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ORIGINAL CONTRIBUTION

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Long-term follow-up on patients treated for abdominal fat using a selective contactless radiofrequency device

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Summary

Background and objective: The aim of this study was to evaluate how abdominal circumferential reduction achieved after using a noninvasive radiofrequency device (BTL Vanquish, BTL Industries Inc., Boston, MA) evolves over a 4-year period.

Methods: This is a follow-up on patients who were treated in our practice for abdominal fat in an earlier published multicenter prospective study. Patients were recalled for biometric data collection 4 years (±60 days) after the last treatment. Body and weight measurements were compared to the historical data. Digital images of the treated area were taken. Independent panelists were asked to recognize the original baseline images from the 4-year follow-up images.

Results: The evaluation encompasses 13 subjects. In the original study, these patients lost on average 5.88 ± 4.14 cm of waist circumference ($P < .001$) while losing on average 1.29 kg. After 4 years, the same subjects had an average reduction of 4.42 ± 2.85 cm ($P < .001$) compared to the baseline, while gaining on average 0.50 kg. In both cases, the waist change was statistically independent of the weight change ($P < .01$). The patients preserved on average 75.2% of the original body contouring effect after 4 years as measured by circumference. None of the patients grew in circumference when compared to the baseline. Reviewers recognized the baseline patient images from the follow-up patient images in 82.1% cases. No long-term side effects were observed that would relate to the treatments.

Conclusions: In the study group, patients with ordinary weight changes preserved most of the original waist reduction after 4 years.

KEYWORDS
apoptosis, body shaping, fat reduction, long-term efficacy, radiofrequency

1 | INTRODUCTION

Over the past decade, the esthetic medicine market has been continuously shifting from invasive procedures to noninvasive treatments. Based on the ASAPS statistics, in 2016 noninvasive cosmetic procedures have grown at a double pace, year over year, compared to surgical procedures.[1] Contrary to surgical approaches, noninvasive body shaping treatments offer modest results. However with advancing technologies, the esthetic changes that can be achieved noninvasively are dramatically improving. The major concern has remained the longevity of the results of noninvasive treatments, as surgical procedures, such as liposuction, are believed to have long-lasting results unless dramatic lifestyle changes occur.[2]

As of today, 5 major noninvasive technologies widely used for the reduction in subcutaneous fat are recognized. These are radiofrequency (RF), low-level laser therapy (LLLT), hyperthermic laser treatment, high-intensity-focused ultrasound (HIFU) and cryolipolysis.[3,4] All these technologies aim to either temporarily or permanently reduce the volume of adipose tissue, while the exact mechanisms of action differ. They vary from induction of apoptosis (RF),[5,6] coagulative necrosis (HIFU),[7] release of lipid contents by creating cell membrane pores (LLLT),[8] lipolysis (laser), to fat cell disruption caused by local panniculitis (cryolipolysis).[9]

It has been proven that the number of fat cells stays constant in adulthood and that the fat mass in adult humans is primarily determined by changes in lipid storage in existing adipocytes.[10] A massive weight loss does not reduce the number of adipocytes, only their size. Similarly, significant weight gain results in body fat increase, driven by an increase in adipocyte volume; not their number. Most people combat body size fluctuations in adulthood, because frequent approaches such as food intake control and weight management programs only provide temporary changes in fat cell volume. This suggests that to achieve long-term control over fat mass in a specific body part, the number of adipocytes needs to be reduced.

There is clinical evidence both on animals and humans that significant increase in apoptotic index in adipose tissue can be achieved by applying noninvasive RF device treatments.[5,6] Apoptosis is defined as programmed cell death[11] which results in cell decomposition and removal. RF may thus be used to reduce the adipocytes by number, not by size.[12] As such, the treatments can potentially cause long-lasting changes in the body's contour and fat mass volume, because the remaining adipocytes are unlikely to expand in size enough to restore the original body contour before treatments. However, very little scientific evidence is out there that would clearly document how body shaping achieved after noninvasive RF treatment develops over time.

An earlier multicenter prospective ethical committee-approved study was published in a peer-reviewed journal, presenting results on patients who had been treated for abdominal fat using a contactless noninvasive radiofrequency device (BTL Vanquish; BTL Industries Inc., Boston, MA, USA). Subjects received 4 weekly treatments and were evaluated at a 1-month follow-up. Significant circumferential reduction was achieved, supported by recognizable before and after digital images. In total, 20 subjects from the original study were recruited and treated in our practice. It is the goal of this study to investigate how the body contour changes originally achieved on those patients have evolved over time.

2 | MATERIALS AND METHODS

2.1 | Study Design

Twenty patients (18 female, 2 male) qualified for this trial. These are the patients who had been treated in our practice as part of the earlier multicenter clinical study.

Patients were called in for a 4-year (±60 days) follow-up. Exclusion criteria were as follows: current pregnancy, any fat reduction or body shaping procedure (invasive or noninvasive) received after the original series of treatments, or use of medication or any medical condition known to affect weight levels and/or to cause bloating or swelling, >10% weight deviation (loss or gain) compared to the historical follow-up.

2.2 | Outcome measures

To ensure consistency and allow for objective evaluation, the same outcome measures were used as those applied to the 1-month follow-up visit in the original study. Subjects were called in for collection of their biometric data. Weight was recorded. Circumference of abdomen was measured using a spring-loaded tape. Standardized photographs were taken with a single-color background.

On top of that, randomized patient photographs from the baseline and the 4-year follow-up were given to 3 independent reviewers for recognition, to see whether the body contour changes are still visible.

Circumference was compared to the historical data to evaluate how the original body shaping effects after RF treatments evolved over time. Weight data were used as a control indicator. Student's *t* test was used for statistical evaluation.

All patients were consented for taking their biometric data and to the use of their photographs without limitation for the purpose of this clinical study.

3 | RESULTS

Three subjects out of the original group of twenty have not responded to the recall action. Two subjects were excluded because they received additional fat reduction treatments after the original study. Two patients were discarded based on exclusion criteria due to >10% weight loss/gain (1 subject lost 7.0 kg, another 1 gained 10.2 kg compared to the original study). The results are thus based on the remaining 13 patients.

In the original study, these subjects lost on average 5.88 ± 4.14 cm of waist circumference (baseline 98.65 cm to 92.77 cm at 1 month; significance of change $P < .001$) while losing on average 1.29 kg (73.05 kg to 71.75 kg). At 4 years, the same subjects had an average reduction of 4.42 ± 2.85 cm (baseline 98.65 cm to 94.23 cm at 4 years; significance of change $P < .001$) while gaining on average 0.50 kg (73.05 kg to 73.55 kg). In both cases, the waist change was statistically independent of the weight change ($P < .01$, two-sample *t* test with unequal variances). This means that at 4 years, the study group preserved on average 75.2% of the original body contouring effect as measured by circumference (4.42 cm of 5.88 cm). The results are not affected by the elimination of 2 subjects with >10% weight change, as their inclusion would change the ratio of preserved waist reduction from 75.2% to 74.9%.

None of the patients grew in circumference when compared to the pretreatment measurements. Subject ID8 got back to the baseline waist size.

Complete overview of biometric data is presented in Table 1.

At 4 years, the average absolute weight deviation was 1.93 ± 1.43 kg compared to the baseline, with the standard deviation exceeding the arithmetic mean (0.50 ± 2.35 kg). This shows that over the course of the years, subjects' weight evolved inhomogeneously up or down, with the average weight slightly increasing. Despite putting on 3.1 kg, Patient ID3 lost additional 1 cm from her waist size, while Patient ID7 decreased in weight by 1.3 kg but only preserved 66% of the original contouring effect.

On average, the reviewers recognized the baseline image from the 4-year follow-up image in 82.1% cases, suggesting that the contour change is still visible in most patients. Images of 8 subjects were uniformly recognized by all 3 reviewers, images of 3 subjects were recognized by 2 reviewers, and photographs of 2 subjects were recognized by only one evaluator. See Figures 1-4 for examples of the images.

None of the subjects has reported any long-term side effects that would have connection with the treatments.

4 | CONCLUSIONS

The primary goal of this study was to investigate how changes in body contour originally induced by a noncontact RF device (BTL Vanquish; BTL Industries Inc.) develop in the long term.

TABLE 1 Changes in patient biometric data over time

		Weight [kg]					Waist circumference [cm]				
ID	BMI before	Before	1M[a]	4Y[a]	1M to before	4Y to before	Before	1M	4Y	1M to before	4Y to before
1	28.7	73.5	72.1	69.5	−1.4	−4	102	100	99	−2	−3
2	29.6	85.5	81.9	86.0	−3.6	0.5	109	98	100	−11	−9
3	21.8	63.7	62.0	66.8	−1.7	3.1	90	85	84	−5	−6
4	28.5	69.4	69.6	70.1	0.2	0.7	99	92	94	−7	−5
5	23.4	62.2	62.2	63.4	0	1.2	84	83	83	−1	−1
6	26.1	79.0	77.0	79.2	−2	0.2	109	96	101	−13	−8
7	23.1	69.0	66.4	67.7	−2.6	−1.3	92	89	90	−3	−2
8	22.4	68.7	68.5	70.3	−0.2	1.6	93	92	93	−1	0
9	26.6	67.2	68.4	71.5	1.2	4.3	91.5	84	86	−7.5	−5.5
10	26.4	91.3	88.1	91.4	−3.2	0.1	102	93	98	−9	−4
11	25.7	73.5	71.0	69.5	−2.5	−4	106	103	103	−3	−3
12	26.9	75.9	75.2	78.0	−0.7	2.1	96	94	94	−2	−2
13	26.0	70.7	70.4	72.7	−0.3	2	109	97	100	−12	−9
14×[b]	25.6	65.7	66.9	59.9	1.2	−5.8	97	94	90	−3	−7
15×[b]	24.1	84.2	85.0	95.2	0.8	11	89	85	91	−4	+2
16×	Excluded—received cryolipolysis on abdomen in 2015										
17×	Excluded—received RF treatment on abdomen in 2015										
Mean (ID 1-13)	25.78	73.05	71.75	73.55	−1.29	0.50	98.65	92.77	94.23	−5.88	−4.42
SD (ID 1-13)	±2.37	±7.97	±7.09	±7.69	±1.40	±2.35	±7.95	±5.96	±6.47	±4.14	±2.85
P value					<.05	>.05				<.001	<.001

[a]1M = 1-month follow-up, 4Y = 4-year follow-up.
[b]Patient discarded due to >10% weight drop/increase 4Y to 1M.

FIGURE 1 Patient ID3 photographs. Baseline, 1 month after, 4 years after (from left to right)

FIGURE 2 Patient ID4 photographs. Baseline, 1 month after, 4 years after (from left to right)

FIGURE 3 Patient ID6 photographs. Baseline, 1 month after, 4 years after (from left to right)

FIGURE 4 Patient ID13 photographs. Baseline, 1 month after, 4 years after (from left to right)

Four years after the last treatment, the subjects preserved on average 75% of their original waist reduction effect as measured by circumference. No data were collected about subjects' lifestyle and/or dietary habits. However, the prevailing waist reduction proved to be highly statistically significant and independent of any weight changes. Weight of the patients evolved inhomogeneously compared to the baseline, with the average change being insignificant (BMI + 0.18 kg/m^2).

The prevailing changes in abdominal contours were further confirmed by a relatively high recognition rate of before and after photographs, reaching 82% based on 3 reviewers.

Based on results of 13 individuals, this study suggests that treatments with the investigated device can cause long-lasting changes in abdominal body contours. As seen in the data, the treatments cannot prevent any future weight gains. However, it concludes that in the investigated study group, patients with ordinary weight changes preserve most of the original effects after 4 years.

5 | DISCUSSION

Although certain noninvasive body shaping procedures based on thermal effects are widely accepted to be causing permanent fat cell disruption, there is lacking evidence on how the results evolve over a longer period of time. Most published clinical studies incorporated a follow-up evaluation 3-12 months after the actual procedures.

This study discloses data on 13 subjects from 4 years after the original treatments. Though on a smaller patient group, this represents the first indication of how the waist changes may evolve in time. It is unclear whether the long-lasting waist reduction in this group is primarily caused by previous reduction in the number of adipocytes in the treated area. However, this theory is in compliance with other scientific evidence,[10] as the remaining adipocytes might be unable to expand in size enough to restore the original appearance before treatments.

All the patients were treated using the early generation of the device. Hayre et al[13] concluded in a study on 36 subjects that the upgraded device can provide better results. Moreover, the 1-month follow-up period from our earlier study might not have been enough to capture the original treatment results fully. It is not well understood how fast the process is, before a complete disposal of apoptotic cells and cell debris from the body occurs.

Additional scientific research and studies with larger patient groups are necessary to bring more evidence, before any findings of this kind can be generalized.

DISCLOSURES

The authors have no commercial interest in BTL and received no compensation for this study. Klaus Fritz and Carmen Salavastru have no relevant conflicts to declare.

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