

## EFFECTS OF CRYOLIPOLYSIS WITH ADIPOSITY PLATES LOCATED WITH THE CRIOPPLACE™ CONCEPT IN WOMEN

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### Abstract

**BACKGROUND:** Cryolipolysis with plates is a method of applying cooling without a vacuum system, which can be used in regions with less chance of forming a "crease." **OBJECTIVE:** To investigate the effects of cryolipolysis using a plate-shaped applicator (Crioplace™) in the treatment of fat. **MATERIALS AND METHODS:** This is an experimental study in which women aged 25 to 45 years with adiposity located in the abdomen participated. Two applications of 75 min were made, using 04 plates in the abdomen regions, with -4°C being programmed as a temperature parameter. Anthropometric and ultrasound assessments were performed, and a satisfaction questionnaire on the validated treatment was conducted. The reassessments were performed 30 and 60 days after the first intervention. **RESULTS:** A reduction in adiposity was observed in the measurements of perimetry, plicometry and abdominal ultrasound ( $p < 0.05$ ). It was found that about 62.5% of the volunteers reported an improvement in water retention, about 62.5% reported the presence of loose clothing, and 31.3% reported satisfaction with the results obtained. It was observed that 18.5% of the volunteers reported that the treatment was excellent. **CONCLUSION:** The Crioplace™ method proved to be effective in reducing adiposity, with a high clinical satisfaction with the reduction in body measurements.

**Keywords:** adipose tissue; cryotherapy; ultrasound.

### INTRODUCTION

Cryolipolysis is a non-invasive method, characterized by the localized cooling of adipose tissue to around -5 to 15°C inducing a local inflammatory response, which triggers a mechanism of adipocyte apoptosis. It has been observed that macrophages began to digest apoptotic adipocytes; then, with the reduction of the inflammatory infiltrate, there was a reduction in the size and number of adipocytes, culminating in the process of reducing localized adiposity (1).

Cooling induces an increase in cellular metabolism, so it uses the energy reserves stored in adipocytes, generating a lipolysis mechanism with hormonal and biochemical adaptations that result in the reduction of adipose tissue reserves (2). Conventional cryolipolysis uses applicators that are connected to the skin through suction with negative pressure, which cool the dermis and hypodermis. Some devices differ in terms of handling, application technique, and type of applicator (3). Equipment without the suction system has been used in clinical practice, providing cryotherapy without suction, thus

avoiding possible complications caused by negative pressure. This type of equipment is indicated for application in areas of difficult coupling, areas that are not “nailable,” such as outer thighs saddlebags, and upper abdomen, with concentration of fibrotic tissue (4, 5, 6). However, we have not found studies with important results on the application in the abdominal region for the treatment of localized adiposity in women, thus generating the need for this investigation.

The disadvantage of the use of plate cryolipolysis is the need to apply it for longer times, when compared to traditional applicators (8, 9). It was possible to verify through ultrasound and photographs that, in a sample of 40 patients, there was a reduction in adiposity in the flanks region with an application time of 1 h and 20 min at  $-5^{\circ}\text{C}$  (5).

Based on these elements, this study sought to investigate the effects of the plate cryolipolysis technique, using the specific equipment model called Criolipolace™, in the treatment of adiposity located in the abdomen and flanks of women.

## MATERIALS AND METHODS

This is an experimental, prospective, randomized trial, following the recommendations of the Consolidated Standards of Reporting Trials - CONSORT. The study was submitted to the ethics and research committee of Potiguar University, UnP, Natal/RN, having been approved under opinion number 3,548,979. Participants were instructed on the procedures that would be performed and signed the Free and Informed Consent Form, in accordance with resolution 466/12 of the National Health Council, and in line with the Declaration of Helsinki.

The population of this study was composed of 32 women, aged 25 to 45 years, who had adiposity located in the abdominal, infraumbilical, and flank regions. The volunteers met the following inclusion criteria: having a body mass index (BMI) between  $18.5\text{ kg/m}^2$  and  $29.99\text{ kg/m}^2$  (normal to overweight), with adiposity located in the infraumbilical region and with flanks larger than 1 cm and smaller than 4 cm, who were not using anti-inflammatory drugs up to 1 week before the start of the study. Volunteers who did not perform the proposed evaluations, missed consecutive

treatment sessions, increased excess weight during the research, or had a severe skin reaction and decreased sensitivity were excluded.

### *Instruments*

The cryolipolysis equipment used was the Criolipolace™, manufactured by Medical San™. We also used: applicators without vacuum, measuring (width x length) 10 x 15 cm and 7.5 x 10 cm, respectively; antifreeze membrane, weighing 400 g and measuring 40 x 30 cm (All Care brand, manufactured by RMC); fat analyzer: MSLPU35 Linear Wireless Probe Ultrasound Scanner (10Mhz) ultrasound device, manufactured by Guangzhou Medsinglong Medical Equipment Co™; thermographic camera, model C2, manufactured by Flir™; and Camera, model SX530 HS, manufactured by Canon™.

### *Experimental protocol*

The 32 volunteers received two treatment sessions with cryolipolysis in the infraumbilical region and flanks, with an interval of 30 days between sessions. The infraumbilical region was treated with two applicators measuring 10 x 15 cm; and the upper abdomen region was treated with two applicators of 7.5 x 10 cm. The applicators were positioned next to each other, covering the target region. The two applications lasted 75 min, using the equipment's adjusted temperature parameter of  $-4^{\circ}\text{C}$ .

During the exam, the volunteers were evaluated three times: before the interventions, 30 days after the first session, and at the end of the treatment 60 days after the first session. Perimetry, plicometry and body weight measurements, photographs, thermography, and ultrasound analyses were used.

The perimetry was performed with the volunteers in an orthostatic position with the measuring tape positioned on two levels on the abdominal region: 4 cm above the umbilical scar, and 4 cm below the umbilical scar. Plicometry was performed in an orthostatic position with the manual fold, and the “clamp” was performed on the left and right lateral regions of the umbilical scar, 4 cm below. The photos were taken standing, and four images were taken: front, left profile, right profile, and back. A neutral colour background was used to obtain standardized images. The measurement of body weight was performed with the volunteer standing on the scale, wearing a bathing suit.

Immediately after removing the applicators and the antifreeze membrane, the skin temperature was evaluated using a thermographic camera to identify the thermal profile of the treated areas, associated to the possible performance of the plate cryolipolysis equipment.

Ultrasonography was performed in the infraumbilical region, with a 10 x 10 cm mold placed in the center of the infraumbilical region on both sides, following three marking points with distances of 5 cm between them in the direction of the white line. The measurement region was marked with the volunteer standing, and the ultrasound examination was performed in the supine position, with the applicator not applying any pressure against the skin.

After 1 week of the second treatment, the volunteers were reevaluated using the same methodology that was used pre-treatment. In addition to the local physical reassessment, they answered a questionnaire reporting the occurrence of possible adverse and/or deleterious effects during and after treatment, and also their satisfaction with the results. The questionnaires were based on Narins (7) Global Aesthetic Improvement Scale (GAIS), and the satisfaction questionnaire was adapted from Segot-Chicq and collaborators (8). Based on these questionnaires, a questionnaire was created for comparative assessment of the appearance of the skin before and after the use of Criolplace™.

To better define the parameters to be used in the study, a pilot study was carried out to verify the performance of the equipment with regards to the cooling provided by the plates, as

well as on the treated skin. In this study, we used the same plate cryolipolysis equipment, Criolplace™ concept, from Medical San™. Then, the temperature was checked at 5-min intervals, for a period of 75 min, using an infrared thermometer and the thermographic camera. It was found that the average temperature on the cooling plate was -4°C, and the temperature on the subject's skin, after removing the applicator, was 1°C.

#### Data analysis

The data descriptive and inferential statistics were performed using the SPSS 22.0 program (Statistical Package for the Social Science - version 22.0). The normality of the data was observed by the Kolmogorov-Smirnov (KS) test. The two-way ANOVA test was performed, with Tukey's post hoc, to compare the measurements obtained in all evaluations (before, after 30 and 60 days). A significance level of 95% (with  $p < 0.05$ ) was adopted.

## RESULTS

According to the study protocol, after 2 months of intervention, with two applications with an interval of 30 days between them, it was observed that eight volunteers abandoned the research, with 24 volunteers remaining until the end.

**Table 1.** Comparison between the anthropometric and ultrasound variables at different times of the study.

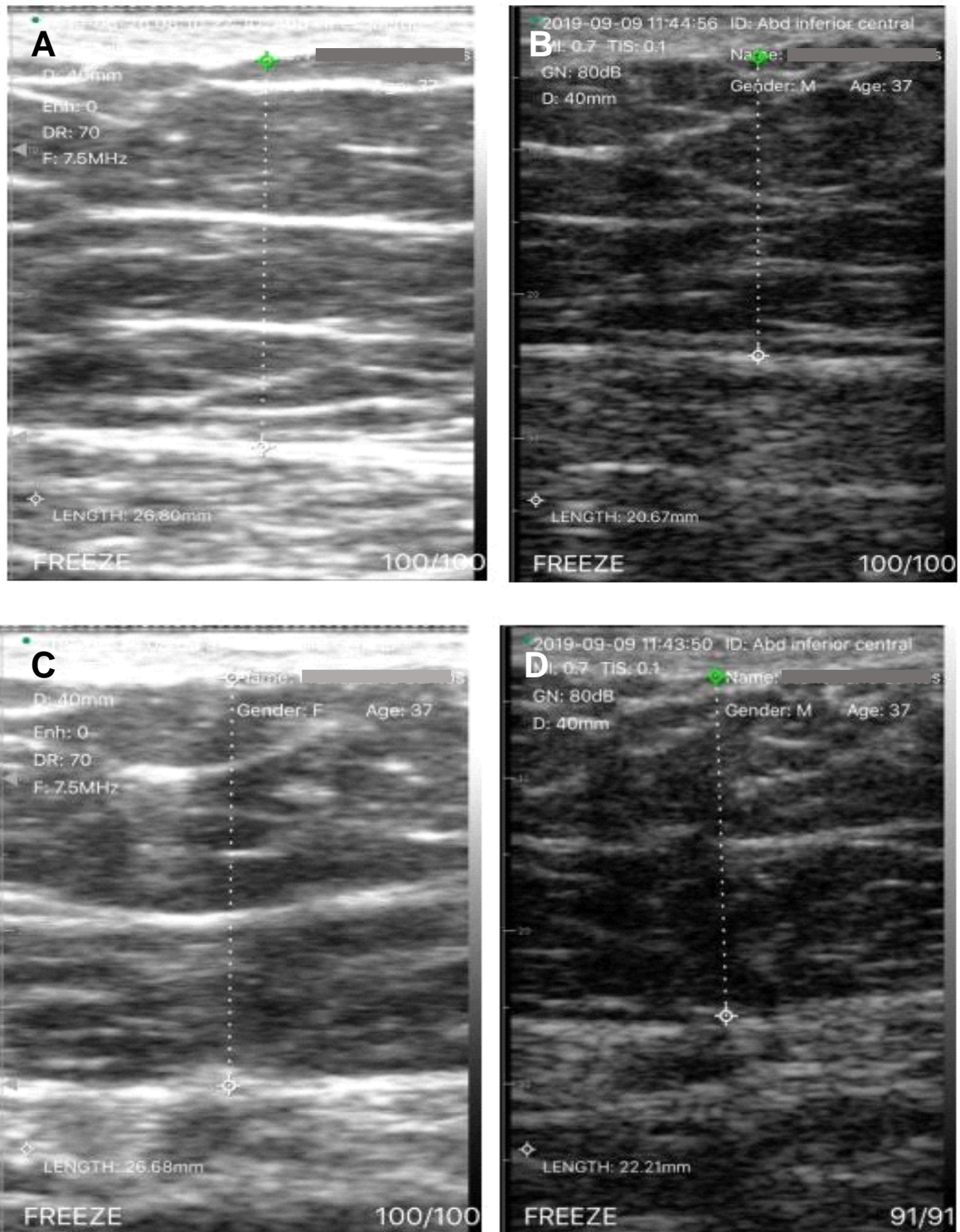
Parameter measured	Initial	30 days	60 days	p value
Weight (kg)	66.8±9.8	66.9±10.6	66.8±9.2	0.87
Supra and infra abdominal perimetry (cm)	84.4±9.6	83.3±9.1	80.3±9.4	0.001*
Right abdominal plicometry (cm)	3.87±0.11	3.278±0.28	3.09±0.9	0.001*
Left abdominal plicometry (cm)	3.45±12.28	3.27±9.67	3.14±7.2	0.04*
Left flank plicometry (cm)	26.63±8.15	26.83±6.59	21.22±6.2	0.02*
Right ultrasonography (cm)	2.5±0.8	1.9±0.8	1.9±0.6	0.02*
Left ultrasonography (cm)	1.75±0.6	1.65±0.9	1.35±0.7	0.001*

\* There was a statistically significant difference

Table 1 presents the results of the comparative analysis of the anthropometric and ultrasound variables for the different moments. It was observed that there was a significant reduction in plicometry, perimetry and

ultrasound measurements after 60 days. Figure 1 shows the ultrasound images of the abdomen, right and left flanks, to show changes at the initial moment and after 60 days.

Figure 2 shows clinical photographs of two



**Figure 1.** A: Ultrasonography of the lower left abdomen (initial), 26.60 mm. B: Ultrasonography of the lower left abdomen (60 days after treatment), 20.67 mm. C: Ultrasonography of the lower right abdomen (initial), 26.68 mm. D: Ultrasonography of the lower right abdomen (60 days after treatment), 22.21 mm.

volunteers, before and after the interventions proposed in the study.

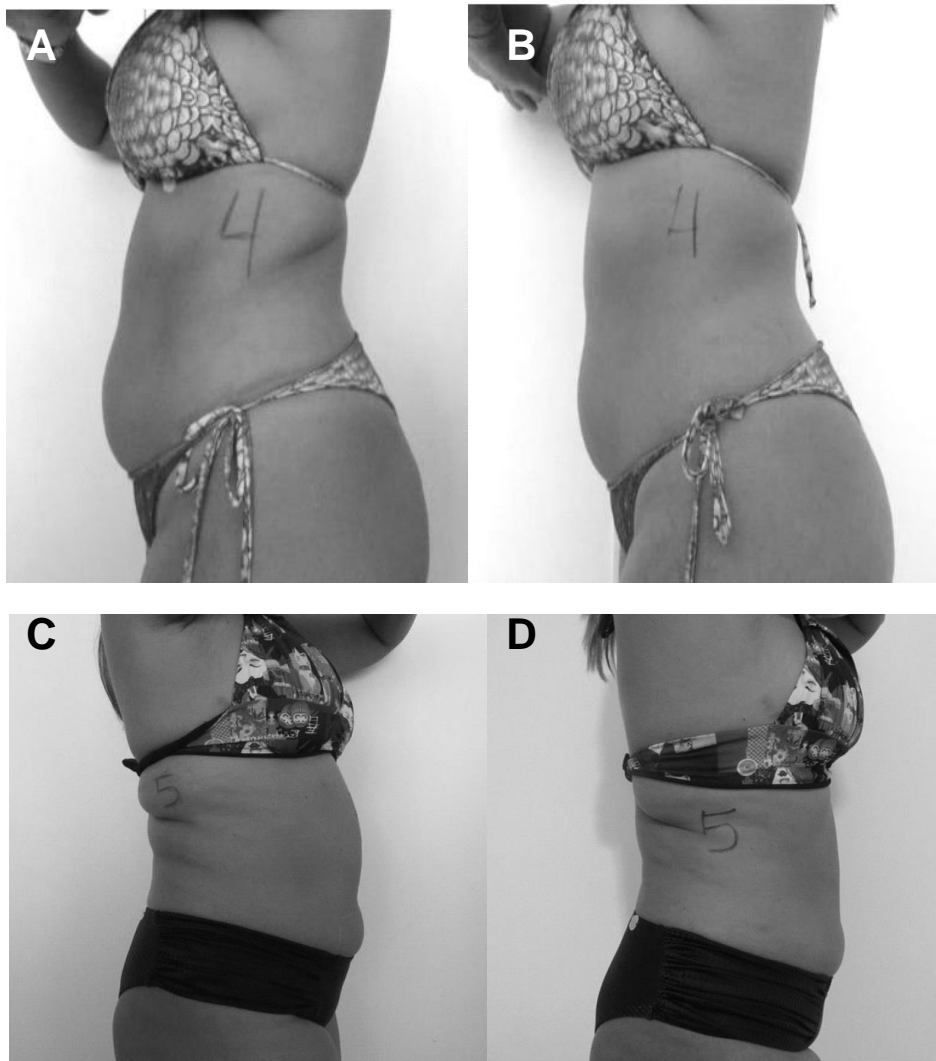
Table 2 presents the results of the Global Aesthetic Improvement Scale (GAIS) (7) questionnaires, and satisfaction questionnaire adapted from Segot-Chicq and collaborators (8).

We verified that about 62.5% of the volunteers reported improvement in water retention, about 62.5% reported the presence of loose clothing, and 31.3% reported satisfaction with the results obtained. It was observed that 18.5% of the volunteers reported that the treatment was excellent, 43.8% reported that it was very good, and 62.5% felt an improvement in the overall aesthetics.

## DISCUSSION

In conventional cryolipolysis, adiposity is retained inside the applicator by the negative pressure of the intense suction that is applied to the area (9, 10, 11, 12). However, in the Crioplace™ method, the applicator does not have a suction system, promoting cooling by surface plates, through a cooling system similar to cryolipolysis. Nevertheless, we observed that there are few studies that can present results of this system without suction with negative pressure.

Significant positive results were observed using the method without negative pressure suction, using Crioplace™. We observed that there was no significant change in body weight, but plicometry measures showed an important reduction in skinfold after 60 days, when



**Figure 2:** A: Left profile (Initial). B: Left profile (60 days). C: Flanks (Initial). D: Flanks (60 days).

**Table 2.** Responses to the questionnaires to verify the aesthetic and global improvement, and clinical satisfaction with the aesthetic interventions.

Response description	Answers	Response (%)
Improved fluid retention	Yes	62.5
	No	37.5
Light shocks during applications	No	91.7
	Yes	8.3
Presence of loose clothing	Did not notice	37.5
	In the first week	18.8
	After the 2 <sup>nd</sup> week	31.3
	After the 4 <sup>th</sup> week	12.5
Satisfaction with the results obtained	I consider my skin much firmer	31.3
Treatment assessment	Excellent treatment	18.5
	Very good treatment	43.8
	Weak treatment	37.7
Overall aesthetic improvement scale	A lot better	6.3
	Much better	25.0
	Better	31.2
	Unchanged	31.2
	Worse	6.3%

compared to the initial moment. We also observed an effective decrease in adipose tissue in the flank region through analysis of the ultrasound, with this reduction occurring in both after 30 and 60 days.

Kennedy et al. (13) carried out a review with more than 27 studies, with about 3000 patients undergoing cryolipolysis, and observed that the greatest effectiveness in reducing adipose tissue occurred in the flank region after 60 days, which our findings corroborate. Other studies have demonstrated the effects of cryolipolysis, with or without a suction system, in reducing localized adiposity, indicating that the cooling provided promotes a physiological response in the target tissue, which can be observed by different evaluation methods such as perimetry, plicometry, histological analysis, and volunteers' satisfaction levels (3, 14, 15, 16).

Additionally, the treatment time of two months, with applications every 30 days, was effective in reducing measurements. This supports the study by Friedmann et al. (17), who used applicators without vacuum in the infraumbilical region, and after analyzing the ultrasound images, also found a more significant measurement reduction after two applications.

Another finding of this study that corroborates those of other studies (3, 9, 18) is the reduction of fat thickness in the treated area, without a concomitant weight reduction. These results can be justified by the cellular apoptosis that occurs through the cooling of the adipose tissue, promoting the modification of tissue organization, in addition to being an indication of localized adiposity treatment, without influencing the measurement of body weight (16, 19, 20).

We observed that about 62.5% of the volunteers reported improvement in water retention and the presence of loose clothing, coinciding with the findings verified in several studies with conventional cryolipolysis, obtaining similar responses (16, 18, 19, 20). These results are also related to the level of satisfaction with the treatment, because better results will generate higher levels of satisfaction; this was also observed in other studies with patients undergoing treatment with conventional cryolipolysis or with different models of applicators without vacuum (5, 12, 16, 18, 19).

When conducting this research, we verified an average temperature of  $-4^{\circ}\text{C}$  on the cooling plate and  $1^{\circ}\text{C}$  on the patient's skin, which is not fully in line with some studies (14, 17, 19) that reported that the use of cryolipolysis equipment

with plates reached temperatures ranging from -5°C to -13°C; that is, with more intense cooling. Even under less intense cooling, Crioplace™ reduced adiposity as seen in plicometry and ultrasound analyses, demonstrating that the lipolysis induction mechanism was activated, using the same equipment, and with a similar methodology, performed in the treatment of men (20). We also observed a high level of satisfaction with the treatment performed, which was considered excellent by the treated individuals, showing that the Crioplace™ system was effective in reducing localized adiposity.

This study was subject to limitations such as the absence of a control group or placebo, which would favour a better interpretation of the results, and the absence of an immunohistochemical analysis of the adipose tissue to identify specific physiological aspects linked to the adipocyte damage after cooling by plate cryolipolysis.

In conclusion, the Crioplace™ method was effective in promoting the reduction of localized adiposity, with satisfactory results in the abdomen and flanks of the treated women. Further studies are suggested to clarify the action mechanism of plate cryolipolysis, and also for better definition of the temperature necessary to guarantee good therapeutic results.

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