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Supporting Technology for Frozen Shoulder Rehabilitation: A Randomized Controlled Trial

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Abstract

Adhesive capsulitis (AC), commonly known as frozen shoulder, is an enigmatic and poorly defined shoulder disorder characterized by a painful, progressive, and disabling loss of active and passive mobility in the glenohumeral joint across multiple planes. To evaluate the effectiveness of robotic therapy in the rehabilitation of patients diagnosed with AC, a therapeutic intervention study was conducted involving 40 patients treated at the Department of Physical Medicine and Rehabilitation of the General Hospital "Dr. Juan Bruno Zayas Alfonso" in Santiago de Cuba. Patients were randomly assigned to one of two groups: robotic therapy (experimental) and regular therapy (control). The Constant–Murley (CM) scale for pain and shoulder range of motion, as well as the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, were measured before and after treatment. All patients treated with robotic therapy showed improvement; 70% advanced to pain grade 3 (almost normal), five to grade 2 (slight omalgia), and one subject reached grade 4 (no pain). In the control group, however, only nine patients (45%) advanced to grade 3, and one achieved grade 4, while the rest

experienced mild, moderate, or severe pain. At the conclusion of the study, the CM scale indicated excellent or good results in 20 patients, 12 of whom were in the robotic therapy group. In the experimental group, 18 patients (90%) had final DASH scores below 50%.

Keywords: adhesive capsulitis, frozen shoulder, rehabilitation, robotic therapy

1. Introduction

Adhesive capsulitis (AC) of the shoulder, commonly known as frozen shoulder, is a disorder characterized by limited shoulder mobility and debilitating pain. This disorder has various causes, including idiopathic origins, diabetes mellitus, trauma, and a history of shoulder joint manipulation after surgery [1].

Since the 1970s, frozen shoulder has been regarded by many specialists as a benign, self-limiting condition that typically resolves without intervention. However, recent literature suggests that many patients do not fully recover and continue to experience residual pain and loss of function [2].

The estimated prevalence of AC is 2–5% of the population, with peak incidence occurring between 40 and 60 years of age. Approximately 20% of patients develop similar symptoms in the opposite shoulder, and simultaneous bilateral involvement is observed in 14% of cases. It is a common condition, affecting about 15% of patients with shoulder pain [3]. Several therapeutic methods have been introduced for treating frozen shoulder, with non-surgical options such as physiotherapy being common [1].

Most published articles on AC report that this condition accounts for 6% of medical practices involving shoulder specialists (traumatologists and rehabilitators). It predominantly affects females over 50 years of age and typically impacts the non-dominant shoulder. It is bilateral in 20–30% of patients [4].

Corbacho et al. [5] state that AC is a common disorder, affecting 8.2% of males and 10.1% of females in working age, with an estimated cumulative prevalence of 2.4 per 1,000 population per year.

Akshay et al. [4] reported a peak incidence between 40 and 70 years in males [4, 6] and in females aged 40–60 years, which is rare below 40 years (except in cases of diabetes mellitus) or above 70 [4, 6].

Research on AC indicates that symptoms are progressive, with phases designated as “freezing,” “frozen,” and “thawing” to describe the natural evolution of the condition. However, differences in the success rates of various interventions may be due to the timing of treatment initiation. Several authors have suggested that patients in the late phase of AC may improve regardless of intervention due to the natural progression of the disease [7–9].

Recent research has challenged the view of AC as a self-limiting disease with guaranteed recovery and spontaneous resolution, as long-term results show that recovery is not always complete, and the natural course can be prolonged for years [10]. Additionally, rehabilitative interventions are often lengthy, costly, and have a significant risk of resulting in functional limitations or permanent disabilities of up to 15% [8].

Multiple treatment options for AC are currently available, with the most invasive being arthroscopic capsular release (ACR) followed by manipulation under anesthesia (MUA), hydrodilatation, physiotherapeutic techniques with steroid injection, and supportive care standards as the least invasive. Treatment is often provided from the least to the most invasive [11, 12].

A systematic review by Challoumas et al. [13] suggests that early use of intra-articular corticosteroid injections, accompanied by a home exercise program to maximize recovery in frozen shoulder of less than 1 year's duration, is associated with improved outcomes.

These techniques, though widely advocated and recommended [5, 8, 11–13], are invasive and carry the risk of adverse effects from these drugs. In contrast, robotic therapy, which has also been shown to improve clinical indices in later stages, is non-invasive.

In 2021, Pandey et al. [3] reported that most patients respond well to a combination of conservative treatments, leading to a gradual resolution of symptoms within 12–18 months.

For these reasons, it was decided to combine each therapy with ultrasound (US) in both groups. US is a modulating physical agent due to its ability to induce physiological, structural, and functional changes in the treated tissue. It can modify the tissue's physical-elastic properties through thermal, mechanical, and biological effects [9]. US increases blood flow by enhancing capillary permeability and tissue metabolism. Additionally, temperature increases of 2–3° C relieve pain and muscle spasms, and increases of 4°C improve the extensibility of collagen tissue and reduce joint stiffness. This is achieved by fragmenting large molecules (depolymerization), decreasing medium viscosity, rupturing fibrotic septa, raising the pain threshold, and improving neuromuscular activity, leading to muscle relaxation [9, 14, 15]. Previous studies have shown that this regular physical therapy approach can improve symptoms [15, 16].

Exoskeleton-based rehabilitation systems offer a solution by enhancing repetitive movements and task-oriented rehabilitation. Extensive research in robotic rehabilitation of the upper extremity has primarily focused on cerebrovascular disease survivors, but significant applications in other disorders, such as orthopedic injuries, joint and muscle stiffness, impaired muscle synchronization, or reduced capacity, have not been highlighted.

Robotic therapy has the potential to selectively activate muscles with abnormal synergistic movement patterns of the arm and shoulder girdle, improve coordination, modify muscle tone, decrease energy expenditure, vary training intensity, and achieve greater functional independence [17, 18].

This study hypothesizes that robotic therapy is more effective than regular physical therapy in improving shoulder range of motion (ROM) and reducing pain levels in patients with AC.

2. *Materials and Methods/Methodology*

2.1. Basic Procedures. Primary Study Variables

A controlled therapeutic intervention pilot study was conducted on patients diagnosed with AC of the shoulder, treated in the Department of Physical Medicine and Rehabilitation at the General Teaching Hospital "Dr. Juan Bruno Zayas Alfonso" in Santiago de Cuba, Cuba, from January 2022 to May 2023. The 40 patients selected were randomly assigned to one of two groups: an experimental group receiving the intervention and a control group receiving conventional therapy. Patients were randomly assigned to one of two groups using a simple randomization method. A computer-generated random number sequence (Statgraphics Centurion XVI) was used to allocate each patient to either the experimental group (robotic therapy) or the control group (conventional therapy) in a 1:1 ratio.

The study was approved by the Institutional Review Board and the Research Ethics Committee of the General Hospital "Juan Bruno Zayas" (*agreement No.14, Res. 139/2023*) and was conducted in accordance with the Declaration of Helsinki. Participants were informed about the study's characteristics, goals, purposes, risks, and expected benefits, and gave their voluntary consent to participate.

The diagnostic criteria included any of the stages or phases of AC: the motor locking stage (any shoulder movement causes pain and limits ROM), the stiff stage (pain may subside, but the shoulder becomes stiff), and the thawing stage (shoulder ROM begins to improve) [19].

Inclusion criteria were voluntary participation, age over 18 years, body weight up to 100 kg, height up to 1.85 m, and joint mobility in abduction of at least 15 degrees. Exclusion criteria included prior treatment with infiltration, MUA, ACR, or other surgical treatments of the affected shoulder, as well as patients with grade 4 pain (no pain). Exit criteria were voluntary dropout, clinical complications interfering with the study or rehabilitation treatment, absence from three therapy sessions, and death.

The primary study variables were age, sex, duration of symptoms, dominance, affected shoulder, comorbidities, capsulitis classification

(primary/secondary), clinical phases or stages, subgroups, etiology, ROM, degree of pain severity, functionality, and therapeutic response.

Basic procedures included obtaining informed consent, conducting anamnesis, reviewing medical records and physiotherapy indications, and gathering results from physical examinations, imaging, and neurophysiological data. This provided general data and the main sociodemographic and clinical characteristics.

2.2. Outcomes Measures

The severity of shoulder pain [20, 21] was classified for assessing baseline and active movement pain (omalgia) with five grades: 0 (severe, pain at rest and limitation in all movements), 1 (moderate, pain and limitation intensified with movement), 2 (mild with active mobilization, no joint limitation), 3 (near normal, pain/limitation with resisted movements), and 4 (no pain).

Joint assessment was performed using goniometry to determine the ROM of the shoulder in active and passive displacement. This process was standardized, and data were homogenized to limit potential biases. Measurements and recordings were consistently performed by the same evaluator.

For functional assessment of the shoulder, the Constant–Murley (CM) scale was used. This outcome rating system assigns scores to various parameters, with a maximum of 100 points: 35 points for subjective variables (pain, activities of daily living including normal activities, sports, sleep, and arm elevation limits) and 65 points for physical assessment of mobility and strength [22].

The Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire [10, 23, 24] was used as a self-administered, universally valid, reproducible, and highly accepted tool for measuring upper limb functional activity. The DASH measures disability associated with musculoskeletal disorders of the upper extremity, with a total disability score derived from an average score converted to 100 points. A high score indicates a greater perception of disability (the higher the score, the greater the disability).

Degree of satisfaction was measured using a 10-point Likert-type scale from 1 (nothing) to 10 (a lot), defining satisfaction with improvement and acceptance of the exoskeleton. This was used at the end of treatment and after 30 completed sessions [20, 25].

Therapeutic response was defined by the evolution of shoulder pain severity and functionality of the patients. It was recorded as:

2.2.1. Satisfactory

Patients who finished treatment with a reduction in initial omalgia to grade 3 (almost normal) or grade 4 (normal), achieving good or excellent results in the CM test (65 points or above), and a score below 50% in the DASH questionnaire.

2.2.2. *Unsatisfactory*

Patients were considered to have an unsatisfactory response if they finished treatment with grade 0 (severe), grade 1 (moderate), or grade 2 (mild) omalgia, achieved average or poor results in the CM test (below 65 points), or a score of 50% or higher in the DASH questionnaire.

The results were statistically analyzed with 95% reliability when compared between admission and the 30 sessions of treatment to evaluate the significance level of improvement. The professional software package Statgraphics Centurion XVI was used, with the Mann–Whitney *U* test, Chi-square, and Fisher's exact tests for comparisons. *P* values of ≤0.05 were considered statistically significant.

As this was a pilot study, a formal a priori sample size calculation was not performed. However, a post hoc power analysis was conducted using G*Power 3.1.9.7 software. Based on the observed effect sizes for the primary outcome (CM score: Cohen's $d = 1.47$), with an alpha level of 0.05 and 20 participants per group, the achieved statistical power exceeded 0.95 for the between-group comparison. For the DASH questionnaire (Cohen's $d = 1.73$), the achieved power was also greater than 0.95. These results suggest that the sample size was sufficient to detect the large effect sizes observed in this study, though future confirmatory trials should employ a priori power calculations to determine optimal sample sizes for detecting smaller but clinically meaningful differences.

2.3. Experimental Protocol

2.3.1. *Intervention Group*

This group consisted of 20 patients, with anthropometric characteristics of 168 ± 12 cm in height and a weight of 75.7 ± 15.4 kg. These patients were treated with an upper limb exoskeleton with 4 degrees of freedom, developed by the Department of Mechanics and Design at the Universidad de Oriente, Santiago de Cuba, Cuba [26, 27] (Figure 1).

The exoskeleton is a grounded robotic platform designed for shoulder and elbow rehabilitation. It enables four primary therapeutic movements: shoulder flexion/extension, shoulder internal/external rotation, shoulder abduction/adduction (achieved through the combination of the shoulder flexion/extension actuator and counterclockwise rotation of a specially designed patient chair), and elbow flexion/extension. The device is actuated by electric stepper motors with gearboxes, controlled via a Siemens PLC (CPU 1, 511-1PN) programmed in STEP 7 using Structured Control Language (SCL). The therapist operates the exoskeleton through a Siemens TP900 Comfort Human–Machine Interface touchscreen, which allows selection of movement routines, number of repetitions, and speed (20–25°/s), as well as play/pause/stop controls. Safety features include software-controlled emergency stops and angular displacement limits constrained to physiological ranges. The device accommodates patients up to 185 cm in height and 100 kg in weight. The complete technical specifications are summarized in Table 1. The

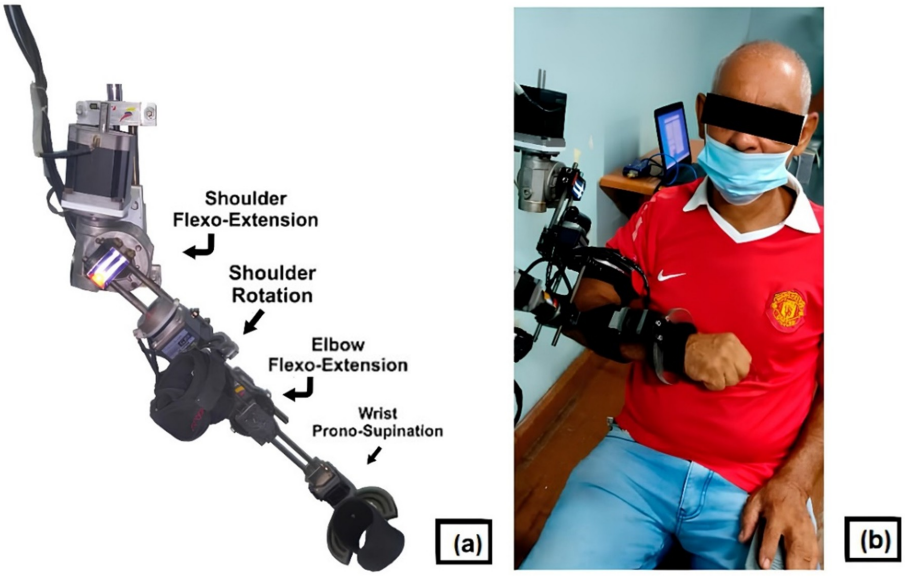

Figure 1. (a) Exoskeleton for upper limb rehabilitation. (b) Patient during a rehabilitation task. Source: authors.

rotational axis of the shoulder flexion/extension actuator is aligned with the anatomical axis of the patient to enable abduction/adduction movements. No additional visual or audiovisual feedback was provided during sessions.

The experimental procedure and safety measures were explained to the participants. Therapy was performed in a seated position from a neutral starting position. The selected movement routines included shoulder and elbow flexion/extension, internal and external rotations, and shoulder abduction/adduction. The exoskeleton allowed a range of movements within physiological limits, controlled through a specially designed interface. The initial ROM values were set from 15 degrees of abduction, taking individual pain tolerance into account.

2.3.2. *Control Group*

This group also consisted of 20 patients, with anthropometric characteristics of 174 ± 6.7 cm in height and a weight of 77 ± 13.1 kg. They were treated with kinesitherapy techniques assisted by a physiotherapist, involving guided exercises progressing through all planes, matching the duration and nature of the movements in the intervention group (shoulder and elbow flexion/extension, internal and external rotations, shoulder abduction).

All 40 patients received therapeutic US prior to exercise with the same prescription: pulsed emission for 10 min, at a frequency of 1 MHz, and intensity of 1 W/cm^2, with an effective radiation area (ERA) of 5 cm^2. Each movement routine consisted of cycles of 10 repetitions at a rate of one effective hour per day.

Table 1. Technical specifications of the upper limb exoskeleton.

Parameter	Specification
Degrees of freedom (DoF)	4 (shoulder flexion/extension, shoulder internal/external rotation, shoulder abduction/adduction, and elbow flexion/extension)
Actuators	Electric stepper motors with gearboxes
Motor drivers	M542 (Leadshine)
Rotation speed	20–25°/s
Control system	PLC-based (Siemens CPU 1511-1 PN) with motion control using STEP 7 (SCL/KOP)
Automation platform	TIA Portal V15.1
Human–machine interface	Siemens TP900 Comfort touchscreen (movement routines, repetitions, speed control, play/pause/stop)
Communication protocol	PROFINET (PN/IE)
Joint torques (at 100 kg)	Shoulder flex/ext: 27.8 N·m; arm rotation: 20.8 N·m; elbow flex/ext: 5.5 N·m; forearm pronation/supination: 0.965 N·m
Safety features	Software-controlled emergency stops; angular displacement limits within physiological ranges
Patient accommodation	Height: up to 185 cm; weight: up to 100 kg

Source: authors.

Both groups participated in five sessions per week, for a total of 30 sessions. The 30-session protocol (five sessions per week over 6 weeks) was selected based on both clinical practice standards and published evidence. Standard rehabilitation protocols for AC typically recommend two to five sessions per week over 6–8 weeks [28, 29]. The 6-week duration aligns with established frozen shoulder rehabilitation guidelines that indicate the greatest improvements in ROM and pain occur within the first 4–8 weeks of structured therapy [3, 13]. Furthermore, a previous pilot study by our group on hemiplegic shoulder pain using the same exoskeleton employed a 3-month treatment protocol with comparable session frequency, demonstrating significant clinical improvements [20]. The 30-session protocol was therefore designed to balance therapeutic efficacy with clinical feasibility, ensuring sufficient treatment

exposure while minimizing the burden on patients. They were also instructed in exercises, stretching, and self-assisted exercises to be performed at home.

3. Results

Table 2 presents the general characteristics of the 40 selected patients with AC included in both study groups. Individuals assigned female were in the majority, with 24 participants (60%). The mean age was 56.8 ± 12.3 years, with the majority being over 55 years old, representing 65% (26 individuals). None of the subjects were older than 69 years.

The robotic device treatment (study group) was applied to seven individuals (17.5%) and 13 assigned male individuals (32.5%), with an average age of 59.1 ± 8.36 years, a height of 171 ± 6.1 cm, and a weight range of 75.7 ± 15.4 kg. The control group consisted of 17 individuals (42.5%) and three individuals (7.5%), with a mean age of 55.9 ± 15 years, a height of 170 ± 4.5 cm, and a weight range of 72.8 ± 5.8 kg.

Right-handedness predominated among the participants (32 patients, 86.5%), and the left shoulder was the most affected (65%), with more than half of the cases (26 out of 40). A history of affected shoulders on both sides was reported by six patients (15%).

Idiopathic or primary AC was present in five patients (12.5%). Eighty percent of patients sought rehabilitation within the first 3 months after diagnosis. Secondary AC was diagnosed in 35 patients (87.5%), with the intra-articular subgroup being the most represented with 17 patients (42.5%). Of these, 15 developed symptoms within 3 months of clinical diagnosis, and 20 subjects had symptoms for over 3 months, with six patients having symptoms for more than 6 months (two patients between 1 year and 15 months). The primary cause of secondary AC was a history of trauma.

Table 2. General characteristics of the patients involved in the study.

Age	Group A (experimental) (n = 20)				Group B (control) (n = 20)				Total (n = 40)			
	Female		Male		Female		Male		Female		Male	
	No	%	No	%	No	%	No	%	No	%	No	%
35–45	–	–	1	2.5	4	10.0	2	5.0	4	10.0	3	7.5
46–55	3	7.5	1	2.5	3	7.5	–	–	6	15.0	1	2.5
56–65	1	2.5	7	17.5	4	10.0	–	–	5	12.5	7	17.5
66–75	3	7.5	4	10.0	6	15.0	1	2.5	9	22.5	5	12.5
Total	**7**	**17.5**	**13**	**32.5**	**17**	**42.5**	**3**	**7.5**	**24**	**60.0**	**16**	**40.0**

Source: authors.

Table 3. Distribution of patients with AC by groups according to the degree of omalgia severity.

AC severity	Group A (experimental) (n = 20)				Group B (control) (n = 20)				Total (n = 40)			
	Admission		Discharge		Admission		Discharge		Admission		Discharge	
	No	%	No	%	No	%	No	%	No	%	No	%
Grade 0	10	50.0	–	–	11	55.0	3	15.0	21	52.5	3	7.5
Grade 1	9	45.0	–	–	6	30.0	3	15.0	15	37.5	3	7.5
Grade 2	1	5.0	5	25.0	3	15.0	4	20.0	4	10.0	9	22.5
Grade 3	–	–	14	70.0	–	–	9	45.0	–	–	23	57.5
Grade 4	–	–	1	5.0	–	–	1	5.0	–	–	2	5.0
Total	**20**	**100**	**20**	**100**	**20**	**100**	**20**	**100**	**40**	**100**	**40**	**100**

Source: authors.

Stage II (rigid) was the most common stage, with 20 individuals (50%), followed by stage I (motor block) and stage III (thawing), each with 10 cases (25%).

Table 3 shows the distribution of omalgia severity, indicating that, on admission, 21 patients (52.5%) had severe arthralgia. In the study group, severe grading appeared in 10 cases, and in the control group, in 11 cases (50% and 55%, respectively), accompanied by a significant limitation of joint range. Grade 1 (moderate severity) included 15 patients (37.5%), with nine (45%) belonging to the robotic therapy group.

In terms of progression, grade 3 (almost normal) was the most prevalent, with 23 patients (57.5%), and only two patients reached grade 4 (normal).

All patients treated with robotic therapy showed improvement, with 70% advancing to grade 3 (14 patients), five to grade 2 (slight omalgia), and one subject reaching grade 4 (no pain or limitation). In the control group, however, nine remained at grade 3 (45%), four at grade 2, six experiencing severe and moderate pain (three in each category), and one patient remained at grade 4 (no pain or limitation).

Table 4 presents the results of the CM test and those provided by the DASH questionnaire.

At admission, the highest number of scores below 50 points on the CM test was observed, with 15 reports representing 75% of the study group and 17 of the control group (85%).

At the outcome measurements, the CM test showed excellent overall results in 15 patients, 10 of whom were in the exoskeleton group. Average results (50–

Table 4. Results of the Constant–Murley test and DASH by groups of patients treated with AC.

AC Questionnaire DASH	Group A (experimental) (*n* = 20)				Group B (control) (*n* = 20)				Total (*n* = 40)			
	Admission		Discharge		Admission		Discharge		Admission		Discharge	
	No	%	No	%	No	%	No	%	No	%	No	%
AC Questionnaire DASH	**Group A (experimental) (*n* = 20)**				**Group B (control) (*n* = 20)**				**Total (*n* = 40)**			
	Admission		**Discharge**		**Admission**		**Discharge**		**Admission**		**Discharge**	
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**
Excellent (+80 pts)	–	–	10	50.0	–	–	5	25	–	–	15	37.5
Good (65–79 pts)	2	10.0	2	10.0	–	–	3	15	2	5	5	12.5
Medium (50–64 pts)	3	15.0	6	30.0	3	15	6	30	6	15	12	30
Poor (<50 pts)	15	75.0	2	10.0	17	85	6	30	32	80	8	20
Total	**20**	**100**	**20**	**100**	**20**	**100**	**20**	**100**	**40**	**100**	**40**	**100**
50% or more	11	55	2	10	14	70	8	40	25	62.5	10	25
Less than 50%	9	45	18	90	6	30	12	60	15	37.5	30	75
Total	**20**	**100**	**20**	**100**	**20**	**100**	**20**	**100**	**40**	**100**	**40**	**100**

Source: authors.

64 points) were observed in 12 subjects (six from each treatment), and poor results (below 50 points) were reduced to eight reports (20%), including two patients from the robotic therapy group.

Regarding strength measurements, 12 members of the robotic group were initially unable to lift any weight, and eight subjects could lift between 1 and 2 kg. Subsequently, 19 of the 20 individuals lifted between 1 and 3 kg in 90° abductions, with one exception who was unable to lift any weight.

In the preliminary strength test, 11 participants in the control group failed to lift any weight, and nine lifted 1 kg. Subsequently, 13 patients were able to lift 1–3 kg without any problems, leaving seven who were unable to lift any weight.

The results provided by the DASH questionnaire are presented in Table 4. At admission, percentages above 50% (greater disability) predominated, corroborating a greater perception of disability (25 subjects for 62.5%). At the end of the study, DASH scores improved, with 30 patients achieving functional independence (75%). In the robotic therapy group, 11 (55%) exhibited elevated

Table 5. Summary statistics of the evaluative indices in both treatments.

AC clinical assessments	Group A (experimental) (n = 20)			Group B (control) (n = 20)			Between-groups p-value
	Admission	Discharge	p-value	Admission	Discharge	p-value	
Pain severity	0.46 ± 0.28	2.86 ± 0.28	0.000006*	0.6 ± 0.35	2.2 ± 0.66	0.021*	0.04*
Constant–Murley	33.1 ± 12.6	77.6 ± 11.1	0.0001*	31.9 ± 8.5	58.1 ± 15.08	0.009*	0.051*
DASH	51.7 ± 12.8	25.8 ± 6.6	0.003*	60.49 ± 8.05	41.04 ± 10.6	0.006*	0.00001*

Source: authors.

DASH scores at admission. Except for two patients at the end of the study, a total of 18 (90%) exhibited final scores below 50%, seven more than at baseline.

The comparative summary statistics (Table 5) for all the indicators analyzed show statistical significance in the two therapy groups, with the greatest differences from admission being confirmed in those treated with the exoskeleton, mainly regarding pain severity, followed by the CM results.

Figure 2 shows the variation in the active ROM between the movements of the shoulder joint complex. In the exoskeleton group, all movements showed statistically significant changes; however, in the conventional physiotherapy group, there was only significance for extension. Statistically significant differences between the groups were found for internal and external rotations.

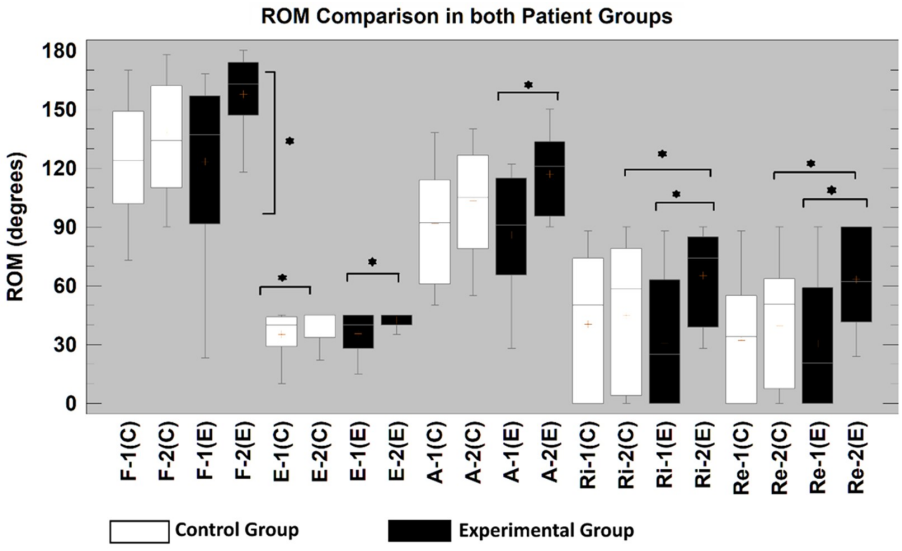

Figure 2. Range of joint movement (ROM) of patients in both therapy groups (1, admission; 2, discharge; f, flexion; e, extension; a, abduction; Ri, internal rotation; Re, external rotation; *$p < 0.05$). Source: authors.

Table 6. Therapeutic response in patients with adhesive capsulitis (AC) by treatment groups.

AC therapeutic response	Group A (experimental) (n = 20)		Group B (control) (n = 20)		Total (n = 40)	
	No	%	No	%	No	%
Satisfactory	12	60	7	35	19	47.5
Unsatisfactory	8	40	13	65	21	52.5
Total	**20**	**100**	**20**	**100**	**40**	**100**

Source: authors.

The analysis of the variable "Therapeutic response" (Table 6) shows that 19 individuals (47.5%) achieved a satisfactory response, 12 (60%) from the intervention group and seven (35%) from the control group.

Patients treated with the exoskeleton expressed their level of satisfaction and acceptance of the therapy with scores above 7.

4. Discussion

The results obtained, with an average age of 56.8 ± 12.3 years, align with the criteria described in the introduction, and none of the patients investigated were over 69 years of age. Female patients predominated over male patients, and although right manual dominance was common, the shoulder most affected by stiffness was the contralateral one (65%); no significant bilateral involvement was found in the patients analyzed.

The sample studied in this work differed in relation to its significant association with diabetes and hypothyroidism, conditions where secondary AC usually appears bilaterally, since the intra-articular subgroup (87.5%) of traumatic etiology and stage II or rigid (50%) was prevalent.

Romeyn et al. [30] have stated that the most important factor determining the success or failure of a particular shoulder rehabilitation protocol is the establishment of a correct diagnosis. While this is true, it can be added that in stiff shoulder rehabilitation, it is essential to start treatment at an early stage, and the results achieved support this.

According to our results, the rigid stage predominated, and clinical cases were established within less than 1 year, mainly between 3 and 6 months. Only=two patients had an evolution of 1 year and 15 months, respectively. At the time of treatment, none of the patients had reached or exceeded 2 years of evolution, nor had they entered the final clinical phase of AC or shoulder thawing. Hence, spontaneous clinical or functional improvement could not be expected; these circumstances were not favorable for increasing the active ROM. Thus, the therapeutic benefits achieved were attributable to the intervention with US and rehabilitation with the exoskeleton.

With the application of the CM scale, excellent final overall results (over 80 points) were verified in 10 patients treated with the exoskeleton (50%), and of these, seven scored over 90 points (five patients with individual scores above 95 points and two patients with 93 and 94 points, respectively).

Regarding the DASH questionnaire, the experimental group had a lower disability index at discharge of 53%, versus 82.5% (higher disability), in the control group. Conversely, robotic therapy caused a decrease below 50% in the DASH score in 18 patients (90%). These results suggest a greater and more positive functional impact provided by the robotic approach, even in patients with initially unsatisfactory results.

Regarding active joint mobility ranges (ROM), only a few papers report results in the treatment of capsulitis using exoskeleton therapy. Wu et al. [15] compared two groups: one received regular physical therapy with exercises (pendulum, relaxation, and controlled elevation, three times a day, three times a week for 8 weeks) and hot compresses, while the second group used robotic therapy for 30 min a day, 5 min per mobilization, three times a week for 8 weeks. The robotic group experienced decreased VAS index (visual analogue scale) and improved ROM values, with significant increases in flexion, abduction, external rotation, and internal rotation.

Alguacil-Diego et al. [31] performed passive movements of conventional therapy using an exoskeleton on seven patients with musculoskeletal injury of the right upper limb. The test included a series of passive mobilizations of the affected upper limb: shoulder flexion, shoulder abduction, and shoulder elevation with an intermediate aperture angle for an undetermined time, showing positive indicators of acceptance. However, the study had limitations due to its non-randomized controlled design, small sample size, and lack of a control group, and it did not include rotation movements or pain assessment scales in the analysis.

In our study, statistically significant changes were observed within the group for all ROM movements. In contrast, in the control group, only extension showed statistical significance. Between the two groups, the most significant differences were found in both external and internal rotations. Additionally, the ranges of active mobility were not statistically significantly related to the age or sex of the patients ($p > 0.05$).

The use of robotic devices for shoulder rehabilitation in AC remains an emerging field, with only a few comparable studies available.

Wu et al. [15] used a joint mobilization apparatus – a single degree-of-freedom device – to treat frozen shoulder over 8 weeks (3 sessions/week and 30 min/session), reporting significant improvements in VAS pain scores and ROM for flexion, abduction, and rotations. In contrast, our 4-DoF exoskeleton enables multi-planar movements within a single session, which may contribute

to the more comprehensive ROM improvements observed across all movement directions.

Alguacil-Diego et al. [31] evaluated ExoFlex, a hybrid exoskeleton for passive mobilization in musculoskeletal injury, reporting positive acceptance indicators in seven patients, though their study lacked a control group and did not assess rotation movements or pain scales. More recently, Kim et al. [32] tested the HEXO-UR30A, an active shoulder exoskeleton, in a randomized controlled trial of 30 stroke patients over 3 weeks (10–30 min sessions), finding slight improvements in ROM compared to standard therapy.

The Armeo Spring, a commercially available 7-axis upper limb exoskeleton combining robotic assistance with virtual reality, has been proposed for AC rehabilitation in a protocol by Belmouhand et al. [33], though results have not yet been published.

These comparisons highlight that while different robotic platforms vary in their degrees of freedom, control methods, and treatment durations, they consistently demonstrate potential benefits for shoulder rehabilitation. The device used in the present study offers the advantage of PLC-based motion control with therapist-adjustable parameters, enabling individualized treatment within physiological safety limits. Future multicenter trials comparing different robotic platforms directly would help establish optimal device characteristics and treatment protocols for AC rehabilitation.

The final therapeutic responses indicated the effectiveness of the treatments employed, with a better evolution in the experimental protocol group. Of the total 19 satisfactory responses, 12 (60%) were in the intervention group, and seven (35%) were in the control group. The therapeutic response was verified in 21 subjects, with eight (40%) cases in the experimental group versus 13 patients (65%) in the control group.

All eight unsatisfactory therapeutic responses in the experimental group were attributable to the CM scale results, as the subjects were unable to reach the 65 points required for a positive evolutionary criterion. However, it is important to note that the scores of these patients improved notably from the initial estimate. It should also be noted that the two patients with AC in the group that received robotic therapy had the worst scores and the longest evolution times (1 year and 15 months, respectively).

4.1. Limitations

This study has several limitations that should be mentioned. First, due to the nature of the intervention, blinding of patients and therapists was not feasible, as the use of the robotic exoskeleton is inherently visible. However, to mitigate

potential bias, outcome assessments (goniometry, CM scale, and DASH questionnaire) were performed by the same evaluator throughout the study, following standardized protocols. Second, the sample size of 40 patients, while adequate for a pilot study, limits the generalizability of the findings. Third, the absence of long-term follow-up beyond the 30-session treatment period precludes conclusions about the durability of the observed improvements. Future studies should incorporate assessor blinding, larger sample sizes with formal a priori power calculations, and extended follow-up periods to confirm these preliminary findings.

5. Conclusion

Therapeutic US combined with exoskeleton-assisted physical therapy improves shoulder ROM and reduces pain in patients with AC more effectively than regular physical therapy alone. The results reinforce the importance of early-stage rehabilitation and suggest that the robotic approach offers superior functional benefits, even for patients with advanced AC. This combined treatment modality could be a valuable addition to current therapeutic options for managing AC.

Author Contributions

Marcia Sandra Hernandez Zayas: Conceptualization, Writing – original draft; **Ruthber Rodríguez Serrezuela:** Writing – review & editing; **Daily Milanés Hermosilla:** Investigation, Software; **Jorge Bonzon Regalado:** Data curation, Writing – review & editing; **Mauricio Torres Quesada:** Investigation, Formal analysis; **Arquímedes Montoya Pedrón:** Validation, Supervision; **Roberto Sagaró Zamora:** Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft, Writing – review & editing, Project administration, Supervision.

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Ethical Statement

This study was conducted in accordance with the Declaration of Helsinki and approved by the Research Ethics Committee of the General Hospital “Dr. Juan Bruno Zayas Alfonso,” Santiago de Cuba, Cuba, in 2023 (Approval reference: Agreement No. 14, Resolution 139/2023, institutional project code PN223LH004-026). All participants provided written informed consent prior to enrollment after being fully informed about the study’s objectives, procedures,

potential risks, and expected benefits. The study was part of the National Science Project "Development of upper limb exoskeletons for rehabilitation tasks" (PN223LH004-026), funded by the Ministry of Science, Technology, and Environment (CITMA) of Cuba.

Data Availability Statement

Data is available from the corresponding author upon request. Legal and ethical considerations related to patient privacy prevent the public from sharing individual-level clinical data.

Conflict of Interest

The authors declare no conflict of interest.

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