

Conservatism Aids CO₂ Laser Success in Dark Skin

BY SHARON WORCESTER
Southeast Bureau

RHODES, GREECE — CO₂ lasers can be an effective and valuable tool in patients with darker skin types, Dr. Mukta Sachdev said at the 15th Congress of the European Academy of Dermatology and Venerology.

"A lot of the fears about treating darker skin are unfounded," she said, describing the favorable results she has achieved for numerous indications in her patients in southern India, who have predominantly Fitzpatrick skin types IV-VI.

The key to good outcomes is careful patient selection and good pre- and posttreatment care, said Dr. Sachdev of Manipal Hospital, Bangalore, India.

She has achieved success with CO₂ lasers for a number of indications, including verrucae, freckles, skin tags, epidermal nevi, traumatic tattoos, granuloma pyogenicum, rhinophyma, xanthelasma,

seborrheic keratosis, acne scars, and deep cystic acne, she said, noting that because of the photoprotection associated with her patients' darker pigmentation, their use for rhytides and resurfacing is minimal.

Selection of an appropriate and conservative parameter for the indication is important, as are test pulses and test spots to observe tissue response. Use adequate cooling, do not overtreating, and cover your

risks for ulcerations, infection, pigmentation, and scarring, she advised.

Postoperative care should include the use of hydrocolloid dressings for at least a month, regular and frequent use of a mild nonsoap cleanser, and

sunscreen. If pigmentation occurs, hydroquinone and kojic acid can be used, and the problem should resolve in 6-8 weeks.

Many dermatologists use hydroquinone and kojic acid prophylactically for at least 3 months to minimize the risk, she noted.

For some conditions, such as xanthelasma and lentigines, results are not permanent, lasting only about 12-18 months.

And for others—such as acne scarring, which is particularly challenging in darker skin types—the results are less impressive. With acne there is typically about a 40% improvement, but patients, if advised of these limitations in advance, are generally happy with the results.

Advantages of the CO₂ laser include its outpatient, routine, and relatively noninvasive nature. Downsides include the need for multiple passes, the risk of bleeding if treatment is too deep, and the potential for complications. Many complications can

be prevented by avoiding overlapping of laser spots or scans and by adhering to strict postoperative recovery regimens; when complications such as infection and pigmentary alterations do occur, most are treatable with a variety of topical and/or oral treatment, she said, stressing that proper training is a must. "Take time to master the art of resurfacing," she advised.

And take time when it comes to obtaining informed consent, she added, noting that "conversation is the heart and soul of obtaining informed consent." ■

Because of the photoprotection associated with patients' darker pigmentation, the use of CO₂ lasers for rhytides and resurfacing is minimal.

Antibiotic Prophylaxis Has Benefits, Risks in Ear Surgery

BY TIMOTHY F. KIRN
Sacramento Bureau

PALM DESERT, CALIF. — Is routine antibiotic prophylaxis necessary for patients who are having a surgical procedure on the ear?

Even though almost half of dermatologists surveyed have not adopted this practice, they probably should consider it, according to three experts who spoke at the annual meeting of the American Society for Dermatologic Surgery.

"We should use an antibiotic because we don't know how extensive the surgery is going to be, and we do need to potentially protect against infection and chondritis, which is not successfully done with topical antibiotics,"

said Dr. Murad Alam, chief of cutaneous and aesthetic surgery at Northwestern University, Chicago.

There are no controlled studies to inform the practice of whether to use antibiotics for ear procedures, nor are any likely to be done in the future, in part because the rate of infection is so low that the study would have to be prohibitively large, Dr. Alam said.

Given this lack of evidence, it's important to weigh the consequences of overusing antibiotics against the welfare of the patient, since an infection could be devastating. In that case, the welfare of the individual patient needs to come first, which often means prescribing an oral antibiotic.

Dr. Alam said he surveyed some dermatologic surgeons about their practice and found that about 60% said they used an antibiotic, mostly ciprofloxacin, to address the possibility of a *Pseudomonas* infection. The rest did not commonly prescribe an antibiotic. An informal poll taken of the audience members attending Dr. Alam's talk had similar results; about 45% said that they did not usually use an antibiotic.

One study did look at the records of 530 Mohs surgery patients and 517 excisional surgery patients to investigate their infection rates, though the study was retro-

spective and not controlled, said Dr. Donald J. Grande, a dermatologist who practices in Stoneham, Mass., who was involved in the study while at the Tufts–New England Medical Center, Boston.

The overall infection rate was 2%, but in ears the rate was greater, as 6 of 48 patients developed an infection for a rate of 12.5% (*Dermatol. Surg.* 1995;21:509-14).

The analysis of those cases indicated that larger defects had been created or more Mohs stages performed, which suggested, in part, that the procedures had taken longer, Dr. Grande said.

The 12.5% rate suggests that patients should receive an antibiotic afterward, particularly those patients with risky features like drainage and crusting of their lesions, a cardiac condition, a prosthesis,

or a history of immunosuppression or a resistant infection after a previous procedure, Dr. Grande said. He noted that caution also was necessary because of the rising incidence of methicillin-resistant *Staphylococcus aureus* infections.

He recommends ciprofloxacin, rather than a cephalosporin, because of its efficacy against gram-negative bacteria.

Also making a plea for antibiotic use was Dr. Perry Robins, the moderator of the meeting session at which Dr. Alam and Dr. Grande spoke.

"I do it because the nurses like it, the patients like it, I like it, and my lawyer likes it," said Dr. Robins, chief of the Mohs micrographic surgery unit at New York University Medical Center, New York.

Dr. Perry said he probably has treated 40,000 surgical cases, about 5% of which involved the ear. Only two of those cases developed a *Pseudomonas* infection, one of which occurred in a patient who did not fill his antibiotic prescription. But that is two cases too many.

"When you are doing an ear case, definitely do Cipro [ciprofloxacin] for your protection," he said. "You don't want to have a case of *Pseudomonas*. And I have found no allergies or difficulties with the patients taking the medication." ■

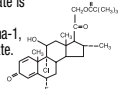
Rx Only Cloderm Cream, 0.1%

(clocortolone pivalate)
FOR TOPICAL DERMATOLOGIC USE ONLY—NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.
WARNING: KEEP OUT OF REACH OF CHILDREN

DESCRIPTION:

Cloderm Cream 0.1% contains the medium potency topical corticosteroid, clocortolone pivalate, in a specially formulated water-washable emollient cream base consisting of purified water, white petrolatum, mineral oil, stearyl alcohol, polyoxy 40 stearate, carbomer 934P, edetate disodium, sodium hydroxide, with methylparaben and propylparaben as preservatives.

Chemically, clocortolone pivalate is 9-chloro-6 α -fluoro-11 β , 21-dihydroxy-16 α , methylpregna-1, 4-diene-3, 20-dione 21-pivalate. Its structure is as follows:



CLINICAL PHARMACOLOGY:

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. (See **DOSE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE:

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS:

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS:

General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See **PRECAUTIONS—Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests: The following tests may be helpful in evaluating the HPA axis suppression:
Urinary free cortisol test
ACTH stimulation test

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy Category C: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation,

delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS:

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

- Burning
- Itching
- Irritation
- Dryness
- Folliculitis
- Hypertrichosis
- Acneiform eruptions
- Hyperpigmentation
- Perioral dermatitis
- Allergic contact dermatitis
- Maceration of the skin
- Secondary infection
- Skin atrophy
- Striae
- Miliaria

OVERDOSAGE:

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

DOSE AND ADMINISTRATION:

Apply Cloderm (clocortolone pivalate) Cream 0.1% sparingly to the affected areas three times a day and rub in gently.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED:

Cloderm (clocortolone pivalate) Cream 0.1% is supplied in 15 gram, 45 gram and 90 gram tubes.

Store Cloderm Cream between 15° and 30° C (59° and 86° F). Avoid freezing.

Distributed by:



CORIA LABORATORIES, LTD.
Fort Worth, Texas 76107

Manufactured by:
DPT LABORATORIES, LTD.
San Antonio, Texas 78215

Reorder No. 13548-031-15 (15g)
Reorder No. 13548-031-45 (45g)
Reorder No. 13548-031-90 (90g)