Randomized Trial

Percutaneous Ultrasound-Guided Coracohumeral Ligament Release for Refractory Adhesive Capsulitis: A Prospective, Randomized, Controlled, Crossover Trial Demonstrating One-Year Efficacy

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Background: Adhesive capsulitis (AC) is a painful and disabling condition with restricted range of motion (ROM) that affects 2% to 3% of the population and up to 20% of patients with diabetes. AC can be idiopathic, iatrogenic, or secondary to shoulder injuries. Some associated conditions include diabetes mellitus, thyroid disorders, dyslipidemia, stroke, prolonged immobilization, and autoimmune conditions. Management ranges from analgesics to physical therapy, local injections, hydrodilatation, and advanced surgical interventions. This study examines percutaneous coracohumeral ligament (PCHL) sectioning with the hypothesis that interruption would improve pain and ROM in patients with AC refractory to conservative management.

Objectives: To use sonographically guided percutaneous interruption of the CHL for the treatment of refractory AC.

Study Design: A prospective, randomized, controlled, cross-over trial.

Setting: Academic medical center.

Methods: Patients were identified based on inclusion and exclusion criteria under the supervision of the Principal Investigator. After primary screening, research staff explained the study, risks, and benefits to the patients, and consent was obtained. Patients' pain score and shoulder ROM were assessed before and after the procedure, at one month, and one year. The Oxford Shoulder Scoring (OSS) questionnaire was also completed before the procedure and in the one-year follow-up visit.

Forty patients were enrolled with refractory AC. Forty-six shoulders were treated; 6 patients underwent a bilateral procedure. Block 2:1 randomization was performed for the 2 groups (PCHL release [PCHLR] and local anesthetic CHL [LACHL]). The LACHL group received a lidocaine injection at CHL, and the PCHLR group received the CHL using a Tenex® (Tenex Health, Lake Forest, CA) needle. ROM, Numeric Rating Scale (NRS-11), and OSS were evaluated at baseline, immediate postprocedure, and long term.

Results: Among 46 shoulders included in the study, 7 were excluded due to lost to follow-up, total shoulder replacement, and shoulder manipulation. Twenty-six were randomized to the PCHLR group and 13 to LACHL group. ROM (external rotation and abduction), pain, NRS-11 score, and OSS score were measured at baseline and long term, confirmed by a nonbiased health care personnel. There was no statistically significant difference in ROM, NRS-11, and OSS between the 2 cohorts at the baseline visit. Nine patients in LACHL group crossed over to the PCHLR arm at one month. Data analysis in the long term revealed durability of the PCHLR group with a statistically significant difference in ROM, NRS-11, and OSS. External rotation improved by double, and abduction improved by almost 30% (P value < .001). NRS-11 decreased from 8 (IQR 8, 9) at baseline to 3 (IQR 2, 7) at long term among those who received PCHLR. The baseline mean OSS in the PCHLR group increased from 7.44 to 31.86 at one-year follow-up and was statistically significant (P value < .001).

Limitations: This study represents a small population of patients with a CHL-related ROM deficit. Patients were not excluded for osteoarthritis or other motion-disabling shoulder conditions. We submit that the strength of the study could have been improved if the physician performing the procedure was blinded and if the patient was blinded as well to minimize operator and patient bias.

Conclusions: We demonstrate that our technique for PCHLR is a safe, effective, and durable procedure that improved ROM, pain, and shoulder function in our patient population when compared to the control.

Key words: Tenex, frozen shoulder, pain, range of motion, function, shoulder, minimally invasive, durable

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The American Academy of Orthopedic Surgeons defines frozen shoulder, also known as adhesive capsulitis (AC), as a condition in which thick bands and adhesions develop in the shoulder's capsule, causing pain, stiffness, and mobility restrictions (1). The prevalence of AC may be as high as 8.2% in the general population (2). Women are more susceptible, and it is more common during the fifth and sixth decades of life.

AC can be idiopathic, iatrogenic, or secondary to shoulder injuries. Some associated diseases and conditions include diabetes mellitus (3,4), thyroid disorders (5,6), dyslipidemia (7), stroke, prolonged immobilization, and autoimmune conditions.

AC is a clinical diagnosis, made primarily by history and physical examination. The most significant symptoms include pain and stiffness, resulting in a decreased level of daily living activities. The key feature is a limited range of motion (ROM) both in active and passive movements. Diagnostic imaging techniques, such as magnetic resonance imaging, x-rays, and ultrasonography, may be helpful in diagnosing secondary and systemic disorders but are not diagnostic (8).

The general approach to AC management is pain control and directed at regaining ROM. Most patients respond to conservative medical management (CMM), including pain medication, physical therapy (PT), corticosteroid injections, and exercise (9). Although pain medications, most commonly nonsteroidal anti-inflammatory drugs, are being prescribed widely, there are no clinical trials or scientific evidence supporting their benefits in the course of the disease (9,10). The effectiveness of PT alone, or in combination with other modalities, is mixed (11-14). Corticosteroid injections have been shown to reduce the pain level at 12 weeks postinjection, but not at 26 weeks (15).

Surgery can be considered for patients for whom AC does not self-resolve or if refractory to CMM (1). There are no definite indications for surgery; however, a failed response to conservative treatment for 3-6 months and disability, due to pain and limited ROM, are considered as general indications (3-6,16-18).

There is currently a treatment gap for patients who have not improved with CMM yet are not surgical candidates. Hydrodilatation has been performed for several years in this group, but convincing efficacy data is lacking. Recent literature (19-21) suggests that percutaneous coracohumeral ligament release (PCHLR) may be an appropriate treatment for these patients, but there has not been a long-term prospective controlled trial to validate these findings. The purpose of the current study was to assess the clinical efficacy of ultrasound-guided PCHLR compared with a control group undergoing ultrasound-guided CHL lidocaine injections with long-term follow-up. We hypothesize that PCHLR is more effective and durable to improve ROM and pain in patients with refractory AC compared with controls.

Methods

We designed a randomized, controlled, crossover trial assessing the effectiveness of PCHLR on patients with recalcitrant AC. This study was approved by our institutional review board (study # 2020-11998). A data and safety monitoring board was assembled, including the Departments of Anesthesiology, Physical Medicine and Rehabilitation, and Orthopedics, to monitor procedure effectiveness and any adverse outcomes.

Patients were identified within various clinical practices inside of our academic institution for screening. Inclusion criteria were: 1) adults between the ages of 21 and 99 years; 2) established diagnosis of AC based on CHL thickness > 3 mm, verified by ultrasound evaluation on screening; 3) decreased shoulder ROM (external rotation and abduction), 50% reduction as compared to the unaffected side, or < 40° of external rotation was an absolute characteristic if bilateral; and 4) patients who had failed 2 different oral pain medica-

tions, at least 6 weeks of PT, and a local steroid injection. Exclusion criteria were: 1) patients with AC but showing improvement in shoulder ROM, 2) patients evaluated by an orthopedic surgeon and deemed to be surgical candidates due to shoulder pathologies other than AC, 3) pregnant patients, and 4) patients on anticoagulation therapy who were not permitted to stop anticoagulation.

Patients were evaluated and consented by the Principal Investigator (PI) and subsequently enrolled into the study by approved research staff. Patients were not financially compensated for participation in the study. A detailed informed consent was taken by the approved research staff to explain the study. This included all risks and benefits, and patients had the right to refuse participation in the study at any point.

Block randomization was performed using SPSS software by the in-house statistician. Minimization was 1:2 (control: CHL release [CHLR]). Unequal allocation randomization is used as the PCHLR is the focus of this clinical trial. With more patients receiving PCHLR, the treatment effects will be more precise and accurate. In addition, it can ease recruitment challenges to meet statistical power as study patients will have a higher chance of being allocated to the PCHLR group.

An SPSS Version 28.01 (IBM Corporation, Armonk, NY) analysis was performed on the data. Using paired t tests and independent t tests, the differences within one group and between 2 groups were compared, respectively. *P* value < 0.05 was considered as a statistically significant measure.

Prior to randomization, goniometric analysis was performed by the PI and verified by an independent health care provider trained in goniometric analysis. The Numeric Rating Scale (NRS-11), as well as the medication log, were documented, and an Oxford Shoulder Score (OSS) survey was completed after measurements were documented. Patients were then randomized into the control local anesthetic CHL (LACHL) group or the PCHLR group.

The control cohort received 5 cc of 1% lidocaine at the CHL using live ultrasound guidance and a 25-G, 1-1.5-inch hypodermic needle after sterile preparation. After 10 minutes elapsed, the goniometric measurement was reperformed. The patient was then brought into our office after 4 weeks. If there was < 50% change in external rotation compared to preinjection measurements and if the patient was not satisfied with their improvement, PCHLR was offered. If these criteria were not met, the patient was not offered PCHLR.

If the patient was selected to be in the CHLR cohort, the procedure was scheduled. Prior to performing this PCHLR, informed consent for the procedure was obtained, the patient underwent goniometric analysis again by the PI, and repeated validation was performed by an independent health care worker trained in goniometric analysis. Details of this technique have previously been described (Appendix 1) (20,22).

Following completion of either procedure, patients were instructed on a home exercise program that consisted of hourly external rotation and circumduction exercises to facilitate shoulder ROM activity.

Patients were then followed-up approximately one year after PCHLR by a practitioner who was not directly involved in the patient's screening process or procedure performance. NRS-11, OSS, and goniometric analysis were repeated using the same methodology discussed above. A chart review was performed to determine if any percutaneous or surgical procedure had been carried out after PCHLR. The results were confirmed by historical assessment as well.

Results

Forty patients were included in the study, from January 2019 to March 2022, of which 6 had bilateral procedures. One patient (a bilateral shoulder PCHLR) was lost to follow-up; 4 were excluded from the study due to total shoulder replacement surgery; and one was excluded because of shoulder trauma, which was unrelated to the study. Thirty-one out of thirty-nine procedures were performed women (80%), and 22/39 were right sided. The mean follow-up time was 16 months among the patients. The ratio of the control LACHL to the PCHLR procedure arm was 1:2 (Table 1).

There was no statistically significant difference in preprocedure ROM between the LACHL and PCHLR

Table 1. *Demographics (* Standard Deviation).*

Variable	Total Number	Mean	SD*
Male	8(20%)	-	-
Female	31(80%)	-	-
Age	39	62.21years	11.37
BMI	39	32.18 kg/m^2	6.47
Right Side	22	-	-
Left Side	17	-	-
CHL Thickness	39	40.5mm	5.13
LACHL Arm	13(33%)	-	-
PCHLR Arm	26(67%)	-	-

groups. The *P* values for preprocedure external rotation and abduction among the patients in the 2 groups were 0.72 and 0.15, respectively. However, immediate (within 5 minutes after completion of the procedure) postprocedural ROM was significantly different between the LACHL and PCHLR groups (*P* values 0.03 and 0.001 for external rotation and abduction, respectively). The analysis of pre- and postprocedure ROM in each cohort showed an immediate ROM response (Table 2).

In addition, there was no difference in ROM between the baseline preinjection and one-month follow-up in the control group. The *P* values for the external rotation and abduction in this group were 0.58 and 0.24, respectively.

Table 2. *Comparison of pre and immediate post procedure ROM in LACHL and PCHLR groups.*

Group	Variable	Mean (degrees)	SD**	*P*-value
LACHL	Pre-procedure Ext.R*	29	8	<.001
LACHL	Post-procedure Ext.R	49	16	
LACHL	Pre-procedure Abduction	53	15	0.002
LACHL	Post-procedure Abduction	64	13	
PCHLR	Pre-procedure Ext.R	30	8	<.001
PCHLR	Post-procedure Ext.R	61	18	
PCHLR	Pre-procedure Abduction	60	16	<.001
PCHLR	Post-procedure Abduction	80	14	
LACHL	Pre-procedure Ext.R	29	8	0.72
PCHLR	Pre-procedure Ext.R	30	8	
LACHL	Pre-procedure Abduction	53	15	0.15
PCHLR	Pre-procedure Abduction	60	16	
LACHL	Post-procedure Ext.R	49	16	0.03
PCHLR	Post-procedure Ext.R	61	18	
LACHL	Post-procedure Abduction	64	13	0.001
PCHLR	Post-procedure Abduction	80	14	

(* External rotation)
(** Standard Deviation)

Table 3. *Comparison of ROM in long-term post PCHLR.*

Variable	Mean (degrees)	SD**	*P*-value
Immediate post PCHLR Ext.R*	63	17	0.64
Long-term post PCHLR Ext.R	62	18	
Immediate post PCHLR Abduction	78	15	0.69
Long-term post PCHLR Abduction	77	21	

(* External rotation)
(** Standard Deviation)

With regards to the durability of the PCHLR, we analyzed the ROM immediately after the procedure and in the long term (10 months to 2 years). The results showed no statistically significant difference as a function of time in external rotation and abduction range in our PCHLR group (Table 3).

NRS-11 also decreased from 8 (IQR 8, 9) at baseline visit to 3 (IQR 2, 7) at the long-term follow-up visit in those who received the PCHLR procedure. Although preprocedure and immediate postprocedure NRS-11 were statistically different in the LACHL group (*P* value .0003), the baseline and one-month median NRS-11 were the same (8, IQR 7, 8 in preprocedure and 8, IQR 7.75, 8.25 at one month).

We also analyzed the OSS in the 2 groups. Baseline mean for the PCHLR group was 7.44 (SD 4.62), while the mean for the control group was 10.8 (SD 7.94), which was not statistically significant. Our control group had a mean of 13.8 (SD 8.29) in the one-month follow-up, which was not significantly different from their baseline OSS score (*P* value 0.87). In contrast, the OSS mean score was 31.86 (SD 11.78) in the long-term follow-up visit in our PCHLR group and was statistically different from their baseline (*P* value < 0.001).

Discussion

The major findings of this study are that ultrasound-guided PCHLR resulted in significantly improved postprocedure abduction and external rotation when compared with a control cohort of patients who underwent ultrasound-guided CHL lidocaine injection. Furthermore, the improvement in motion was maintained at a mean follow-up time of 16 months, making this the most enduring evidence for this therapy.

AC can be due to a thickening of the CHL, and/or the glenohumeral ligaments (8,23,24). The CHL and middle glenohumeral ligament restrict external rotation and the inferior glenohumeral ligament restricts abduction. Percutaneous interruption of the CHL has demonstrated improvements in external rotation in several publications (20-22). The CHLR method performed in this study has been validated with cadaveric correlation and a case series (20,22), which demonstrated clinical improvement in external rotation and pain. The authors hypoth-

esized that external rotation would improve greater than abduction due to the restrictive biomechanical function of thickened CHL seen in AC patients (25) and, in fact, was validated here in a randomized controlled trial.

Furthermore, the new information that this study provides is the durability of relief with ultrasound-guided PCHLR, as well as functional improvement related to the procedure. External rotation is the required initial movement to achieve internal rotation (placing one's hand on the low back) and the primary movement to place one's hand on the back of the head (26). Therefore, this motion is needed for daily grooming, dressing, and hygiene. The authors believe that this may be why patients reported appreciable improvement in overall shoulder function despite a similar improvement in abduction. This data also shows safety of the procedure, as no patients participating in our study had a poor outcome despite a mean body mass index of 39, suggesting that the procedure can be performed safely in medically challenging patients who may have risk factors for medical or open surgical management.

The patients selected for the study failed multiple conservative measures, including at least 2 oral pain medications, one local steroid injection, and physiotherapy. This represents the patient population that may benefit from this procedure in a community setting. We elected to perform randomization on a 1:2 ratio, with more patients receiving the percutaneous release, to improve our ability to accurately measure our treatment outcomes. In addition, it eased recruitment challenges to meet statistical power because our study patients, who had failed several treatments prior to the CHLR, knew that they would have a higher chance of being in the CHLR group. Study design also allowed for a crossover from the control group to the CHLR group to improve recruitment. A significant majority of the control group (9/13) crossed over due to failure of the long-term benefit of the LA injection.

We selected external rotation as a primary outcome measure, as previous studies (21,22) used the same data point. We also elected to evaluate pain and OSS as secondary outcome measures to correlate for daily living activities. The LACHL arm received a lidocaine injection to the CHL, similar to the anesthesia that we would provide to our PCHLR patients. Both groups were advised to perform external rotation and circumduction exercises every hour for 60 seconds. This was done in hopes of improving ligamentous laxity and to evaluate whether active capsular stretching or the release of the CHL would provide the most benefit. Lack of long-term improvement in the LACHL cohort suggested that improved capsular laxity was not achieved with exercising alone; CHL disruption was required for meaningful outcomes. Furthermore, our results demonstrated that immediate postprocedure ROM in the PCHLR cohort was better than in the LACHL group, suggesting that mechanical disruption of the CHL is superior to simple elimination of the nociceptive stimulus for AC-related movement limitation. Long-term follow-up external rotation in the PCHLR group was double the preprocedure value, and abduction sustainably improved by approximately 25%. The results demonstrated that there was a significant difference in pain and ROM in the pre- and immediate-post-LACHL group, but not at one month. This was important, as the authors demonstrated that a LACHL injection supplemented with ROM improvement did not change shoulder biomechanics, but CHLR created a clinically meaningful change. The results also indicated that there was no significant difference between external rotation and abduction immediately after CHLR and at long-term follow-up, supporting our hypothesis that the procedure, and not the exercises, was responsible for the improvement in ROM (Figs. 1-3).

Patient pain levels were also significantly improved in the PCHLR group compared to the LACHL cohort. NRS-11 decreased from 8 at baseline to 3 at the long-term follow-up visit in the PCHLR group. As part of our

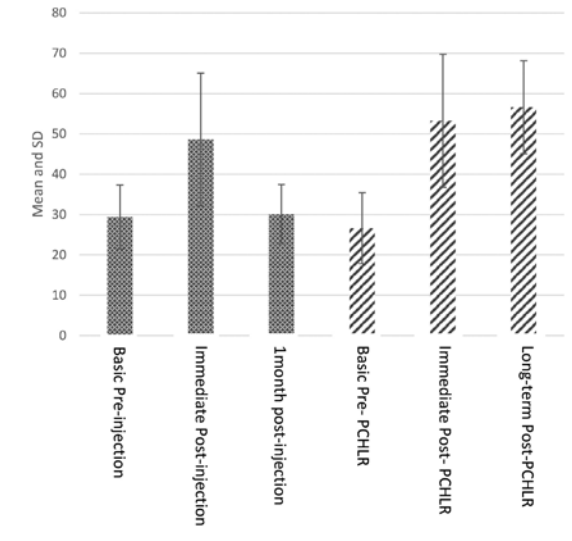

Fig. 1. *Comparison of External Rotation between two groups in different timelines.*

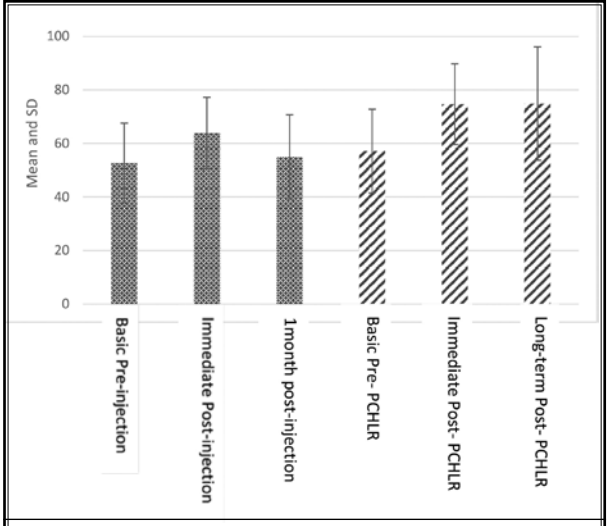

Fig. 2. *Comparison of abduction between 2 groups in different timelines.*

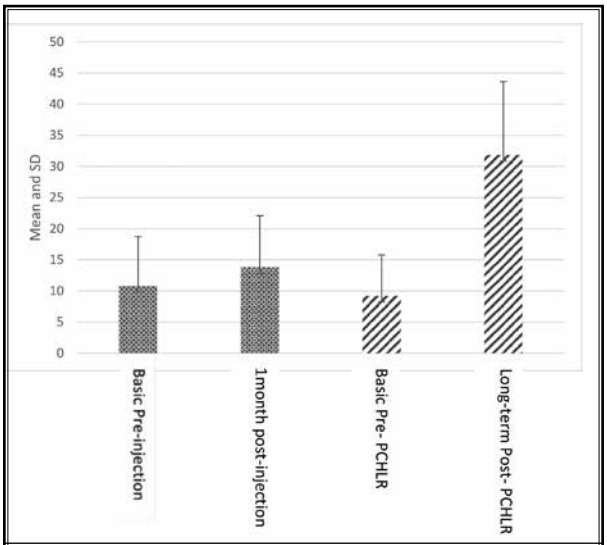

Fig. 3. *Comparison of OSS in 2 groups in different timelines.*

pain evaluation, all patients' charts were monitored for interval changes, pain medication, and injections. All patients in both cohorts were allowed to receive further treatment if our interventions were not sufficient to meet their pain or functional needs. However, there were no patients in the PCHLR group who received additional pain medications or a local pain injection at the anatomical site for which they enrolled in the study. The chart review was confirmed by a health care practitioner who was not directly associated with the patients' clinical care.

An OSS survey was performed to identify functional changes in each group. The baseline score in the PCHLR group was 3 points lower as compared to the control group, indicating that patients in the PCHLR group had a lower baseline functional score than the LACHL group. The control group's OSS score was not statistically different at preinjection baseline and one-month follow-up. However, the long-term follow-up OSS score in our PCHLR group was 21 points higher when compared to their preprocedure baseline (*P* value < 0.001), which is considered as a significant change in the management of one's shoulder pain.

The follow-up duration of the study ranged from 10 months to 2 years. Four patients were assessed at 10 or 11 months, 3 were assessed at one year, and all other patients were evaluated at least 14 months from the time of the procedure. The range in follow-up duration was a consequence of patients' follow-up in our clinic, largely affected by the COVID pandemic, which prevented patients from timely follow-ups at the intended one-year mark. Although our follow-up time-frame was not uniform due to uncontrollable factors, most assessments demonstrated greater durability of the intervention than what the authors originally had hypothesized. This was evident as differences between improvements in ROM were sustained in the PCHLR group even with a prolonged follow-up window.

Limitations

This study represents a small population of patients with a CHL-related ROM deficit. Patients were not excluded for osteoarthritis (OA) or other motion-disabling shoulder conditions. When designing the study, the authors regret not excluding patients with severe OA to preserve a primary AC pathology, as it may have demonstrated more impressive outcomes.

There were several patients in the study who were identified with shoulder OA during our retrospective subgroup analysis. Seventeen shoulders had OA in our study (4 grade 1, 2 grade 2, and 11 with grade 3 or 4). Though inclusion of this group weakened our results, it provided important insight for population selection of PCHLR. Though patients with OA did not demonstrate a statistically significant difference in improvement when compared to other patients in our PCHLR analysis, a retrospective analysis identified patients with grade 3 or 4 OA as being the worst responders in the study. Eleven patients with severe OA were identified and 4 required total shoulder arthroplasties. However, grades 1 and 2 OA may still be considered for this procedure, if

believed that their ROM deficits may be complicated by AC. Though our results suggest the importance of characterizing severe arthritis as a possible exclusion criterion for PCHLR, a subgroup analysis of these patients should be performed to evaluate if they improved in any of the outcomes described here. However, a multicenter study with more detailed analysis in a larger cohort of patients should be performed to verify our hypothesis.

We acknowledge that the strength of the study could have been improved if both the physician performing the procedure and the patient were blinded, to minimize operator and patient bias.

Although our results demonstrate that CHLR may be a reasonable treatment for patients with refractory AC, a large-scale study assessing other pain and ROM cofactors, such as OA, tendon, and labral pathology, should be performed to determine the true value of PCHLR in patients with chronic shoulder pain.

Conclusions

We demonstrate that our technique for PCHLR is a safe, effective, and durable procedure that improved ROM, pain, and shoulder function in our patient population with AC when compared to control.

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Appendix 1

The patients were placed on their backs in a supine position, with their shoulders rotated mildly internally and their hands on their abdomens. At this point, the ROM, including external rotation and abduction, was examined. A sterile drape covered their cleaned anterior shoulders. A General Electric S8® USG machine with a Matrix 5-8 Hertz probe (General Electric Medical Systems, Boston, MA) was used to identify the coracoid process in the sagittal plane, obtaining a longitudinal image of the CHL. In order to avoid breaching the inferior border and avoid penetrating the artery, the skin above the coracoid process was marked by identifying the axillary artery below the coracoid process. An angled probe of 15-20° was inserted into the long axis with a 25-G needle. Two to three cubic centimeters of 1% lidocaine and another 5 cc were delivered along the lateral border of the coracoid process for local anesthesia and to create an anesthetic track and skin wheal at the site of the needle entry, respectively. Following this, the skin wheal site was punctured with an 11-blade scalpel. An anterior approach was used to introduce a 2-inch Tenex® needle (Tenex Health, Lake Forest, CA) through the incision site, using the standard technique. The tip was delivered to the lateral border of the coracoid process/medial border of the CHL. The Tenex® device's cutting action was set at a "medium" setting, and short 5-10 mm retracting and protracting strokes were performed while walking along the CHL's lateral border until the CHL was interrupted. At this point, the probe was able to penetrate the CHL at all lateral attachment points. Upon penetration of the CHL, the underside of the ligament was gently raised with the probe using 3-5 mm oscillatory and sweeping strokes in the coronal plane to manually disengage any remaining connected fibers. Care was taken not to advance the needle tip near the axillary artery. Throughout the cutting process, the needle tip was identified at all times. When the cutting procedure was completed, the fluid was aspirated from the subcutaneous tissue using the equipment's aspiration feature after approximately 200-300 passes and 6-7 minutes of cutting. Afterward, gauze and Tegaderm® (3M, St. Paul, MN) were used to dress the incision. An immediate postprocedure ROM assessment was conducted in the same arm position as the preassessment (described by Wahezi et al [22]).