RESEARCH ARTICLE

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Exercise Therapy, Systemic Acupuncture and Silicon Oxide Tablets in the Rehabilitation of Physical and Functional Disorders in Breast Cancer Survivors: Randomized Clinical Trial

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Abstract

Objective: To compare three rehabilitation treatments, exercise therapy, acupuncture, and silicon oxide tablets (Stiper®), in women undergoing breast cancer surgery, assessing pain, depression, upper limb function, and range of motion parameters (ROM). **Methods:** Seventy-nine women with pain above 3 on the visual analog pain scale (VAS) were divided into three groups: exercise group was treated with exercise therapy, acupuncture group was treated with acupuncture, and Stiper® group was treated with silicon oxide tablets in place of needles. **Results:** Sixty-seven patients completed the treatment, 26 from exercise group, 23 from acupuncture group, and 18 from Stiper® group . There was an improvement of pain over time in all groups, the first session compared with the fifth ($p < 0.001$) and with the tenth ($p < 0.001$), but not between groups. There was a statistically significant difference in depressive symptoms using the Beck questionnaire over time in the three groups, between the first and tenth sessions ($p = 0.001$), between the first and fifth sessions ($p = 0.052$), but not between groups. Regarding the DASH questionnaire for shoulder function, there were significant differences over time at all evaluated moments ($p<0.001$), but not between groups. There was a statistically significant difference in ROM over time in the three groups, but not between groups. **Conclusion:** The rehabilitation of physical dysfunctions in women who survived breast cancer through exercise therapy, acupuncture, and silicon oxide tablets in pain, depression, upper limb function, and ROM, proved to be effective, without statistical difference between the groups.

Keywords: Breast cancer- exercise therapy- acupuncture- depression- pain- range of motion

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Introduction

Cancer is a global public health problem and is among the leading causes of death. Its incidence and mortality are increasing worldwide due to aging and population growth, associated with the prevalence of risk factors secondary to socioeconomic development, in different types of cancer depending on the country or region [1, 2]. Breast cancer is the most frequent type of female cancer in the world.

The treatment of breast cancer is complex and involves the combination of different therapeutic modalities, such as surgery, radiotherapy, chemotherapy, immunotherapy, hormonal and biological therapy [3].

Despite advances in surgical techniques for the treatment of breast cancer, many women have physical and psychological difficulties that can affect their quality of life, such as lymphedema, shoulder or upper trunk pain, changes in body image, limitation of range of motion (ROM), loss of upper limb strength (UL), skin retraction, postural changes, shoulder joint dysfunction, decreased functional capacity, flexibility, and joint mobility depression, among others. Thus, the rehabilitation of these patients is essential for pain reduction, functional rehabilitation, and promotion of quality of life [4-7].

Kinesiotherapy plays an important role in the treatment of these complications and is a technique widely recognized in the literature with very satisfactory results [8, 9].

The WHO recognizes the therapeutic action of acupuncture in 43 types of diseases, such as migraines, gastrointestinal problems, allergies and various pains. In the West, acupuncture has gained credibility, mainly for its analgesic effect. Studies have shown that acupuncture increases plasma levels of opioid substances such as enkephalins and endorphins and that the level of immunoglobulins rises from the first week of treatment. It is also used in non-painful conditions, being able to stimulate the synthesis of neuropeptides that control

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human body functions and play an important role in cardiovascular physiology and hormone secretions. Some studies show that acupuncture stimulation can result in systemic effects by increasing the secretion of neurotransmitters and neurohormones, improving blood flow, and stimulating immune function [10, 11].

Another method that is part of acupuncture is the Stiper®, which is a micronized quartz silicon oxide tablet whose microparticles are organized in a hypoallergenic blanket, which is 13 mm in diameter and 3 mm in thickness [12]. It can be used on the same acupuncture points as a replacement for needles.

The main objective was to compare the efficacy in the rehabilitation of women submitted to surgical treatment for breast cancer in three distinct treatment groups: kinesiotherapy, acupuncture, and silicon oxide tablets, according to the parameters pain, depression, upper limb function, and ROM.

Materials and Methods

Randomized, non-blind clinical trial was conducted in the Breast Ambulatory Unit of the Department of Gynecology at the Federal University of São Paulo (UNIFESP). The study was approved by the ethics committee of UNIFESP, under number 1.543.582, and registered in the Clinical Trials, with number NCT02798263.

The research participants received all the necessary information regarding the performance of the study before the research was initiated. After the clarification of the research and acceptance, the participants signed the free and informed consent term, based on Resolution 466/2012 of the National Health Council, before being included in the study. All participants were aware that their participation was according to their will, being free to give up whenever they wanted.

During the period from May 2016 to July 2021, this study included patients older than 18 years who underwent surgical treatment of breast cancer, radical or conservative, and complained of pain in the scapular girdle and upper limb region, including pain in the thoracic or cervical spine, after 3 months of surgery. The level of pain should be ≥3 on the visual analog scale (VAS). The study excluded patients with bilateral breast surgery, metastatic disease, vascular and tactile sensitivity disorders, uncompensated diabetes mellitus (DM) type I and II, and those with a lower education level than 4 years

For randomization, a sequence generated in a computer program available on the site was www.randomization.com. The algorithm used by the website to generate the randomization process was Java math.random function. Range: From 1 to 79.

The patients were divided into three randomized groups that received weekly treatment for 10 weeks, exercise group was treated with predefined standard kinesiotherapy, based on stretching of the neck muscles and scapular girdle, exercises for ROM and upper limb muscle strength, lasting 30 minutes; acupuncture group treated with 30 minutes of acupuncture with needles at predefined points and, in Stiper® group, the same acupuncture points of acupuncture group were used, but silicon oxide tablets were used instead of needles. If the patients still presented pain at the end of the 10 sessions, they would receive 10 more treatment sessions with the protocol of another group.

The therapeutic protocol used was the same as in the study of Giron et al. [13]. All exercises, in both members, were done in the standing position, regardless of the operated side. Each stretch was sustained for 30 seconds. The active-free and strength exercises were performed in a series of 10 repetitions for each movement and gradually increased so that, according to the patient's physical capacity, they did not exceed the maximum of three sets of 10 repetitions for each movement. To increase the level of resistance of each exercise, the patient should be able to perform two consecutive sessions with the same strength without difficulties or complaints about the arm.

The exercises used are as follows: neck, shoulders, arms, and trunk muscles stretching; active free or exercises with the aid of a cane for shoulder flexion, extension, adduction, abduction, external rotation, and internal; muscular strength exercises with the use of elastic bands and dumbbells for the movements described above, with addiction of biceps and triceps muscle training. The execution of the exercise was isotonic, done slowly, and within the range of motion achieved by the patient. The resistance was adequate to muscular capacity according to each patient. Finally, relaxation exercises were performed.

The needle insertion protocol was preceded by antisepsis of all acupoints with 70% alcohol and then sterile and disposable needles (0.25 mm x 30 mm) were inserted into the contralateral limb and at a distance, in the order of puncture from top to down, according to the recommendations of the Standards for Reporting of Controlled Trials in Acupuncture (RCTA) [14] and based on Traditional Chinese Medicine (TCM). The depth of needle insertion was determined according to the application site, patient age, body composition, and intensity of the reaction to the needle. The patients were positioned in a comfortable position, in supine, or lateral decubitus, for 30 min. For the application of silicon oxide tablets, there was also the antisepsis of the acupoints, and its fixation was made with adhesive tape. The points were used: CV 3, SP 9, ST 36, KI 7, LR 3, GB 21, LI 15, HT 14, LU 5, LI 4, ST 38, and BL 60.

The patients answered an evaluation form about their clinical and socio-demographic profile, shoulder ROM with the use of a manual goniometer, pain, the intensity was performed using the Visual Analog Pain Scale (VAS), upper limb function, through the DASH questionnaire, and depression, using the Beck questionnaire. Patients were evaluated at the beginning of treatment, after 5 weeks, and at the end of 10 weeks.

The sample size was calculated by considering pain improvement as the main response, as assessed by the VAS. According to the study by Crew et al., the mean VAS is 4.5 points (standard deviation of 2.2) in patients who were not treated with acupuncture and 2.6 points in patients undergoing acupuncture. Assuming that similar results would be observed, with a significance level of 0.05 and test power of 80%, it was estimated that a total of 78

patients would be needed. The present study included 79 patients [15].

Statistical analysis was performed in the Statistica program (version 13.5). Descriptive analysis (means of the standard deviation was used ± for the characterization of the groups. The Shapiro-Wilk test was used to verify the normality of the variables and then the ANOVA test was used to compare normal and Kruskall-Wallis distribution data for non-normal distribution data. For categorical data, differences between groups were evaluated by the Chi-square test. The factorial ANOVA of repeated measures was used for differences over time and between groups during treatment, with the use of Mauchly's measurelessness tests, Greenhouse-Geisse and Huynk-Feldt, and post hoc Bonferroni tests. The study adhered to CONSORT (Consolidated Standards of Reporting Trials) guidelines [16].

Results

Of the 79 patients evaluated, 67 completed the treatment, 26 from the exercise group, 23 acupuncture group and 18 Stiper® group, as described in Figure 1. Among the reasons for the withdrawal we can mention allergy (in the silicon oxide tablets), the evolution of the disease, the return to work, and Covid 19 pandemic.

Demographic features

Registration and social data were collected, such as age, profession, race, education, among others; in addition to collecting information from the medical records about breast cancer treatment, such as clinical stage, type of surgery, radiation and/or chemotherapy, breast reconstruction and clinical data for objective classification of pain.

Table 1 presents the demographic, social, and clinical data, and the groups were homogeneous in all variables.

Pain

Pain intensity was classified using the Visual Analogue Scale (VAS), which consists of a 10 cm line, with verbal anchors of "absence of pain" on the left, coinciding with the number zero and "the worst possible pain" on the right, this being number 10.

There was an improvement in terms of pain over time in the three groups, which was statistically significant, but not between the groups. Post-hoc Bonferroni analyses showed that there was a significant decrease in pain levels between the first session compared to the fifth ($p < 0.001$) and the tenth ($p < 0.001$). However, between the fifth and tenth sessions, there was no statistically significant difference in pain levels ($p = 0.624$).

Beck Depression Inventory Scale

The assessment of depressive symptoms was carried out using the Beck Depression Inventory Scale, which is a questionnaire developed to assess the presence and intensity of depressive symptoms.

The Beck questionnaire showed a statistically significant difference in depressive symptoms over time in the three groups, but not between the groups. Bonferroni's posthoc analysis showed that there was a statistically significant reduction in depression levels between the first and the tenth session ($p = 0.001$). Between the first and fifth sessions ($p = 0.052$), the difference was marginally non-significant. However, between the fifth and the tenth session, there were no statistically significant differences in the levels of depression ($p=0.79$).

Disabilities of the Arm, Shoulder, and Hand Questionnaire

The Disabilities of the Arm, Shoulder and Hand Questionnaire was used to assess functional capacity in illnesses of the upper limb and measure the abilities to perform certain activities, as well as symptoms.

Regarding the DASH questionnaire, which evaluated the functional capacity of the UL, the Factorial Repeated Measures ANOVA also showed statistically significant differences over time, but not between the groups. Bonferroni's post hoc analysis noted that there was a significant decrease between the first session compared with the fifth ($p < 0.001$) and the tenth ($p < 0.001$). Furthermore, there were statistically significant differences between the fifth and tenth sessions ($p < 0.001$) (Table 2).

Shoulder range of motion

Shoulder range of motion was measured using a manual goniometer, in the following movements: flexion, extension, adduction, abduction, internal rotation and external rotation. The movements were made in an active-free manner and bilaterally.

Regarding the results of the intragroup evaluation of shoulder ROM, there were statistically significant differences over time in all the evaluated movements. However, in intergroup analyses, no statistically significant difference was identified (Table 3).

Discussion

Breast cancer incidence starts to be more expressive from age 40, with most cases occurring from age 50, which corroborates this sample that presented a mean age of 52, 8 years [17].

Most women in this study underwent mastectomy (57%) and axillary lymphadenectomy (AL) (67.1%), being more aggressive surgeries and with greater chances of developing physical and psychological complications, such as pain, limitation of UL function, limitation of shoulder ROM and depressive symptoms [3, 4].

Post-mastectomy musculoskeletal changes occur on both affected and unaffected sides. Mastectomy changes the resting tilt and alignment of the scapula, leading to a cascade of changes in the shoulder joint. Scapular incoordination and loss of strength are reported up to 6 years after surgery, which corroborates the findings in this study, where the mean time between surgery and the beginning of treatment was 25.6 months, which is consistent with the condition. of chronic pain [18, 19].

The damage is in part due to the direct effect of tissue breakdown during surgery, followed by fibrosis, inflammation, and scar formation [18, 19].

The performance of AL causes damage to the lymphatic system and, depending on the number of lymph

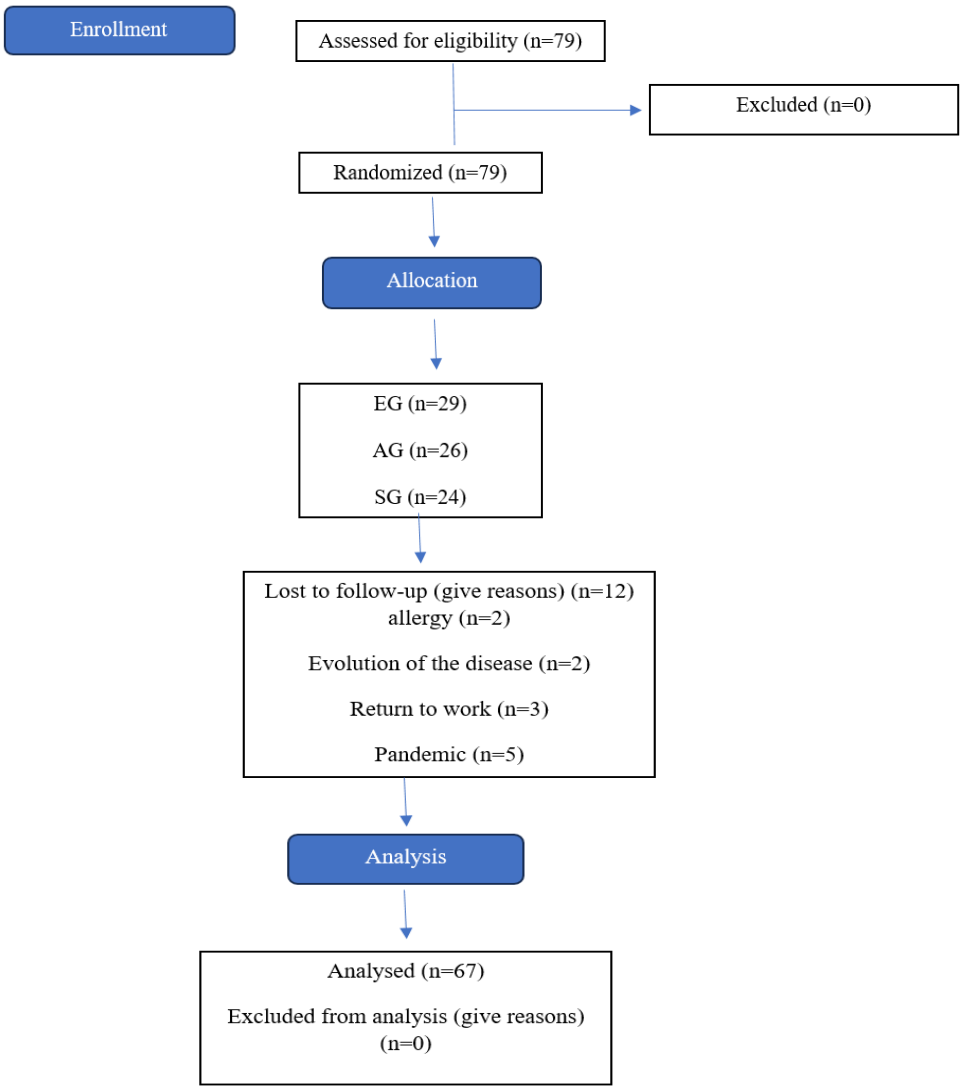

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) workflow. Source: http:// www.consort-statement.org/

nodes removed, is associated with an increased risk of lymphedema and pain in the UL and shoulder [20, 21]. This procedure can damage the intercostobrachial nerve and other brachial plexus components [22].

Nerve injury can also be worsened by radiotherapy, as it leads to cell death with cytokine release, tissue damage, and fibrosis, which will significantly increase dysfunction and long-term pain [23]. Most women in this study underwent radiotherapy (77.2%). Physiotherapy plays an important role in treating these complications and should be performed early, to reduce the possibility of ROM restriction and pain complaints, in addition to preserving functionality. Kinesiotherapy is a technique widely recognized in the literature, and acupuncture is also widely studied, mainly to control pain symptoms. Regarding pain, in the three groups there was a good response with a significant reduction when compared to the 1st with the 5th session (d = 1.22) and the 1st with the 10th session (d = 1.17), the average pain in the VAS scale it was 7.13 in the 1st session (considered severe above 7), 3.9 in the 5th session and 3.4 in the 10th session (considered moderate between 3 and 7). No statistically significant improvement was observed between the 5th and 10th sessions, which leads us to believe that a significant improvement occurred in the first five sessions. Eighteen women had zero VAS after 10 sessions [24, 25].

Groef et al. 2015, in a systematic literature review, found that physical therapy with stretching and active exercises was effective in the therapy of postoperative pain and shoulder ROM after breast cancer treatment [26]. In a prospective, randomized, and controlled clinical study with women undergoing postoperative follow-up of breast cancer who presented with pain and fibrosis of the lymphatic collector, to evaluate the effects on shoulder function, pain, lymphedema, and QOL, were submitted to a physical therapy program, where one group performed exercises (stretching and strengthening) and another performed combined exercises with lymphatic drainage, 3 times a week for 4 weeks. QOL, shoulder flexor strength, DASH, and pain significantly improved statistically in both groups [27].

Li et al. [28] , through a systematic review and meta-analysis, concluded, based on the available data, that acupuncture is a safe treatment with some mild

Table 1. Sample Characterization

Variable	EG (n=29) Mean (SD)	AG (n=26) Mean (SD)	SG (n=24) Mean (SD)	p
Clinical Data				
Age (Years)	52.8 (10.4)	53.65 (9.3)	52.1 (9.3)	0.6$^{\alpha}$
Body Mass Index (kg/m^2)	29.1 (5.2)	28.2 (5.8)	30.6 (5.9)	0.3$^{\beta}$
Associated Diseases	N (%)	N (%)	N (%)	
Arterial hypertension	13 (44.8)	13 (50)	10 (41.6)	0.8 $^{\pi}$
Diabetes Mellitus	6 (20.6)	1 (3.8)	3 (12.5)	0.1 $^{\pi}$
Surgical Data				
Breast				0.4 $^{\pi}$
Right	12 (41.3)	13 (50)	8 (33.3)	
Left	17 (58.6)	13 (50)	16 (66.6)	
Type of Surgery				0.1 $^{\pi}$
Conservative	9 (11.39)	12 (15.18)	13 (16.45)	
Radical	20 (25.31)	14 (17.72)	11 (13.92)	
Axillary Approach				0.1 $^{\pi}$
Axillary evacuation	23 (79.3)	18 (69.2)	12 (50)	
Sentinel lymph node biopsy	6 (20.6)	9 (34.6)	11 (45.8)	
Reconstruction	14 (48.2)	11 (42.3)	11 (45.8)	0.9 $^{\pi}$
	Mean (SD)	Mean (SD)	Mean (SD)	
The time between surgery and initiation of treatment (months)	25.9 (43.9)	25.3(29.6)	25.7(41.9)	0.7 $^{\alpha}$
tumor type	N (%)	N (%)	N (%)	0.1 $^{\pi}$
Invasive	29 (93)	25 (96)	18 (75)	
In situ	2 (7)	1 (4)	6 (25)	
Radiotherapy	24 (82.7)	18 (69.2)	19 (79.1)	0.4 $^{\pi}$
Chemotherapy	23 (79.3)	19 (73)	15 (62.5)	0.3 $^{\pi}$
Endocrinotherapy	17(58.6)	17 (65.3)	19 (79.1)	0.2 $^{\pi}$

EG, Exercise Therapy Group; AG, Acupuncture Group; SG, Stiper® Group; p-value, Kruskal-Wallis α test for non-parametric data; ANOVA test β for parametric data; Chi-square test π for categorical data

adverse events. In this study, acupuncture significantly reduced multiple symptoms related to breast cancer treatment, such as pain intensity, fatigue, depression, hot flashes, and neuropathy, that is, there are evidence-based recommendations to incorporate acupuncture into the clinical treatment of patients. with symptoms secondary to breast cancer treatment [28].

Another systematic review and meta-analysis evaluated the use of acupuncture in the treatment of disorders in post-treatment breast cancer patients and the data showed that the severity of pain in the acupuncture group significantly decreased when compared to the control group [29].

In a case report on therapy of a patient with post-mastectomy pain syndrome who used silicon oxide tablets as an element for pain treatment, during five sessions, it was noted that the patient had complete pain resolution, as measured by VAS, and the absence of pain symptoms persisted 6 months after the end of therapy [30].

According to the literature, patients with breast cancer may present depressive symptoms in different intensities and severity during or after treatment, which directly affects QOL. The result of the application of the Beck questionnaire in this research showed that the patients presented depressive symptoms of mild to moderate intensity (score between 10 and 18) [31]. There was a significant reduction in depression levels between the first and tenth sessions, between the first and fifth sessions the difference was marginally non-significant, and between the fifth and tenth sessions, there were no significant differences.

Patsou et al. [32] studied the effects of physical activity on depressive symptoms in women who survived breast cancer through a meta-analysis of randomized clinical trials between 2011 and 2016, with 1,701 breast cancer patients. The study concluded that there were significant differences between the exercise and control groups (improvement of depressive symptoms) so an exercise program should be administered to patients after breast cancer treatment [32].

Aydin et al., (2021), in a randomized clinical trial, found similar results, where 48 women were divided into a group that received a 12-week program of aerobic and resistance exercises and the control group. As a result, the study group's depression levels markedly decreased with exercise, while depression levels increased in the control group [33, 34]. The systematic review by Li et al. [28] corroborates the results found in the present study, about treatment with acupuncture, in the systematic review by Zang et al. 2021, there was no statistical difference

Table 2. VAS, BECK, DASH, Group Mean with 95%Confidence Interval

		Session 1 Mean ± SD (CI 95%)	Session 5 Mean ± SD (CI 95%)	Session 10 Mean ± SD (CI 95%)	p-time effect	p-between groups
VAS					<0.001	0.496
	EG	6.6 ± 1.8 (6.10 to 7.48)	3.4 ± 2.3 (3.20 to 4.98)	3.3 ± 2.6 (2.31 to 4.44)		
	AG	7.0 ± 1.9 (6.10 to 7.60)	4.5 ± 2.0 (3.91 to 5.52)	2.6 ± 2.7 (1.47 to 3.76)		
	SG	7.8 ± 2.1 (6.79 to 8.33)	4.0 ± 3.3 (2.86 to 5.77)	4.5 ± 3.9 (2.65 to 6.47)		
BECK					<0.001	0.871
	EG	11.7 ± 7.6 (8.75 to 14.3)	10.5 ± 5.3 (8.57 to 12.5)	9.1 ± 6.6 (6.63 to 11.8)		
	AG	16.2 ± 8.8 (12.1 to 19.5)	14.1 ± 7.7 (10.9 to 17.4)	12.5 ± 9.3 (8.61 to 16.4)		
	SG	15.3 ± 12.0 (9.93 to 18.5)	12.7 ± 9.7 (9.02 to 17.2)	12.1 ± 9.8 (7.42 to 16.8)		
DASH					<0.001	0.59
	EG	41.3 ± 20.5 (33.8 to 48.0)	34.6 ± 19.0 (26.5 to 41.0)	28.3 ± 19.7 (20.7 a 35.8)		
	AG	40.3 ± 17.7 (33.4 to 46.9)	34.8 ± 14.9 (28.5 to 41.0)	28.3 ± 15.5 (21.9 a 34.8)		
	SG	50.2 ± 28.3 (35.6 to 56.8)	38.8 ± 29.7 (28.2 to 52.6)	36.5 ± 30.0 (22.3 a 50.8)		

EG, Exercise Therapy group; AG, Acupuncture group; SG, Stiper® group; SD, Standard Deviation; CI, Confidence Interval

Table 3. ROM of the Shoulder Ipsilateral to the Surgery, the Meaning of the Groups with 95% Confidence Interval

	Session 1 Mean ± SD (CI 95%)	Session 5 Mean ± SD (CI 95%)	Session 10 Mean ± SD (CI 95%)	p-time effect	p-between groups
Flexion (degrees)				<0.001	0.865
EG	138.9 ± 32.5 (130 to 153)	148.8 ± 16.4 (143 to 156)	152.3 ± 21.3 (144 to 160)		
AG	144.9 ± 24.3 (134 to 153)	150.7 ± 23.8 (141 to 161)	155.0 ± 23.6 (145 to 165)		
SG	126.2 ± 32.5 (118 to 144)	135.6 ± 31.2 (120 to 149)	137.9 ± 31.3 (123 to 153)		
Extension (degrees)				0.002	0.081
EG	62.38 ± 11.0 (58.8 to 66.5)	66.54 ± 10.1 (63.2 to 70.9)	65.00 ± 12.2 (60.3 to 69.7)		
AG	61.86 ± 12.8 (57.5 to 67.2)	67.50 ± 9.48 (63.5 to 71.5)	70.00 ± 8.59 (66.4 to 73.6)		
SG	62.35 ± 12.5 (60 to 69.6)	64.76 ± 11.5 (61.1 to 71)	62.18 ± 12.8 (56.1 to 68.3)		
Adduction (degrees)				<0.001	0.4
EG	35.1 ± 7.23 (32.4 to 37.7)	39.81 ± 7.68 (37 to 42.7)	40.0 ± 6.78 (37.4 to 42.6)		
AG	35.8 ± 11.1 (31.5 to 40)	37.9 ± 12.0 (32.8 to 42.9)	38.2 ± 11.9 (33.2 to 43.2)		
SG	30.6 ± 10.9 (27 to 37.2)	59.8 ± 12.9 (14.5 to 96.6)	36.3 ± 10.0 (31.5 to 41.1)		
Abduction (degrees)				<0.001	0.959
EG	135.5 ± 32.5 (127 to 150)	146.9 ± 33.3 (136 to 161)	153.1 ± 33.3 (140 to 166)		
AG	137.1 ± 39.1 (122 to 151)	150.9 ± 36.7 (136 to 166)	158.6 ± 36.4 (143 to 174)		
SG	116.2 ± 46.4 (107 to 143)	129.2 ± 42.2 (109 to 146)	134.7 ± 46.3 (113 to 157)		
Internal Rotation (degrees)				<0.001	0.82
EG	72.8 ± 15.3 (67.7 to 78.4)	80.2 ± 10.7 (76.5 to 84.6)	81.5 ± 10.6 (77.5 to 85.6)		
AG	75.3 ± 10.2 (71.5 to 79.3)	80.9 ± 9.21 (77.1 to 84.8)	82.9 ± 7.18 (80 to 86)		
SG	70.8 ± 10.8 (70.2 to 79.7)	75.1 ± 11.3 (71.3 to 81.3)	77.3 ± 10.8 (72.2 to 82.4)		

EG, Exercise Therapy group; AG, Acupuncture group; SG, Stiper® group; SD, Standard Deviation; CI, Confidence Interval

between acupuncture and control groups, regarding the depression outcome [28, 29].

In a randomized controlled clinical study that compared the effectiveness of the treatment of depression in a patient with breast cancer who used combined therapy of acupuncture and auricular acupressure versus western medication, it was observed that the combined therapy had a positive effect in the treatment of depression and fewer side effects, as well as high safety. Efficacy was superior to treatment with western medication used alone [30].

UL morbidity after breast cancer surgery is frequent and has an important impact on QOL. Regarding the DASH questionnaire, patients in the three groups improved significantly, comparing the 1st with the 5th session, the 1st with the 10th session, and the 5th with the 10th session. The average of the groups in the 1st session was 43.93, in the 5th session it was 36.06 and in the 10th session, it was 31.03. Cho et al. 2015, in a prospective, randomized, and controlled clinical study with women in the postoperative period of cancer who underwent a physical therapy program, where one group performed exercises (stretching and strengthening) and the other

performed exercises combined with lymphatic drainage, three times per week for four weeks. Positive results were observed in all aspects studied, including UL morbidity assessed by the DASH questionnaire [27].

Another study that corroborates these findings is that of Bruce et al. [35], who conducted a randomized clinical trial with 392 women who underwent surgical treatment of breast cancer. A structured program of exercises was used to improve functionality and QOL and, after evaluation through the DASH questionnaire, it was noted that there was an improvement in the functional capacity of the UL [35].

In our study, there was an improvement in ROM over time at all times and, all evaluated shoulder joint movements in all groups, with no statistical difference between them. The literature corroborates these findings and agrees that kinesiotherapy is a widely recognized technique for the therapy of ROM limitation in women after breast cancer treatment [13, 14, 19, 25-27, 30].

In a 2008 case series, Alem and Gurgel evaluated shoulder ROM gain, lymphedema, and symptoms of heaviness and tightness in the arm in women after breast cancer surgery. They performed 24 acupuncture sessions and noticed a significant increase in shoulder flexion and abduction ROM, a decrease in lymphedema, and a sensation of heaviness and tightness in the UL ipsilateral to the surgery [36]. Similar results were found in our previous project, which compared a group treated with kinesiotherapy and another group with kinesiotherapy and acupuncture. Both groups showed a statistically significant improvement in all aspects studied, being the same as in this study, that is, pain, depression, UL function, and ROM, without superiority between the groups [36].

According to Mazer et al. [37], the improvement with silicon oxide tablets is because this material is in constant contact with the skin and causes permanent stimulation. The silicon oxide contained in the tablets comes into contact with the body's energy and regulates the excess or deficiency to improve local metabolism, accelerate enzymatic reactions, increase capillary permeability, relax smooth and striated muscles, activate blood and lymphatic circulation, reinforce phagocytosis and consequent balance of energy channels [37].

A clinical trial that compared treatments for mechanical chronic low back pain with systemic acupuncture and Stiper®, with 30 volunteers randomly divided into two groups with fifteen people each, where group A was treated with Stiper® and group B with systemic acupuncture. For the initial and final evaluation, the Roland Morris Lumbar Disability Questionnaire and the VAS were used to quantify pain. Both groups obtained satisfactory and equivalent results for the improvement of low back incapacity and the quantification of pain. The authors concluded that the therapies analyzed are equivalent in terms of analgesia and improvement of lumbar function [12].

The use of kinesiotherapy and systemic acupuncture with needles in the rehabilitation of these patients is already well-reported in the literature, but acupuncture through the application of silicon oxide tablets still does not have an appropriate basis, and further randomized clinical studies are needed and controlled to prove its effectiveness since its use seems to have a therapeutic effect similar to that of acupuncture needles when applied to the same meridian points determined by traditional Chinese medicine. In addition, there is the advantage of not offering any risk of infection, as it does not use needles, and has the additional advantage of being able to be used in people with aicmophobia. A negative point of the use of silicon oxide tablets, in our study, was the fact that some women were allergic to the tape. This adversity could be remedied with the use of hypoallergenic adhesives.

Another positive point of this randomized clinical trial is the fact that patients showed significant improvement in the first five sessions, which is an advantage, as it reduces the time needed for effective treatment.

The use of kinesiotherapy, acupuncture, and silicon oxide tablets in the rehabilitation of physical-functional disorders in women who survived breast cancer resulted in a significant improvement in pain, depression, UL function, and ROM, with no statistically significant difference between the groups, which leads us to conclude that acupuncture with the use of needles and silicon oxide tablets, despite not showing superior results when compared to kinesiotherapy, promoted a similar benefit to the standard treatment.

Author Contribution Statement

All authors contributed to the study. Material preparation, data collection, and analysis were performed by Patricia Santolia Giron. The first draft of the manuscript was written by Patricia Santolia Giron, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript. .

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Declarations Ethics approval and consent to participate

The approval of the Research Ethics Committee of the Federal University of São Paulo was approved by the Research Ethics Committee of the Federal University of São Paulo (CEP, version 3, CAAE: 82293618.8.0000.5505, approval number 1.543.582, and registered in the Clinical Trials, with number NCT02798263.

Consensus term in accordance with Resolution 466/2012 of the CEP/CONEP (Research Ethics Committees/National Research Ethics Commission). All participated voluntarily and without remuneration.

Conflict of interest

I declare no conflict of interest.

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