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RF Energy Device Safely Benefits Skin

BY MITCHEL L. ZOLER
Philadelphia Bureau

GRAPEVINE, TEX. — Radio frequency energy treatment of the face and neck led to modest but discernible improvements in rhytids, skin laxity, and photoaging in a small series of patients, Dr. Macrene R. Alexiades-Armenakas said at the annual meeting of the American Society for Laser Medicine and Surgery.

The dual-mode radio frequency device she used was the Accent system made by Alma Lasers. Although the device was not approved by the Food and Drug Administration when Dr. Alexiades-Armenakas did the study, the unit received FDA marketing approval in late April for the treatment of rhytids and wrinkles (SKIN & ALLERGY NEWS, June 2007, p. 9). She disclosed no financial relationship with Alma.

The device produces both unipolar and bipolar radio frequency energy. In unipolar mode, the device creates an alternating electric field that heats tissue at a depth of 2-4 mm by rapidly changing the polarity of charged particles in the skin. The heat produces volumetric changes to a depth of up to 20 mm. In bipolar mode, the device creates an electromagnetic field that heats tissue by causing rapid movement of water molecules, which also produces volumetric changes to a depth of up to 20 mm.

The most discernible effects on facial and neck skin were achieved with a protocol that combined both modes, said Dr. Alexiades-Armenakas, a dermatologist in private practice in New York.

Treatment began with four sequential, 30-second unipolar passes over the skin at 100 J/cm² to produce a target tissue temperature of 40° C. They were quickly followed by a series of four bipolar passes of 30 seconds each at 70 J/cm² that were also designed to produce a target temperature of 40° C.

To help maintain the target temperature during treatment, all passes were completed on one side of the face before the other; the neck was done last. No topical anesthesia was used.

In several patients, this regimen produced an immediately discernible skin tightening, she said.

Dr. Alexiades-Armenakas reported results for the first 10 patients in this series after they received one to three treatments (average 1.3) given at monthly intervals. The impact of treatment was rated on a blinded basis by two experienced dermatologists. They judged that treatment produced an average improvement in overall appearance of about 10%.

Treatment was most effective for improving neck laxity, and was noteworthy for being painless and offering rapid treatment and recovery times, with no adverse effects or complications so far, she said.

The assessment of these patients was truly blinded. "I received a stack of photographs of patients, and I did not know

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BenzaClin® Topical Gel

(clindamycin - benzoyl peroxide gel)

Brief summary. Please see full prescribing information for complete product information.

Topical Gel: clindamycin (1%) as clindamycin phosphate, benzoyl peroxide (5%) For Dermatological Use Only - Not for Ophthalmic Use *Reconstitute Before Dispensing*

INDICATIONS AND USAGE

BenzaClin Topical Gel is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS

BenzaClin Topical Gel is contraindicated in those individuals who have shown hypersensitivity to any of its components or to lincomycin. It is also contraindicated in those having a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis.

WARNINGS

ORALLY AND PARENTERALLY ADMINISTERED CLINDAMYCIN HAS BEEN ASSOCIATED WITH SEVERE COLITIS WHICH MAY RESULT IN PATIENT DEATH. USE OF THE TOPICAL FORMULATION OF CLINDAMYCIN RESULTS IN ABSORPTION OF THE ANTIBIOTIC FROM THE SKIN SURFACE. DIARRHEA, BLOODY DIARRHEA, AND COLITIS (INCLUDING PSEUDOMEMBRANOUS COLITIS) HAVE BEEN REPORTED WITH THE USE OF TOPICAL AND SYSTEMIC CLINDAMYCIN. STUDIES INDICATE A TOXIN(S) PRODUCED BY CLOSTRIDIA IS ONE PRIMARY CAUSE OF ANTIBIOTIC-ASSOCIATED COLITIS. THE COLITIS IS USUALLY CHARACTERIZED BY SEVERE PERSISTENT DIARRHEA AND SEVERE ABDOMINAL CRAMPS AND MAY BE ASSOCIATED WITH THE PASSAGE OF BLOOD AND MUCUS. ENDOSCOPIC EXAMINATION MAY REVEAL PSEUDOMEMBRANOUS COLITIS. STOOL CULTURE FOR *Clostridium Difficile* AND STOOL ASSAY FOR *C. difficile* TOXIN MAY BE HELPFUL DIAGNOSTICALLY. WHEN SIGNIFICANT DIARRHEA OCCURS, THE DRUG SHOULD BE DISCONTINUED. LARGE BOWEL ENDOSCOPY SHOULD BE CONSIDERED TO ESTABLISH A DEFINITIVE DIAGNOSIS IN CASES OF SEVERE DIARRHEA. ANTIPERISTALTIC AGENTS SUCH AS OPIATES AND DIPHENOXYLATE WITH ATROPINE MAY PROLONG AND/OR WORSEN THE CONDITION. DIARRHEA, COLITIS, AND PSEUDOMEMBRANOUS COLITIS HAVE BEEN OBSERVED TO BEGIN UP TO SEVERAL WEEKS FOLLOWING CESSATION OF ORAL AND PARENTERAL THERAPY WITH CLINDAMYCIN.

Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *C. difficile* colitis.

PRECAUTIONS

General: For dermatological use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents.

The use of antibiotic agents may be associated with the overgrowth of nonsusceptible organisms including fungi. If this occurs, discontinue use of this medication and take appropriate measures.

Avoid contact with eyes and mucous membranes.

Clindamycin and erythromycin containing products should not be used in combination. *In vitro* studies have shown antagonism between these two antimicrobials. The clinical significance of this *in vitro* antagonism is not known.

Information for Patients: Patients using **BenzaClin Topical Gel** should receive the following information and instructions:

- BenzaClin Topical Gel** is to be used as directed by the physician. It is for external use only. Avoid contact with eyes, and inside the nose, mouth, and all mucous membranes, as this product may be irritating.
- This medication should not be used for any disorder other than that for which it was prescribed.
- Patients should not use any other topical acne preparation unless otherwise directed by physician.
- Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using **BenzaClin Topical Gel**. To minimize exposure to sunlight, a wide-brimmed hat or other protective clothing should be worn, and a sunscreen with SPF 15 rating or higher should be used.
- Patients should report any signs of local adverse reactions to their physician.
- BenzaClin Topical Gel** may bleach hair or colored fabric.
- BenzaClin Topical Gel** can be stored at room temperature up to 25°C (77°F) for 3 months. Do not freeze. Discard any unused product after 3 months.
- Before applying **BenzaClin Topical Gel** to affected areas wash the skin gently, then rinse with warm water and pat dry.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. The clinical significance of this is unknown.

Benzoyl peroxide in acetone at doses of 5 and 10 mg administered twice per week induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment.

In a 52 week dermal photocarcinogenicity study in hairless mice, the median time to onset of skin tumor formation was decreased and the number of tumors per mouse increased following chronic concurrent topical administration of **BenzaClin Topical Gel** with exposure to ultraviolet radiation (40 weeks of treatment followed by 12 weeks of observation).

Genotoxicity studies were not conducted with **BenzaClin Topical Gel**. Clindamycin phosphate was not genotoxic in *Salmonella typhimurium* or in a rat micronucleus test. Clindamycin phosphate sulfoxide, an oxidative degradation product of clindamycin phosphate and benzoyl peroxide, was not clastogenic in a mouse micronucleus test. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *S. typhimurium* tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells. Studies have not been performed with **BenzaClin Topical Gel** or benzoyl peroxide to evaluate the effect on fertility. Fertility studies in rats treated orally with up to 300 mg/kg/day of clindamycin (approximately 120 times the amount of clindamycin in the highest recommended adult human dose of 2.5 g **BenzaClin Topical Gel**, based on mg/m²) revealed no effects on fertility or mating ability.

Pregnancy: Teratogenic Effects: Pregnancy Category C:

Animal reproductive/developmental toxicity studies have not been conducted with **BenzaClin Topical Gel** or benzoyl peroxide. Developmental toxicity studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (240 and 120 times amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (100 and 50 times the amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) revealed no evidence of teratogenicity.

There are no well-controlled trials in pregnant women treated with **BenzaClin Topical Gel**. It also is not known whether **BenzaClin Topical Gel** can cause fetal harm when administered to a pregnant woman.

Nursing Women: It is not known whether **BenzaClin Topical Gel** is excreted in human milk after topical application. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of this product in pediatric patients below the age of 12 have not been established.

ADVERSE REACTIONS

During clinical trials, the most frequently reported adverse event in the **BenzaClin** treatment group was dry skin (12%). The Table below lists local adverse events reported by at least 1% of patients in the **BenzaClin** and vehicle groups.

Local Adverse Events - all causalities in >= 1% of patients		
	BenzaClin n = 420	Vehicle n = 168
Application site reaction	13 (3%)	1 (<1%)
Dry skin	50 (12%)	10 (6%)
Pruritus	8 (2%)	1 (<1%)
Peeling	9 (2%)	-
Erythema	6 (1%)	1 (<1%)
Sunburn	5 (1%)	-

The actual incidence of dry skin might have been greater were it not for the use of a moisturizer in these studies.

DOSAGE AND ADMINISTRATION

BenzaClin Topical Gel should be applied twice daily, morning and evening, or as directed by a physician, to affected areas after the skin is gently washed, rinsed with warm water and patted dry.

HOW SUPPLIED AND COMPOUNDING INSTRUCTIONS

Size (Net Weight)	NDC 0066-	Benzoyl Peroxide Gel	Active Clindamycin Powder (In plastic vial)	Purified Water To Be Added to each vial
25 grams	0494-25	19.7g	0.3g	5 mL
50 grams	0494-50	41.4g	0.6 g	10 mL
50 grams (pump)	0494-55	41.4g	0.6 g	10 mL

Prior to dispensing, tap the vial until powder flows freely. Add indicated amount of purified water to the vial (to the mark) and immediately shake to completely dissolve clindamycin. If needed, add additional purified water to bring level up to the mark. Add the solution in the vial to the gel and stir until homogenous in appearance (1 to 1½ minutes). For the 50 gram pump only, reassemble jar with pump dispenser. **BenzaClin Topical Gel** (as reconstituted) can be stored at room temperature up to 25°C (77°F) for 3 months. Place a 3 month expiration date on the label immediately following mixing.

Store at room temperature up to 25°C (77°F) (See USP).

Do not freeze. Keep tightly closed. Keep out of the reach of children.

US Patents 5,446,028; 5,767,098; 6,013,637

Brief Summary of Prescribing Information as of February 2006.

Rx Only

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New Laser May Make One-Pass Treatment Possible

BY DAMIAN McNAMARA
Miami Bureau

PALM BEACH, FLA. — A new laser with a unique wavelength holds promise for skin rejuvenation and offers advantages over fractional resurfacing, Dr. David J. Goldberg reported at the annual meeting of the Florida Society of Dermatology and Dermatologic Surgery.

The Pearl 2790-nm yttrium-scandium-gallium-garnet laser (Cutera Inc.) "is different from a fractional device. The laser treats the whole epidermis, so you don't need multiple treatments," said Dr. Goldberg, director of laser research and Mohs surgery at Mount Sinai School of Medicine, New York.

Dermatologists will be able to target uneven skin texture and improve fine lines and photodamage with the new laser, and treatment of mild acne scarring is another potential indication, said Dr. Goldberg, who is a researcher for Cutera.

"It's brand new. I am going to guess no one here has this laser yet," he said at the meeting. The company plans to launch the laser in select cities this summer.

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what the treatment was or what the outcome was supposed to be. I looked at each picture and rated the appearance from 0 to 4 with 0.5-point increments," said Dr. Jeffrey S. Dover, a dermatologist in private practice in Chestnut Hill, Mass., who was one of the two dermatologists who rated the outcomes.

Although the 47 patients in the study were followed for 1 year after treatment, Dr. Alexiades-Armenakas had not fully tabulated all of the results at the time of her meeting presentation. She stressed that the treatment regimen for this device is still being optimized.

Her preliminary results from the combined treatment protocol showed progress beyond the results she had obtained in an earlier study that used either unipolar or bipolar energy. In that series, 10 patients were treated in a split-face fashion, with the unipolar device used on one side and the bipolar device on the other.

The unipolar treatment involved one or two passes of 20 seconds each at 100 J/cm² to produce a target temperature of 40° C, followed by three additional passes that delivered energy at steadily decreasing levels to maintain the tissue temperature at 40°. On the opposite side of the face, patients received bipolar energy at 70 J/cm² for one or two 20-second passes to produce a target temperature of 40°, followed by three additional passes with steadily decreasing energy levels. All patients received four treatments at weekly intervals.

Those treatments were also painless and rapid, and caused no adverse effects aside from mild and transient erythema. Blinded assessment of the patients showed an average improvement of about 5% with unipolar energy and about 6% with bipolar energy, Dr. Alexiades-Armenakas said. ■

The Pearl 2790-nm laser is indicated for skin types I to III, "with use for skin type IV as a goal," he noted. Fast treatment time is another feature. A full-face treatment takes approximately 30 minutes.

Longer downtime is a tradeoff, however, compared with fractional resurfacing. Patients "are in pain for a while, no question about it. But the results are great," Dr. Goldberg said. "Now more and more people will accept a little downtime if they get a better cosmetic outcome."

In general, flaking begins 2 days after treatment. Peeling starts on day 3 with skin reepithelialization; some erythema will still be seen on day 4. Most patients are ready to return to work and daily activities by this time.

"It is a pretty simple procedure. One pass is required," he said. Apply topical anesthesia for 30-45 minutes beforehand to minimize pain during the procedure.

The energy ranges from about 1 J/cm² to 3 J/cm². Most people use the 2.3 J/cm²

setting. There is some flexibility—adjusting the fluence changes the extent of epithelial damage, Dr. Goldberg said.

The user interface is simple and the 9-ounce hand piece is very lightweight, he said. Also, there are no disposables with this system.

The 2790-nm wavelength is near, but not at, the peak of water absorption in the skin. This allows for a small amount of beneficial thermal effect and controlled ablation of the skin, he explained. ■

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