



A randomized double-blind trial evaluating the efficacy and tolerability of topical body treatment with TriHex Technology[®] combined with abdomen cryolipolysis or radiofrequency procedures

Amir Moradi MD, MBA¹ | Jeanette Poehler BA, CCRC¹ | Michaela Bell BS, MBA² 

¹Moradi MD, Vista, California

²ALASTIN[®] Skincare, Carlsbad, California

Correspondence

Michaela Bell, ALASTIN[®] Skincare, 3129
Tiger Run Court #109, Carlsbad, CA 92010.
Email: mbell@alastin.com

Abstract

Background: Nonsurgical fat reduction procedures using cryolipolysis and radiofrequency are among the most popular noninvasive aesthetic procedures. In a previous study, TransFORM Body Treatment (TFB) with TriHex Technology[®] (ALASTIN[®] Skincare) improved the contour and reduced skin laxity following cryolipolysis of the arms. This product is formulated using a combination of peptides and other active ingredients designed to stimulate the autophagic breakdown of lipid droplets and expedite the apoptotic process after fat reduction procedures.

Aims: To assess the changes in abdominal volume after application of TFB for 12 weeks following cryolipolysis and radiofrequency procedures.

Methods: Following abdominal cryolipolysis or radiofrequency therapy, the subjects (N = 15) received TFB product and placebo and were randomly assigned to apply to the right or left sides of the abdomen for 12 weeks. Using 3-dimensional digital imaging analysis, subjects were evaluated at 4, 8, and 12 weeks posttreatment.

Results: Topical TFB resulted in increased volume loss, which was greater than that for placebo at weeks 4 ($P = .0511$), 8 ($P = .0238$), and 12 ($P = .0078$), respectively, and statistically significant at weeks 8 and 12. There were no reported adverse events.

Conclusion: In this study, Topical application of TFB significantly increased adipose volume loss and improved clinical outcomes of nonsurgical fat reduction procedures.

KEYWORDS

abdomen cryolipolysis, nonsurgical fat reduction procedures, radiofrequency procedures, topical body treatment

1 | INTRODUCTION

There has been a rising trend in the number of noninvasive fat reduction procedures, including cryolipolysis and radiofrequency, reaching more than 375 000 cases in 2018.¹ These devices work by

delivering either cold or heat to the tissue, thus damaging the membrane of the adipocytes. This results in the release of free fatty acids that induce activation of macrophages and other inflammatory mediators stimulating the lipolytic process.^{2,3} As the lipid droplets are large compared with the macrophages, it takes time to break them

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down, digest them, and clear them from the body, thereby delaying the result of fat reduction procedures. Details regarding the science behind adipose tissue physiology have recently been published.²

A topical product (TransFORM Body Treatment [TFB] with TriHex Technology®, Alastin® Skincare) showed enhanced contour and reduced skin laxity following cryolipolysis of the arms.⁴ In that randomized, double-blind pilot study, the TFB product was compared with a bland moisturizer lotion (Cetaphil® Lotion, Galderma Laboratories). After 12 weeks, the subjects treated with the TFB product achieved greater reduction in arm contour and skin laxity than those treated with a bland moisturizer.

Based on these promising results, the following clinical study was designed to examine the effects of TFB product when applied following abdominal cryolipolysis or radiofrequency therapy.

2 | MATERIALS AND METHODS

2.1 | Subjects

Eligible subjects were women between 25 and 55 years of age with clearly visible bilateral subcutaneous adipose tissue appearing as a distinct bulge of fat in the abdomen with soft, pliable tissue and sufficient volume for treatment on both sides. The enrolled subjects expressed their willingness to avoid starting a major diet or exercise program and to maintain a constant weight within 5% of the baseline measure. Subjects were recruited from the general population and within the clinical site database.

Exclusion criteria included prior fat reduction procedures or implants in or near the planned treatment area, previous surgery in the abdomen area, excessive laxity or any contra-indication to device usage, such as existing diseases or drug use, pregnancy, lactation, or planned pregnancy during the study.

2.2 | Procedures

Prior to the procedure, the planned treatment areas were traced and photographed to ensure that only the treated areas of the body were mapped on 3-dimensional (3-D) volumetric photographs. Subjects underwent abdominal cryolipolysis (CoolSculpting® System, Allergan) or radiofrequency of the abdomen (Vanquish ME™, BTL). Subjects treated with cryolipolysis received up to four cycles during one treatment session. A 3-minute manual massage was performed immediately following treatment. Subjects treated with radiotherapy received six treatment sessions approximately 1 week apart.

The topical products were provided in a randomized, double-blind fashion with bottles labeled for use on the right or left side of the treated abdomen. Subjects were instructed to apply two to three full pumps of the product twice daily to the appropriate side of the abdomen as marked on the bottles. The product was applied after bathing or showering without manual massage, and the area was allowed to dry prior to wearing clothes. Subjects

TABLE 1 Difference in fat volume reduction using the TransFORM Body Treatment with TriHex Technology® versus placebo

N = 13 PATIENTS			
Week	Mean (SD) mL	P-value ^a	P-value ^b
4	-8.1 (13.4)	.0511	.0547
8	-12.2 (16.9)	.0238	.0425
12	-24.0 (27.1)	.0078	.0078

^aPaired *t* test.

^bSigned-rank test.

were instructed to wash their hands in between right and left side application.

Subjects were evaluated during the follow-up visits at 4-, 8- and 12-weeks post treatment. At each visit, change in volume on each side of the abdomen was objectively measured using a volumetric 3-D camera system (3-D LifeViz® Infinity system. QuantifiCare). The 3-D system captured eight 360° body images, which were joined to produce "life-like" 3-D body images. The camera software compared volume and contour changes over time. Using the volume map, the changes were highlighted with blue to represent volume reduction and red to represent volume increase. Efforts were made to ensure that the subjects' photographs were obtained at the same time of the day.

2.3 | Statistical analysis

For each subject, the difference in fat volume reduction was computed by subtracting the volume reduction readings on the placebo side from the TFB side. The means and standard deviations of differences at weeks 4, 8, and 12 were then computed. Parametric (paired *t* test) and nonparametric tests (signed-rank test) were used to determine whether the mean difference in abdominal volume at each follow-up visit was statistically significant to ensure that the data

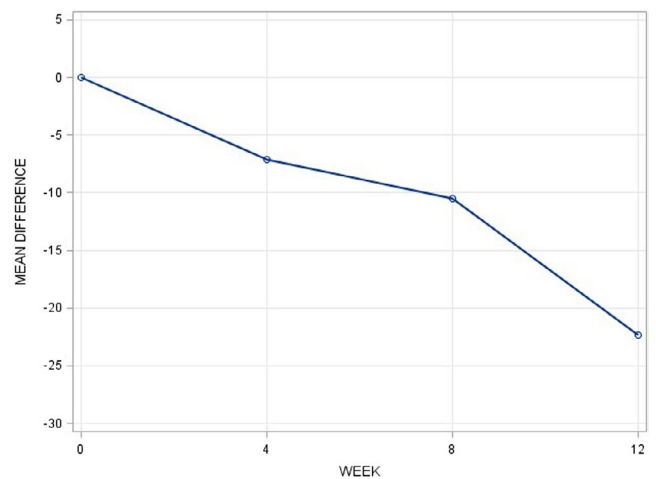
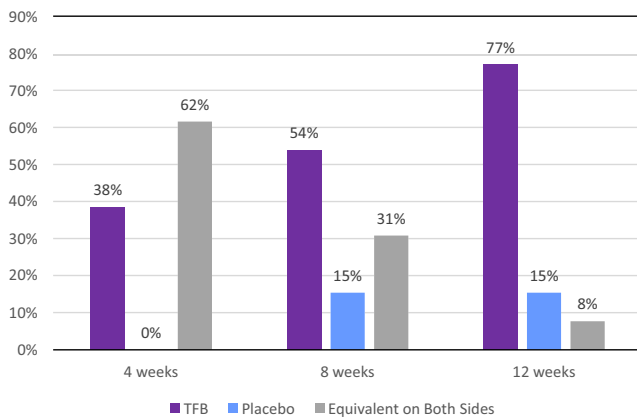


FIGURE 1 Change in abdominal fat volume. Treatment with TFB yielded greater reduction in fat volume than the bland moisturizer over time with varying magnitudes

TABLE 2 Three-dimensional volumetric assessment per subject

Subject	Treatment	Week 4	Week 8	Week 12
		TFB/placebo (mL)	TFB/placebo (mL)	TFB/placebo (mL)
1	Radiofrequency	-53/-20	-40/-4	-6/+14
2	Radiofrequency	-13/-13	-50/-12	-110/-64
3	Cryolipolysis	-5/-2	-76/-77	-84/-60
4	Cryolipolysis	-74/-59	-62/-60	-62/-37
5	Cryolipolysis	-48/-52	-14/-21	-42/-52
6	Cryolipolysis	-14/-11	+4/+16	-4/+19
7	Cryolipolysis	+4/+4	-25/-12	-8/+1
8	Cryolipolysis	No change	No change	No change
9	Cryolipolysis	No change	No change	No change
10	Cryolipolysis	-12/-13	-98/-68	-58/-34
11	Cryolipolysis	-19/-16	-12/-23	-37/-40
12	Cryolipolysis	+43/+42	-26/-29	-162/-112
13	Cryolipolysis	-12/-12	-29/-29	+49/+27
14	Cryolipolysis	-64/-27	-31/-3	-43/+6
15	Cryolipolysis	-24/-7	-30/-9	-153/-76
Total volume loss		-291/-186	-489/-331	-720/-408

**FIGURE 2** Percentage of subjects with a greater volume loss on the TransFORM body treatment side compared with placebo side. Subjects with volumes within 10% of each other are considered equivalent

analysis was robust, regardless of which statistical methods were used.

3 | RESULTS

Fifteen female subjects, Fitzpatrick Skin Types I-V, were enrolled and treated with radiofrequency ($n = 2$) and cryolipolysis ($n = 13$). All subjects completed the study and remained within 5% of their baseline weight. Two subjects were excluded from analysis due to them not losing volume on either side of the treatment area throughout the course of the study (nonresponders to devices).

Treatment with TFB reduced the mean fat volume by 8.1 (SD 13.4) mL, 12.2 (SD 16.9) mL, and 24.0 (SD 27.1) mL more than that

with placebo at weeks 4, 8, and 12, respectively. These reductions in fat volume of the treatment side were significant at weeks 8 and 12 (for each, $P < .05$). The data are summarized in Table 1.

Figure 1 shows that treatment with TFB resulted in continuous reduction in fat volume over time. Subjects' volume loss compared with baseline for each visit/timepoint is listed in Table 2. Using this table, Figure 2 displays the percentage of subjects with greater volume loss on either the TFB or the placebo side. Volumes within 10% of each other were noted as equivalent on both sides. 38% of subjects had a greater volume loss on the TFB side at week 4, 54% at week 8 and 77% at week 12.

Digital images representing several study subjects are shown in Figures 3-5.

4 | DISCUSSION

Topical TFB resulted in increased volume loss, which was greater for the treatment side than that for placebo at weeks 4 (38%), 8 (54%), and 12 (77%), respectively, and statistically significant at weeks 8 ($P = .0238$) and 12 ($P = .0078$). There were no reported adverse events.

Nonsurgical fat reduction procedures using various devices continue to gain popularity as new technology emerges. The therapeutic basis for these devices is causing damage to fat cells, which are then gradually eliminated through apoptosis and lipid droplet dissolution.² Owing to the size of these lipid droplets, it is difficult for macrophages to digest and clear them from the body; however, lipid droplets are eventually removed by the process of autophagy.²

The topical TFB product was developed using active peptides that stimulate autophagy. Liposomal coating of the peptides

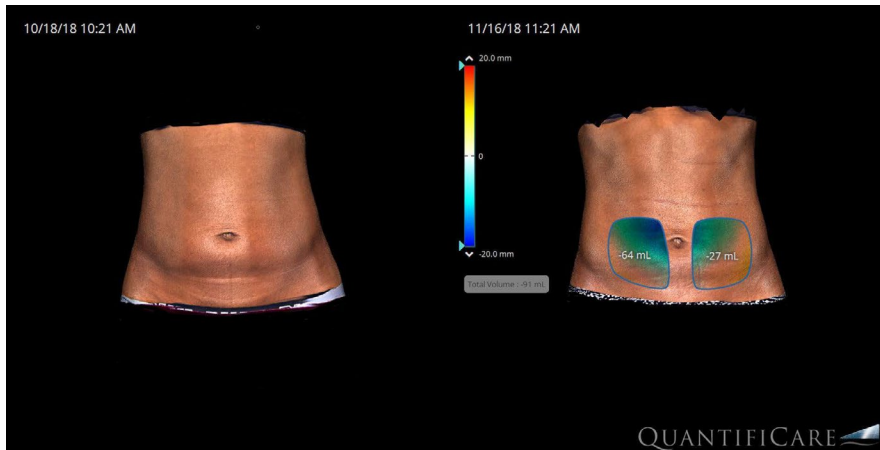


FIGURE 3 One month post cryolipolysis of the lower abdomen: Accelerated volume reduction on the TransFORM body treatment with TriHex Technology® side (Subjects' Right Side)

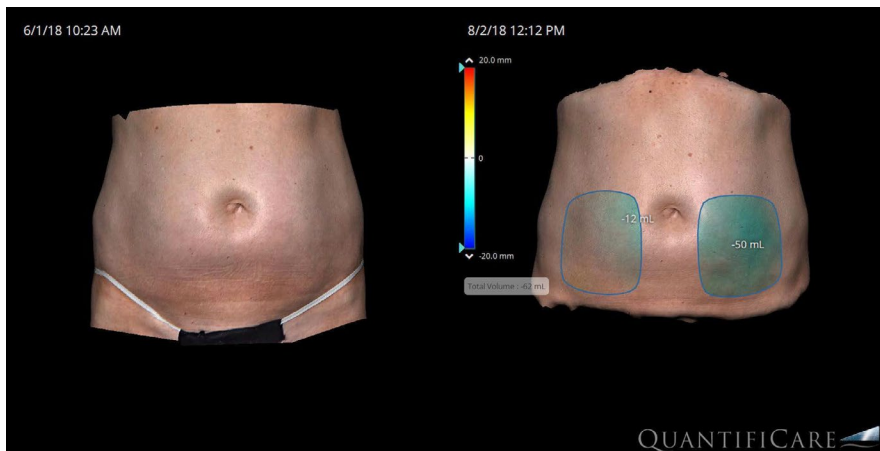


FIGURE 4 Two months post radiofrequency of the abdomen: Accelerated volume reduction on the TransFORM body treatment with TriHex Technology® side (Subjects' Left Side)

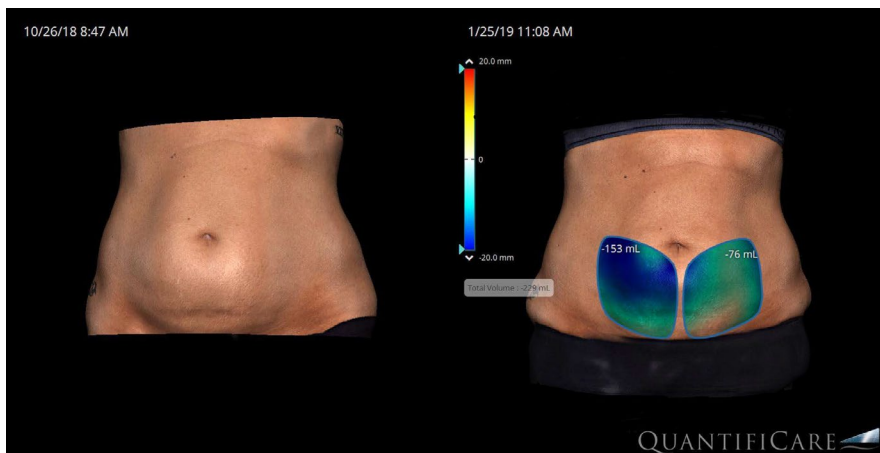


FIGURE 5 Three months post cryolipolysis of the lower abdomen: Accelerated volume reduction on the TransFORM body treatment with TriHex Technology® side (Subjects' Right Side)

ensures easy entry to the target area *via* hair follicles where they enter the dermal white adipose tissue *en route* to the subcutaneous fat.² The autophagy process facilitates the autodigestion of the extruded lipid droplets by “repackaging” the large lipid fragments into smaller digestible units that attract macrophages and encourage phagocytosis.² Furthermore, other peptides in the formulation stimulate elastin and collagen neogenesis, thus improving skin tone.

In a similar pilot study, this topical TFB product was assessed using a split arm design (TFB versus bland moisturizer) following

cryolipolysis on the arms. The results showed significant improvements in contour and laxity on the TFB-treated arms after 8 weeks with continuing improvements through week 24.⁴ The current study demonstrated that similar results could be obtained when topical TFB was added to noninvasive abdominal fat reduction procedures. While the decrease in fat volume was significant after 8 and 12 weeks, additional decreases may occur with longer use.

In conclusion, nonsurgical fat reduction is a popular procedure for a variety of body areas, including abdominal contouring. The

results of this study and those of a previous pilot study showed a significant improvement in adipose volume loss when topical TFB is added to the regimen.

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ORCID

Michaela Bell  <https://orcid.org/0000-0003-4662-7274>

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