RESEARCH ARTICLE

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Effect of Exercise Therapy, Systemic Acupuncture and Silicon Oxide Tablets on Muscular Strength, Lymphedema, and Quality of Life in Breast Cancer Survivors: Randomized Clinical Trial

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Abstract

Objective: The purpose of this study was to compare the effectiveness of three different rehabilitation treatments (exercise therapy, acupuncture, and silicon oxide tablets (Stiper®) in women who have undergone breast cancer surgery. The study assessed the impact of these treatments on strength, lymphedema, and quality of life. **Methods:** The study included seventy-nine women who reported pain levels above 3 on the visual analog pain scale (VAS) and had undergone surgery more than 90 days prior. Group I received exercise therapy for 30 minutes, Group II received acupuncture for 30 minutes using predefined points, and Group III received acupuncture at the same points as Group II using silicon oxide instead of needles at the same points as Group II. **Results:** The results showed an improvement in upper limb muscle strength over time in all groups, except for abduction and internal rotation movements. During treatment, there was no increase in the number of patients with lymphedema, and there was no statistical difference between the groups. Nine out of the fifteen factors analyzed in the EORTC QLQ-C30 quality of life questionnaire showed significant differences between sessions. The factors that did not show significant differences between the three groups were Social Function, Nausea and Vomiting, Dyspnea, Loss of Appetite, Constipation, and Diarrhea. **Conclusion:** The rehabilitation of physical dysfunctions in women who survived breast cancer through exercise therapy, acupuncture, and silicon oxide tablets in upper limb muscle strength, lymphedema, and quality of life, proved to be effective, without difference between groups.

Keywords: Breast cancer- exercise therapy- rehabilitation- acupuncture- muscle strength- lymphedema- quality of life

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Introduction

Breast cancer is the most prevalent cancer among women, with approximately 2.1 million new cases each year, and is the leading cause of cancer-related-deaths in women worldwide [1]. However, continuous advances in the early detection and treatment of breast cancer have led to a significant reduction in mortality, as a result, the number of survivors who face sequelae of the disease and its therapies has increased [2, 3]. Breast cancer treatment is complex and involves a combination of different therapeutic modalities, such as surgery, radiotherapy, chemotherapy, hormonal and biological therapy [4]. After breast cancer treatment, many women may experience physical and psychological challenges that can affect their quality of life, this may include lymphedema, loss of upper limb (UL) strength, shoulder joint dysfunction, decreased functional capacity, flexibility, and joint mobility. Studies have shown that muscle strength during treatment decreases by 12% to 16% in the upper limb compared to healthy individuals [5-7].

Evaluating the quality of life (QoL) of cancer patients is currently an important criterion for assessing treatment outcomes. According to the World Health Organization (WHO), QOL is defined as "an individual's perception of their position in life, taking into account the cultural and value systems in which they live, and their goals, expectations, standards, and concerns" [8, 9]. In addition to surgery, other factors associated with the risk for the development of lymphedema include tumor stage, radiotherapy, age, scar complications (such as seroma and infection), edema, ipsilateral chemotherapy infusion, and high body mass index (BMI) [10].

Lymphedema is a chronic, progressive disease that is generally incurable. It is characterized by the abnormal accumulation of proteins in the interstitium, which leads to edema and chronic inflammation of an extremity. Upper limb lymphedema may be associated with other symptoms such as pain, feeling of heaviness and tightness in the arm, decreased range of motion (ROM), difficulty in activities

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of daily living (ADL), and affected motor skills, with a negative impact on personal, work, and personal care areas. Studies suggest that one in five women who survive breast cancer will develop lymphedema, thus being an important public health factor [11, 12].

Exercise therapy is well-established in the literature on these complications, recent studies have shown that physical therapy, through exercise protocols that employ stretching, active-free, and resistance exercises, results in the prevention and treatment of physical-functional complications in the postoperative breast cancer and also improve various aspects of quality of life (QOL), such as physical function, functional performance, fatigue, pain, and insomnia [13, 14]. Among the techniques used for rehabilitation, acupuncture is an option for treating these patients. It is considered a safe procedure, minimally invasive, and well tolerated that can reduce the physical and psychological difficulties of women undergoing surgical treatment for breast cancer, improving their QOL [15]. A method that has been used in Europe since the 1990s and has recently been introduced to Brazil is silicon oxide tablets (Stiper®) these tablets are made of micronized silicon oxide quartz and are organized in a hypoallergenic blanket that is 13 mm in diameter and 3 mm thick. It is known that more than 3% of the human organic constitution is formed by silicon, and the silicon oxide tablets could be recognized by the organism and would have the function of coordinating its waves and frequencies [16]. It can be used at the same acupuncture points instead of needles. Thus, to better understand the benefits of acupuncture, it is necessary to conduct a randomized study to compare its therapeutic effects with those of exercise therapy to minimize the complications that may occur in the population of women undergoing surgical treatment of breast cancer. Acupuncture is expected to be superior to standard kinesiotherapy treatment and is an option for patients.

Therefore, the main objective of this study was to compare the effectiveness of rehabilitation in three different treatment groups, namely: kinesiotherapy, acupuncture, and Silicon oxide tablets manufactured by Stiper®, regarding muscle strength, lymphedema, and quality of life of women who underwent surgical treatment for breast cancer.

Materials and Methods

A randomized, non-blind clinical trial was conducted at the Breast Ambulatory Unit of the Department of Gynecology at the Federal University of São Paulo (UNIFESP). Patients were recruited, selected, and informed about the study objectives. Subsequently, the patients who wished to participate in the study protocol signed an informed consent form, based on Resolution 466/2012 of the National Health Council.

During the period from May 2016 to July 2021, women who underwent surgical treatment for breast cancer, either radical or conservative, received post-surgical follow-up in the mastology section 90 days after surgery, provided they were over 18 years old. Patients with bilateral breast surgery, metastatic disease, vascular alterations, and tactile sensitivity, and patients with decompensated type I and II diabetes mellitus, and with a level of education of fewer than four years were excluded.

The patients were randomly assigned to one of three groups using a computer program available at www.randomization.com. The algorithm used by the website to generate the randomization process was Java Math. Random function (Range: From 1 to 79).

Each group received weekly treatment for 10 weeks, Group I was treated with standard, pre-defined kinesiotherapy, based on stretching of the cervical muscles, shoulder girdle, and upper limb ROM exercises lasting 30 minutes; Group II was treated with 30 minutes of acupuncture using predefined points and group III used the same acupuncture points as group II, but using silicon oxide tablets instead of needles. If patients experienced pain at the end of the 10 sessions, they were treated with the protocol of the other group.

The exercise protocol used was identical to that in the Giron et al. [17] study. The Kinesiotherapy exercises were performed under the guidance and presence of the responsible researcher, as follows: stretching the muscles of the neck, shoulders, arms, and trunk; active-free exercises or with the aid of a stick for flexion, extension, adduction, abduction, external and internal rotation of the shoulder; muscle strength exercises with the use of elastic bands and dumbbells, for the movements above added to the muscle training of biceps and triceps. The exercises were performed isotonic, performed slowly, and within the range of motion achieved by the patient. Resistance was adjusted according to each patient´s muscular capacity.

All exercises were performed in an orthostatic position, regardless of the operated side, on both limbs. Each stretch was held for 30 seconds. Active-free and strength exercises were performed in a series of 10 times for each movement and gradually increased so that, according to the patient's capacity, it did not exceed a maximum of three series of 10 repetitions for each movement.

The acupuncture protocol and procedures were followed per the recommendations of the Standards for Reporting of Controlled Trials in Acupuncture (STRICTA) [18] and based on Traditional Chinese Medicine. The needle insertion protocol was preceded by antisepsis of all acupoints with 70% alcohol. Then, sterile and disposable needles (0.25 mm x 30 mm) were inserted into the contralateral limb and at a distance, with the puncture order of top to bottom. The depth of needle insertion was determined according to the application site, patient's age, physical constitution, and intensity of the reaction to the needle.

Silicon oxide tablets manufactured by Stiper® were applied along with acupoint antisepsis and fixation with tape [19].

The treatment involved the use of CV 3, SP 9, ST 36, KI 7, LR 3, GB 21, LI 15, HT 14, 5 LU, LI 4, ST 38, and BL 60 points.

The patients were studied at the beginning of treatment, after 5 weeks, and at the end of 10 weeks. They responded to an evaluation form about their registration and social data, including age, profession, race, and education, among others; additionally, medical records were reviewed

to collect information on breast cancer treatment, such as the type of surgery, radio and/or chemotherapy, breast reconstruction, and clinical data.

The physical examination consisted of measuring muscle strength and upper limb perimetry.

The assessment of muscle strength was performed manually with a handheld Dynamometer (model 01163, Lafayette® Instrument Company), which records the peak force, in kilograms, during five seconds of muscle contraction, with the beginning and end of this contraction occurring through an audible signal. Flexion, extension, adduction, abduction, and internal and external rotation of the shoulder were performed, and two measurements were taken for each movement and considered the average.

Perimetry assessment was performed by measuring upper limb circumference at eight different points on the arm. These points were labeled as follows: point A – 21 cm above the olecranon; point B – 14 cm above and point C – 7 cm above the olecranon. Point D – circumference at the height of the olecranon; point E – 07 cm below this point; F point – 14 cm below and G point – 21 cm below the olecranon. Point H – is the measurement of the hand, involving the entire circumference of the back and palm, at the height of the metacarpals with the base of the 1st finger [20]. The presence of lymphedema was defined as when there is a difference of 2 cm or more in the circumference of one limb concerning the other.

After that, they answered the Quality of Life Questionnaire C30 (QLQ-C30) version 3.0 of the European Organization for Research and Treatment of Cancer (EORTC). It assesses three domains of quality of life: global health, functional, and symptom scale.

The sample size was calculated based on a similar study, where one group was treated with traditional Chinese acupuncture and the other with Sham 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 [21].

Statistical analysis was conducted using the Statistica program (version 13.5). Descriptive analysis was used to characterize the groups (means ± standard deviation). The Shapiro-Wilk test was used to verify the normality of the variables and then, the ANOVA test was used to compare normal distribution data and the Kruskall-Wallis test for non-normally distributed data. Differences between groups for categorical data were assessed using the chi-square test. Factorial repeated measures ANOVA was used for differences over time and between groups during treatment, using the Mauchly sphericity test, Greenhouse-Geisse, and Huynk-Feldt correction, and post hoc Bonferroni.

The study adhered to CONSORT (Consolidated Standards of Reporting Trials) guidelines.

Results

Out of the 79 evaluated patients, 67 completed the treatment, with 26 in the Kinesiotherapy group (G1), 23 in the Acupuncture group (G2), and 18 in the Stiper® group (G3), as shown in Figure 1. Among the reasons for withdrawal, we can mention 02 allergy (in the Stiper® group), 02 the evolution of the disease, 03 return to work, and 05 the pandemic due to the new coronavirus (G1 n=3, G2 n=3, G3 n=6).

Demographic features

The characterization of the sample is described in Table 1 and the groups were homogeneous to with concerning all variables.

The total sample consisted of women with a mean age of 52.8±9.6 years and a mean BMI of 29.29±5.6 kg/m², 45.5% had SAH as comorbidity and 12.6% had DM. Regarding the treatment performed, all women underwent surgical treatment, with 41.7% operated on the right breast (R), 58.2% on the left breast (L), 57% underwent radical surgery and 43% conservative, 67.1% LA, and 32.9% BLS; and 45.5% underwent breast reconstruction.

In terms of tumor types, 75.9% of the cases were invasive carcinoma of a non-special type, 11.4% were ductal carcinoma in situ and 12.7% were other types. Regarding adjuvant treatment, 77.2% received radiotherapy, 72.1% received chemotherapy, and 67.1% received hormone therapy. Regarding the time between surgery and the beginning of treatment, there was an average of 25.6±38.6 months.

Muscle Strenght

Muscle strength was performed with the Lafayette® Instrument Company Hand-Held Dynamometer, the assessment of upper limb muscle strength showed statistically significant differences over time, except for abduction and internal rotation movements. However, no differences were identified between the groups (Table 2).

Lymphedema

The presence of lymphedema was measured by perimetry of the upper limb, lymphedema was present in only one patient in group 1 and two patients in group 3, whereas in group 2 there was none. During the treatment, there was no increase in the number of patients with lymphedema and there was no statistically significant difference between the groups (Table 3).

EORTC-QLQ-C30 quality of life scale

The ANOVA results for the EORTC QLQ C30 quality of life questionnaire, indicate that 9 out of the 15 domains (60%) exhibited statistically significant differences between sessions. The domains that did not show differences between sessions were Social Function, Nausea, and Vomiting, Dyspnea, Loss of Appetite, Constipation, and Diarrhea. However, no statistically significant difference was found among the 3 groups. Although the ANOVA results showed statistically significant differences, the post hoc Bonferroni test only indicated marginally significant differences between sessions for Financial Difficulties (Table 4).

Discussion

The patients included in this study had risk factors associated with the development of breast cancer, such as

Table 1. Sample Characterization

Variable	G1 (n=29) Mean (SD)	G2 (n=26) Mean (SD)	G3 (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/m2)	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 $^{\pi}$

G1, Kinesiotherapy Group; G2, Acupuncture Group; G3, 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

a mean age compatible with a higher incidence of breast cancer, overweight, and associated diseases such as DM and SAH [1, 4, 22]. Mastectomy and LA were performed in most of these patients and it is known that the greater the size of the surgery, the greater the possibility of complications [6, 23].

Upper limb muscle strength is clinically relevant, as it is necessary for daily activities such as self-care, household chores, and return to work. The study found an increase in upper limb muscle strength over time, except for abduction and internal rotation movements, with no difference between the groups. These results are consistent with those found in the literature.

A study that evaluated shoulder muscle strength in patients undergoing surgical treatment for breast cancer found a significant reduction in values about preoperative parameters. There was a gradual increase in strength over the following months, due to the implementation of a physical therapy protocol [24].

A systematic literature review with a meta-analysis of randomized controlled trials involving adult patients who had completed cancer treatment (mostly breast cancer, 65%) evaluated the effect of an exercise program on physical functions, physiological parameters, psychosocial and quality of life compared to sedentary or non-exercise control groups. As a result, there was a statistically significant improvement in muscle strength, fatigue, depression, and quality of life in the exercise groups for patients with breast cancer [25].

Physiotherapy plays an important role in treating complications and should be performed early, to reduce the possibility of complications, in addition to preserving functionality. Kinesiotherapy is a technique widely recognized in the literature, and acupuncture has also been extensively studied [13-15, 26].

To date, there are no studies in the literature involving needle acupuncture and Stiper® as rehabilitation after breast cancer surgery shoulder muscle strength.

Lymphedema was present in only one patient in group 1 and two patients in group 3, while in group 2 there was none. During treatment, there was no increase in the number of patients with lymphedema and there was no statistical difference between the groups. This result is corroborated by Nelson et al. (2016), in a systematic review study, where the authors compiled the results of randomized clinical trials that investigated the effect of resistance exercise in people with or at risk of developing lymphedema to determine whether breast cancer survivors

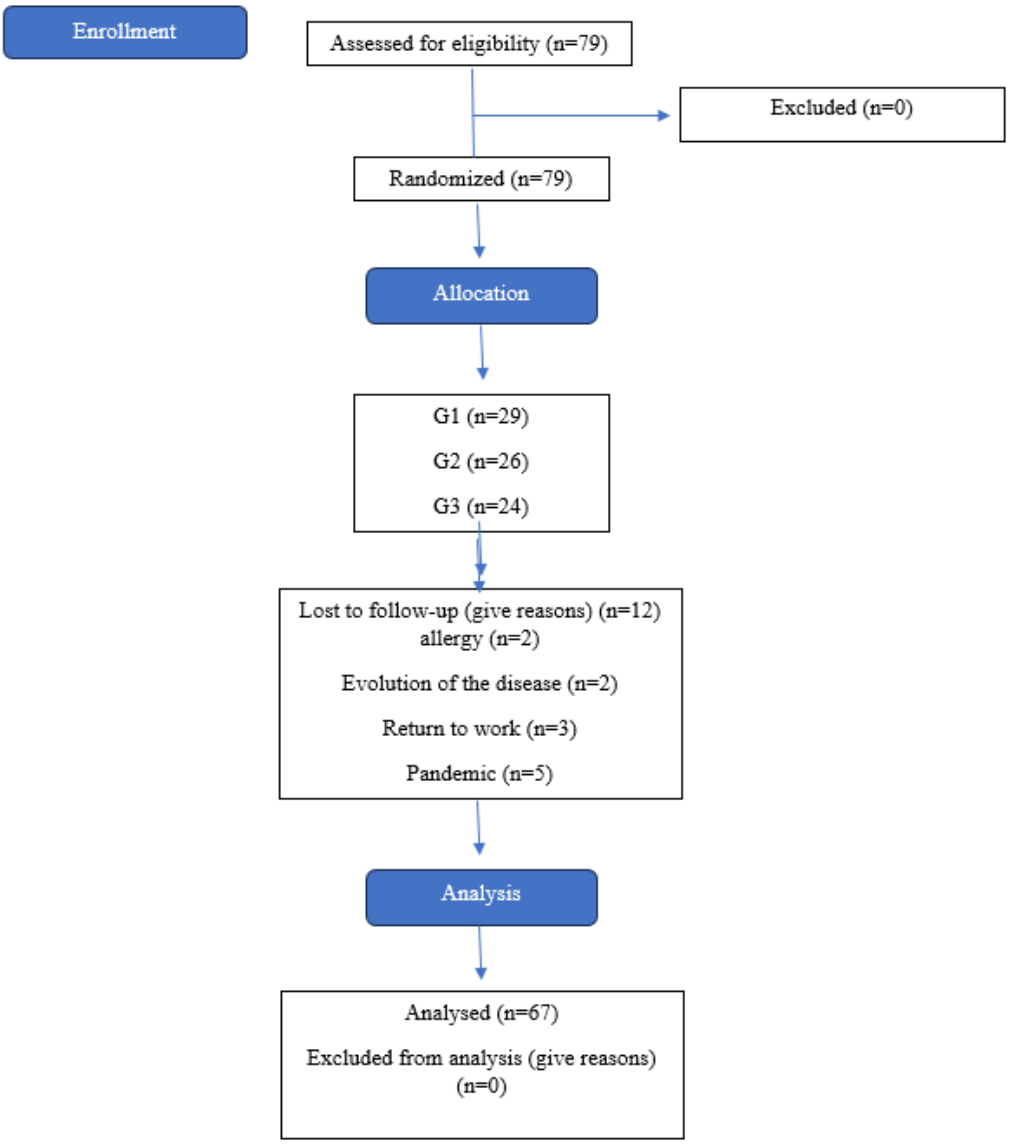

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) workflow. Source: http://www.consort-statement.org/

could perform resistance exercise in intensities sufficient to obtain strength gains without causing worsening or incidence of lymphedema. The results indicated that breast cancer survivors can perform resistance exercises at sufficiently high intensities to obtain strength gains without triggering changes in lymphedema status. There is strong evidence indicating that resistance exercises produce significant gains in muscle strength without causing lymphedema [27]. In the systematic review by McNeely et al. (2010), there was also no significant increase in the risk of developing lymphedema with exercise after surgical treatment of breast cancer [28].

Acupuncture regulates the neuroendocrine and neurophysiological system, having the potential to control lymphedema. In a systematic review with meta-analysis on the effect of acupuncture on breast cancer-related lymphedema, it was concluded that acupuncture is safe and tends to improve symptoms, but trials did not measure outcomes. In this study, acupuncture produced no significant improvement in the extent of lymphedemas compared with the control intervention. None of the studies reported serious adverse events. Acupuncture is safe and tends to improve breast cancer-related lymphedema, but it significantly reduces the circumference of the arm with lymphedema [29].

The randomized clinical trial conducted by Bao et al., in 2018, found no statistically significant difference in arm circumference or impedance between patients with moderate to severe lymphedema who received 12 acupuncture sessions over 6 weeks and the control group. In addition to acupuncture, patients were allowed to simultaneously perform standard treatment for lymphedema, such as drainage, elastic cuff, exercises, pneumatic pump, and bandaging. As these therapies are effective, the authors found it difficult to discern the isolated benefit of acupuncture [30].

Alem et al., 2008 reported in a case series study of 29 women who had lymphedema after breast cancer surgery and underwent acupuncture once a week for 24 weeks. There was a significant improvement in the shoulder range of motion, the sensation of heaviness in the arm, and the degree of lymphedema [31].

Table 2. Muscle Strength of the Upper Limb Ipsilateral to the Surgery, Mean of the Groups with 95% Confidence Interval

	1st Session mean ± SD (95% CI)	5th Session mean ± SD (95% CI)	10th Session mean ± SD (95% CI)	p-time effect	p-between groups
Flexion (Kg)				<0.001	0.42
G1	7.71 ± 3.26 (6.78 a 9.36)	9.31 ± 3.22 (8.08 a 10.5)	9.49 ± 3.59 (8.11 a 10.9)		
G2	7.53 ± 2.54 (6.89 a 9.2)	8.78 ± 3.06 (7.5 a 10.1)	9.37 ± 3.25 (8.02 a 10.7)		
G3	7.72 ± 3.39 (6.82 a 10.2)	8.67 ± 4.68 (6.77 a 11.5)	8.40 ± 4.04 (6.48 a 10.3)		
Extension (Kg)				0.002	0.692
G1	8.35 ± 3.28 (7.38 a 9.7)	9.49 ± 2.51 (8.59 a 10.5)	9.48 ± 2.83 (8.39 a 10.6)		
G2	8.45 ± 2.62 (7.88 a 9.98)	9.14 ± 2.66 (8.03 a 10.3)	9.01 ± 2.85 (7.82 a 10.2)		
G3	8.14 ± 3.85 (6.99 a 10.4)	9.03 ± 4.39 (7.16 a 11.3)	9.58 ± 4.49 (7.45 a 11.7)		
Adduction (Kg)				<0.01	0.931
G1	5.92 ± 2.28 (5.26 a 6.96)	6.53 ± 1.75 (5.83 a 7.14)	6.81 ± 1.91 (6.08 a 7.54)		
G2	6.13 ± 2.35 (5.38 a 7.43)	6.71 ± 2.45 (5.69 a 7.74)	6.81 ± 2.46 (5.79 a 7.84)		
G3	6.00 ± 2.79 (5.28 a 7.59)	6.46 ± 3.00 (5.44 a 8.22)	6.64 ± 2.79 (5.31 a 7.97)		
Abduction (Kg)				0.03	0.918
G1	6.19 ± 2.46 (5.29 a 7.09)	5.96 ± 2.49 (5.66 a 7.13)	6.10 ± 3.13 (5.86 a 7.75)		
G2	6.47 ± 2.31 (5.58 a 7.36)	5.97 ± 3.33 (6.1 a 8.01)	5.84 ± 3.30 (5.94 a 7.87)		
G3	5.93 ± 2.33 (5.14 a 7.45)	5.24 ± 3.72 (5.22 a 8.31)	5.39 ± 4.27 (5.76 a 8.82)		
Internal Rotation (Kg)				0.24	0.7
G1	5.79 ± 2.57 (4.85 a 6.72)	5.62 ± 2.49 (5.28 a 6.8)	5.79 ± 3.03 (5.54 a 7.39)		
G2	6.02 ± 2.44 (5.06 a 6.94)	5.36 ± 3.15 (5.38 a 7.3)	5.51 ± 3.29 (5.48 a 7.54)		
G3	5.44 ± 2.67 (4.51 a 7.3)	4.89 ± 3.69 (4.74 a 8.19)	4.49 ± 3.86 (4.55 a 7.6)		
External Rotation (Kg)				0.001	0.763
G1	5.79 ± 2.79 (4.93 a 6.99)	6.46 ± 2.42 (5.6 a 7.39)	6.75 ± 2.62 (5.75 a 7.76)		
G2	6.06 ± 2.29 (5.39 a 7.18)	6.69 ± 2.40 (5.68 a 7.69)	6.51 ± 2.36 (5.52 a 7.5)		
G3	5.09 ± 2.42 (4.44 a 7.05)	5.82 ± 3.15 (4.39 a 7.58)	6.20 ± 3.14 (4.7 a 7.7)		

G1, Kinesiotherapy; G2, Acupuncture; G3, Stiper®; SD, Standard Deviation; CI, Confidence Interval

No studies were found in the literature relating lymphedema and acupuncture through silicon oxide tablets as rehabilitation after breast cancer surgery.

The results of the EORTC QLQ-C30 quality of life questionnaire showed significant differences between sessions in 9 out of the 15 domains (60%). The domains that did not show any significant differences between the sessions were Social Function, Nausea, and Vomiting, Dyspnea, Loss of Appetite, Constipation, and Diarrhea, these results are consistent with those reported in the literature.

Exercise has the potential to improve the physical and psychological functioning of women who have survived breast cancer. In a randomized clinical trial conducted by Aydin et al., 2021, 24 women received an exercise program, and another 24 women were assigned to the control group. The exercise group engaged in aerobic and resistance activities for 12 weeks, while the control group was encouraged to maintain their normal level of physical activity and exercise habits throughout the study. The EORTC QLQ-C30 score indicated a positive impact on quality of life in the functional and symptom scales for the exercise group. However, there were no significant differences observed in Cognitive Performance, Nausea, Vomiting, Dyspnea, Loss of Appetite, Constipation, and Diarrhea [32].

The review with the meta-analysis by Zeng et al. (2014) investigated exercise intervention in women after breast cancer treatment about QOL and concluded that exercise has statistically significant effects on the overall quality of life as well as positive trends for site-specific quality of life domains cancer (breast and upper limb

Table 3. Lymphedema

Lymphedema	G1 (n=29) n (%)	G2 (n=26) n (%)	G3 (n=24) n (%)	p-value (between groups)
1st session	1 (3.4)	0 (0)	2 (8.3)	0.3
5st session	1 (3.4)	0 (0)	2 (8.3)	0.2
10st session	1 (3.4)	0 (0)	2 (8.3)	0.2

G1, Kinesiotherapy Group; G2, Acupuncture Group; G3, Stiper® Group

Table 4. EORTC QLQ-C30 Quality of Life Questionnaire, Group mean with 95% Confidence Interval.

	1st session mean ± SD (95% CI)	5st session mean ± SD (95% CI)	10st session mean ± SD (95% CI)	p-time effect	p-between groups
Global Health				0.027	0.475
G1	66.9 ± 24.4 (57.7 a 75)	73.4 ± 18.5 (66.5 a 80.4)	69.1 ± 25.3 (63.5 a 80.1)		
G2	61.7 ± 24.8 (52.3 a 70.7)	73.1 ± 14.1 (67.2 a 79)	73.8 ± 18.2 (66.2 a 81.5)		
G3	54.6 ± 27.4 (46.4 a 66.8)	57.5 ± 28.7 (44.9 a 70.1)	57.5 ± 38.2 (52.6 a 82.7)		
Physical functioning				0.002	0.903
G1	32.0 ± 21.1 (25.1 a 40.2)	30.5 ± 16.0 (24.1 a 36.1)	25.6 ± 19.3 (18.2 a 33.1)		
G2	33.6 ± 19.2 (28.2 a 44.6	30.6 ± 19.0 (22.6 a 38.6)	27.6 ± 15.7 (21 a 34.1)		
G3	44.3 ± 24.1 (29.4 a 49)	39.2 ± 26.1 (26.8 a 49.2)	34.1 ± 26.6 (21.4 a 46.8)		
Role functioning				0.003	0.848
G1	35.2 ± 33.7 (23.9 a 47.4)	30.7 ± 35.8 (16.2 a 43.1)	24.9 ± 35.0 (11.5 a 38.5)		
G2	40.1 ± 38.0 (27.9 a 56.7)	31.8 ± 26.7 (20.7 a 43)	28.0 ± 30.6 (15.2 a 40.8)		
G3	51.9 ± 41.2 (29.1 a 61.2)	39.2 ± 44.5 (21.4 a 58.6)	34.3 ± 41.4 (14.6 a 54)		
Emotional functioning				0.006	0.751
G1	34.6 ± 31.2 (25.3 a 48.3)	32.7 ± 29.6 (21.1 a 43.1)	26.9 ± 26.7 (16.7 a 37.2)		
G2	44.7 ± 33.5 (33.3 a 59)	36.4 ± 29.8 (23.9 a 48.8)	35.6 ± 30.6 (22.8 a 48.4)		
G3	52.9 ± 35.5 (38.5 a 64.3)	41.2 ± 40.8 (26.5 a 60.2)	38.2 ± 39.8 (19.3 a 57.2)		
Cognitive functioning				0.006	0.751
G1	34.6 ± 31.2 (25.3 a 48.3)	32.7 ± 29.6 (21.1 a 43.1)	26.9 ± 26.7 (16.7 a 37.2)		
G2	44.7 ± 33.5 (33.3 a 59)	36.4 ± 29.8 (23.9 a 48.8)	35.6 ± 30.6 (22.8 a 48.4)		
G3	52.9 ± 35.5 (38.5 a 64.3)	41.2 ± 40.8 (26.5 a 60.2)	38.2 ± 39.8 (19.3 a 57.2)		
Social functioning				0.092	0.435
G1	14.7 ± 21.2 (6.81 a 21.9)	12.2 ± 17.4 (5.25 a 18.2)	9.6 ± 22.7 (0.892 a 18.3)		
G2	18.2 ± 33.7 (7.31 a 32.4)	9.1 ± 19.0 (1.13 a 17.1)	13.6 ± 26.0 (2.75 a 24.5)		
G3	25.5 ± 31.2 (11.8 a 35.4)	24.5 ± 33.9 (9.47 a 38.9)	13.7 ± 27.1 (0.817 a 26.6)		
Fatigue				<0.001	0.933
G1	41.9 ± 25.0 (34 52.6)	33.3 ± 23.1 (24.8 a 41.9)	25.2 ± 26.2 (15.1 a 35.3)		
G2	48.5 ± 33.5 (36.4 a 61.9)	41.4 ± 28.3 (29.6 a 53.2)	32.3 ± 27.6 (20.8 a 43.9)		
G3	50.3 ± 37.1 (37.1 a 65.7)	37.9 ± 36.2 (25.9 a 58.5)	34.6 ± 33.3 (18.8 a 50.5)		
Nausea and Vomiting				0.553	0.716
G1	12.8 ± 20.2 (6.08 a 20.4)	13.5 ± 19.4 (6.38 a 20.8)	8.9 ± 15.8 (2.9 a 15)		
G2	9.8 ± 17.6 (3.04 a 16.2)	7.6 ± 15.2 (1.23 a 13.9)	7.6 ± 15.2 (1.23 a 13.9)		
G3	15.7 ± 18.1 (6.62 a 21.2)	14.7 ± 27,6 (2.07 a 24.6)	15.7 ± 27.3 (2.71 a 28.7)		
Pain				<0.001	0.628
G1	58.9 ± 32.7 (31.8 a 93.2)	38.5 ± 29.3 (25.8 a 48.2)	32.7 ± 32.1 (20.3 a 45)		
G2	65.9 ± 26.9 (62.8 a 91)	45.4 ± 33.0 (31.7 a 59.2)	31.8 ± 32.5 (18.2 a 45.4)		
G3	696 ± 32.4 (74.5 a 103)	53.9 ± 40.6 (38.9 a 72.8)	49.9 ± 39.1 (31.4 a 68.6)		
Dyspnea				0.25	0.415
G1	20.5 ± 29.9 (10-33.7)	15.4 ± 23.5 (6.04 a 23.6)	11.5 ± 24.8 (1.99 a 21.1)		
G2	22.7 ± 33.1 (11.9 a 39.3)	18.2 ± 32.0 (4.77 a 31.6)	16.7 ± 26.7 (5.5 a 27.8)		
G3	33.3 ± 40.8 (11.2 a 41.6)	25.7 ± 39.9 (8.21 a 42.1)	37.2 ± 38.9 (18.8 a 55.7)		
Insomnia				0.001	0.809
G1	58.9 ± 38.0 (41.3 a 69)	43.6 ± 42.9 (28.5 a 60.4)	37.2 ± 41.4 (21.2 a 53.1)		
G2	54.5 ± 39.2) (42.1 a 73.3)	53.0 ± 43.2 (35 a 71.1)	36.4 ± 45.9 (17.2 a 55.5)		
G3	62.7 ± 43.9 (38.1 a 73)	49.0 ± 44.3 (29.1 a 67.6)	35.3 ± 46.3 (13.3 a 57.3)		
Appetite loss				0.143	0.278
G1	11.5 ± 26.6 (1.11 a 19.6)	17.9 ± 32.9 (6.27 a 30.8)	11.5 ± 28.2 (0.701 a 22.4)		
G2	24.2 ± 37.3 (13.4 a 43)	22.7 ± 40.3 (5.87 a 39.6)	9.09 ± 18.3 (1.42 a 16.8)		
G3	11.8 ± 20.2 (3.87 a 21.1)	11.8 ± 23.4 (1.87 a 21.5)	11.8 ± 23.4 (0.643 a 22.9)		

G1, Kinesiotherapy Group; G2, Acupuncture Group; G3, Stiper® Group

Table 4. Continued

	1st session mean ± SD (95% CI)	5st session mean ± SD (95% CI)	10st session mean ± SD (95% CI)	p-time effect	p-between groups
Constipation				0.226	0.511
G1	19.2 ± 34.2 (9.17 a 34.5)	21.8 ± 35.2 (7.87 a 34.1)	15.4 ± 31.6 (3.24 a 27.5)		
G2	18.2 ± 35.2 (2.71 a 28.1)	15.1 ± 28.6 (3.2 a 27.1)	18.2 ± 35.2 (3.46 a 32.9)		
G3	29.4 ± 43.9 (12.3 a 46)	29.4 ± 42.3 (14.4 a 52.3)	19.6 ± 39.2 (0.978 a 38.2)		
Diarrhea				0.555	0.543
G1	7.69 ± 23.7 (0.0385 a 20.7)	5.13 ± 18.1 (-1.77 a 11.6)	3.84 ± 14.4 (-1.68 a 9.37)		
G2	7.58 ± 22.8 (0.701 a 22.4)	1.51 ± 7.10 (-1.45 a 4.48)	3.03 ± 9.81 (-1.07 a 7.13)		
G3	3.92 ± 11.1 (-0.339 a 8.67)	5.88 ± 24.2 (-4.8 a 14.8)	7.84 ± 25.1 (-4.08 a 19.8)		
Financial difficulty				0.039	0.4
G1	33.3 ± 35.3 (20.8 a 45.9)	34.6 ± 34.6 (22.8 a 48.8)	32.0 ± 33.3 (19.2 a 44.9)		
G2	34.8 ± 37.8 (21.7 a 52.7)	15.1 ± 22.4 (5.8 a 24.5)	30.3 ± 27.0 (19 a 41.6)		
G3	52.9 ± 47.2 (31.6 a 68.4)	45.1 ± 42.4 (24.3 a 62.3)	39.2 ± 42.8 (18.8 a 59.6)		

G1, Kinesiotherapy Group; G2, Acupuncture Group; G3, Stiper® Group

symptoms) [33].

Zhang et al., 2021, in a systematic review of the effects of acupuncture in women with breast cancer on QOL measured using the QLQ-C30, Functional Assessment of Cancer Therapy-Endocrine Symptoms (FACT-ES), Functional Assessment of Cancer Therapy-General/ Breast (FACT-G/B) and Menopause-Specific Quality of Life Questionnaire (MENQOL) noted significant improvement. Current evidence suggests that acupuncture may improve QOL and symptoms related to breast cancer treatment, such as pain, fatigue, hot flashes, sleep disturbances, and anxiety [34].

In the study by Frisk et al., 2012, they evaluated the effects of electroacupuncture, and hormone therapy applied for 12 weeks on health-related quality of life and sleep in breast cancer survivors with vasomotor symptoms. Both electroacupuncture and hormone therapy increased QoL and sleep [35].

According to a systematic review by Chan et al., 2021 aimed to investigate the potential benefits and safety of acupuncture in the management of drug therapy-induced side effects in breast cancer patients using a systematic review and standard PRISMA meta-analysis. It was concluded that acupuncture has a beneficial adjuvant role in breast cancer patients receiving drug therapies. No serious adverse events were observed in all randomized controlled trials and the safety of acupuncture was demonstrated [36].

So far in the literature, there are no reports on the use of silicon oxide tablets to improve the quality of life in women treated for breast cancer.

The treatment of physical-functional dysfunctions in women who survived breast cancer through kinesiotherapy, acupuncture, and silicon oxide tablets seems to be equivalent, superiority tests were negative. While kinesiotherapy and acupuncture are well-founded in the literature, randomized and controlled clinical studies are needed to prove the effectiveness of acupuncture treatment using silicon oxide tablets, since it is an interesting resource, as there is the advantage of not offering risk of infection by not using needles, in addition to being used in people with aichmophobia. However, it has the disadvantage that some women are allergic to tape, which could be minimized with the use of hypoallergenic patches.

Additionally, the randomized clinical trial demonstrated that patients experienced significant improvement within the first five sessions. This is advantageous as it reduces the time required for effective treatment.

Therefore, we conclude that rehabilitation of women who have survived breast cancer through kinesiotherapy, acupuncture, and silicon oxide tablets on upper limb muscle strength, lymphedema, and quality of life, proved to be effective, with no statistically significant difference between the groups, which leads us to conclude that acupuncture did not present superior results when compared with kinesiotherapy.

Limitations of the study: Some women have reported experiencing an allergy to adhesive tape when using the Stiper®, this issue could be remedied with the use of hypoallergenic patches.

It was not possible to blind the evaluator.

Author Contribution Statement

Author contribution: 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 by 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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