

Thermage + Liposuction = Tighter Abdominal Skin

Comparison of Abdominal Area Reductions

Postop	Liposuction + Thermage	Liposuction Only	Thermage Only
4 weeks	3%	3%	2%
8 weeks	8%	5%	4%
12 weeks	10%	6%	6%
16 weeks	14%	7%	8%
28 weeks	18%	10%	10%

Source: Dr. Avram

BY DOUG BRUNK
San Diego Bureau

LAS VEGAS — Combining liposuction with Thermage—a radiofrequency energy system that heats the skin to produce collagen tightening and shortening—led to clinically significant tightening of abdominal skin at 28 weeks, compared with either treatment alone, results from a small study suggest.

Combining the two procedures “can be particularly useful in patients with loose skin or striae prior to liposuction,” David Avram, M.D., said at the 13th In-

ternational Symposium on Cosmetic Laser Surgery. “This can be a way of enhancing our results in those patients. However, this was a small study. We obviously need to perform more studies with more patients.”

For the study, Dr. Avram and his associates treated 14 patients with standard tumescent liposuction plus Thermage (group 1), four patients with liposuction only (group 2), and two patients with Thermage only (group 3).

After liposuction, patients in group 1 had four tattoo markers placed in a rectangular pattern in areas of loose abdominal skin. The area was calculated and recorded prior to treatment with Thermage, said Dr. Avram, a cosmetic dermatologist who practices in New York City.

Patients were treated three times with Thermage at 4-week intervals (4, 8, and 12 weeks postoperatively). The treatments were done in a single pass using the ThermoCool TC System. Energy levels ranged from 13.5 J/sec to 15.0 J/sec at each visit. Patients were asked to return for follow-up visits at 1 month and at 4 months after the last Thermage treatment. Two independent observers recorded the size of the treated area at each follow-up visit.

“We’ve heard a lot of subjective data about Thermage,” Dr. Avram commented. “I think what’s nice here is that we really went for objective data with tattoo markers to see if there would be any [skin] tightening.”

Patients in group 2 had tattoo markers placed in the abdominal area 4 weeks after liposuction. Investigators recorded the area of tattoo markers during postoperative follow-up visits at 8, 12, 16, and 28 weeks.

Patients in group 3 had tattoo markers placed in the abdominal area on the initial visit and then underwent the same Thermage treatment and follow-up regimen as patients in group 1.

At 4 weeks, there were no differences in skin tightening among patients in the three groups. (See box.) However, by 28 weeks, patients in group 1 achieved 18% skin tightening while patients in groups 2 and 3 achieved only 10% skin tightening.

The 10% tightening seen in the group 2 patients “is probably from the trauma that’s caused from liposuction,” Dr. Avram said. So Thermage is as effective in tightening skin as is liposuction only. “When you combine the treatment modalities, you are able to have skin tightening up to 18%.”

Dr. Avram noted that patients treated with Thermage had “moderate discomfort” during treatment, but no long-term adverse events were observed. Lidocaine topical anesthetic cream was applied 1 hour before treatment, and no oral pain medicines were given.

One patient had four superficial blisters after treatment, “but they healed without a scar,” he said.

He added that he is using combined liposuction and Thermage to treat fat on the arms and noted that some clinicians are applying it to breast reduction.

The current Food and Drug Administration-approved indications for the ThermoCool TC System are for noninvasive treatment of wrinkles in the periorbital area as well as full-face treatment. ■



BRIEF SUMMARY

For Dermatologic Use Only—Not for Ophthalmic, Oral, or Intravaginal Use
Rx only

CONTRAINDICATIONS

FINACEA® Gel, 15%, is contraindicated in individuals with a history of hypersensitivity to propylene glycol or any other component of the formulation.

WARNINGS

FINACEA® Gel, 15%, is for dermatologic use only, and not for ophthalmic, oral, or intravaginal use. There have been isolated reports of hypopigmentation after use of azelaic acid. Since azelaic acid has not been well studied in patients with dark complexion, these patients should be monitored for early signs of hypopigmentation.

PRECAUTIONS

General: Contact with the eyes should be avoided. If sensitivity or severe irritation develops with the use of FINACEA® Gel, 15%, treatment should be discontinued and appropriate therapy instituted. The safety and efficacy of FINACEA® Gel, 15%, has not been studied beyond 12 weeks.

Information for Patients: Patients using FINACEA® Gel, 15%, should receive the following information and instructions:

- FINACEA® Gel, 15%, is to be used only as directed by the physician.
- FINACEA® Gel, 15%, is for external use only. It is not to be used orally, intravaginally, or for the eyes.
- Cleanse affected area(s) with a very mild soap or a soapless cleansing lotion and pat dry with a soft towel before applying FINACEA® Gel, 15%. Avoid alcoholic cleansers, tinctures, and astringents, abrasives, and peeling agents.
- Avoid contact of FINACEA® Gel, 15%, with the mouth, eyes and other mucous membranes. If it does come in contact with the eyes, wash the eyes with large amounts of water and consult a physician if eye irritation persists.
- The hands should be washed following application of FINACEA® Gel, 15%.
- Cosmetics may be applied after FINACEA® Gel, 15%, has dried.
- Skin irritation (e.g., pruritus, burning, or stinging) may occur during use of FINACEA® Gel, 15%, usually during the first few weeks of treatment. If irritation is excessive or persists, use of FINACEA® Gel, 15%, should be discontinued, and patients should consult their physician (See ADVERSE REACTIONS).
- Avoid any foods and beverages that might provoke erythema, flushing, and blushing (including spicy food, alcoholic beverages, and thermally hot drinks, including hot coffee and tea).
- Patients should report abnormal changes in skin color to their physician.
- Avoid the use of occlusive dressings or wrappings.

Drug Interactions: There have been no formal studies of the interaction of FINACEA® Gel, 15%, with other drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential of FINACEA® Gel, 15%. Azelaic acid was not mutagenic or clastogenic in a battery of *in vitro* (Ames assay, HGPRT in V79 cells [Chinese hamster lung cells], and chromosomal aberration assay in human lymphocytes) and *in vivo* (dominant lethal assay in mice and mouse micronucleus assay) genotoxicity tests.

Oral administration of azelaic acid at dose levels up to 2500 mg/kg/day (162 times the maximum recommended human dose based on body surface area) did not affect fertility or reproductive performance in male or female rats.

Pregnancy: Teratogenic Effects: Pregnancy Category B

There are no adequate and well-controlled studies of topically administered azelaic acid in pregnant women. The experience with FINACEA® Gel, 15%, when used by pregnant women is too limited to permit assessment of the safety of its use during pregnancy.

Dermal embryofetal developmental toxicology studies have not been performed with azelaic acid, 15%, gel. Oral embryofetal developmental studies were conducted with azelaic acid in rats, rabbits, and cynomolgus monkeys. Azelaic acid was administered during the period of organogenesis in all three animal species. Embryotoxicity was observed in rats, rabbits, and monkeys at oral doses of azelaic acid that generated some maternal toxicity. Embryotoxicity was observed in rats given 2500 mg/kg/day (162 times the maximum recommended human dose based on body surface area), rabbits given 150 or 500 mg/kg/day (19 or 65 times the maximum recommended human dose based on body surface area) and cynomolgus monkeys given 500 mg/kg/day (65 times the maximum recommended human dose based on body surface area) azelaic acid. No teratogenic effects were observed in the oral embryofetal developmental studies conducted in rats, rabbits, and cynomolgus monkeys.

An oral peri- and postnatal developmental study was conducted in rats. Azelaic acid was administered from gestational day 15 through day 21 postpartum up to a dose level of 2500 mg/kg/day. Embryotoxicity was observed in rats at an oral dose that generated some maternal toxicity (2500 mg/kg/day; 162 times the maximum recommended human dose based on body surface area). In addition, slight disturbances in the postnatal development of fetuses was noted in rats at oral doses that generated some maternal toxicity (500 and 2500 mg/kg/day; 32 and 162 times the maximum recommended human dose based on body surface area). No effects on sexual maturation of the fetuses were noted in this study. Because animal reproduction studies are not always predictive of human response, this drug should be used only if clearly needed during pregnancy.

Nursing Mothers:

Equilibrium dialysis was used to assess human milk partitioning *in vitro*. At an azelaic acid concentration of 25 µg/mL, the milk/plasma distribution coefficient was 0.7 and the milk/buffer distribution was 1.0, indicating that passage of drug into maternal milk may occur. Since less than 4% of a topically applied dose of AZELEX® Cream, 20%, is systemically absorbed, the uptake of azelaic acid into maternal milk is not expected to cause a significant change from baseline azelaic acid levels in the milk. However, caution should be exercised when FINACEA® Gel, 15%, is administered to a nursing mother.

Pediatric Use: Safety and effectiveness of FINACEA® Gel, 15%, in pediatric patients have not been established.

Geriatric: Clinical studies of FINACEA® Gel, 15%, did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

ADVERSE REACTIONS

In the 2 vehicle controlled, identically designed U.S. clinical studies, treatment safety was monitored in 664 patients who used FINACEA® Gel, 15%, (N=333), or the gel vehicle (N=331), twice daily for 12 weeks.

Table 3. Cutaneous Adverse Events Occurring in ≥1% of Subjects in the Rosacea Trials by Treatment Group and Maximum Intensity*

	FINACEA® Gel, 15% N=333 (100%)			Vehicle N=331 (100%)		
	Mild n=86 (26%)	Moderate n=44 (13%)	Severe n=20 (6%)	Mild n=49 (15%)	Moderate n=27 (8%)	Severe n=5 (2%)
Burning/ stinging/ tingling	66 (20%)	30 (9%)	12 (4%)	8 (2%)	6 (2%)	2 (1%)
Pruritus	24 (7%)	14 (4%)	3 (1%)	9 (3%)	6 (2%)	0 (0%)
Scaling/dry skin/xerosis	21 (6%)	8 (2%)	4 (1%)	33 (10%)	12 (4%)	1 (0%)
Erythema/ irritation	6 (2%)	6 (2%)	1 (0%)	8 (2%)	4 (1%)	2 (1%)
Edema	3 (1%)	2 (1%)	0 (0%)	3 (1%)	0 (0%)	0 (0%)
Contact dermatitis	2 (1%)	2 (1%)	0 (0%)	1 (0%)	0 (0%)	0 (0%)
Acne	2 (1%)	1 (0%)	0 (0%)	1 (0%)	0 (0%)	0 (0%)
Seborrhea	2 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Photo- sensitivity	1 (0%)	0 (0%)	0 (0%)	3 (1%)	1 (0%)	1 (0%)
Skin disease	1 (0%)	0 (0%)	0 (0%)	1 (0%)	2 (1%)	0 (0%)

*Subjects may have >1 cutaneous adverse event; thus, the sum of the frequencies of preferred terms may exceed the number of subjects with at least 1 cutaneous adverse event.

FINACEA® Gel, 15%, and its vehicle caused irritant reactions at the application site in human dermal safety studies. FINACEA® Gel, 15%, caused significantly more irritation than its vehicle in a cumulative irritation study. Some improvement in irritation was demonstrated over the course of the clinical studies, but this improvement might be attributed to subject dropouts. No phototoxicity or photoallergenicity were reported in human dermal safety studies.

In patients using azelaic acid formulations, the following additional adverse experiences have been reported rarely: worsening of asthma, vitiligo depigmentation, small depigmented spots, hypertrichosis, reddening (signs of keratosis pilaris), and exacerbation of recurrent herpes labialis.

OVERDOSAGE

FINACEA® Gel, 15%, is intended for cutaneous use only. If pronounced local irritation occurs, patients should be directed to discontinue use and appropriate therapy should be instituted (See PRECAUTIONS).

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