

Abdominal Perimeter Reduction with a Non-Contact Transdermal Radiofrequency Device at 27.12 Mhz and 300 Atts of Power: Retrospective Results Study

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Abstract: Introduction: The global demand for non-invasive fat reduction procedures is continuously increasing. Numerous procedures have been developed for this purpose, such as ultrasound, focused ultrasound, cryolipolysis, radiofrequency, and laser, which can be used alone or combined. Several of these procedures do not have publications with evident results, and others, although they obtain results, have described adverse effects and moderate and severe complications. **Methods:** Retrospective patient records evaluation. Forty patients, twenty-three women and seventeen men, treated between August 2017 and December 2019, fulfilled a control at 30 days post-treatment (PT), with ages between 19 and 84 years, an average of 50 years, who underwent complete treatment of 6 and 8 sessions with non-contact transdermal radiofrequency equipment (NCTR) of 27.12 Mhz and 300 watts of power. **Results:** The patient's abdominal perimeter average reduction obtained was 1.35 cm (range of 0 cm to 6 cm) on patients who performed six sessions. The patient's abdominal perimeter average reduction was 2.47 cm (range 0.5 cm to 13 cm) on patients who completed eight sessions. The abdominal perimeter average reduction in all 40 patients was 1.91 cm (range 0 cm to 13 cm). Only two patients of the group of six sessions didn't show any reduction. A significant abdominal perimeter reduction measure decreased according to the increase of sessions number: 54.65 % more reduction comparing the eight sessions group against the six sessions group of treated patients. More abdominal circumference reduction was found in males, an average of 2.7 cm, compared to females, an average of 1.5 cm, in the total of 40 patients comparing at 30 days post-treatment control results. It means that males obtain 55% more response to the treatment than females. Four fatty tissue induration that did not generate deformity or symptomatology appear as side effects. Resolved spontaneously without treatment in 7 days in the whole series appear. **Conclusion:** NCTR device at 27.12 Mhz and 300 watts of power turned out to be a safe and effective treatment to eliminate abdominal and flank fat, reduce circumference, and improve abdominal contour in most patients treated. A significant increase in abdominal perimeter reduction was found according to the rise in NCTR sessions. This significant reduction is noticed better at 30-day PT control than at the end of the treatment. Males obtain a better response to the treatment. Carrying out prospective studies with a larger number of subjects and long-term follow-up and adding better fat tissue reduction controls like ultrasound, computed axial tomography in all patients will make it possible to objectify better the results obtained.

Keywords: Radiofrequency, Body Contouring, Abdominal Reduction, Non-Invasive Fat Reduction, Non-Contact Transdermal Radiofrequency.

INTRODUCTION

Obesity and localized obesity affect a high percentage of the population and generate many medical consultations. It defines localized obesity as accumulations of fat in certain areas of the body that cause dissatisfaction in patients on an aesthetic level. It is challenging to solve only with diet and exercise. While general obesity, especially visceral obesity, responds better to diet and exercise, localized obesity can remain even with the patient's available weight reduction. Surgical procedures have been described as an effective resolution for localized excess fat tissue, but not without complications, some of them fatal [1, 2, 3].

Non-invasive localized fat tissue removal treatments have increased their demand worldwide. Medical technology companies are increase investments and research in emerging new technologies such as cryolipolysis, ultrasound, high intensity focused ultrasound, radiofrequency (RF), and laser devices. These destroy adipose tissue through various mechanisms, including apoptosis or necrosis [4, 5, 6, 7, 8, 9,10]. Passing an RF current from the delivery electrode to the return electrode generates an electrothermal reaction with consequent heating by the tissue through which it passes. A different form of RF, known as the RF field, operates without contact. The emitter and receiver panels of the electrodes do not rest on the skin and generate a powerful,

radiofrequency equipment (NCTR) is 27.12 Mhz. This frequency has a high absorption affinity for superficial fatty high-speed, oscillating electromagnetic field. The frequency of one of the non-contact transdermal tissue. [11,12]. This electromagnetic field causes vibratory changes within the adipocyte, generating kinetic energy and thus causing an increase in its temperature between 42 to 45 ° C. At this temperature level, increased for a period greater than 15 minutes, it will be obtained adipocyte proteins' denaturation, apoptosis, or programmed cell death. [13].

The adipose tissue has a higher resistance and low conductivity of RF at 27.12 Mhz, so it generates a more excellent absorption than other tissues, including the skin, nerves, blood vessels, and muscles. Therefore this technology selectively targets adipocytes and not other tissues at a specific depth of 15 millimeters and not beyond this depth [14]. Due to its high selectivity for fatty tissue, when applying NCTR, the skin temperature never exceeds 43 ° C, thus avoiding burns. These adipocytes with their altered membrane will be eliminated by the immune system, mainly macrophages, which will proceed to their phagocytosis and transport through the lymphatic system. Therefore, raising and maintaining the adipocytes' temperature above the apoptotic threshold induces apoptosis of the superficial fatty tissue. Subsequently, these altered adipocytes are phagocytosed, decreasing their quantity, which results in a reduction in excess fat volume in the treated area [13].

METHODS

Out of a total of patients treated for fat tissue reduction between August 2017 and December 2019 with NCTR of

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27.12 Mhz and 300 watts of power in various body areas (arms, thighs, male chest, upper back, abdomen, and flanks), it was decided to take into account this work the patients treated in the abdominal area and flanks, who were according with the inclusion and exclusion criteria determined by the author.

Inclusion Criteria

- Indistinct sex
- Indistinct age
- Abdominal area and flanks as treated areas
- Body Mass Index between 18 and 30

Exclusion Criteria

- Weight gain greater than 1.5 kg during treatment and until 30-day post-treatment control (30-day PT control).
- Any other treatment on the treated area during the treatment period and up to 30-day PT control.
- Who do not comply with the full treatment of 6 or 8 sessions.
- 30-day PT control not present
- There are some particular contraindications for NCTR.

They are the following ones:

- Pregnancy
- Presence of a pacemaker or cardiac defibrillator.
- Presence of osteosynthesis or metallic material in the treatment area; Ongoing skin disease in the treatment area.

A total of 40 patients, 24 women and 16 men, treated between August 2017 and December 2019, fulfilled a control at 30 days post-treatment (30-day PT control), with

ages between 19 and 84 years, an average of 48 years, who underwent complete treatment of 6 and 8 sessions with NCTR, complete the inclusion and exclusion criteria. All the patients included signed a written consent explaining the treatment's characteristics and agreed to attend a check-up after approximately 30-day PT control.

Patients were recommended to drink plenty of fluids after each session to fluidize body fluids and facilitate macrophagocytic work through the lymphatic system. They were asked not to change their usual eating and physical activity habits. Patients were advised that they cannot gain more than 1 kilogram of body weight during treatment and until the 30-day PT control. One of the exclusion criteria being that they would have gained more than 1.5 kg. The equipment used was the enCurve (Lutronic, Goyang, South Korea), NCTR equipment of 27.12 Mhz, with a maximum power of 300 watts. The standard 77 cm x 22 cm head was used, equivalent to 0.16 m². This head size allows treating the lower and central abdomen and the flanks in the same session, and it was placed approximately 5 cm away from the skin (Figure 1). The sessions were weekly and lasted 60 minutes in all cases.

At the beginning of the treatment, at the end of it, and in the control of the 30 days post-treatment, photographic controls, weighing, and abdominal girth measurements were carried out. Standardized digital clinical photographs were taken: sony 8.1 megapixel digital camera, same room, on the same background at the same distance (1.5 meters) and with the same artificial lighting. All patients were controlled for weight and height to determine their Body Mass Index (inclusion criteria). In each session and post-treatment control, patient's weight was controlled to ensure that they did not exceed the weight gain's permitted kilogram. Abdominal perimeter measurements were taken at the navel level at the beginning, at the end of the treatment, and in control at 30 days PT. All the parameters were controlled and taken by a single operator to avoid dispersions.

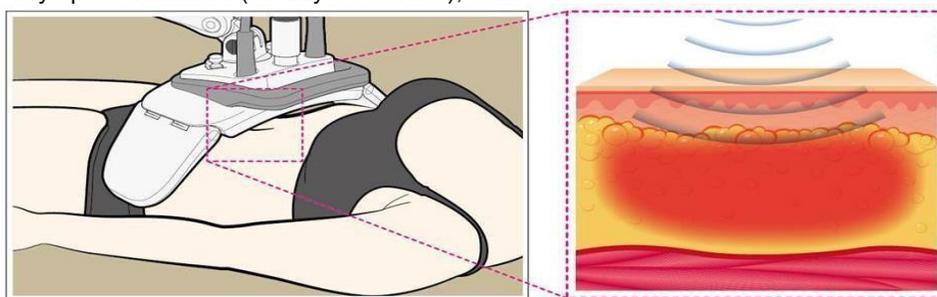


Figure 1: NCTR equipment of 27.12 Mhz, with a maximum power of 300 watts. The standard 77 cm x 22 cm head was used. This head size allows treating the lower and central abdomen and the flanks in the same session, and it was placed approximately 5 cm away from the skin. The adipose tissue has a higher resistance and low conductivity of RF at 27.12 Mhz, so it generates a more excellent absorption than other tissues, including the skin, nerves, blood vessels, and muscles. (Figure courtesy Lutronic).

RESULTS

Of the forty patients who completed the treatment, twenty completed six sessions, five males and fifteen females, and twenty completed eight sessions, twelve males and eight females. All the patients treated and controlled at four weeks post-treatment to evaluate and measure the reduction in their umbilical perimeter (Figure 2, Figure 3, and Figure 4).

At the umbilical level, the reduction of the abdominal perimeter was from 0 cm to 13 cm, with an average decrease of 1.4 at the end of the treatment and a reduction of 1.8 cm at the 30-day PT control (average starting measurement 90.9 cm, average measurement at the end treatment 89.5 cm and mean measurement at 30 days PT of 89.1 cm). See Table 1.

Dividing the patients according to whether they have completed 6 or 8 sessions, we find these results:

Table 1

Six Sessions

Pre-Treatment			
Age	Sex	Abd Circumference	Weight
29	F	82	62,4
37	M	84	70,9
58	F	96	56,9
65	F	103	88,4
73	F	85	61,6
41	F	86	59
48	F	90	59,3
37	F	76	56,6
65	F	87,5	58,8
56	F	93	70,3
53	F	95	82,9
39	M	89	70,4
39	M	97	85,6
46	M	95	78
58	F	90	70,9
34	M	85	77,7
58	F	93	75
61	F	77	53,4
63	F	77	62,2
55	F	97	77,9

Post Treatment	
Abd Circumference	Weight
80	61,9
84	70,3
95	56,6
103	87,1
83	61,6
83	59
87	60
75	56,6
83	57,9
91,5	69,6
98,5	82,9
88	70,7
94	83,9
92,5	79
90	71
83	76,5
91	73,6
75	53,3
77	62
97,5	77,9

30 days Post Treatment	
Abd Circumference	Weight
82,5	59,6
83,5	69,8
93,5	56
103	89,7
83	60,4
81	57,6
89	59,8
78	56,6
85	58
92,5	70
94	81,7
88	70,4
91	82,2
92,5	79
90	72
80,5	75,6
90,5	73,2
76	52,7
79,5	62,5
97,5	79,9

Eight Sessions

Pre-Treatment			
Age	Sex	Abd Circumference	Weight
60	F	88	72,1
57	M	84	76,9
38	M	102	85,5
28	F	89	59
50	M	97,5	88,4
35	F	70,5	46,2
75	M	110	92,7
52	M	108	105
50	M	84,5	67,8
35	F	87	67,7
61	M	113	101,5
56	F	94	70
43	M	93	86,5
44	M	92	83,4
37	F	68,5	46,8
47	F	90,5	67,2
62	M	105	97,6
56	M	86,5	64
55	M	90	79,9
55	F	108,5	95,9

Post Treatment	
Abd Circumference	Weight
84	71,1
86	75,5
96,5	83,1
86	56,6
96	87
67,5	45,5
111	93,9
109	106,5
80,5	66,3
87,5	68,8
111	102,1
93	69,7
90,5	83,4
93	82,5
67	46,4
88	66,8
105	97,5
83	62,7
90	79
107	96,5

30 Days Post Treatment	
Abd Circumference	Weight
86	71,5
87	77,4
89	79,9
82	56,1
95	87,7
67,5	45,5
112	94,5
107	104,5
80	65,5
85,5	68,8
111	102,3
93	70,8
88	82,6
94	83,8
65	46,8
88,5	65,4
104	95
80	60,4
88,5	78,3
109	95,7



Figure 2a (before)



Figure 2b (30-day PT control)

Figure 2: Male, 55 years-old, 8 NCTR sessions, 10 cm perimeter abdominal reduction, 1000 mg less weight.



Figure 3a (before)

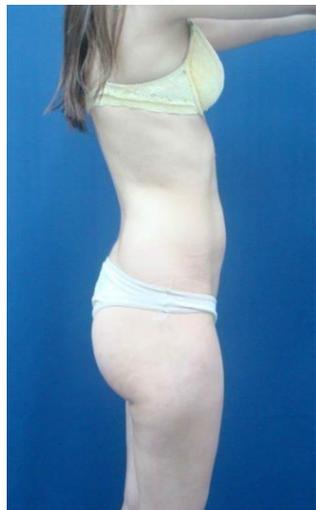


Figure 3b (30-day PT control)

Figure 3: Female, 35 years-old, 8 NCTR sessions, 4.5 cm perimeter abdominal reduction, 0 mg less weight.



Figure 4a (before)



Figure 4b (30-day PT control)

Figure 4: Female, 50 years-old, 6 NCTR sessions, 4.0 cm perimeter abdominal reduction, 1500 mg less weight.

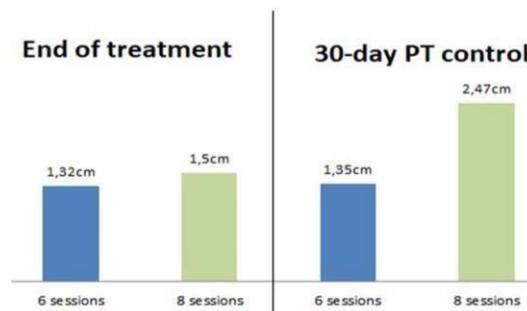
Six Sessions

At the umbilical level, the average reduction of the abdominal circumference was 1.32 at the end of the treatment and a decrease of 1.35 cm at the 30-day PT control (average start measurement 88.87 cm, average measurement at the end of treatment 87.55 cm, and average measurement 87.52 cm at 30-day PT control). Two patients of this group didn't show any reduction.

Eight Sessions

At the umbilical level, the average reduction in abdominal circumference was 1.5 at the end of treatment and a decrease of 2.47 cm at the 30-day PT control (mean starting measurement 93.07 cm, average measurement at the end of treatment 91.57 cm, and average measurement at 30 days 90.60 cm PT). These measurements are shown comparatively in Figure 5. The average initial weight of the 40 patients was 73.30 kg (maximum 105 kg, minimum 46.2 kg) with an average decrease at the end of the treatment of 72.80 kg, an average reduction of 500 grams (maximum 106 kg, minimum 45.5 kg), and a moderate decrease to the 30-day control PT of 72.48 kg, average reduction of 820 grams (maximum 104.2 kg, minimum 45.5 kg). The whole series appeared 4 cases of panniculitis, asymptomatic induration of the fatty tissue, which resolved spontaneously after seven days. Four patients (9.75% of total patients), two females with six sessions and two males with eight sessions, didn't show improvements in their abdominal area.

Figure 5



DISCUSSION

Today, health professionals live a growing demand in our offices to achieve permanent results in reducing localized obesity without resorting to surgery. Some cases have an exclusive indication for surgery, such as localized obesity associated with dermatochalasis, several affected areas of the body, greater expectations of reduction on the part of the patient, and the impossibility of long-term waiting results. Conventional liposuction and the same assisted by technologies, ultrasound, and laser, is not without complications and severe adverse effects [1, 2, 3].

There are a large number of patients who do not want to suffer pain, do not want the inherent risk of any operative act, cannot take the necessary time of post-operative rest, and whose expectations of reduction are in line with what the non-invasive technologies for the elimination of localized fatty tissue. New non-invasive methods and devices, including transdermal lasers, cryolipolysis, high-intensity focused ultrasound, and RF devices, allow non-

invasive fatty tissue removal. However, some of them still have complications or adverse and secondary effects [15,16,17,18] (Figure 6).



Figure 6: 44 years-old patient who underwent cryolipolysis six months ago in another medical center. Presented complication, pain, prolonged dysesthesia, induration, prolonged fatty tissue, and paradoxical hyperplasia that required surgical resolution.

Evaluating different non-invasive technologies, there are some of them do not generate necrosis or apoptosis of the adipocyte, so their results are not usually permanent; others generate immediate pain or delayed pain, prolonged induration, visible and palpable asymmetries that can last months, dysesthesia, burns, skin necrosis, paradoxical effect with increased growth of fatty tissue or depending on the correct and careful implementation by the operator to obtain any result [6, 7]. Among the multiple technologies for the transdermal elimination of fatty tissue at the abdominal level, the author decided on 27.12 Mhz NCTR equipment 300 watts of power. The majority of the patients included in the present study, 38 cases (95 %), presented a reduction in the abdominal perimeter, from a minimum of 0.5 cm to a maximum of 13 cm, an average decrease of 1.91 cm the 30-day PT control.

Evaluating different non-invasive technologies, there are some of them do not generate necrosis or apoptosis of the adipocyte, so their results are not usually permanent; others generate immediate pain or delayed pain, prolonged induration, visible and palpable asymmetries that can last months, dysesthesia, burns, skin necrosis, paradoxical effect with increased growth of fatty tissue or depending on the correct and careful implementation by the operator to obtain any result [6, 7]. Among the multiple technologies for the transdermal elimination of fatty tissue at the abdominal level, the author decided on 27.12 Mhz NCTR equipment 300 watts of power. The majority of the patients included in the present study, 38 cases (95 %), presented a reduction in the abdominal perimeter, from a minimum of 0.5 cm to a maximum of 13 cm, an average decrease of 1.91 cm the 30-day PT control.

Were found a significant difference between patients who did six NCTR sessions and those who did eight NCTR sessions: 1.35 cm less in comparison to 2.47 cm less. It is representative of a 54.65 % more abdominal perimeter

reduction in patients who performed eight sessions. In conclusion: more NCTR sessions, more abdominal perimeter reduction. More abdominal circumference reduction was found in males, an average of 2.7 cm, compared to females, an average of 1.5 cm, in the total of 40 patients comparing at 30-day PT control results. It means that males obtain 55% more response to the treatment than females.

In a preclinical, experimental study, Kwon et al. observed that adipocytes reached by NCTR can present different degrees of apoptosis even after 90 days PT. Therefore, the phagocytosis time to eliminate the adipocytes run by the NCTR can be longer than 30 days. [12]. Mathew and Rosemary demonstrated in 2009 the persistence of inflammation and phagocytosis after more than 30 days of having carried out non-invasive treatment of the fat tissue. [19]

It reflected in the more significant reduction in abdominal circumference at the time of the 30-day PT control compared to that obtained at the end of treatment: 1.44 cm at the end of treatment compared to 1.91 at 30-day PT control, an average of 24.7 % more reduction. Even without performing any treatment and only by asking the patient not to gain weight between the last session and the 30-day PT control, we were able to show a more significant decrease in abdominal circumference in the majority of the patients in this study.

The evolution of the total patients' weight in this sample marked a very slight reduction between the start and end of treatment, an average of 500 grams, and with the control at 30-day PT control, an average of 820 grams. A weight reduction of less than 900 mg cannot justify a waist average circumference reduction of 1.91 cm by itself. It makes the results of the treatment much more reliable. There were four side effects in the whole series. In all cases were panniculitis, a non-infectious inflammation of the fatty tissue. Asymptomatic induration, in only one side of the abdomen and near the last treatment sessions. It resolved spontaneously without treatment at seven days. It may correspond to an increased sensitivity of the patient to NCTR. Currently, there are no permanent complications with this technology.

CONCLUSIONS

NCTR device at 27.12 Mhz and 300 watts of power turned out to be a safe and effective treatment to eliminate abdominal and flank fat, reduce circumference, and improve abdominal contour in most patients treated. A significant increase in abdominal perimeter reduction was found according to the rise in NCTR sessions. This significant reduction is noticed better at 30-day PT control than at the end of the treatment.

Males obtain a better response to the treatment. Carrying out prospective studies with a larger number of subjects and long-term follow-up and adding better fat tissue reduction controls like ultrasound, computed axial tomography in all patients will make it possible to objectify better the results obtained.

Knowledge: My assistant Sabrina Figueiras and my secretary Natalia Mora helped me with data obtained, tables and figures.

Ethical Statements

Conflict of Interest: The author declares that he has no conflict of interest.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. For this kind of retrospective observational study, no ethical approval is required.

Informed Consent: Informed consent was obtained from the patient included in the study.

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