[24] Furthermore, the long-term effects of potential glenohumeral instability resulting from the tearing of the anterior capsule have not been established. It is for these reasons that we prefer not to manipulate frozen shoulder patients within the first six symptomatic months but instead prefer to treat patients with persistent frozen shoulder symptoms with the TERT-maximizing conservative protocol. For the very small percentage of patients (2.8% of patients in the current study) who fail the TERT-maximizing protocol, we feel that arthroscopic capsular release is the safest and most effective surgical treatment option.

This study was not without limitation. The 36 patients were treated at 19 different outpatient PT clinics; thus, the individual PT programs undoubtedly differed among patients. Despite the risk of inconsistent treatment among therapists, this retrospective case series demonstrated that daily adjunctive use of the HIS mechanical therapy device in combination with routine outpatient PT resulted in improved motion and outcome scores with a minimal risk of reoperation. Although the results of this study are promising, future prospective, randomized controlled trials are necessary to evaluate the TERT-maximizing protocol.

In conclusion, we used a TERT-maximizing rehabilitation protocol consisting of outpatient PT, HIS home mechanical therapy, and nonsteroidal anti-inflammatory drugs to treat frozen shoulder patients. Regardless of the patient's irritability classification, the protocol resulted in significant gains in glenohumeral external rotation and abduction and significant improvements in ASES scores, with a very low rate of reoperation (2.8%).

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