

## CAVITATION AND RADIOFREQUENCY VERSUS CRYOLIPOLYSIS ON SUBCUTANEOUS FAT IN CENTRAL OBESE ADOLESCENT: A RANDOMIZED CONTROLLED STUDY

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### ABSTRACT

**Objective:** To investigate cryolipolysis versus ultrasound cavitation radiofrequency on hunger level, waist-hip ratio, skin fold, body weight, subcutaneous fat and visceral fat thickness in adolescent with abdominal obesity.

#### Material and Methods:

Sixty adolescent central obese whose age ranged from 13 to 16 years were allocated randomly into 3 groups. Each of them was 20 participants. Subjects in study group (A) underwent cavitation radiofrequency plus dietary regimen, subjects in the second study group (B) underwent cryolipolysis in conjunction with the same diet program, and subjects in control group (C) received the same diet program only. Patients in all groups were evaluated on height, weight, skinfold, waist-hip ratio, hunger level and MRI were carried out shortly before to the start of the intervention techniques and again two months afterwards.

**Results:** After two months of intervention, there were no statistically significant differences in BMI, weight, or visceral adipose tissue (VAT) between groups. However, there was a significant difference between the three groups in Suprailiac skin fold, waist-hip ratio, subcutaneous adipose tissue (SAT) and hunger level (P= 0.001) with the Cavitation and radiofrequency group (A) showing better reduction than the Cryolipolysis group (B) and the Cryolipolysis group was better than the diet group (C).

#### Conclusion:

Cavitation radiofrequency have a favorable effect compared to Cryolipolysis on reduction of skin folds, waist-hip ratio, subcutaneous adipose tissue and hunger level. However, there is no difference between groups on BMI, body weight and VAT.

**KEYWORDS:** Cryolipolysis, Adolescent Central obesity, Cavitation Radiofrequency, subcutaneous fat, hunger level.

## 1. INTRODUCTION

Obesity is becoming extremely prevalent in both children and adults. Obesity in the abdomen is linked to a higher risk of death rates, as well as being a common cause of diabetes and heart disease. Obesity is becoming increasingly common in both adults and children. Obesity is linked to arterial atherosclerosis and many vascular problems<sup>(1,2)</sup>. Obesity that develops early in life has led to a rise in the incidence of obesity-related illnesses later in life, including coronary artery disease, insulin resistance, diabetes mellitus, high blood pressure, sleep problems, arthritic changes, malignancy, stroke, and heart problems<sup>3,4,5</sup>. Obesity in children is linked to a high rate of mortality. Furthermore, it has been related to adult obesity and is a predictive of considerable medical complications in young adulthood<sup>5</sup>.

Body contouring is an important medical cosmetic requirement all around the world. People's desire for a better body shape has sparked the fast development of new, non-invasive, but safe treatments with little risk<sup>6</sup>. Despite the fact that liposuction is efficient for fat reduction, there is still a need for more safe alternatives. The majority of people avoid non-safe procedures and surgical intervention in favor of safe techniques that progressively reduce fat and enhance body contouring<sup>6,7</sup>.

The most today's technology that are being described as effective strategies for decreasing lipid stores include Radiofrequency (RF) and cavitation. Cavitation has been utilized for fat removal, both invasively and non-invasively, for many years<sup>8</sup>. Non-invasive cavitation can provide identical fat removal and body shape improvement results as invasive ultrasound liposuction while being less expensive, less risky, and safer<sup>9</sup>. Cavitation is a new ultrasound technology that does not require surgery. It sends an energy waves via the skin to disturb fat tissue<sup>10</sup>. The circumference of the targeted regions has been demonstrated to be considerably reduced by this method. One of the most notable differences between ultrasonic cavitation and liposuction is the absence of the disadvantages that come with surgical treatments<sup>11,12</sup>. The radiofrequency is established on an electric charge between particles, that is ultimately converted to thermal energy<sup>13</sup>. Radiofrequency causes electric fields to be transmitted through skin, causing old collagen to be rebuilt, fibroblasts to produce new collagen, and lipolysis to be stimulated<sup>14</sup>.

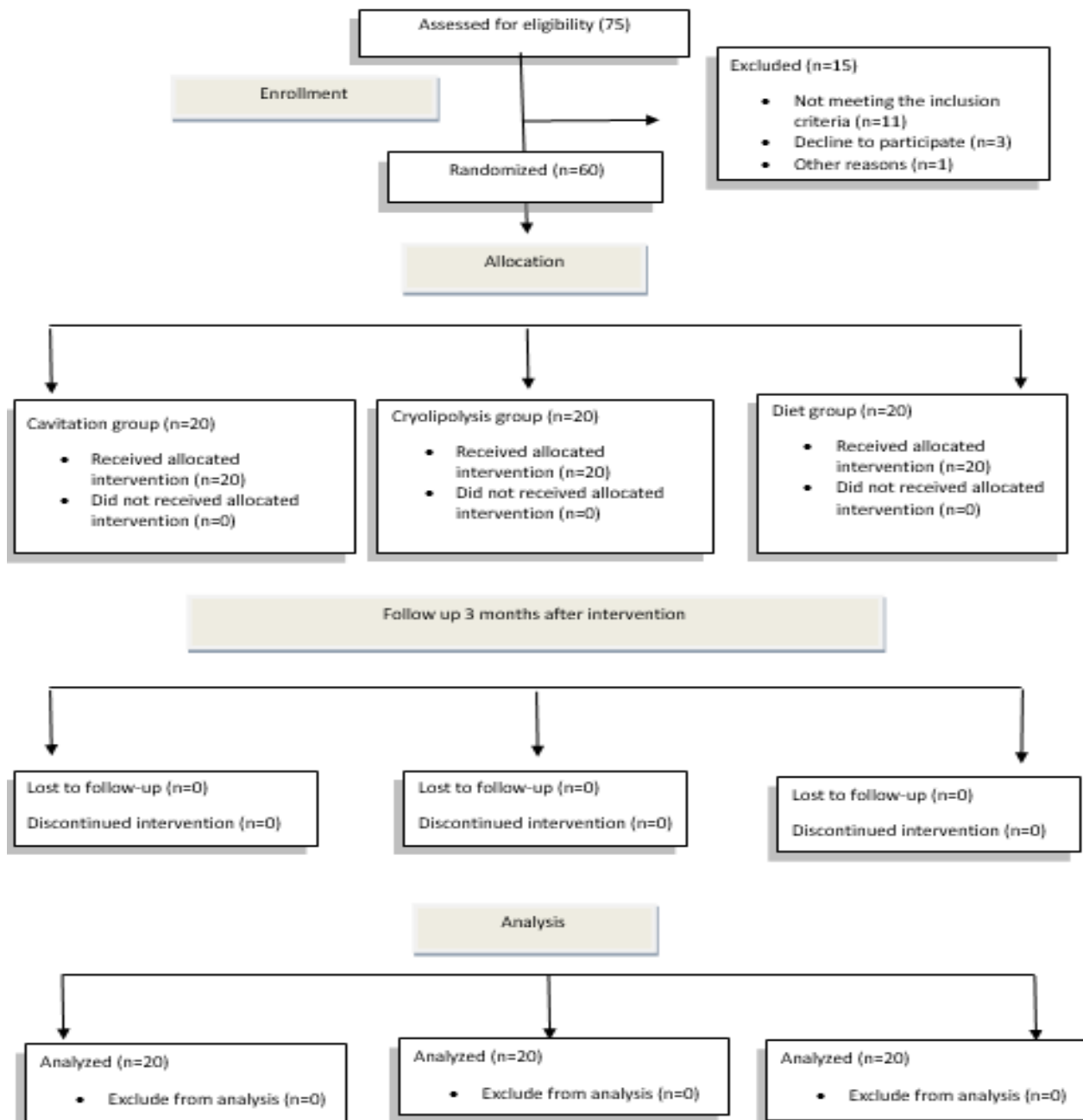
Cryolipolysis is a new cooling-based technique for targeted fat removal. Fat has more sensibility to cold than adjacent soft tissues, which is the basis for this technique. Exposure to cold has been shown to cause selective destruction to the fat, causing a decrease in subcutaneous fat. Cryolipolysis is safe and causes no negative changes in the skin, thus it may be used again<sup>15,16,17,18</sup>.

There is a shortage of research on the effect of cryolipolysis, compared to cavitation and radiofrequency, on adolescent abdominal obesity. This study aimed to investigate effect of ultrasound cavitation radiofrequency versus cryolipolysis on hunger level, waist-hip ratio, skin fold, body weight, subcutaneous fat and visceral fat thickness in adolescent with abdominal obesity.

## 2. MATERIAL AND METHODS:

### Design and setting:

The methods were followed by this pre-test post-test control group design research following approval of kid families with written consent in accordance with the acceptance of the institutionally ethical board. The research was accepted by the "Ethical Committee for Human Research at faculty of Physical therapy, Cairo University, Egypt (Reference number P.T.REC/012/002379)". The purpose of this study was to compare the effects of cavitation and radiofrequency vs cryolipolysis on central obese teenager. Sixty individuals of both males and females were randomised to 3 groups of equal size (20 participants per group). Participants were chosen at random from the population based on various criteria: They were between the ages of twelve to sixteen. They had normal liver enzymes and no present or past neurological, musculoskeletal, or cognitive problems. They can recognize and follow the test's spoken orders. The subjects were assigned into 3 groups at random. Twenty adolescents with central obesity in group (A) got radiofrequency, cavitation and a diet. Group (B) consisted of 20 adolescents with central obesity got cryolipolysis and a diet program. Group (C) consisted of 20 adolescents with central obesity. Only a diet was given to participant in group (C).



**Figure 1:** Flow chart displaying the subjects' progress through each phase of the clinical experiment

### 3. PROCEDURE

#### Methods for Assessment

**1. Weight evaluations:** Pre and post two months of therapy, weight was assessed using the Hanson professional scale<sup>19</sup>.

**2. Waist-to-hip ratio assessment:** With a tape measure, the waist and hip circumferences for every participant were measured, then divided the waist by the hip measures.

**3. Body mass index (BMI):**  $\text{weight (kg)} / [\text{height (m)}]^2$ <sup>19</sup>.

**4. Skin fold calipers:** The skin fold at the Suprailiac level was measured by pulling it away with the calliper. Women skinfolds were dragged obliquely and picked above the iliac crest along the anterior axillary line, while men skinfolds were dragged perpendicularly and 2 cm to the side of the umbilicus. Skinfold was measured pre and post therapy to evaluate progression<sup>20</sup>.

**5. Magnetic resonance imaging:** Images were acquired with a Magnetom Vision 1.5 Tesla total body scanning to quantify abdominal fat (Siemens, Mississauga, Canada)<sup>21</sup>. To evaluate abdominal fat, a “T1-weighted fast-spin echo pulse sequence was utilised (TR 322 ms, TE 12 ms). Subjects were instructed to remain laying in the magnet with their arms spread above their heads. To lessen the effect of respiratory motion on the images, A breath-hold sequence was used (22 seconds per capture). All of the images were taken with a 256 X 256 mm matrix and a 480mm field of view. At the umbilical cord level, a single picture was acquired, and the photo was recovered from the scanner by using Digital Imaging and Communications in Medicine technique. Two qualified inspectors utilised image processing software to divide the axial image into visceral adipose tissue (VAT) and subcutaneous adipose tissue (SAT) (Slice-Omatic, version 4.2; Tom vision Inc, Montreal, Canada)”<sup>21 22</sup>.

#### **6. Visual analogue scale measurements (VAS)**

Subjects were asked to assess their appetite, hunger, satisfaction, and anticipated meal intake by a VAS for appetite measurement consisted of a series of 100-mm horizontal lines anchored with extreme appetite perceptions on both ends of each line (e.g., not at all hungry–very hungry). They were used to answer each of the following 4 questions: 1-how hungry are you? (not at all hungry–very hungry); 2-how full do you feel? (not at all full–very full); 3-how strong is your desire to eat? (not at all strong–very strong); and, 4-how much food do you think you can eat? (none at all–a large amount)The assessment completed before breakfast was used as the fasting evaluation for all four factors.<sup>23</sup>.

The tester who took the measurements was not aware of the group assignment.

#### **4. METHODS FOR TREATMENT**

1. Group A underwent ultrasound cavitation using the Proslimelt device (PromoItalia, Naples, Italy) and the Magic pot bipolar RF (EunSung Global Co Ltd., Seoul, Korea) therapeutic setting at 0.8 MHz. The cavitation instrument generates low-frequency ultrasonic pulsed waves ranging from 30 to 70 kHz through a transducer with a diameter of 45 mm and a power of 3 watts/cm<sup>2</sup>. The individual was positioned in a comfortable supine posture, and the transducer was placed on an abdominal region already coated with conduction gel. For two months, abdomen area was treated with one 30-minute session every two weeks. The patient was treated in a relaxed supine resting position. The radiofrequency application was performed after cleaning the treated area and applying glycerol oil to the treated area as a conductive medium. Every two weeks, one 40-minute treatment was given to the treated area in the hypogastrium, 5 cm below the umbilicus (6 sessions per 2 months). Apply pressure to the targeted area with the radiofrequency tripolar head in a circular motion over the area in addition to same diet regimen as group C.
2. Group B received Cryolipolysis (CoolSculpting, Zeltiq, Pleasanton, CA) over the umbilical region once a week for two months using a suction application for 60 minutes, as well as the same two-month diet as group C. The Cooling Intensity Factor (CIF) measures the amount of heat extracted from a tissue; a higher CIF implies a quicker amount of heat extracted or a cooler phase. Each abdomen was treated with CIF 41.6 (73mW/cm<sup>2</sup>). In a supine relaxed position, cryolipolysis was done. A reevaluation was done two months following therapy<sup>22</sup>.
3. Group C was given diet only for 2 months. Each of the three groups were provided a well-balanced low caloric diet ranging from 1,200 to 1,500 calories per day, based on their requirements. The meal was modified according to the child's age and eating habits. It featured a low-fat level (20% – 25%), a high complex carbohydrate content (50-60%), and sufficient protein (25-30 percent). No vitamins or other dietary supplements were provided<sup>24</sup>.

#### **Statistical Analysis**

According to a statistical power calculation, the size of a sample of 20 participants for each group was necessary to obtain more than 80% power. To identify a normal distribution, the data was initially examined using the Kolmogorov– Smirnov test. Descriptive statistics were in the form of mean, stander deviation and median. The paired t-test was used to examine the differences between the pre- and post-intervention measures. One way ANOVA and a post hoc, less square (LSD) test were used, to compare the 3 groups on BMI, skinfold, waist-hip ratio, hunger level, weight, subcutaneous and visceral fats. All tests were given a significance level of 0.05. SPSS version 20 was used to conduct statistical analysis.

## 5. RESULTS

### Demographic Characteristics

No significant difference was in height or age across groups, with P-values > 0.05. As shown in Table 1, there was no significant difference in gender distribution among groups (P>0.05). As shown in Table 2, there was no significant difference in BMI, skinfold, waist-hip ratio, weight, subcutaneous and visceral fats, and hunger level before therapy, with (P>0.05). Pre-post-treatment the difference in significance among the groups showed that all assessed variables had a value of 0.001 for all the groups except the level of VAT and hunger. As shown in Table 3, there was no significant difference among pre- and post-treatment for VAT in all groups (P>0.05), also there was no significant difference between pre- and post-treatment for hunger level in the diet group alone (P-value of 0.07). Post-treatment differences between the three groups found no significant differences in BMI, weight, or VAT (P>0.05), but significant differences in Suprailiac skin fold, waist-hip ratio, SAT, and hunger level (P-value of 0.001), as demonstrated by ANOVA as shown in Table 4. As indicated by a post hoc test, group A (Cavitation and radiofrequency) had a better decrease in skinfold than group B (Cryolipolysis) and group C (diet alone) as (P=0.02) and (P=0.001), respectively, however group B had a better lowering in skin fold than group C (P=0.001). In terms of waist-to-hip ratio Cavitation and radiofrequency groups (A) demonstrated greater decrease than Cryolipolysis group (B) and diet group (C), with P=0.03 and (P=0.001), respectively, while Cryolipolysis group revealed a superior waist-to-hip ratio decrease than diet group (P=0.001). Cavitation and radiofrequency groups reduced SAT more effectively than Cryolipolysis and diet groups (P=0.001) and (P=0.001), respectively, whereas the Cryolipolysis group reduced SAT well than the diet group (P=0.001). Cavitation and radiofrequency groups reduced hunger levels better than Cryolipolysis and diet groups (P=0.004) and (P=0.001), respectively, whereas Cryolipolysis group reduced hunger levels better than diet group (P=0.001).

**Table1.** Means and Standard Deviations of Demographic Characteristics of the Subjects at the Beginning of the Study

<i>Characteristics</i>	<i>Group (A)</i>	<i>Group (B)</i>	<i>Group (C)</i>	<i>(P-value)</i>
	<i>(n= 20)</i>	<i>(n= 20)</i>	<i>(n= 20)</i>	
	$\bar{x}$ : mean	$\bar{x}$ : mean	$\bar{x}$ : mean	
<i>Age (year)</i>	14.1 ± 1.8	14.3 ± 2.13	13.8 ± 1.5	0.72
<i>Height (cm)</i>	158.9 ± 4.34	159.43 ± 5.8	160.4 ± 3.7	0.54
<i>Gender</i>				Non-significant.
<i>Female</i>	11	8	9	
<i>male</i>	9	12	11	

**Table2.** ANOVA Pre-Treatment Comparing of the Groups in All Tested Variables Results

	<b>Group (A) <math>\bar{x}</math> :</b> mean	<b>Group (B) <math>\bar{x}</math> :</b> mean	<b>Group (C) <math>\bar{x}</math> :</b> mean	<b>P-value</b>
<b>BMI</b>	27.9±1.5	28.4±2.3	28.9±1.2	0.20
<b>Suprailiac skinfold(mm)</b>	20±3.4	21±4.1	21.5±4.6	0.49
<b>Waist-hip ratio (%)</b>	0.95±0.046	0.94±0.05	0.93±0.053	0.45
<b>weight (kg)</b>	73.11±7.22	71.14±6.34	72.16±5.77	0.63
<b>SAT (cm2)</b>	534±27	527±20	529±23	0.62
<b>VAT (cm2)</b>	65±17	63±14	64±15	0.91
<b>Hunger level(mm)</b>	73.2±11.3	74.1±10.9	74.7±12.1	0.92

Non-significant.

**Table3.** Pre-Post-Treatment Comparing among groups in All Measured Variables (ANOVA)

<b>Variables</b>	<b>TIME</b>	<b>Group (A) <math>\bar{x}</math> ±SD</b>	<b>Group (B) <math>\bar{x}</math> ±SD</b>	<b>Group (C) <math>\bar{x}</math> ±SD</b>
<b>BMI</b>	Pre	27.9±1.5	28.4±2.3	28.9±1.2
	Post	26.9±0.9	26.6±1.6	27.7±0.66
	P-value	0.001*	0.001*	0.001*
<b>Suprailiac skinfold (mm)</b>	Pre	20±3.4	21±4.1	21.5±4.6
	Post	11.2±2.1	15.5±2.8	18.5±3.3
	P-value	0.001*	0.001*	0.001*
<b>Waist hip ratio (%)</b>	Pre	0.95±0.046	0.94±0.05	0.93±0.053
	Post	0.82±0.076	0.87±0.069	0.89±0.038
	P-value	0.001*	0.001*	0.001*
<b>Weight (kg)</b>	Pre	73.11±7.22	71.14±6.34	72.16±5.77
	Post	61.29±3.4	61±2.9	60.4±2.7
	P-value	0.001*	0.001*	0.001*
<b>SAT (cm2)</b>	Pre	534±27	527±20	529±23
	Post	471±17	495±15	517±20
	P-value	0.001*	0.001*	0.001**
<b>VAT (cm2)</b>	Pre	65±17	63±14	64±15
	Post	64.4±14	62.6±11	63.1±10
	P-value	0.59	0.68	0.71
<b>Hunger level\$</b>	Pre	73.2±11.3	74.1±10.9	74.7±12.1
	Post	43.5±8.4	53.2±11.1	67.9±10.5
	P-value	<0.001*	<0.001*	0.07

\*Significant



**Table4.** ANOVA Post-Treatment Comparison of All Measured Variables Among Groups

Variables	Group (A) $\bar{x} \pm$ mean	Group (B) $\bar{x} \pm$ mean	Group (C) $\bar{x} \pm$ mean	P-value
<b>BMI</b>	26.9±0.9	26.6±1.6	27.7±0.66	0.46
<b>Suprailiac Skinfold (mm)</b>	11.2±2.1	15.5±2.8	18.5±3.3	0.001*
<b>Waist hip ratio (%)</b>	0.82±0.076	0.87±0.069	0.89±0.038	0.001*
<b>Weight (kg)</b>	61.29±3.4	61±2.9	60.4±2.7	0.42
<b>SAT (cm2)</b>	471±17	495±15	517±20	0.001*
<b>VAT (cm2)</b>	64.4±14	62.6±11	63.1±10	0.67
<b>Hunger level\$</b>	43.5±8.4	53.2±11.1	67.9±10.5	< 0.0001*

\*Significant

## 6. DISCUSSION

Up to the authors knowledge, there have been no prior researches comparing the effects of ultrasonic cavitation, radiofrequency, and cryolipolysis on hunger levels in adolescent with central obesity. This study results revealed that following therapy, there was no significant difference in body BMI or weight between the 3 groups. While radiofrequency and cavitation group outperformed the cryolipolysis group, the cryolipolysis group outperformed the diet group in terms of post-therapy subcutaneous adipose tissue, hunger level, skin fold and waist-hip ratio.

There is no consensus among the researchers regarding which body contouring technique is the best; one research found an equal effect, while another found cryolipolysis to be the best, and yet another found cavitation to be the best<sup>25 26 27</sup>.

Concerning the impact of radiofrequency and cavitation, the findings of the current study agree with Mahla A et al., who reported that radiofrequency and cavitation are efficient for body contouring through decrease of waist circumferences and subcutaneous fats. Other studies recorded a waist circumference decrease in central obesity by using radiofrequency and cavitation<sup>15 27 28</sup>.

Compression and expansion phases are produced by ultrasonic waves, resulting in positive and negative pressure, respectively. As a result of the pushing and pulling force, fat cells may rupture. The chemicals, triglycerides primarily, are dispersed into the interstitial space when the fat cells are destroyed, and then transferred to the liver through the lymphatic vessels. Cavitation triggers fat cell destruction while causing no damage to adjacent tissues, resulting in a reduction in subcutaneous fat thickness<sup>29 30 31</sup>.

It's also considered that Radiofrequency heat stimulus causes fibroblasts to generate new collagen and elastin, and several other chemicals to improve skin integrity. Heat activation of fatty tissue is considered to lead in high - temperature activation of fat cell metabolism and activation of lipase-mediated enzyme breakdown of triglycerides into free fatty acids and glycerol. Another hypothesised process is the development of death in body fat<sup>32</sup>.

Concerning the Cryolipolysis group's results, we agreed with Lilit Garibyan 2014, who presented a significant and definite substantial decrease in size two months after a single cryolipolysis treatment of the flank. According to this study, there is an average of 40 percent fat volume decrease two months after a single cryolipolysis therapy. The mean estimated fat size decrease of the flank was 56.2 cc and 16.6 cc, which was statistically very significant (P=0.001). Finally, cryolipolysis is a nonsurgical lipid removal treatment which is usually efficient, and acceptable<sup>33</sup>.

These results are consistent with those of Nils Krueger et al., 2014 who propose how precisely applying freezing temperatures causes adipocytes to die, which are then swallowed and eaten by macrophages. There are no obvious risks in subcutaneous fat following therapy. Within 3 days of therapy, an inflammatory response triggered by adipose tissue death manifests itself as an inflow of inflammatory cells, which peaks 14 days later when the fat cells are encircled by lymphocytes, histiocytes, and other cells. As a normal reaction to damage, phagocytes and macrophages, encapsulate, and disintegrate the fat 14–30 days after therapy. The inflammation decreases and the adipose tissue volume decreases four weeks following therapy. Adipose mass in the area of application appears to have reduced at this time, and the septae account for the bulk of the target tissues<sup>34</sup>. Furthermore, according to Stevens WG et al., 2013, who discovered how cryolipolysis is safe over all types of skin and may be used without any dermal alterations. Those who exercised on a regular basis and eat a healthy diet have visible fat bulges on the trunk, have successful outcomes, and are ready to sustain the effects of cryolipolysis with a healthy life instructions are the best participants<sup>18</sup>.

Sasaki GH et al., 2014 demonstrated that the cooling created in cryolipolysis had no long-term impacts upon its overlying skin, which validated our decision to use cryolipolysis in this investigation. However, cellular swelling, decreased Na-K-ATPase function, accumulation of lactic acid and reduced adenosine triphosphate may all contribute to cellular damage in fatty tissue<sup>35</sup>.

In terms of hunger reduction, the cavitation and radiofrequency group outperformed the Cryolipolysis group, and the group of Cryolipolysis was more outperformed than the group of diet in reducing hunger. This can be explained by the fact that subcutaneous fat destruction caused by this body contouring equipment results in a decrease in leptin levels (hunger regulating hormone), which in turn decreases appetite and improves hunger levels<sup>36</sup>. The advantage of cavitation and radiofrequency over cryolipolysis in appetite suppression, as well as the superiority of cryolipolysis over diet in appetite suppression, might be related to the superiority of their influence on the amount of subcutaneous fat loss. As leptin levels are proportional to body fat percentage<sup>37 38 39 40</sup>. Also Mahla A et al. confirmed these findings, concluding that the impact of cavitation and radiofrequency decrease subcutaneous fat and have a major role in reduction of leptin level<sup>41</sup>.

The study was limited to expensive evaluation and treatment costs. The research was restricted to examining the short-term effect of cavitation radiofrequency and cryolipolysis there for further studies to evaluate the long-term effects.

### **Recommendation**

Protracted research into the impacts of cavitation, radiofrequency, and cryolipolysis on subcutaneous and visceral fat tissue and their effects over a long period.

## **7. CONCLUSION**

Cavitation and radiofrequency have a favorable effect compared to Cryolipolysis in the decreasing of subcutaneous adipose tissue, skin fold, waist-hip ratio and hunger level. In terms of visceral adipose tissue reduction, weight and body mass index, there is no significant difference between them.

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### **Author contribution:**

We are 8 authors for this work, and we did all requirement to accomplish this work, there are no other researchers participate in this work.

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### **CONFLICT OF INTEREST**

The authors disclose no competing interests in this work.



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