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Randomized Control Trial

Percutaneous Coracohumeral Release for Patients with Adhesive Capsulitis: Two-Year Results from a Randomized Control Crossover Study

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Background: Adhesive capsulitis (AC) causes a variety of symptoms, including but not limited to pain, stiffness, and a gradual restriction of active and passive range of motion (ROM). The coracohumeral ligament (CHL) plays an important role in this disease process, and percutaneous CHL release (PCHLR) has demonstrated efficacy in treating manifestations of this disorder that are refractory to pain medication, physical therapy, and local injections. Our previous study demonstrated one-year efficacy and durability, and this study examines 2-year data from our original randomized control crossover cohort.

Objective: To highlight the importance of extended follow-ups evaluating PCHLR's efficacy in AC management.

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

Setting: An academic medical center.

Methods: Patients with AC refractory to oral medication, physiotherapy, and at least one local injection were included in our original study. In all, there were initially 40 patients (46 shoulders), including 6 patients who underwent bilateral PCHLR using the Tenex® system. In this prospective study, 2 groups, the experiment group (scheduled to receive PCHLR) and the control group (scheduled to receive a local anesthetic in the coracohumeral ligament [LACHL]) were determined through 2-to-1 block randomization. Of these 46 shoulders initially treated, 39 remained in the study at one year. Twenty-six of the 39 shoulders were assigned to the PCHLR group whereas 13 were assigned to the LACHL group. Nine out of 13 shoulders in the LACHL group crossed over to the PCHLR group. Ultimately, 31 shoulders remained in the PCHLR group for 2-year analysis. The effectiveness of these interventions was assessed using a variety of parameters. Pain scores, ROM, and the Oxford Shoulder Score (OSS) were evaluated before the procedure and at one-year and 2-year follow-up visits.

Results: In this 2-year follow-up study, a total of 31 shoulders were sampled, comprising 22 women and 5 men, with 4 patients undergoing bilateral procedures. The mean age of the patients was 65 years (± 11.48). Patients' mean body mass index (BMI) was 36.33 (± 6.55), and the mean CHL thickness was 38.5 (± 3.45). Osteoarthritis was present in 11 cases. The mean follow-up period for the study was 29.7 months (± 6.39). The baseline mean external rotation was 30° (± 8), which increased to 62° (± 18) at one year and 53° (± 18) at 2 years. The baseline mean abduction was 60° (± 16), which improved to 77° (± 21) at one year and 68° (± 20) at 2 years. The median NRS decreased from 8 (IQR: 8, 9) at baseline to 3 (IQR: 2, 7) at one year and 5 (IQR: 2, 7) at 2 years. The baseline median OSS was 7 (IQR: 3, 10), which increased to 32 at one year and 22 (IQR: 15, 35) at 2 years.

Limitations: The present investigation has a limited sample size of patients who have ROM impairment caused by CHL thickening.

Conclusions: While the algorithm for AC care has seen little change for several decades, the authors suggest that PCHLR is a safe, durable, and effective option for cases of AC that are refractory to traditional management.

Key words: Coracohumeral ligament, pain, range of motion, shoulder, percutaneous coracohumeral ligament release, adhesive capsulitis

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Adhesive capsulitis (AC), commonly referred to as frozen shoulder, is a frequent shoulder pathology that causes pain, stiffness, and a gradual restriction of the active and passive range of motion (ROM). The etiology of AC remains elusive, yet various pathogenetic mechanisms of the condition have been proposed, and it is accepted that the coracohumeral ligament plays an important role in the ROM limitations seen in AC patients (1).

Clinical criteria and noncontrast magnetic resonance imaging (MRI) of the shoulder offer accurate and consistent AC diagnoses. Some types of MRI findings, such as coracohumeral ligament thickening, rotator interval infiltration of subcoracoid fat, and axillary recess thickening, exhibit high specificity for AC. Nevertheless, AC diagnoses rely primarily on clinical assessment, with MRI recommended for evaluating other shoulder pathologies rather than confirming AC (2). Recent advances in diagnostic techniques, specifically ultrasonography, have provided new insights into shoulder pathology. Homsi et al (3) have demonstrated that ultrasound-confirmed thickening of the coracohumeral ligament (CHL) is indicative of AC, offering a potential avenue for targeted intervention. This discovery has prompted exploration into ultrasound-guided percutaneous coracohumeral ligament release (PCHLR) as a therapeutic strategy for refractory AC.

At present, conservative approaches constitute the first line of treatment for AC (4). However, evidence supporting the efficacy of these therapies is limited, and a treatment gap exists for patients unresponsive to conservative approaches and those who are not suitable candidates for surgery (5). The literature suggests that PCHLR could be a viable option for these patients, yet robust long-term prospective controlled trials studying the procedure are scarce (5-7). Longer follow-up studies could offer insight into PCHLR's sustained effectiveness and durability in the management of recalcitrant AC.

A prior study from our institution assessed the one-year outcomes of PCHLR procedures that utilized the Tenex system (Tenex Health Inc.) to treat refractory AC (1). This technique was associated with significantly improved pain and functional ROM as well as the functional improvement of the Oxford Shoulder Score (OSS). Longer follow-up studies could offer insight into PCHLR's sustained effectiveness and durability in managing recalcitrant AC. Therefore, the purpose of the current study was to test the authors' hypothesis that PCHLR had similar durability at 2 years after the procedure.

Methods

This prospective study originally enrolled 40 patients with refractory AC across 46 shoulders, including 6 patients who underwent bilateral procedures. This study was approved by our institutional review board (study #2020-11998). The 2 intervention groups, classified as PCHLR and local anesthetic coracohumeral ligament (LACHL), were determined through 2-to-one block randomization. The LACHL group received a lidocaine injection at the CHL, while the PCHLR group underwent CHL release using a Tenex needle that was discussed in the approach and provided indicative images in our earlier paper that demonstrated one-year results (1,6,8).

Of the 46 shoulders initially treated, 39 remained in the study at one year. Randomization resulted in 26 shoulders assigned to PCHLR and 13 to LACHL. Notably, 9 out of 13 patients in the LACHL group crossed over to the PCHLR group, as reported in our recent publication (1). For the 2-year investigation, 2 shoulders were lost to follow-up, and 2 were excluded due to reverse arthroplasty surgery. Consequently, a total of 31 shoulders remained in the PCHLR group for the 2-year analysis.

To assess the effectiveness of the interventions, the ROM (external rotation and abduction), pain score on the Numeric Rating Scale (NRS), and OSS were measured at the baseline, immediately after the procedure, and at the one-year and 2-year marks. Grades of osteoarthritis were also determined based on the Kellgren and Lawrence system (9). Unbiased healthcare personnel confirmed these measurements. We used SPSS® software (version 28.01, IBM Inc.) to analyze the data with paired t-tests. A *P*-value of less than 0.05 indicated statistical significance.

Results

Demographics

In this 2-year follow-up study, a total of 31 shoulders were sampled, comprising 22 women and 5 men, with 4 patients undergoing bilateral procedures. The mean age of the patients was 65 years (± 11.48), and their mean body mass index (BMI) was 36.33 (± 6.55). In our study, the patients' average CHL thickness was 38.5 (± 3.45) mm, whereas the CHL thickness for healthy individuals was measured as one mm-1.35 mm (10). Osteoarthritis was present in 11 cases. The mean follow-up period for the study was 29.7 months (± 6.39) (Table 1).

Table 1. *Demographic information.*

Variable	Total Number	Mean	SD
Sample Size	31*	-	-
Men	5	-	-
Women	22	-	-
Age	-	65 years	11.48
BMI	-	36.33 kg/m^2	6.55
Right Side	15	-	-
Left Side	16	-	-
CHL Thickness	-	38.5mm	3.45
Osteoarthritis	11	Median: 4 (Grade 1-4)	IQR (2, 4)
Follow-Up Duration	-	29.7 (21-58)	6.39

BMI, body mass index; CHL, coracohumeral ligament
* 4 patients had bilateral procedure.

Statistical Measures

Statistical measures the comparing baseline and 2-year results are summarized in Table 2. The baseline mean external rotation was 30° (± 8), which increased to 62° (± 18) at one year and 53° (± 18) at 2 years. The baseline mean abduction was 60° (± 16), which improved to 77° (± 21) at one year and 68° (± 20) at 2 years. The median NRS decreased from 8 (IQR: 8, 9) at the baseline to 3 (IQR: 2, 7) at one year and 5 (IQR: 2, 7) at 2 years. The baseline median OSS was 7 (IQR: 3, 10), which increased to 32 at one year and 22 (IQR: 15, 35) at 2 years.

Table 2. *Clinical outcomes of PCHLR from baseline to final follow-up.*

Variable	Mean (Degree), +/-SD	Median (IQR)	*P* value
Baseline External Rotation	30 (± 8)	-	< 0.001
2-Year External Rotation	53 (± 18)	-	
Baseline Abduction	60 (± 16)	-	0.025
2-Year Abduction	68 (± 20)	-	
Baseline NRS	-	8 (8, 9)	< 0.001
2-Year NRS	-	5 (2, 7)	
Baseline OSS	-	7 (3, 10)	< 0.001
2-Year OSS	-	22 (15, 35)	

NRS, numeric rating scale; OSS, Oxford shoulder score.

Change of ROM in Different Time Frames

The change of range of motion in different timelines is summarized in Fig. 1. Measurements were taken before the Tenex procedure, immediately post-procedure, one year after the procedure, and 2 years post-procedure (with an average of 29.7 months). A significant improvement in ROM was observed immediately after the procedure, and this improvement was sustained at one year. However, the 2-year measurements indicated a reduction in ROM compared to the immediate post-procedure and one-year scores. Despite this, significant improvements in external rotation and abduction over the baseline measurements were noted at all time points measured after the procedure.

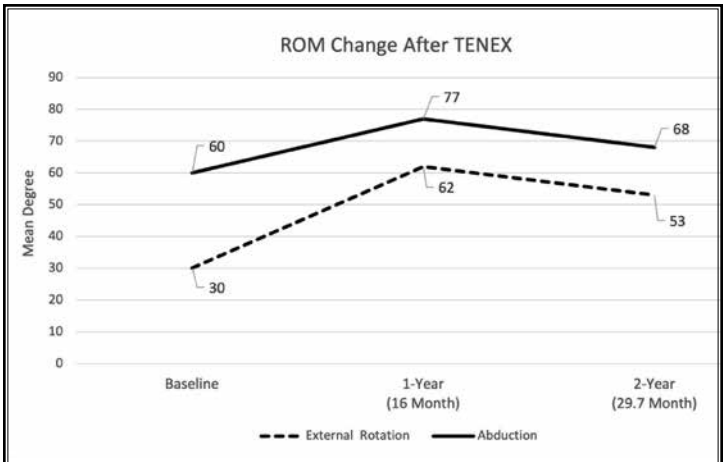

Fig. 1. *Change of external rotation and abduction in different timelines.*

NRS and OSS Comparison in Different Timelines

OSS comparisons at both the one-year and 2-year marks demonstrated improvements from the baseline (Fig. 2). NRS scores decreased significantly from the baseline (Fig.

3), indicating a reduction in pain levels over the course of the study.

Discussion

The present investigation is the first to examine the long-term clinical changes associated with PCHLR. Pain, ROM, and OSS were all significantly maintained at 30 months in patients who had AC refractory to medication, physiotherapy, and local injection. Furthermore, PCHLR responders remained abstinent from medical or interventional treatments during their follow-up period. At one year, 39 of the 46 patients remained in our study; 2 were lost to follow-up, and 2 had reverse arthroplasty due to preexisting osteoarthritis. The authors considered this attrition rate acceptable (11). There were no adverse effects related to the interventions in our study. However, the theoretical adverse effects of PCHLR are infection, brachial plexus ligation, local tendon or muscle laceration or rupture, and invasion of the axillary artery. Several enrolled patients had concomitant glenohumeral arthritis, and none whose condition was more severe than grade 3 improved with PCHLR.

The statistical measures and change of ROM analyses provide a comprehensive understanding of the intervention's impact on shoulder function and pain levels over the 2-year follow-up period. The reduced pain scores and sustained improvements in external rotation and abduction suggest that the studied intervention may yield positive outcomes.

Our 2-year study demonstrated a regression from the one-year results. We believe that this issue occurred because of an inherent flaw in our original study's design. The authors did not exclude patients with osteoarthritis and other chronic shoulder conditions that naturally worsened over time; therefore, many of the patients in the study might have had restricted ROM due to a host of reasons, including but not limited to AC. Thus, the magnitude of improvement and relative durability in this orthopedically complex cohort remains impressive to the authors at this 2-year endpoint.

Most second-year findings showed a slight deterioration while maintaining a statistically significant improvement over to the baseline. Speculation arises regarding the underlying factors for this discrepancy. One possibility is the natural progression of AC, in which the disease's prolonged course may manifest in gradual declines in ROM and OSS, accompanied by slight increases in pain scores over time despite initial intervention. Another cause could be a potential recovery plateau, suggesting that further gains become progressively more challenging to achieve beyond the initial one-year follow-up period. Additionally, the slight decrease in outcomes may indicate a lack of sustained rehabilitation efforts after the first year, highlighting the necessity for prolonged rehabilitation in managing AC and maintaining gains achieved through interventions like PCHLR.

Hypothetically comparing these results to alternative interventions for AC, such as standard physical therapy, corticosteroid injections, and surgical options like arthroscopic capsular

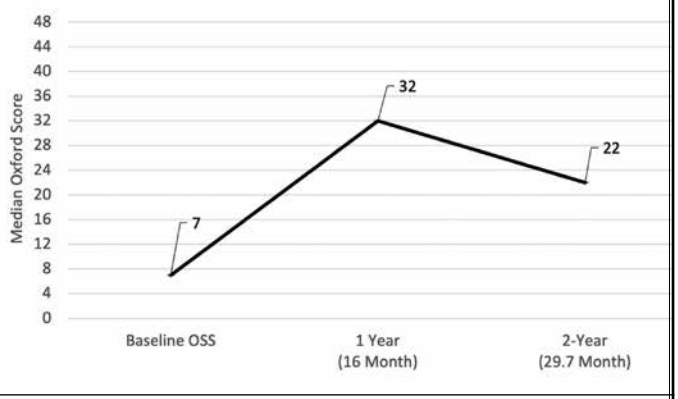

Fig. 2. *Change of OSS in different timelines.*

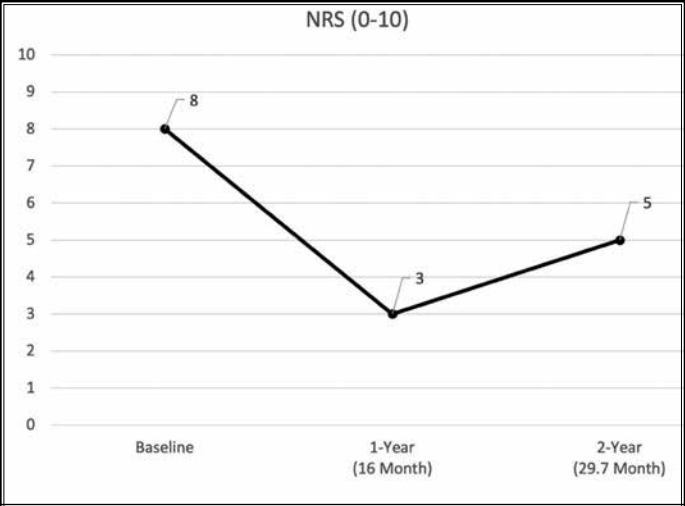

Fig. 3. *Change of NRS score in different timelines.*

release, may provide valuable context, emphasizing the long-term effectiveness and potential advantages of PCHLR in comparison to other treatment modalities for the condition.

Though our study included patients with thickened CHL, it did not exclude intra-articular shoulder pathology. Nonetheless, PCHLR demonstrated significantly durable results in our pathologically complex elderly population. (The patients' average age was 65 years). Several patients in our population had preexisting glenohumeral osteoarthritis; patients with severe diseases did not demonstrate improvement; however, patients with mild diseases demonstrated similar outcomes to those without osteoarthritis. The authors submit that mild shoulder osteoarthritis and other intra-articular glenohumeral pathologies minimize the ROM, causing a pain-limited ROM that may lead to secondary AC (12). Therefore, PCHLR likely improves symptoms in these patients despite the preservation of their underlying diseases. The authors assert that this result establishes the importance of CHLR as a treatment for multifactorial geriatric shoulder pain (13) while mirroring the real-world population who has this condition, though a larger-scale study may need to be performed to validate our findings. An investigation of pure AC without a preexisting shoulder pathology might have provided even better outcomes than those presented in our papers and may be an area for future research. In addition, a study evaluating associations between PCHLR and improvements in rotator cuff, labral, or other soft tissue diseases may be important to better define the CHL's relative role in pain and ROM among these cohorts.

Conclusion

PCHLR administered through the Tenex system is a durable option for refractory AC and should be considered an addition to the algorithm of AC care for patients who do not have significant glenohumeral arthritis.

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