Short Stretch Bandages Yield Long-Term Benefits

BY HEIDI SPLETE Senior Writer

OTTAWA — The smart compression technique using short stretch bandages facilitates healing by extruding edema and lymphedema from a wound, Dr. John MacDonald said at the annual conference of the Canadian Association of Wound Care.

"Lymphedema is a major impediment to wound healing," said Dr. MacDonald,

a retired cardiovascular surgeon who is now with the department of dermatology and cutaneous surgery at the University of Miami.

"If you have a bandage that moves as the muscles move, nothing happens," Dr. MacDonald explained. "But if you have a bandage that gives resistance to the motion of the muscle, there is pressure on the tissue that stimulates pressure on the lymphatic fluid and pushes it out of the limb."

"Every chronic wound has a lymphatic

pathology," he explained. The lymphatic system accounts for 10%-15% of cardiac output, so be sure to consider what could be wrong with the lymphatic system in any chronic wound.

Lymphatic vessels are easily injured, and they can't move fluid to and from a chronic wound without help; but if the external pressure from a compression bandage is high enough, the lymphatic capillaries start to fill with fluid and the fluid moves away from the wound and back toward the



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® GeI, 15%, is to be used only as directed by the physician.
 FINACEA® GeI, 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® GeI, 15%. Avoid alcoholic cleansers, tinctures, and astringents, abrasives, and peeling agents. Avoid contact of FINACEA® GeI, 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 presists.
 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 Protection any roots and beverages and thermally hot drinks, including that busing (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%, the studies of th

with other drugs.

Carcinogenesis. Mutagenesis. Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential of FINACEA® GeI, 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 organogeneisis 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 Find on perform gestational developmental study was conducted in rats. Azerat acid was adminis-tered 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 mataution of the fetuses were noted in this study. Because animal reproductions 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 μ g/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 azelaic acid cream, 20%, is systemically absorbed. the uptake of azelaic acid into maternal milk is not expected to cause a significant change from baseline aclaic 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

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

Overall, treatment related adverse events, including burning, stinging/tingling, dryness/tightness/ scaling, itching, and erythema/irritation/redness, were 19.4% (24/124) for FINACEA® Gel, 15%, and 7.1% (9/127) for the active comparator gel at 15 weeks.

In two vehicle controlled, and one active controlled U.S. clinical studies, treatment safety was monitored in 788 patients who used twice daily FINACEA® Gel, 15%, for 12 weeks (N=333) or for 15 weeks (N=124), or the gel vehicle (N=331) for 12 weeks.

Table 3. Cutaneous Adverse Events Occurring in ${\geq}1\%$ of Subjects in the Rosacea Trials by Treatment Group and Maximum Intensity*

	FINACEA® Gel, 15% N=457 (100%)			Vehicle N=331 (100%)		
	Mild n=99 (22%)	Moderate n=61 (13%)	Severe n=27 (6%)	Mild n=46 (14%)	Moderate n=30 (9%)	Severe n=5 (2%)
Burning/ stinging/ tingling	71 (16%)	42 (9%)	17 (4%)	8 (2%)	6 (2%)	2 (1%)
Pruritus	29 (6%)	18 (4%)	5 (1%)	9 (3%)	6 (2%)	0 (0%)
Scaling/dry skin/xerosis	21 (5%)	10 (2%)	5 (1%)	31 (9%)	14 (4%)	1 (<1%)
Erythema/ irritation	6 (1%)	7 (2%)	2 (<1%)	8 (2%)	4 (1%)	2 (1%)
Contact dermatitis	2 (<1%)	3 (1%)	0 (0%)	1 (<1%)	0 (0%)	0 (0%)
Edema	3 (1%)	2 (<1%)	0 (0%)	3 (1%)	0 (0%)	0 (0%)
Acne	3 (1%)	1 (<1%)	0 (0%)	1 (<1%)	0 (0%)	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. Post-marketing safety-Skin: facial burning and irritation; Eyes: iridocyclitis on accidental exposure with FINACEA® Gel, 15%, to the eye (see **PRECAUTIONS**).

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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heart. "It is external pressure from the compression bandage that is moving this fluid," Dr. MacDonald said. The steady, constant pressure (5-10 mm Hg) on the delicate lymphatic vessels can propel the fluid back into the cardiovascular system.

Smart compression takes into account both resting pressure and working pressure on the affected area. Resting pressure is the pressure applied by a bandage to a body part, such as a leg, when that part is at rest. Working pressure develops when the muscles contract and push against the compressing bandage; there is a dynamic pulsation between the muscles and the bandage. Working pressure develops

Adding smart compression to wound care is 'like sending your patient home with their own massage therapist 24 hours a day.'

internally and has a positive effect on the deeper muscles when the bandage restrains muscle expansion, he said.

Smart compression is uniform, not like squeezing а tube of toothpaste, and short stretch ban-

dages are the best way to achieve it.

The short bandage creates a lower resting pressure and a higher working pressure, which is the safest treatment option for a compromised limb, Dr. MacDonald noted. External compression is extremely important in controlling edema and lymphedema because it promotes fluid absorption, which is critical to the healing of any chronic wound.

To treat a patient with smart compression, Dr. MacDonald recommends using inelastic short stretch bandages that are left on 24 hours a day, 7 days a week. Although the bandages on the wound itself are to be changed regularly, the patient doesn't get a break from the compression for more than the time needed to change the dressing. The steady, constant compression helps Continued on following page



This wound in patient with grade three lymphedema is shown before treatment.



The patient is shown approximately 21/2 months after treatment.

Continued from previous page

move the lymphatic fluid out of the swollen, wounded area.

Padding is needed underneath the bandage to fill in crevices and to equalize pressure over the area to be treated, he added.

Adding smart compression does not detract from the principles of basic wound care. "It was the missing link," Dr. Mac-Donald said. Healing is restricted when debris in a wound can't drain via the lymphatic system. Smart compression is "like sending your patient home with their own massage therapist 24 hours a day," he said. Smart compression with short stretch

bandages also can be used to treat lymphedema in patients with metastatic lesions, as well as wounds in obese patients or patients with cellulitis or diabetes.

There has never been a study to show that using compression will shorten the life of someone with metastatic disease," said Dr. MacDonald.

Smart compression should be used to treat lymphedema in obese patients with wounds below the knee, which is the site of most wounds in these patients. "You can't do anything about their weight, but if you use continuous sustained compression, you will stop that drainage and heal the wounds," he explained.

Proven efficacy

– **VERBATIM** —

'I don't believe in the "Jiffy-Lube" approach to PDT. You don't bring the patient in, put on the ALA [for 10 minutes], treat them, and send them out the door. It just doesn't work.'

> Dr. E. Victor Ross, on why he prefers topical therapy as first-line treatment for acne, p. 64.

> > Fungal cell

Liposuction Is Effective for Some **Breast Reduction**

LAS VEGAS — Liposuction can be an effective alternative to breast reduction surgery in select patients, according to a presentation at an international symposium on cosmetic and laser surgery.

Traditional breast reduction can require significant postoperative recovery and cause unnatural-looking breast lift, Dr. Cameron Rokhsar said. In addition, many patients are left with an inverted T scar. In contrast, liposuction with local anesthesia does not lift the breast and often leaves only small scars, said Dr. Rokhsar, a dermatologist in private practice in New York City.

Liposuction is a common cosmetic procedure in the United States. "The procedure has evolved from one under general anesthesia with massive blood loss to an outpatient procedure with minimal blood loss," Dr. Rokhsar said.

The fat removal technique became "extremely safe" with the advent of the tumescent technique, he added. For example, a survey of 66 physician members of the American Society of Dermatologic Surgery found that there were no deaths among 15,336 patients they treated with tumescent liposuction (Dermatol. Surg. 1995;21:459-62).

After baseline mammography, Dr. Rokhsar measures breast size through water displacement and makes radial markings. Cannulas are introduced through two tiny holes to remove the fat from the breast. The process can suction up to 50%-70% of breast fat. In an unpublished study of 30 of Dr. Rokhsar's patients, this procedure reduced breast size by an average of one cup size. A follow-up mammography is performed at 6 months as a new baseline reference.

The patient can sit up afterward—it is a very simple procedure," said Dr. Rokhsar, who is also on the dermatology faculty at Albert Einstein College of Medicine in New York.

Liposuction is contraindicated for a breast composed primarily of glandular tissue versus fat, Dr. Rokhsar said.

Patients with nipple ptosis, a family history of breast cancer, or patients looking for significant breast lift are generally not candidates for breast liposuction, he added. -Damian McNamara Crush. Kill. Destroy.

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In clinical trials, cutaneous adverse events occurred in 2% of patients receiving Ertaczo and in 2% of patients receiving vehicle. These reported adverse events included contact dermatitis, dry skin, burning skin, application site reaction, and skin tenderness.

Please see full prescribing information on the next page.

References: 1. Data on file, OrthoNeutrogena. 2. Ertaczo [prescribing information]. Los Angeles, Calif: OrthoNeutrogena; November 2005. Ertaczo is a registered trademark of OrthoNeutrogena. © 2006 OrthoNeutrogena 06DD0074 5/06 Printed in USA

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