

PCI Journal™

Journal of the Society of Dermatology SkinCare Specialists
Official Organ of the International Guild of Hair Removal Specialists
Official Organ of the Medical Spa Society

Highlights of this Issue:

4th Annual Medical Esthetic Conference

August 27, 2007

Moscone South – San Francisco, CA

- What's New in the Medicine Chest?
- Hair Stimulation Following Laser and Intense Pulsed Light Photo-Epilation
- Combination Regimens for Treatment of Acne Vulgaris
- Can Sun Protection Knowledge Change Behavior?

SAVE THE DATE

**6th Annual Society of Dermatology
SkinCare Specialists Meeting**

**February 4-7, 2008
El Tropicano Riverwalk - San Antonio, TX**

SKIN^{INC} magazine is proud to present *Face & Body Partners in Education*

We are pleased to partner once again with *PCI Journal* on the Medical Esthetic Conference during the annual *Face & Body Spa & Healthy Aging Conference and Expo*.

4th Annual Medical Esthetic Conference

Monday, August 27 (additional fee)
Moscone South
San Francisco

Register before August 1 and receive rates as low as \$275.
Prices to increase after August 1.

9-9:15 AM

Welcome from Austine Mah, managing editor of *PCI Journal*

9:15-11 AM

The Art of Consultative Selling: Taking Your Practice to the Next Level—There is a difference between hard sell and “heart” sell. Strengthen the connections you make with every patient. Do you know how to present intellectually while appealing to patients emotionally? Do you know what you are selling? Hint: it’s not treatments or surgery! Let us show you the five steps on presenting the benefits of treatment and new self-image to patients.

Karen Zupko, Karen Zupko & Associates, Inc.

11-11:15 AM Morning Break

11:15 AM-NOON

Working with Skin of Color—Broaden your perspectives for working with skin of color. Take away key lessons and gain the knowledge that is needed for pre- and post-operative considerations with skin of color.

Austine Mah, *PCI Journal*

NOON-1 PM Lunch on Your Own/
Visit the Expo Floor

1:15-3 PM

Medical Spa Startup: Are You Ready?—The presentation will take you through the business end of setting up a medical spa, including staffing, technology acquisition, practice format, competition, budgeting and more.

Greg Washington, Patient Unlimited Marketing Consultants

3-3:15 PM Afternoon Break

3:15-4:45 PM

What’s New in Combination Therapies?—This lecture will address how combining treatment modalities will maximize outcomes in the treatment of photoaging and wrinkles. Topics will include Botox, soft tissues fillers and noninvasive lasers.

Tomi L. Wall, MD, FAAD

4:45-5 PM Evaluation and
Closing Remarks



Susanne S. Warfield
Publisher, *PCI Journal*

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**Society of Dermatology
SkinCare Specialists**

For Membership Information and Annual Meeting Registration, visit their website at: www.sdss.tv

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Class size is limited and is available on a first-come, first-served basis.

Separate registration fees required.

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Mission Statement

The mission of the PCI Journal™, *The Medical Journal for Skin Care Professionals*®, is to provide its readers with the latest technological, scientific, and economic developments in the areas of dermatology, plastic surgery, cosmetic chemistry, and complementary therapies.

With the formation of the Society of Dermatology SkinCare Specialists (SDSS), additional educational opportunities, specific to dermatology, will be an added benefit for those who join the SDSS.

The Green Journal (as it is now known), started as a 4-page newsletter to the consulting clients of Paramedical Consultants, Inc. Through numerous letters it became evident that the emerging field of skin care professionals working in a medical facility or medical spa were in need of an educational journal.

The abstracts published in the PCI Journal are derived from peer-reviewed medical journals that we review each month.

What’s New In the Medicine Chest?
New Options Improve
Treatment Outcomes

By James Z. Dell Rosso, D.O., F.A.O.C.D.
Published in *Skin & Aging* 2007, 15;1:s3–s9

This article’s author asked what the most current tools and practices were in treating skin disorders. Fortunately, there were new ingredients and also more effective ways to use current options to positively impact treatment outcomes.

The Impact of Skin Care in Response
to Medications

For many dermatologic disorders, skin care products significantly impact the results of treatment regardless of what medications are prescribed. One study investigated the impact of skin care products and evaluated the use of Dove® (Unilever, London, UK), a synthetic detergent soap, versus a soap bar. The study tested Dove’s influence on symptomatology in patients using Differin® (Galderma Laboratories, Ft. Worth, TX) and Benzamycin® (Dermik Laboratories, Berwyn, PA). Patients using bar cleansers and experiencing irritation switched to Dove. With the switch, there was a marked reduction of acne symptoms, indicating that by changing a cleanser, the degree of acne irritation is decreased.

A similar study determined that as skin care product use is specified and controlled in clinical trials, specific skin care regimens contributed to the efficacy and tolerability results of medications. It was the skin care plus the medication, which equaled the final outcome, especially with disorders such as acne, rosacea or atopic dermatitis. A third study evaluated the symptoms of patients using a physician suggested regimen versus those using a patient preferred regimen. The group using the recommended regimen saw a greater reduction in symptomatology. This study emphasized how vital it is to educate patients on the details of product use, especially as it relates to improved therapeutic outcome and decreased potential medicine-related irritation.

Value of Moisturization

Patients with atopic dermatitis typically had a reduction in skin barrier integrity and the skin was more sensitive and permeable to external irritants and allergens. For example, this article found that the skin was compromised by “cracks in the cement” (fissures and exudation) of the brick wall analogy of the skin. As a result, there was an open invitation for *staphylococcus* infections. The skin of the patient with atopic dermatitis was in great need of moisture, which served to help protect the skin.

There were several new products, both over-the-counter and prescription, which aimed to provide such

moisture. One such option was multi-vesicular emulsion (MVE). With a patented vehicle technology of spheres of oil and water, MVE has been used in Salex™ (Healthpoint Dermatology, Ft. Worth, TX) and was found to be an effective delivery system with highly favorable skin tolerability.

The study of MVE technology in CeraVe™’s (Coria Laboratories, Ltd. Fort Worth, TX) hydrating cleanser, cream and lotion was undertaken. Patients using Lidex® (Medicis, Scottsdale, AZ) (fluocinonide 0.05%) were divided into 3 groups: Group A used only Lidex, Group B used the MVE cleanser, while Group C used the cleanser and the cream. Using both products in conjunction with Lidex, Group C exhibited the greatest clinical and symptomatic improvement. Clearly this study stressed the importance of appropriate skin care as a vital component in the overall skin care management plan.

Delivery Systems

Product delivery systems varied and influenced product usage, application technique and patient compliance. The pump, a new delivery system for benzoyl peroxide and Retin-A Micro 0.04% (OrthoNeutrogena, a division of Ortho-McNeil Pharmaceuticals, Inc. Skillman, NJ) offered users a clear meter for usage. The manufacturer stated that 2 pumps were enough for the entire face. With 400 pumps per container, 2 pumps applied twice daily, the product should last 6.6 months. Approximately 90% of users saw the ability to quantify use as easy and as taking the guesswork out of application.

Foam Vehicle Formulation

Until recently VersaFoam® (Stieffel Laboratories, Coral gables, FL), a hydroethanolic foam (HF), was the only foam delivery system available. Although there were a number of advantages to using HF including rapid skin penetration of active ingredients and easy spreadability, it had high ethanol content, causing stinging in eczema patients. However, an ethanol-free foam, incorporating desonide 0.05% did become available. This petrolatum-based emulsion was FDA approved to treat atopic dermatitis in patients as young as 3 months. While both products were easy to use and have great skin penetration, it was determined that the later contains petrolatum and light mineral oil and was better for eczema and dermatitis. Additionally, 70% of patients found it to be moisturizing. A majority preferred the later product over other vehicles they had used previously.

The Resurrection of Desonide

Desonide was the low potency topical corticosteroid most prescribed by dermatologists. A new foam version was approved in September 2006 and was tested in terms of penetration against creams and ointments

versions. Results were favorable due to maximum penetration as well as quickness and ease of penetration. In a pivotal clinical study of those with atopic dermatitis, after 4 weeks of twice daily application, 58% of the participants rated clear or almost clear compared to 21% of those treated with another vehicle. Additionally, itching was resolved or very minimal after 4 weeks with 67% of patients treated with desonide 0.05 foam, versus 26% of the vehicle-treated patients. Finally, because of the petrolatum, reactions such as stinging were less than 3%.

High-Potency Topical Corticosteroids
and Delivery Systems

Previously to achieve maximal effect with topical corticosteroids, one needed to prescribe an ointment. However that is no longer the case because of the new super-potent topical corticosteroid Vanos® (Medicis, Palo Alto, CA) (fluocinonide 1%). Twice as potent as Lidex, fluocinonide 0.05% was approved for use on psoriasis and atopic dermatitis.

Another conventional notion was that lotions are weaker in potency. On the contrary, Clobex Lotion® (Galderma Laboratories, Ft. Worth, TX) was found to be a super-potent topical corticosteroid. Studies and experience supported the efficacy of this formulation especially in cases of severe eczema.

Spray formulations were also showing impressive efficacy in results. In clinical trials of Clobex Spray®(Galderma Laboratories, Ft. Worth, TX), after two and four weeks respectively, 55% and 78% of patients with plaque psoriasis were clear or almost clear. Four weeks after discontinuation of therapy, 44% of patients remained clear or almost clear and another 28% exhibited minimal involvement. At the close of the four-week study, an impressive 72% of patients using the spray exhibited only mild disease or better, with close to half remaining completely clear.

Combination Therapy Approaches
with Topical Corticosteroids

While corticosteroids clearly were central to psoriasis and atopic dermatitis treatment management, there were new combination therapies showing promise, including Dovonex® (Warner Chilcott Inc., Rockaway, NJ) (the vitamin D analog, calcipotriene). Previously shown to be unstable, calcipotriene when used in combination with betamethasone dipropionate (Taclonex® (Warner Chilcott Inc., Rockaway, NJ), stayed stable for at least two years. There were a number of trials evaluating this combination with hopeful results. An efficacy profile consistent among these studies with application once daily was a Psoriasis Area Severity Index (PASI). Patients saw a reduction in severity of 40% after one week, 60% after 2 weeks, and 70% after 4 weeks.

New Shampoo Formulations
for Seborrheic Dermatitis

There were also new options in treating seborrheic dermatitis. Use of anti-fungal agents such as Loprox®

(Medicis, Palo Alto, CA) and Nizoral® (Johnson & Johnson, New Brunswick, NJ) reduced the growth of yeast, the organism thought to trigger seborrheic dermatitis inflammation. Another option was Salex™ Shampoo (Healthpoint Dermatology, Ft. Worth, TX) a 6% salicylic acid shampoo, which was approved for use in scalp psoriasis. Because the salicylic acid facilitated the separation of corneocytes due to desmoylic activity, the cellular clumping that lead to flaking and scaling in seborrheic dermatitis diminished. In addition, Salex Shampoo created a significant lather and had many humectants and conditioners that maintained hair texture. Finally studies showed no adverse effects on dyed hair, and very low potential for eye irritation.

Hair Growth Formulations

In pre-clinical testing minoxidil 5% (Rogaine® Pfizer US Pharmaceuticals, New York, NY) with Versafoam technology, showed two to three times the follicular penetration as other vehicles without adverse side effects. Male patients were assessed on hair count, detailed questionnaires and photos. After 16 weeks, clinical patients who used minoxidil foam 5% had at least 20 new hairs in the target area while those who used the vehicle had up to 5 new hairs. The corresponding photographs were impressive and patients reported a high degree of preference and satisfaction with the minoxidil 5% foam.

Optimizing Treatments

New products and vehicles along with improvements in current options provide therapeutic improvements in dermatology. They provide better ways to treat patients safely and efficiently.

Reprint requests to: Skin & Aging, HMP Communications, LLC, 83 General Warren Boulevard, Malvern, PA 19355.

Pneumatic Skin Flattening (PSF):
A Novel Technology For Marked Pain
Reduction in Hair Removal with High
Energy Density Lasers and IPLs

By G. Lask, M.D., D. Friedman, M.D., M. Elman, M.D.,
N. Fournier, M.D., R. Shavit M.D., & M. Slatkine M.D.
Published in *J Cosmet Laser Therapy* 2006, 8;2:76–81

Background and Objectives

Aesthetic laser treatments are often painful, thus resulting in the need to use topical analgesic creams or the application of less effective energies. Exploring new technology to afford the ability to treat without the necessity of lowering the fluences has been examined with the use of pneumatic skin flattening (PSF). Additionally, the reduction of post treatment erythema

Abstracts (continued)

is a result of higher fluences utilized during intensified-pulsed light and laser.

Materials and Methods

Laser hair removal and treatment of lentigines with high energy pulsed lasers or IPLs were studied. A vacuum chamber with a transparent window that pulled and compressed the skin against the window was used. This study compared the pain and efficacy of laser hair removal and IPL treatment of lentigines on 70 sites with and without PSF.

Results

Pain reduction with the use of the PSF and 30% higher energy levels were applied. Erythema and edema were reduced due to the blood expulsion from the laser beam or IPL pathway, which resulted in increased efficacy in most cases.

Discussion

This study found the use of the PSF resulted in gating effect of pain nerves in the dorsal horn by the compression of the pain receptors in the skin.

Conclusion

The use of the PSF reduced the pain associated with laser hair removal and removal of lentigines with IPL, which eliminated the use of analgesic creams, enabled increased energy densities and reduced post treatment erythema. PSF was a repeatable process and adaptable to most lasers and IPLs.

Reprint requests to: Informa Healthcare, Taylor & Francis Journals, 222 Rosewood Drive, Danvers, MA 01923.

Adapalene 0.1% Gel in Combination with Microdermabrasion Treat Acne

By C. Virtue, LA & J. Campbell, JR M.D., MS

Published in *Cosmet Dermatol* 2007, 20;4:248–254

Introduction

Teenagers have suffered the most from the dermatologic disease acne vulgaris. Acne vulgaris affects the individuals self-esteem causing threatening anxiety, depression and suicide. Treatment of this condition is important and can be very effective for self-confidence and body image.

Adapalene, tazarotene and tretinoin are US Food and Drug Administration (FDA) approved drugs for the treatment of acne. When using retinoids there were side

effects in the early stages, such as: peeling, erythema, dryness, burning and itching. Avoiding the sun and using moisturizers helped reduce some of these side effects. One effective treatment for acne was adapalene 0.1% gel (Differin® Galderma Laboratories, Forth Worth, TX), with a low potential for skin irritation. Microdermabrasion has been very effective for improving the appearance of hyperpigmentation, photo aging, stretch marks and acne.

Microdermabrasion is a cosmetic procedure that incorporates aluminum oxide crystals to resurface the face. This procedure can be provided by an esthetician in a dermatologists office and does not require an anesthetic. Microdermabrasion can increase the skin's sensitivity to topical therapies such as retinoids.

Method

Fourteen participants with moderate to severe acne were invited to participate in a 14-week study with Fitzpatrick skin types I, II, III and VI. All participants were younger than 18 years.

For daily cleansing, participants were given Cetaphil® (Galderma Laboratories, Forth Worth, TX) gentle skin cleanser and Cetaphilmoisturizing cream to use as needed. Adapalene 0.1% gel was initiated once nightly as described in the package insert for 14 days prior to microdermabrasion. Microdermabrasion treatments were initiated at week two after starting the skin care regime. Microdermabrasion treatments were given every other week through week 12 and adapalene 0.1% gel continued nightly for the 14-week study. Participants were seen at two-week intervals. There was a baseline of acne lesions taken initially and at each two-week visit. At each two-week visit, interval ratings of tolerability were taken, as well as an evaluation for erythema, scaling dryness, stinging, and burning before microdermabrasion treatment.

Photographs were taken at weeks: 4, 6, 8, 10, 12 and 14. Six microdermabrasion treatments were performed during the study. At weeks: 2, 4, 6, 8, 10 and 12 the primary outcomes of interest were reduction in acne lesion counts and tolerability.

Results

Over the 14-week study, all patients successfully completed the study with progressive improvement. A decrease in both non-inflammatory and inflammatory lesions was noted. The most noted improvements were skin texture and appearance.

Conclusion

The most effective topical agent for treating acne was adapalene 0.1% gel with the rapid onset of action within one-week. With regard to the tolerability factor, patients

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tended to be very compliant. Microdermabrasion was used in combination with adapalene 0.1% to treat acne because of its mild nature. Other retinoids have greater skin irritation and may not be suitable to be used with microdermabrasion.

Microdermabrasion can address abnormalities such as, fine lines, wrinkles, acne scarring and photodamaged skin. This study showed the results of adapalene 0.1% used in conjunction with microdermabrasion every 2-weeks. Participants only experienced mild redness or stinging. All participants reported progressive improvements in skin texture and appearance throughout the 14-week study. This treatment protocol proved to be very effective for the treatment of acne.

Reprint requests to: Cosmetic Dermatology, Quadrant HealthCom Inc., 7 Century Drive, Suite 302, Parsippany, NJ 07054-4603.

Scarring Occurs at a Critical Depth of Skin Injury: Precise Measurement in a Graduated Dermal Scratch in Human Volunteers

By C. S. J. Dunkin, MRCS, J. M. Pleat, MRCS, P. H. Gillespie, FRCS, M. P.H. Tyler, FRCS, A. H. N. Roberts, FRCS, & D. A. McGruther, FRCS, M.Sc.

Published in *Plast Reconstr Surg* 2007, 119;6:1722–32

Introduction

This study’s authors tested the hypothesis of a threshold depth of skin injury for scarring. They questioned whether a wound meeting a certain depth or below, would cause scarring while a shallower wound would not. The testing involved 113 volunteers with the same dermal wound at the same site to determine the scarring response to dermal injury at different depths and to define the threshold depth for scarring.

Patients and Methods

Gillespie, one of the study’s authors, produced a surgical instrument consisting of a blade block to secure a number 11 blade, and a wedge-shaped base block with a central slot to accommodate the blade. This jig produced an elongated teardrop shape dermal wound, extending deep into the deep dermis on one end, and into the superficial dermis on the other.

A group of 113, male and female, healthy volunteers were assembled for the study. There were a number of exclusions including non-whites, those with circulatory or inflammatory disease as well as others, including skin

disorders. Each volunteer was marked with the jig on the lateral aspect of the hip along lines of relaxed skin tension, midway between the anterior superior spine and the greater trochanter. EMLA® cream (Abraxis Pharmaceutical Products, Chicago, IL) was applied to the area, the wound sites were created under aseptic conditions and the wound was hygienically dressed throughout the study.

The hip markings were reviewed immediately post-operatively, every week for first month, then at 6, 10, 18, 24 and 36 weeks. Assessment of scarring was done with digital photography (surface area, length and width) and high frequency ultrasound (depth) scanning. Finally measurements of skin thickness were taken at the deep end, two probe widths from the deep end, and at the superficial end. To ensure reproducibility of results, the measurements were done by both the author and an independent observer.

Results

As wound healing progressed, a fibrous scar developed at the deep end, whereas the superficial end resolved without visible scarring. This scar was quantified as a reduction in the length, shape, surface area, and depth of the wound obtained from various digital images and high frequency ultrasound.

Immediately after injury the wound length was 51.3(+/-) .6 mm. There was no significant decrease until week 3 when the wound length was 46.3/4 mm. The greatest reduction was seen between weeks 3 and 6. Afterward there was no significant reduction in wound length. By week 36, the mean length of the scar was 34.9/1.0 mm. Approximately 68% of the wound length healed with a scar and the remaining 32% had none.

The changing shape of the wound as healing progressed was quantified by measuring width at four standardized points along the length of the wound. There was a significant difference between the width of the wound at different depths of dermal injury, with the widest part of the wound at the deep end and the narrowest part at the superficial end.

Discussion

The ability to heal cutaneous wounds was fundamental to the survival of higher vertebrate animals. The body’s ability to heal after wounding involved an inflammatory phase and triggered a cytokine cascade. However, there was massive redundancy in the inflammatory response so that the regenerative capacity of the dermis was over-run, resulting in a fibrotic scar.

Specialists in burns and reconstructive surgery have long recognized the association between the degree of scarring and the depth of dermal injury. However, the threshold depth of injury required to produce scarring

had not been demonstrated previously and the relationship between the depth of injury and scarring remained poorly understood.

Three factors, resistance of subject’s skin to the blade, depth of penetration due to downward pressure on jig, and lateral tension placed on skin contributed to the variability in the length of the wound and depth of dermal penetration. To minimize effect, all of the wounds were produced by two investigators: one applying consistent downward pressure and the other applying lateral tension.

Additionally tension across the wound may have influenced healing. To reduce this effect, wound depth was limited to the dermis. However analysis of digital images and high frequency ultrasound suggested that tension across the wound was not a factor in the scarring response in this study.

The depth of dermal injury was calculated because the initial depth of dermal injury could not be measured directly. Image analysis was performed using modified standard software. Finally, the results for the use of high-frequency ultrasound were consistent with other studies in which it was used to measure skin thickness.

These methods of scar monitoring were noninvasive, reproducible, and relatively easy to use. However they were insufficiently sensitive to monitor disruption of the dermal structure at the superficial end of the scar. Further study with more sensitive monitoring devices would demonstrate changes in the superficial wound.

There was a depth of dermal injury that resulted in a fibrotic scar, however; if this depth was not met, the wound healed with regeneration rather than fibrosis, and there was no scarring. Different depths of dermal injury may result in different inflammatory responses and cytokine profiles, which in turn provide the environment for different fibrotic responses. This response was less so with a superficial injury. Further study was in the works to determine differences in blood flow at different depths of dermal injury and the cellular and molecular basis of these differences.

Conclusion

In sum, the dermal scratch provided a well tolerated, standardized, and reproducible wound model that promoted the study of healing response of dermal injury of different depths. Scarring appeared to occur when injury reached a critical depth of wounding, which can be quantified. The study authors concluded that further study at other body sites was necessary.

Reprint requests to: Williams & Wilkins, Author Reprints Department, 351 W. Camden Street, Baltimore, MD 21201.

Null Mutations in the Filaggrin Gene (FLG) Determine Major Susceptibility to Early-Onset Atopic Dermatitis That Persists Into Adulthood

By J. N.W.N. Baker, C. N.A. Palmer, Y. Zhao, H. Liao, P. R. Hull, S. P. Lee, M. H. Allen, S.J. Meggitt, N. J. Reynolds, R. C. Trembath & W.H. Irwin McLean

Published in *J Invest Dermatol* 2007, 127;3:564-567

Introduction

Profilaggrin is the main protein component of the keratohyalin granules within the last living layers of the epidermis. Upon further differentiation the profilaggrin breaks down to filaggrin, which aggregates the keratin filaments, brings about squame formation and is essential for skin barrier formation. It was recently shown that one of two loss of function (null) mutations occur in about 10% of people of European origin and that these cause a complete absence of filaggrin processing in the epidermis.

Additional filaggrin mutations have been linked to severe ichthyosis vulgaris in the homozygous or compound heterozygous state and have been shown to be a major predisposing factor for atopic dermatitis (AD).

The purpose of this study was to determine role of the filaggrin genes in the development and persistence of AD.

Results and Discussion

Adults with childhood onset and persistent AD had a 6-fold elevated frequency of over representation of the null alleles over the control sample. Forty-two percent of this AD cohort had one or more of these two alleles. These results supported the concept that a skin barrier defect was central to the cause of AD and that defects in filaggrin were a major contributor to the barrier defect. Since adult AD was greater in those with occupations that damaged the skin barrier, therapeutic strategies aimed at early correction or improvements of the skin barrier were likely to produce long-term benefits.

Reprint requests to: William H.I. Mclean, Epithelial Genetics Group, Human Genetics Unit, Division of Pathology and Neuroscience, University of Dundee, Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom.

Use of Complementary and Alternative Medicine for Weight Control in the United States

By P. A. Sharpe, PhD, H. M. Blanck, PhD, J. E. Williams, PhD, B. E. Ainsworth, PhD, & J. M. Conway, PhD
Published in J Altern Complemen Med 2007, 13;2:217–222

Introduction

The purpose of this study was to assess the prevalence and correlation of complementary and alternative medicine (CAM) use for weight control in the United States. Recent findings revealed that 36% of adults in the United States have used CAM in the previous year. When the use of prayer specifically for health reasons was added to the definition of CAM, CAM use increased to 62%. In the general population, CAM use is highest among women, whites, persons of higher educational attainment and income and persons who are widowed or divorced, middle-aged, have poorer perceived health, or live in the western United States. Overall, however; little is known about the prevalence and correlation of CAM use for weight loss and weight control. Given the obesity epidemic in the United States, CAM use for weight control has significant public health implications.

Materials and Methods

The National Physical Activity and Weight Loss Survey (NPAWLS) was a nationwide telephone survey conducted between September 2002 and December 2002. Survey questions included items pertaining to overall health status and quality of life, weight-control measures, and participation in physical activity. The overall objective of the study was to obtain data on individual physical activity and nutrition risk behaviors. The sample of respondents was drawn from the total non-institutionalized US adult population residing in telephone-equipped locations. The survey was conducted in both English and Spanish, and used a population-based sample rather than a convenience sample. The study design was a list-assisted, random-digit-dialed sample of telephone-equipped households in the United States generated by preparing a list of all current operating telephone exchanges within each US area code. The study was designed to obtain adequate representation of Hispanic respondents and non-Hispanic black respondents.

The survey had a total of 11,211 completed interviews.

Results

Of the 11,211 respondents, 372 respondents had used CAM for weight control in the past 12 months. Yoga,

including breathing techniques, was named by the largest proportion of respondents as their most used therapy in the last 12 months, followed by meditation, massage, acupuncture, and Eastern martial arts. Other responses included hypnosis, subliminal messages, prayer, Pilates, guided imagery/visualization/affirmation, chiropractic, light therapy, colon cleansing and energy healing. The mean estimated number of days respondents had used the primary CAM method in the previous 12 months was 146, with a range of 1-265 days and a median of 93 days. Discussion This report provided new information about CAM use for weight control in a very large sample of US adults. The results showed that people who had engaged in other weight control behaviors were more likely to have used CAM in the previous 12 months, a finding that suggested people may be using physical activity, lower carbohydrate/higher protein diets, and nonprescription weight loss products in conjunction with other CAM methods for weight control, or trying them one after the other. This pattern may indicate persistent unsuccessful attempts to lose weight by multiple methods. Only 3% (weighted) of the total respondents had used CAM for weight control in the previous 12 months. 5% (weighted) of respondents who were trying to lose weight at the time of the interview had done so. These results indicated that the use of CAM therapies for weight loss, other than nonprescription supplements, was relatively low. The method of choice by far was yoga, trailed by medication, massage, acupuncture and Eastern martial arts as the top five. Neither the potential direct effects of these methods of weight control, nor the potential indirect effects have been adequately investigated. Thus, the effectiveness of these methods for weight control and weight loss remains unknown.

Reprint requests to: Patricia A. Sharpe, PhD, Prevention Research Center Arnold School of Public Health, University of South Carolina, 730 Devine Street, Columbia, SC 29208.

Hair Stimulation Following Laser and Intense Pulsed Light Photo-Epilation: Review of 543 Cases and Ways to Manage It

By A. Willey, M.D., J. Torrontegui, RN, J. Azipaniazu, M.D. & N. Landa, M.D.
Published in Lasers and Medicine 2007, 39;4:297–301

Background

Terminal hair growth stimulation following photo-epilation is often misunderstood with significant clinical relevance. Observation of this problem was reported in the dermatological laser practice in the Basque County of Spain. A retrospective chart review was performed on all patients who received intense pulse light (IPL) and laser photo-epilation at this single center within a five-year period: between December 1998 through December 2003. Photo images of before and after treatments were compared as well as medical history of all patients.

Methods

Five-hundred-forty-three patients with Fitzpatrick skin types II, III, and IV ranging in age from 16 to 52 years received IPL or laser hair photo-epilation of the beard, neck and chin areas, the upper lip was excluded. Patients received treatments in ranges from 3-23. Treatments were usually performed every 2-3 months. Hair epilation treatments were performed using 1,064 nm Nd:Yag (Lyra-i™, Iridex Corporation, Mountainview, CA), IPL source (Epilight™, Lumenis, Santa Clara, CA) and a long pulsed 755nm alexandrite laser (Gentlelaser™, Candela, Wayland, MA). Ten percent of the treatments were performed using the 1064 nm Nd:Yag, 85% were performed with the alexandrite laser, 10% received treatments with the IPL and 5% with the Nd:Yag. Parameters used were within the manufactures suggested guidelines for each Fitzpatrick skin type.

Results

Of the 543 patients who received laser/IPL, hair photo-epilation, 57 demonstrated an increase in hair growth in the area that was treated in the baseline. Increased hair growth was noted in the bordering areas that were treated with an appearance of thicker and darker hairs. Forty-four patients demonstrated no reduction in hair growth following treatments. Four-hundred-twenty-six patients demonstrated a decrease in hair growth with ongoing treatments. Fourteen patients were discharged for near to complete hair reduction. The increase in terminal hair growth occurred mostly in areas where fine or coarse hair was present prior to the onset of treatments. Frequency of hair growth occurred in more patients treated with the alexandrite and IPL devices compared to those treated with the Nd:Yag, however; the later device was used less. The age groups of the patients that developed terminal hair were 10-21 years, 44 patients, 30-40 years, 8 patients, 5 patients

were 40 years or older. Terminal hair increased between the third and tenth treatments in 39 of the 57 patients, 11 of the 57 patients developed hair between the third and fourth treatment. 16 patients had irregular menses or documented ovarian cysts, otherwise histories were within the normal range. It was thought that the sub-therapeutic thermal energy delivered to the treated areas induced terminal hair growth in the near by follicles. Cold pack application was applied to the treatment areas and surrounding treatment areas on subsequent treatments followed with two passes had minimal increase of terminal hair growth. Discussion The widespread use of lasers and IPL for hair reduction has resulted in an unknown mechanism of photo-epilation. Light is absorbed over millisecond pulse duration by the melanosomes in the hair matrix and kertinocytes in the hair shaft. The heat energy is transferred from the follicle matrix to the surrounding non-pigmented epithelium and perifollicular dermis. Miniaturization of the follicle is a result of the thermal injury, which makes the follicle clinically unapparent for a variable amount of time. The exact targets of the melanosomes or the biologic events that lead to clinical hair reduction are not understood. Cells critical for recycling of the follicle, stem cells of the follicular bulge area located within the outer root sheath and cells of the follicular papilla are all targets of the photo-epilation including the population of cells that are essential for follicular morphogenesis itself. Histological studies revealed that cells within the photo-epilated areas may not receive thermal injury, which suggested that some follicles were more susceptible to photo-thermal injury than others. Melanin differences in differing stages of hair growth cycles may account for the lack of energy during photo-epilation. With different hair growth cycles, melanogenesis ceases during catagen and telogen, resuming production during the anagen phase. Early anagen follicles have been thought to be more susceptible to photo-epilation since the melanin located high in the dermis is related to the anagen follicle residing deep in the subcutaneous tissue beyond the optical penetration of red and near infrared wavelengths. The degree of melanin within the anagen hair was associated with the efficacy of treatment, the amount of melanin in the hair shaft versus the matrix played a role in affecting efficacy. This depended upon whether the target of thermal injury was primarily in the follicle stem cell located within the bulge or the follicular papilla. Heat transfused from the shaft may have heated primarily the follicular infundibulum, whereas heat transferred from the matrix may have effected primarily the lower section of the follicle. The efficacy of laser hair removal was fluence dependent upon the amount of energy absorbed with higher results occurring with higher fluences. Stimulation of hair growth occurred at the periphery of the areas treated, which

Abstracts (continued)

Localized hypertrichosis can be acquired in various settings of dermal injury, including terminal growth at the periphery of a burn, transient limb hypertrichosis associated with casting, peri-incisional hair growth following knee surgery or fracture sites, distal hair growth following lymphadenectomy, terminal hair growth at the site of bug bites and verruca vulgaris, localized reaction measles, smallpox, scratching and biting associated different clinical settings. A common factor in these widely varied clinical presentations was the hypothesis that local inflammation may lead to localized terminal hair growth.

Key Factors

These key factors are associated with failure to epilate and risk of hair stimulation:

1. **Thickness of treated hair.** Thicker hair was easier to heat since the follicle reached a high enough tem-

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Other evaluations included itching, assessed at each visit by the subject on a 100-mm analog scale and global improvement assessed by the investigator on a 7-point scale.

Conclusion

Results showed that an application of clobetasol propionate for 5 and 10 minutes provided a similar mean percentage decrease of TSS, and the mean percentage decrease of TSS for all active groups.

Reprint requests to: Cutis, c/o Quadrant HealthCom Inc., 7 Century Drive, Suite 302, Parsippany, NJ 07054.

Primary Focal Hyperhidrosis: Scope of the Problem

By D. A. Glaser, M.D., A. A. Hebert, M.D., D. M. Pariser, M.D. and N. Solish, M.D.

Published in Cutis 2007, 79;5:s5–s17

Focal hyperhidrosis (HH) is an over activity of the eccrine sweat glands that results in excessive, bilateral, relatively symmetric sweating beyond the amount necessary to maintain a body temperature within normal limits. Patients suffering from HH found that it was generally idiopathic (primary) and most commonly occurred in the axillae, palms, soles and face. It was reported that between 0.6% and 2.8% of the US population suffered from HH, greatly impacting the quality of life (QOL) both physically and emotionally.

Treatments for HH reviewed in this article included topical agents, oral agents, tap water iontophoresis (TWI), and surgical therapies along with new data supporting the use of botulinum toxin (BTX) therapy for focal HH. This article presented the clinical experiences of Glaser et al and developed a best practice recommendation for what dilution of BTX to use, injection sites and number of injections.

Treatment Options

A variety of options were available for patients who suffered from HH, however their impact on QOL for patients may not be much greater than the HH itself. These treatments may be inconvenient or have side effects that impact the patients.

Topical Treatment

OTC antiperspirants and AICI3 were the two most common topical treatment options for HH. Patient concerns included skin irritation, messiness of the product, staining of clothing, inconvenient application and cosmetic concerns (mainly with facial HH).

Iontophoresis

TWI delivered a direct current to the area of skin affected by HH using large, shallow pans of tap water and an electrode device. TWI required 6 to 10 treatments to achieve results with maintenance treatments every 1 to 4 weeks. This treatment was only logistically possible for treatment of palmar and plantar HH. Patients may have experienced discomfort during treatment and irritation could occur.

Oral Agents

No oral agents had been approved by the FDA for treatment of HH, however; oral anticholinergic agents had been used. Common side effects included dry mouth, blurred vision, urinary retention, and constipation. Botulinum Toxins–BTX-A received FDA approval for treating axillary HH and was proven safe and effective. Off label use for treating the palms, soles, and face for HH has shown positive results. The only reported side effects were slight temporary muscle weakness or decrease in muscle tone. Adequate anesthesia was required.

Surgical Treatments

Endoscopic transthoracic sympathectomy (ETS) should be considered only when all other treatment options have failed. This surgery interrupts the sympathetic nerve input to the sweat glands, ultimately causing permanent cessation of sweating by those glands. Patient satisfaction ratings were low for this treatment option, and it also included the general risks of undergoing surgery.

Best Practice Techniques for Treating Palmar and Plantar HH with Botulinum Toxin A

Glaser et al recommended using 4-mL dilution of BTX-A, drawn up in four 1 cc syringes, which provided 2.5 U per 0.1 mL of injection. Insulin syringes were recommended with a 31 or 32 gauge needle for reduced patient pain, though the final selection was based on physician’s preference.

Injection depth is the deep dermis, at or near the subcutaneous tissue, which is where the sweat glands are located. Care must be taken to not inject too deeply, or the patient may experience muscle weakness. Depending on the size of the patient’s hand or foot, there will be approximately 45 to 50 injection sites, spread approximately 1 to 1.5 cm apart. Injection site volume should remain between 0.05 and 0.1 mL.

Best Practice Techniques for Treating Facial HH with Botulinum Toxin A

The chief concern for facial HH was the cosmetic look of the injections, though they were generally temporary. BTX-A should be diluted with 2.5 mL of 0.9% nonpreserved saline, which is the standard for cosmetic use. The drug should be drawn into five 0.5 cc syringes,

enabling 2 or 4 U BTX-A to be injected in volumes of 0.05 or 0.1 mL, respectively. Recommended needle gauge is the same as for palmar or plantar injections.

The injections should be intradermal, where the sweat glands are located. Depending on the pattern of sweating, the average total dose is 40 U BTX-A for the forehead alone, but may range from 33 to 100 U, with a series of 20 to 30 injections. The entire affected area should be treated with 2 to 3 U BTX-A per site, with sites spaced approximately 2 cm apart.

Conclusion

Choosing the appropriate treatment for focal hyperhidrosis can greatly improve a patient’s quality of life. Older treatment therapies may have provided results, but the side effects often made the patient more uncomfortable than the HH. Botulinum Toxin treatments provided a safe and effective treatment for HH when used within the best practice recommendations for treatment.

Reprint requests to: Cutis, c/o Quadrant HealthCom Inc., 7 Century Drive, Suite 302, Parsippany, NJ 07054-4603.

Allergy to Tea Tree Oil: Retrospective Review of 41 Cases with Positive Patch Tests Over 4.5 Years

By T. Rutherford, MB BS, R. Dixon, FACD, M. T. Tam, FACD & B. Tate, FACD

Published in Australasian J Dermatol 2007, 48;2:83–87

Introduction

Tea tree oil is the essential oil derived from the tea tree, native to Australia. Currently being used and marketed for its “natural” antimicrobial and anti-inflammatory properties, tea tree oil usage at concentrations between .5% and 100% is on the rise. Demand for tea tree oil rose 25% in 2003-2004 and 13% in 2004-2005. Along with the increase in use have come more reports of tea tree oil skin reactions including allergic contact dermatitis (ACD).

Methods

Patients with positive patch test results between January 2000 and June 2004 to tea tree oil at 5% or 10% concentrations were identified from the contact dermatitis and occupational dermatitis databases at the Skin and Cancer Foundation in Melbourne Australia.

The 5% commercial allergen was provided by Chemotechnique Diagnostics (Malmo, Sweden). The 10% patch test was prepared by diluting neat (100%) tea tree oil that had first been allowed to oxidize for several days. Patches were applied to the upper back and left on

for 48 hours. Reactions were recorded 30 minutes after patch removal, at 48, 96 or 120 hours according to the International Contact Dermatitis Research Guidelines. Reactions were measured as irritant, equivocal, weak positive, strong positive, or extreme positive. Only patients with weak positive, strong positive or extreme positive results were analyzed.

Results

In total, 41 of 2320 (1.8%) patients presented with positive reactions to tea tree oil. Positive reactions were more common in women than men, with a mean age of 49 years. Of the 41 positive reactions, 17 (41%) were deemed relevant, as defined by a history of use of tea tree oil-containing products, which explained the presenting dermatitis. For the 24 patients with a positive reaction that was not considered relevant or of uncertain relevance, the reaction may have occurred as a result of unrecognized or forgotten tea tree oil exposure or a cross-reaction to other allergens.

Discussion

The prevalence of a positive reaction (1.8%) was higher than had been reported by previous studies performed outside of Australia. Reports of increasing incidence of tea tree oil ACD have been partly attributed to an overall increase in usage of tea tree oil but also to the more widespread availability of neat tea tree oil.

At least 13 components of tea tree oil have been identified as potential sensitizers. Factors that affect the composition of tea tree oil include the distillation process and oxidation. The sensitizing factors of tea tree oil are strengthened by oxidation such that oxidized tea tree oil has a sensitizing capacity three times stronger than fresh oil. The tea tree oil prepared for commercial products has been intermittently exposed to light, moisture, heat and air, the products used by consumers may actually be more allergenic than those preparations used in patch testing.

Given the findings of a tea tree allergy of 1.8% in a patch test population, tea tree oil allergy should be added to all standard patch-test series in Australia. It was recommended that the testing occur with 10% tea tree oil as it appears to increase the sensitivity of the patch test compared with testing at 5% concentration. The application of more concentrated solutions of tea tree oil, particularly on eczematous or broken skin, was strongly discouraged; moreover, manufacturers are suggested to include appropriate warnings on their products.

Reprint requests to: Dr. Rosemary Dixon, Occupational Dermatology Research and Education Centre, P.O. Box 132, Carlton South, Victoria 3053, Australia.

A Horse Chestnut Extract Which Induces Contraction Forces in Fibroblasts, is a Potent Anti-Aging Ingredient
By T. Fujimura, M.D., K. Tsukahara, M.D., S. Moriwaki, M. Hotta, M.D., & T. Kitahara, M.D.
Published in J Cosmet Sci 2006, 57;5:369–76

Introduction

In a recent search among various plant extracts, with a model that such ingredients generate cell contraction using fibroblast to determine cell structure, vasoconstriction, and/or wound healing; the extract of horse chestnut (*Aesculus hippocastanum*) was able to generate the desired result.

Materials and Methods

Clinical tests of the extract were performed using photo scales as the visual scoring base. The testing was started with 40 female volunteers applying a 0.3% gel formulation, of the extract, to the eye area three times daily for 9 weeks.

Conclusion

After a 6-week evaluation, considerable decreases in the wrinkles were observed compared with the control group. After 9 weeks the same results were apparent.

The papillary layer sits just under the epidermis. It connects the dermis to the epidermis and is the vascular layer of the skin. The reticular dermis is under the papillary layer. It is best known for its role as a supportive layer where the collagen and elastin fibers provide the support, strength and flexibility to the skin. It is in the dermis that you will find fibroblast cells, mast cells and phagocytic cells. The fibroblast cells create the skin’s support structure where the collagen and elastin are produced.

The conclusion of the study suggested that an extract of horse chestnuts can generate contraction forces in fibroblasts and can be a potent anti-aging ingredient.

Reprint requests to: Blackwell Publishing, 9600 Garsington Road, Oxford OX4 2DQ, United Kingdom.

A Comparative Review of the Efficacy and Tolerability of Retinoid-Containing Combination Regimes for Treatments of Acne Vulgaris
By James L. Campbell Jr., M.D., MS
Published in J Drugs Dermatol 2007, 6;6:623–629

Introduction

This article presented a review of several studies comparing the efficacy of combination treatments for acne vulgaris. Acne vulgaris, a chronic skin disorder, affects 70-87% of prepubescent teens. The condition is characterized by abnormalities in follicular epithelial desquamation, sebum production, bacterial proliferation and inflammation. Many topical retinoids have been approved by the Food and Drug Administration to treat acne vulgaris. Most commonly used are: adapalene, tazarotene, and tretinoin.

Retinoids are effective because they target the primary lesion of acne, the microcomedone, and have therefore played an important role in treatments. This article reviewed studies of combination therapies, which included a topical retinoid as well as an oral antibiotic. These therapies have proved more effective than monotherapy.

The studies presented all displayed similar levels of efficacy, however they differed in reports of patient tolerability, safety and satisfaction. Therefore, the comparison of these studies can be used to determine the best combination therapy for individual patients.

Retinoids and Oral Antibiotics

Study #1

The first study looked at the combination of adapalene gel 0.1% and doxycycline. In a 12-week study, 467 patients with severe acne were randomly administered a 100 mg capsule of doxycycline daily, and either adapalene gel 0.1% or adapalene gel vehicle. While both groups experienced reduction in lesions, the success rate was significantly higher with the adapalene gel 0.1%. Both groups experienced positive local cutaneous tolerability.

Erythema, dryness, scaling and burning/stinging were mild in severity. Greater adverse effects were reported in the group who used the vehicle and doxycycline as opposed to the adapalene 0.1% gel and doxycycline. Overall, patients in this group reported great satisfaction with the combination therapy and the results. A follow-up study supported that 75% of subjects that showed at least moderate improvement in the

treatment phase, maintained the results during the maintenance period.

Study #2

A second study examined the results of combination treatment with minocycline and tazarotene gel 0.1%. 189 patients with severe acne were treated with a 100 mg capsule of minocycline plus tazarotene gel 0.1% once daily for 12 weeks. After 12 weeks, patients with 75% and higher rates of global improvement were randomized to 12 weeks of maintenance with taratozene gel 0.1% and placebo capsules, vehicle gel and minocycline or taratozene gel 0.1% and doxycycline.

The combination therapy proved most effective in reduction of lesions and overall global improvement. However, all regimens were well tolerated with the most common adverse effects to treatment being burning (3%) peeling (3%) and erythema (2%).

Retinoids and Topical Antimicrobials

Study #3

A third study compared the effects of once-a-day application of combination tretinoin 0.025%/clindamycin 1% hydrogel, clindamycin 1% hydrogel alone, tretinoin hydrogel 0.025% alone, or vehicle hydrogel on 1,136 patients with facial acne for 12 weeks. The study had an attrition rate of 87%, By the end of the treatment the patients in the combination treatment group showed the greatest reduction in lesions. The three active treatments were well tolerated, with a 36% report of adverse events and less than 1.1% discontinuation based on these events.

Study #4

A fourth study compared 105 patients who used applied adapalene gel 0.1%, benzoyl peroxide (BPO) 5%, or a combination of the two each evening. Patients were evaluated after 6 months. All three regimens proved effective in treating both inflammatory and noninflammatory lesions. There were no statistical differences between the effectiveness of the three groups. Further, there were no statistically significant differences among the regimens in erythema, dryness and burning. However, 2 patients in each the adapalene gel 0.1% group and the adapalene gel plus benzoyl peroxide lotion group discontinued therapy due to acute contact dermatitis.

Retinoid and Topical BPO/AB Combination Therapy

Another combination therapy study was conducted to measure the efficacy of retinoids used with topical BPO/AB. The MORE trial viewed the results of adapalene gel 0.1% combined with topical BPO/AB. In a 12-week study, 1,720 patients found high levels of improvement in non-inflammatory and inflammatory lesions. Further, there were high percentages in tolerability, most patients having none or mild peeling/scaling or dryness. Patients commonly

reported being very satisfied with the combination therapy.

Tazarotene cream 1% was also used in combination with topical BPO/AB gel. In this study, 121 patients were treated over 12 weeks with the tazarotene cream in the evening, and some were treated with either a BPO/AB gel or a vehicle gel. The improvements in the combination group therapy were numerically, but not significantly higher. However, the patients using the combination therapy reported milder grades of peeling.

Discussion

The data reviewed indicated the advantage of including topical retinoids in the treatment of acne vulgaris. Based on patient satisfaction and low occurrence of adverse events, adapalene gel 0.1% offered better tolerability in comparison to tazarotene or tretinoin in combination regimens. Further, the lower irritation potential and intrinsic anti-inflammatory properties of adapalene resulted in patient preference. The data showed the importance of seeking out treatments for acne vulgaris that do not require long-term antibiotic use. Due to the increase of antibiotic-resistant microbes, it is important to look at combination therapies to treat acne vulgaris. Emphasis was made on the importance finding appropriate treatments that can be effectively maintained. More research is required to determine the most effective therapies that can be successfully maintained. This review focused on comparing topical retinoids as a part of combination therapy. Topical retinoids were shown to be an integral part of treatment strategies to control acne vulgaris. Therefore, this review is useful in identifying the most appropriate treatment for acne vulgaris.

Reprint requests to: Journal of Drugs in Dermatology, 377 Park Avenue South, 6th Floor, New York, NY 10016.

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Can Sun Protection Knowledge Change Behavior in a Resistant Population?

By J.E. Swindler, M.D., J.R. Lloyd, DO, K.M. Gil, PhD
Published in Cutis 2007, 79;6:463–470

Introduction

Skin cancer is the most common type of cancer and melanoma, the fastest increasing form of cancer, is occurring most frequently in women aged 25 through 29. The best treatment for melanoma is prevention, efforts are being made to increase public awareness. Studies have been made to assess sun protection knowledge and behavior in adolescents and monitor changes after educational intervention. This study was designed to assess the effectiveness of educational intervention by educating high school students in the risks of unsafe sun practices, assess the change in knowledge immediately afterwards, and assess the change in attitude and behavior in the four months afterwards.

Methods

Students from one high school in Ohio attended a 45 minute standardized lecture and PowerPoint presentation on the dangers of sun exposure and its contribution to skin cancers and premature aging. They took a test before and after the lecture to assess changes in knowledge. Four months later they took the test again as well as a survey to assess changes in attitude and behavior.

Results

Gender differences in knowledge were considered statistically irrelevant. Knowledge of sun damage increased significantly both immediately after the lecture and four months later. Gender differences in attitude and behavior were more significant. As a result of the lecture, male students used less sunscreen than female, but wore more protective clothing. For both groups the two main reasons for not using a sunscreen were the same, wanting a tan and forgetting or not wanting to put it on. The more female students wanted to have a tan and the females, in general wanted darker tans. Four months after the lecture, both males and females expressed a greater intention to use sun protective clothing and sunscreen, but no change in the reported importance of tanning. In fact, there was an increase in the percentage of male and female students who reported they would get a dark tan.

Comments

It is apparent that in the adolescent population, risk perception does not always inhibit risk behavior. The study

results were consistent with others performed elsewhere and using different materials in the lecture. Recommended changes in the strategy to engender “safe sun” practices in adolescents included a new approach in targeting this age group, using mass media or targeting students at a younger age.

Reprint requests to: Jennifer R. Lloyd, DO, Lloyd Dermatology & Laser Center, 8060 Market Street, Youngstown, OH 44512.

Habit Reversal Training for the Itch-Scratch Cycle Associated with Pruritic Skin Conditions

By M. Grillo, RN, MNg, R. Long, BMBS, FRANZCP, & D. Long, BMBS
Published in Dermatol Nursing 2007, 19;3:243–248

Clinical Brief

Habit reversal therapy has been found to be an effective treatment to help patients with eczema and other skin conditions deal with the urge to scratch. This therapy was recommended for patients to improve their quality of life and allow the skin to heal. While managing chronic itching caused by disease requires medical intervention, the authors noted that scratching calls for a psychological approach. In the habit reversal method, patients were first educated about the itch-scratch cycle and then taught alternative behaviors to scratching such as exercising their hands. The authors said their clinical experience shows it was possible to diminish the scratch habit with reversal therapy, but said follow-up may be necessary to evaluate effectiveness long-term. This is where an interested professional comes in, they say, as motivation and guidance are keys to success.

Reprint requests to: Dermatology Nursing, East Holly Avenue Box 56, Pitman, NJ 08071-0056.

From the American Academy of Dermatology

Academy of Dermatology Warns that Skin Cancer is Leaving Its Mark on Athletes

The dangerous effects from the sun can disrupt athletes and their game. It is especially important to practice proper sun protection while outdoors. Since sun exposure is the most preventable risk factor for skin cancer, the American Academy of Dermatology recommends athletes and weekend sports enthusiasts be Be Sun Smart™. Sun exposure is the most preventable risk factor for skin cancer. You can have fun in the sun and Be Sun Smart™. Here’s how to do it:

- Generously apply sunscreen to all exposed skin using a Sun Protection Factor (SPF) of at least 15 that provides broad-spectrum protection from both ultraviolet A (UVA) and ultraviolet B (UVB) rays. Re-apply every two hours, even on cloudy days, and after swimming or sweating. Look for the AAD Seal of Recognition™ on products that meet these criteria.
- Wear protective clothing, such as a long-sleeved shirt, pants, a wide-brimmed hat and sunglasses, where possible.
- Seek shade when appropriate, remembering that the sun’s rays are strongest between 10 a.m. and 4 p.m.
- Use extra caution near water, snow and sand as they reflect the damaging rays of the sun which can increase your chance of sunburn.
- Protect children from sun exposure by applying sunscreen.
- Get vitamin D safely through a healthy diet that includes vitamin supplements. Don’t seek the sun.
- Avoid tanning beds. Ultraviolet light from the sun and tanning beds can cause skin cancer and wrinkling. If you want to look like you’ve been in the sun, consider using a sunless self-tanning product, but continue to use sunscreen with it.
- Check your birthday suit on your birthday. If you notice anything changing, growing, or bleeding on your skin, see a dermatologist. Skin cancer is very treatable when caught early. by applying a broad-spectrum sunscreen with an SPF of 15 or higher, wearing protective clothing and seeking shade whenever possible.

This year, more than 1 million new cases of skin cancer will be diagnosed in the United States, making it the most common form of cancer. Even more alarming is the fact that an estimated 10,850 people will die of skin cancer this year.

No reprints available.

From the National Rosacea Society

New Survey Maps Emotional Toll Of Rosacea As Severity Increases

Rosacea has been shown to inflict significant damage to quality of life and emotional well-being in direct proportion to its physical effects. It is a disorder that affects an estimated 14 million Americans and is becoming increasingly widespread as the populous baby boom generation enters the most susceptible ages. This survey was conducted on 603 patients, 76% said rosacea’s effect on their personal appearance had lowered their self-confidence and self-esteem, and nearly half said it had diminished their outlook on life. Moreover, for those who described their condition as severe, 94% said it had damaged their self-confidence and 77% said their rosacea had negatively affected their outlook. More than 69% of the total survey respondents said they had experienced embarrassment, 65% reported feelings of frustration and 41% experienced anxiety over their condition. 35% said they had felt helpless; 25% suffered depression; and 18 % felt isolated. The respondents with severe symptoms, nearly 61% said they avoided face-to-face contact during flare-ups, and 38% said they even canceled meetings or social engagements because of rosacea’s effect on their appearance. With greater public awareness, it has been determined that more people are seeking medical attention before their rosacea becomes increasingly severe. Therefore the impact of rosacea has been managed before the emotional consequences become even more intrusive on daily lives. The good news is that for 80% of the survey respondents, the results of effective medical therapy have improved or somewhat improved their emotional well-being. Many rosacea patients said they had learned to successfully cope with their condition and that openly discussing their disorder with others helps dispel any embarrassment or social unease. Nearly 56% of the respondents said they have explained their medical condition to others during a flare-up, and 56% said they carried on their lives as usual. The signs and symptoms of rosacea can be effectively controlled with medical treatment and lifestyle changes.

No reprints available.

Legal Issues Q & A

Legal Issues Q & A



By Padraic Deighan, MBA, JD
Aston McLauren, LLC.

Question:

I am an esthetician and I would like to work in a physician's office. I have seen and heard many times that an esthetician license is "not recognized in a physician office. What does this mean?

Answer:

There are several states that will not recognize an esthetician license in a physician's facility. State regulatory boards that govern your license must be able to provide protection for consumers. They do so by periodically inspecting licensed facilities where the licensee works. If a consumer files a complaint, the board has the right and responsibility to inspect that licensee within the facility where they are performing the services.

Physicians (by their licenses) are permitted to designate or delegate the performance of many (but not all) services to subordinates or employees. They are permitted this discretion pursuant to their licensure. The physician is responsible for the performance and outcomes. According to *PCI Journal's* most recent study conducted of state regulatory boards (that govern cosmetologists and estheticians), there are over 28 boards that have chosen NOT to govern licensees when they don't work in a traditional salon or spa setting. Their decisions are partially based on what I have said above—that, physicians may designate or delegate, and according to the results of the survey, the inspectors would not have adequate knowledge about services that could be designated by the physician to the licensee.

In other facilities such as your own salon or spa, you need a license (in 49 states). The license is not necessarily required in a physician's office. If the physician is satisfied that you are capable, he or she may designate many services to you. Your license may be part of the reason that the physician is comfortable in delegating services to you, but it is not the legal vehicle in which they are delegating to you.

A few years ago, several state Boards of Cosmetology tried to take action against both physicians and estheticians.

The theory was that the esthetician was not working for a cosmetologist and there could be action taken against the esthetician license. The further theories were that the physicians could not supervise the estheticians because they were not cosmetologists. Other issues were that the physician's office had not adequately licensed the facility with the State Board of Cosmetology. In many states, the licensed esthetician is required to be working in a "licensed" facility. There also are professional liability concerns as well.

Fortunately, these actions failed to impart any changes in the concept that individuals are permitted to perform services designated by the physician.

Some may be of the opinion that you should not promote that you are an "esthetician" while you are performing services for a physician. The thought is that since you are not performing the services pursuant to your license, you should not promote the fact that you have the license. I am also familiar (first handed experience with clients in multiple states) that when a state Board of Cosmetology visits a physician's office on a compliance matter, there is little that they can do to the physician or esthetician working in this setting. What I have noticed is that it is a good practice to have your license posted in the office. This seems to satisfy the boards in many states. It also gives tacit approval of the concept to refer to yourself as an esthetician!

Professional envy has been a motivator to many compliance or regulatory matters (including those discussed above). Most boards are required by law to investigate a claim regardless of how apparent it may be, that it is motivated by illegitimate reasons. Many of these situations that I have encountered have been as a result of one esthetician reporting to a board that another esthetician is engaging in improper conduct.

If you are choosing to work in a physician's office, please remember to comply with state licensure requirements to maintain your license and/or facility licenses, if required. If there are continuing education requirements, be sure to comply with them even though you are working in a physician's office.

My final commentary on this issue is that if you are choosing to work for a physician, choose one that is already performing services similar to what you will be offering. It would be better to work with a "core" physician that is practicing cosmetic or aesthetic medicine. The "core" physicians are dermatologists and plastic surgeons. They are the physicians that by training and experience are practicing cosmetic and aesthetic medicine.

(Continued on Page 25)

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- Visible lightening of moderate-to-severe melasma in 1 month with 77% of patients clear or nearly clear in 8 weeks^{1,2}
- Proven safe for intermittent use up to 6 months within a 12-month period³
- The only FDA-approved treatment for melasma
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Melasma control you can stay with.

Mild-to-moderate redness, peeling, burning, dryness, or itching may be experienced. People with allergic reactions, such as asthma, to sulfites should not use Tri-Luma® Cream. The safety and efficacy of Tri-Luma® Cream in patients with skin types V and VI have not been studied. Excessive bleaching resulting in undesirable cosmetic effects in patients with darker skin cannot be excluded. The safety and efficacy of Tri-Luma® Cream in pregnant women and nursing mothers have not been established. Tri-Luma® Cream contains hydroquinone, which may produce exogenous ochronosis, a gradual blue-black darkening of the skin, whose occurrence should prompt discontinuation of therapy. Tri-Luma® Cream contains the corticosteroid fluocinolone acetonide. Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for corticosteroid insufficiency after withdrawal of treatment. Exposure to sunlight, sunlamps, or UV light and extreme heat, wind, or cold should be avoided. Use of a broad-spectrum sunscreen with SPF of 30 or higher is required. Wear protective clothing and change to nonhormonal forms of birth control if hormonal methods are used.

Please see next page for brief summary of Prescribing Information.

www.triluma.com

#1 prescribed by dermatologists for melasma

TRI-LUMA® Cream
(fluocinolone acetonide 0.01%, hydroquinone 4%, tretinoin 0.05%)
Brief Summary For External Use Only Not for Ophthalmic Use **Rx only**

INDICATIONS AND USAGE:
TRI-LUMA Cream is indicated for the short-term intermittent treatment of moderate to severe melasma of the face, in the presence of measures for sun avoidance, including the use of sunscreens.

The following are important statements relating to the indication and usage of TRI-LUMA Cream:

- TRI-LUMA Cream, a combination drug product containing corticosteroid, retinoid, and bleaching agent, was proven safe for the inter-mittent treatment of melasma, with cumulative treatment time of at least 180 days. Because melasma usually recurs upon discontinuation of TRI-LUMA Cream, patients can be retreated with TRI-LUMA until melasma is resolved. Patients need to avoid sunlight exposure, use sunscreen with appropriate SPF, wear protective clothing, and change to non-hormonal forms of birth control, if hormonal methods are used.
- In clinical trials used to support the use of TRI-LUMA Cream in the treatment of melasma, patients were instructed to avoid sunlight exposure to the face, wear protective clothing and use a sunscreen with SPF 30 each day. They were to apply the study medication each night, after washing their face with a mild soapless cleanser.
- The safety and efficacy of TRI-LUMA Cream in patients of skin types V and VI have not been studied. Excessive bleaching resulting in undesirable cosmetic effect in patients with darker skin cannot be excluded.
- The safety and efficacy of TRI-LUMA Cream in the treatment of hyperpigmentation conditions other than melasma of the face have not been studied.
- Because pregnant and lactating women were excluded from, and women of child-bearing potential had to use birth control measures in the clinical trials, the safety and efficacy of TRI-LUMA Cream in pregnant women and nursing mothers have not been established (See PRECAUTIONS, *Pregnancy*).

CONTRAINDICATIONS: TRI-LUMA Cream is contraindicated in individuals with a history of hypersensitivity, allergy, or intolerance to this product or any of its components.

WARNINGS: TRI-LUMA Cream contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening asthmatic episodes in susceptible people.

The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

TRI-LUMA Cream contains hydroquinone, which may produce exogenous ochronosis, a gradual blue-black darkening of the skin, whose occurrence should prompt discontinuation of therapy. The majority of patients developing this condition are Black, but it may also occur in Caucasians and Hispanics.

Cutaneous hypersensitivity to the active ingredients of TRI-LUMA Cream has been reported in the literature. In a patch test study to determine sensitization potential in 221 healthy volunteers, three volunteers developed sensitivity reactions to TRI-LUMA Cream or its components.

PRECAUTIONS: General: TRI-LUMA Cream contains hydroquinone and tretinoin that may cause mild to moderate irritation. Local irritation, such as skin reddening, peeling, mild burning sensation, dryness, and pruritus may be expected at the site of application. Transient skin reddening or mild burning sensation does not preclude treatment. If a reaction suggests hypersensitivity or chemical irritation, the use of the medication should be discontinued.

TRI-LUMA Cream also contains the corticosteroid fluocinolone acetonide. Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced by systemic absorption of topical corticosteroid while on treatment. If HPA axis suppression is noted, the use of TRI-LUMA Cream should be discontinued. Recovery of HPA axis function generally occurs upon discontinuation of topical corticosteroids.

Information for Patients: Exposure to sunlight, sunlamp, or ultraviolet light should be avoided. Patients who are consistently exposed to sunlight or skin irritants either through their work environment or habits should exercise particular caution. Sunscreen and protective covering (such as the use of a hat) over the treated areas should be used. Sunscreen use is an essential aspect of melasma therapy, as even minimal sunlight sustains melanocyte activity.

Weather extremes, such as heat or cold, may be irritating to patients treated with TRI-LUMA Cream. Because of the drying effect of this medication, a moisturizer may be applied to the face in the morning after washing. Application of TRI-LUMA Cream should be kept away from the eyes, nose, or angles of the mouth, because the mucosa is much more sensitive than the skin to the irritant effect. If local irritation persists or becomes severe, application of the medication should be discontinued, and the health care provider consulted. Allergic contact dermatitis, blistering, crusting, and severe burning or swelling of the skin and irritation of the mucous membranes of the eyes, nose, and mouth require medical attention. If the medication is applied excessively, marked redness, peeling, or discomfort may occur.

This medication is to be used as directed by the health care provider and should not be used for any disorder other than that for which it is prescribed.

Laboratory Tests: The following tests may be helpful in evaluating patients for HPA axis suppression

ACTH or cosyntropin stimulation test

A.M. plasma cortisol test

Urinary free cortisol test

Drug Interactions: Patients should avoid medicated or abrasive soaps and cleansers, soaps and cosmetics with drying effects, products with high concentration of alcohol and astringent, and other irritants or keratolytic drugs while on TRI-LUMA Cream treatment. Patients are cautioned on concomitant use of medications that are known to be photosensitizing.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies to determine the carcinogenic potential of TRI-LUMA Cream have not been conducted.

Studies of hydroquinone in animals have demonstrated some evidence of carcinogenicity. The carcinogenic potential of hydroquinone in humans is unknown.

Studies in hairless albino mice suggest that concurrent exposure to tretinoin may enhance the tumorigenic potential of carcinogenic doses of UVB and UVA light from a solar simulator. This effect has been confirmed in a later study in pigmented mice, and dark pigmentation did not overcome the enhancement of photocarcinogenesis by 0.05% tretinoin. Although the significance of these studies to humans is not clear, patients should minimize exposure to sunlight or artificial ultraviolet irradiation sources.

Mutagenicity studies were not conducted with this combination of active ingredients. Published studies have demonstrated that hydroquinone is a mutagen and a clastogen. Treatment with hydroquinone has resulted in positive findings for genetic toxicity in the Ames assay in bacterial strains sensitive to oxidizing mutagens, in *in vitro* studies in mammalian cells, and in the *in vivo* mouse micronucleus assay. Tretinoin has been shown to be negative for mutagenesis in the Ames assay. Additional information regarding the genetic toxicity potential of tretinoin and of fluocinolone acetonide is not available.

A dermal reproductive fertility study was conducted in SD rats using a 10-fold dilution of the clinical formulation. No effect was seen on the traditional parameters used to assess fertility, although prolongation of estrus was observed in some females, and there was a trend towards an increase in pre-and post-implantation loss that was not statistically significant. No adequate study of fertility and early embryonic toxicity of the full-strength drug product has been performed. In a six-month study in minipigs, small testes and severe hypovolemia were found when males were treated topically with the full strength drug product.

Pregnancy: Teratogenic Effects: Pregnancy Category C: TRI-LUMA Cream contains the teratogen, tretinoin, which may cause embryo-fetal death, altered fetal growth, congenital malformations, and potential neurologic deficits. It is difficult to interpret the animal studies on teratogenicity with TRI-LUMA Cream, because the availability of the dermal applications in these studies cannot be assured, and comparison with clinical dosing is not possible. There are no adequate and well-controlled studies in pregnant women. TRI-LUMA Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Summary Statement on Teratogenic Risk

TRI-LUMA Cream contains the teratogen, tretinoin, which may cause embryo-fetal death, altered fetal growth, congenital malformations, and potential neurologic deficits. However, human data have not confirmed an increased risk of these developmental abnormalities when tretinoin is administered by the topical route.

Clinical considerations relevant to actual or potential inadvertent exposure during pregnancy:

In clinical trials involving TRI-LUMA Cream in the treatment of facial melasma, women of child-bearing potential initiated treatment only after having had a negative pregnancy test and used effective birth control measures during therapy. Thus, safety and efficacy of TRI-LUMA Cream in pregnancy has not been established. In general, use of drugs should be reduced to a minimum in pregnancy. If a patient has been inadvertently exposed to TRI-LUMA Cream in pregnancy, she should be counseled on the risk of teratogenesis due to this exposure. The risk of teratogenesis due to topical exposure to TRI-LUMA Cream may be considered low. However, exposure during the period of organogenesis in the first trimester is theoretically more likely to produce adverse outcome than in later pregnancy.

The prescriber should have the following clinical considerations in making prescribing decisions:

- The potential developmental effects of tretinoin are serious but the risk from topical administration is small.
- Exposure during the period for organogenesis in the first trimester is theoretically more likely to produce adverse outcome than in later pregnancy.
- The risk to the mother for not treating melasma should be determined by the physician with the patient. Mild forms of melasma may not necessarily require drug treatment. TRI-LUMA Cream is indicated for the treatment of moderate to severe melasma. Melasma may also be managed with other forms of therapy such as topical hydroquinone in the presence of sunlight avoidance, or stopping the use of hormonal birth control methods. If possible, delaying treatment with TRI-LUMA Cream until after delivery should be considered.

- There are no adequate and well-controlled studies in pregnant women. TRI-LUMA Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Data Discussion: Tretinoin is considered to be highly teratogenic upon systemic administration. Animal reproductive studies are not available with topical hydroquinone. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

1. Human Data

- In clinical trials involving TRI-LUMA Cream in the treatment of facial melasma, women of child-bearing potential initiated treatment only after having had a negative pregnancy test, and used effective birth control measures during therapy. However, 15 women became pregnant during treatment with TRI-LUMA Cream. Of these pregnancies, 6 resulted in healthy babies, 6 outcomes still unknown, 2 were reported as miscarriages, and 1 case was lost to follow-up.

- Epidemiologic studies have not confirmed an increase in birth defects associated with the use of topical tretinoin. However, there may be limitations to the sensitivity of epidemiologic studies in the detection of certain forms of fetal injury, such as subtle neurologic or intelligence deficits.

2. Animal Data

- In a dermal application study using TRI-LUMA Cream in pregnant rabbits, there was an increase in the number of *in utero*

deaths and a decrease in fetal weights in litters from dams treated topically with the drug product.

- In a dermal application study in pregnant rats treated with TRI-LUMA Cream during organogenesis there was evidence of teratogenicity of the type expected with tretinoin. These teratological alterations included cleft palate, protruding tongue, open eyes, umbilical hernia, and retinal folding or dysplasia.

- In a dermal application study on the gestational and postnatal effects of a 10-fold dilution of TRI-LUMA Cream in rats, an increase in the number of stillborn pups, lower pup body weights, and delay in preputial separation were observed. An increase in overall activity was seen in some treated litters at postnatal day 22 and in all treated litters at five weeks, a pattern consistent with effects previously noted in animals exposed *in utero* with retinoic acids. No adequate study of the late gestational and postnatal effects of the full-strength TRI-LUMA Cream has been performed.

- It is difficult to interpret these animal studies on teratogenicity with TRI-LUMA Cream, because the availability of the dermal applications in these studies could not be assured, and comparison with clinical dosing is not possible.

All pregnancies have a risk of birth defect, loss, or other adverse event regardless of drug exposure. Typically, estimates of increased fetal risk from drug exposure rely heavily on animal data. However, animal studies do not always predict effects in humans. Even if human data are available, such data may not be sufficient to determine whether there is an increased risk to the fetus. Drug effects on behavior, cognitive function, and fertility in the offspring are particularly difficult to assess.

Nursing Mothers: Corticosteroids, when systemically administered, appear in human milk. It is not known whether topical application of TRI-LUMA Cream could result in sufficient systemic absorption to produce detectable quantities of fluocinolone acetonide, hydroquinone, or tretinoin in human milk. Because many drugs are secreted in human milk, caution should be exercised when TRI-LUMA Cream is administered to a nursing woman. Care should be taken to avoid contact between the infant being nursed and TRI-LUMA Cream.

Geriatric Use: Safety and effectiveness of TRI-LUMA Cream in pediatric patients have not been established.

Pediatric Use: Clinical studies of TRI-LUMA Cream did not include sufficient number of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS: In the controlled clinical trials, adverse events were monitored in the 161 patients who used TRI-LUMA Cream once daily during an 8-week treatment period. There were 102 (63%) patients who experienced at least one treatment-related adverse event during these studies. In the long-term clinical study, from a total of 314 patients treated with TRI-LUMA Cream for at least 180 cumulative days, there were 202 (64%) patients who experienced at least one treatment-related adverse event. No significant increase in severity or incidence of the adverse events was observed from long term use of TRI-LUMA Cream compared with events reported during the 8-week controlled clinical studies. The most frequently reported adverse events that were observed from the controlled clinical trials, and the long term safety were erythema, desquamation, and burning, at the site of application. The number and percentages of these events were markedly lower in the long-term study than in the controlled clinical studies. The great majority of these events were mild to moderate in severity.

Adverse events reported by at least 1% of patients and judged by the investigators to be reasonably related to treatment with TRI-LUMA Cream from the controlled clinical studies and the long-term study are summarized (in decreasing order of frequency).

Incidence and Frequency of Treatment-related Adverse Events with TRI-LUMA Cream in at least 1% or more of Patients (N=161)		
Adverse Even	Number (%) of Patients	
Erythema	66 (41%)	
Desquamation	61 (38%)	
Burning	29 (18%)	
Dryness	23 (14%)	
Pruritus	18 (11%)	
Acne	8 (5%)	
Paresthesia	5 (3%)	
Telangiectasia	5 (3%)	
Hyperesthesia	3 (2%)	
Pigmentary changes	3 (2%)	
Irritation	3 (2%)	
Papules	2 (1%)	
Acne-like rash	1 (1%)	
Rosacea	1 (1%)	
Dry mouth	1 (1%)	
Rash	1 (1%)	
Vesicles	1 (1%)	

In an open-label long-term safety study, patients who have had cumulative treatment of melasma with TRI-LUMA Cream for 6 months showed a similar pattern of adverse events as in the 8-week studies.

Summary of Most Common Treatment-related Adverse Events (TRAE)* Study 29		
Number (%) of Patients		
Treatment Group		
TRI-LUMA		
Patients with at least 180 Cumulative Days of TRI-LUMA Treatment (N=314)		
Preferred Term	All Patients (N=569)	
Total number of TRAE*	326 (57.29)	202 (64.33)
Application site erythema	166 (29.17)	105 (33.44)
Application site desquamation	145 (25.48)	91 (28.98)
Application site dryness	46 (8.08)	27 (8.60)
Application site burning	38 (6.68)	25 (7.96)
Application site inflammation	31 (5.45)	24 (7.64)
Application site reaction nos	31 (5.45)	17 (5.41)
Application site rash	30 (5.27)	18 (5.73)
Application site pruritus	24 (4.22)	18 (5.73)
Application site pigmentation changes	23 (4.04)	18 (5.73)

* Defined as "probably" or "possibly" related to study medication

Data source: Section 14.3, Tables 8.1.1, 8.1.2, and 8.1.3

The severity, incidence and type of adverse events experienced from 6 months cumulative use were not significantly different from the events reported for all patients.

The incidence of application site pigmentation changes that occurred in both the controlled and long-term safety studies included 11 occurrences of hypopigmentation and 18 occurrences of hyperpigmentation in 27 patients.

The following local adverse reactions have been reported infrequently with topical corticosteroids. They may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, and milaria.

TRI-LUMA Cream contains hydroquinone, which may produce exogenous ochronosis, a gradual blue-black darkening of the skin, whose occurrence should prompt discontinuation of therapy. Cutaneous hypersensitivity to the active ingredients of TRI-LUMA Cream has been reported in the literature. In a patch test study to determine sensitization potential in 221 healthy volunteers, three volunteers developed sensitivity reactions to TRI-LUMA Cream or its components.

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Manufactured by:

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20024-1203 Revised: December 2003

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GALDERMA



Any physician may delegate esthetician services to you, but these “core” physicians are the ones most suited to do so. This is a legal issue. Non-“core” physicians probably should not be delegating esthetician services since it is outside their training and experience.

The practical issue regarding this is that the dermatologists and plastic surgeons will be able to refer far more clients to you because of their volume and the nature of their practice. Be cautious when a physician is looking to expand his or her practice into esthetic services and utilizing your services to do so. Better to work for physicians that are already engaged in aesthetic or cosmetic medicine.

Padraic B. Deighan, MBA, J.D. Padraic Deighan is the President of Aston McLaren LLC., a medical and spa consulting firm and the former President and Chief Executive Officer of DermAmerica, Inc., the largest network of dermatology and plastic surgery centers. Mr. Deighan has been a health care attorney for over 20 years. He is a former American Bar Association committee chairman for the Health and Insurance. He has numerous written publications on the subjects of cosmetic surgery, medical management, spa and medical spa issues as well as business strategies and development and is a frequent national speaker on these subjects.

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- Demystify the Skin Structure Rachel Rowen, BA
- History of Exfoliations and AHAs. Elliot Millstein, BA
- Value of Physician-Dispensed Skin Care Mary P. Lupo, M.D.
- Laser Safety and Legal Uses TBA
- A Clinically Proven Paradigm for Photoaging Therapy Karl Thornfeldt, M.D.
- New Technologies in the Medical Spa. TBA
- Product Inventory Management TBA
- New Technology for the Treatment of Sebosuppression & Acne Tatiana Kononov
- State Legislative Update Susanne S. Warfield
- plus more...

Courses subject to change without notice.

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Cosmedix, LLC.*
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Doctor's Dermatologic Formula
Dermastart, Inc.
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Genesis Biosystems
Hill Dermaceuticals, Inc.
Iredale Mineral Cosmetics, Ltd.*
Is Clinicl By Innovative Skincare
Jan Marini Skin Research, Inc.*
La Roche Posay*
Nia 24 (Formerly Niadyne)
N.V. Perricone, M.D., Ltd.*
Obagi Medical Products
PCI Publishing/PCI Journal*

PCA Advanced SkinCare Systems
Physicians Complex
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Photo Medex - ProCyte
SkinCeuticals, Inc.*
Skin Health Solutions/DermHA
Skin Medica, Inc.*
Syneron*
Vivant Skin Care Inc.
Young Pharmaceuticals*

**Corporate Members*

The SDSS Annual Meeting is Open to Non-Members.

Exhibit Hours

Tuesday, February 5th 9:00 am – 5:00 pm

EDUCATION SESSIONS

Scientific Sessions

Monday February 4th 8:00 am – 5:00 pm

Exhibitor Classroom Sessions

Tuesday February 5th 8:00 am – 5:00 pm

Scientific Sessions

Wednesday February 6th 8:00 am – 5:00 pm

*International Guild of Hair Removal Specialists

Scientific Session

Thursday February 7th 8:00 am – 4:00 pm

*NCEA Certified - 7 Hour Prep Class

Thursday February 7th 8:00 am – 4:00 pm

POST CONFERENCE SESSIONS

**Additional Registration Fee Required*

- NCEA Certified
- International Guild of
Hair Removal Specialists

Registration for the SDSS Meeting

Early Bird Registration - \$295.00* Before
January 20th, 2008.

Hotel Registration and Meeting Registration will begin as of September 1st, 2007

Register online at www.sdss.tv

Cancellation Policy: Registration fees, less a \$100.00 administrative fee, will be refunded upon notice of cancellation. All cancellations must be submitted in writing and postmarked by January 4, 2008, in order to receive a refund. There will be no refund of fees for cancellations received after this date.



Society of Dermatology SkinCare Specialists

MEMBERSHIP APPLICATION

BENEFITS: **Check website www.sdss.tv for additional benefits as they become available...*

- Subscription to the PCI Journal™ Official Journal of the SDSS.
- Subscription Discounts to Skin Inc. magazine, Cosmetic Surgery Times, Dermatology Times.
- Membership Certificate.
- Discounted rates to educational conferences, meetings and products.
- Membership Roster to network with other skin care professionals.

Preferred Address for SDSS Mailings:

Dues: \$150

Name: _____

Physician Name: *(If applicable)* _____

Practice/Company Name: *(If applicable)* _____

Address: _____

City: _____ **State:** _____ **Zip** _____ + 4 _____

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**Monthly SDSS eNewsletter sent via email*

Optional Information

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Are you a licensed esthetician _____ Cosmetologist _____ Nurse _____ Other _____

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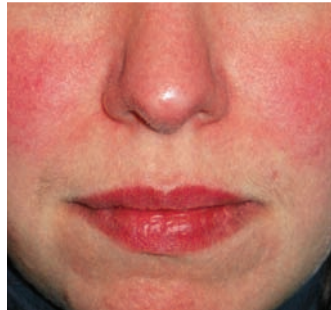
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9/06

Rosacea



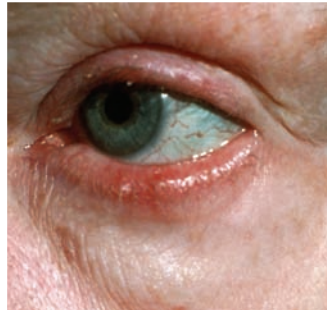
Subtype 1
(erythematotelangiectatic rosacea)



Subtype 2
(papulopustular rosacea)



Subtype 3
(phymatous rosacea)



Subtype 4
(ocular rosacea)

Onset

Rosacea is a chronic and potentially life-disruptive disorder primarily of the facial skin, often characterized by flare-ups and remissions.

Location

Often found on the cheeks, nose, chin or forehead, the redness and flare-ups tend to come and go. In some cases it may also occur on the neck, chest, scalp or ears.

History

Left untreated, bumps and pimples often develop, and in severe cases the nose can become swollen and bumpy from excess tissue. This condition, rhinophyma, can appear as a bulbous nose.

Description

Four subtypes of rosacea have been defined as common patterns or groupings of signs and symptoms.

Subtype 1 (erythematotelangiectatic rosacea), characterized by flushing and persistent redness, and may also include visible blood vessels.

Subtype 2 (papulopustular rosacea), characterized by persistent redness with transient bumps and pimples.

Subtype 3 (phymatous rosacea), characterized by skin thickening, often resulting in an enlargement of the nose from excess tissue.

Subtype 4 (ocular rosacea), characterized by ocular manifestations such as dry eye, tearing and burning, swollen eyelids, recurrent styes and potential vision loss from corneal damage.

General Characteristics

Typically beginning after age 30 as a redness. Fair skin individuals who tend to flush or blush easily are believed to be at greatest risk. The disease is more frequently diagnosed in women, but more severe symptoms tend to be seen in men.

Etiology

Persistent redness is the most common individual sign of rosacea, and may resemble a blush or sunburn that does not go away.

Treatment

Oral and topical medications may be prescribed to treat the bumps, pimples and redness. Physicians usually prescribe initial treatment with oral antibiotics and topical therapy to bring the condition under immediate control, followed by long-term use of the topical therapy alone to maintain remission.

Laser treatments, intense pulsed light sources or other medical and surgical devices may be used to remove visible blood vessels, reduce extensive redness or correct disfigurement of the nose. Ocular rosacea may be treated with oral antibiotics and other therapy.

Follow-up

For additional information:
National Rosacea Society
800 S. Northwest Hwy., Suite 200
Barrington, IL 60010
Tel: (888) NO-BLUSH



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Practice Marketing

Publicizable Treatments



By Nancy Trent, President
Trent & Company
Public Relations

Is your menu getting press for your spa?

The spa treatments you offer can be used to garner publicity that keeps your rooms full and helps your marketing efforts for a greater return on investment.

Off the Beaten Path

Media love what's new and different. Adopting a quirky new spa treatment will get their attention, as long as the treatment is effective.

Edgy treatments can move from new age to mainstream fast. Likewise, being the first to offer a breakthrough treatment will get you press before the rest. And, sometimes what's old is new again, especially right now with the return or ancient global healing rituals on spas menus.

Hot Ingredients

Beauty editors are ingredient mavens and often use the contents of spa products to develop stories for their magazines. Whether it is pomegranate, red tea, or licorice, media are always on the look out for the new healing element.

Ingredients can also help garner vertical press in trade publications. For example, wine and grape seed extracts are the hottest new ingredients for nurturing the body from the outside in and fighting the causes of aging. The trend, which has invaded Europe and Asia's most elite spas, is now making a splash in spa treatments across the U.S. From wine baths to grape seed scrubs, skin care companies are infusing wine and grape seed extracts into some products for superior protection against free radicals and aging. Packed with powerful Bioflavonoids from the essence of grapes, including Resveratrol and Polyphenols, these wine blends support the capillaries and health of the skin from harsh environmental conditions, stimulate collagen synthesis, promote tissue elasticity and calm the skin.

The Whole Package

Packaging spa treatments are a great way to sell more and keep repeat customers, but they are also a great publicity hook. After recent press about couples taking vacations when they find out they are expecting a baby, spas began introducing "Babymoon packages" for couples to plan a private getaway to celebrate their pregnancy. Babymoon packages make a great gift idea for friends and family members who announce their big news.

Promotional Days

Father's Day, Mother's Day, Valentine's Day and other holidays, are great promotional opportunities. Contact your Chamber of Commerce, local tourist attractions, charitable organizations, surrounding colleges and universities, radio and TV stations, and any other businesses to arrange cross-promotions. Work with their promotion directors to get exposure for your spa and exchange a giveaway, such as a signature spa service or basket of spa products.

Holidays present great opportunities to make your promotions fun, timely and attractive. Those are the ones that are likely to get the attention of new clients and the media. But it's up to you to make your spa's promotions interesting and newsworthy. From fabulous gift certificate programs and special events, to creating healthy holiday spa cuisine recipes, you can garner a wealth of media attention that will help your spa rise above the competition.

Since many people make New Year's resolutions, promote treatments that reduce stress or help with weight management and breaking bad habits. These would certainly be newsworthy especially if they were conducted by your spa as a community service.

Changing your menu of treatments for each season will create ongoing news hooks for your spa. Developing packages, promotions and sales will give you reasons to contact editors each quarter. Lifestyle magazine and newspapers often list "sales and bargains" shopping information. The spa industry is a retail industry. Beauty products have a shelf life and treatment needs change with skin needs. Promoting a cellulite treatment before the summer and putting it on sale after the summer will get two different stories from the same evergreen treatment.

Gifting a Story

Gift certificates in general are a good publicity hook. Creating certificates for specific treatments will help garner press for that item. You can start by promoting your holiday gift certificate program. For instance, for everyone who buys a gift certificate or a holiday present in the spa, the spa gives them a special holiday gift. Again, that gift may be a sample of some of your other products that are sold in the spa retail store.

Editors appreciate knowing about unusual holiday gifts. Contact the newspaper's business editor and tell him about your corporate gift certificates for company employees and their best customers.

A Picture's Worth a Thousand Words

Think about interesting visuals for your treatment. When Gwyneth Paltrow was photographed with circular burn marks on her back, spas offering an ancient therapeutic treatment called "cupping" saw a surge in requests for people looking to have cups of flaming alcohol pressed to their skin.

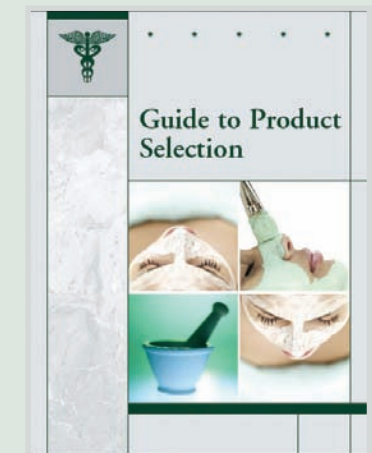
What's in a Name?

Generally speaking, Americans are obsessed with celebrities' lives. If there aren't celebrities in your area dropping by your spa, naming a treatment after one can help market and publicize a treatment. It helps people remember it and associate it with their favorite stars. A trendy or catchy name will be well received by media and not easily forgotten by current or prospective clients. Try luring women into your spa in packs with a "Desperate Housewives" package of day long pampering for four.

Adopting a trendy treatment isn't going to bring in new customers unless you generate that buzz. Public relations is critical to circulating your message to reach a large number of people through media that are most read, watched and listened to by your target audience.

Nancy Trent is the owner and founder of Trent & Company, Inc., a New York City-based public relations firm that specializes in publicity for the healthcare, fitness and spa industries.

She can be reached at (212) 966-0024 or through e-mail at nancy@trentandcompany.com. You may also visit www.trentandcompany.com.

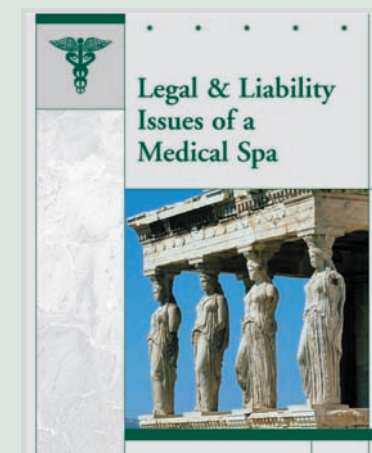


Guide to Product Selection By Sarah Burns

Price: \$ 42.95

Chapters include:

- Speciality Products
- Chemical Exfoliants
- Professional Products
- Primary Products
- Labeling, Components & Packaging
- Ingredient Descriptions
- Developing Vendor Relationships
- How to Retail Merchandise



Legal & Liability Issues of a Medical Spa By Cohen & Warfield

Price: \$ 99.95

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Practice Management

Leaving the Right Impression with Business Card Etiquette

By Dr. Kathleen D. Pagana, R.N.



Recently, while attending a conference, a lot of interesting people met at a dinner banquet. At the end of the meal, several wanted to exchange business cards. Two people were embarrassed to admit that they did not have cards, but said they planned to get them. Are you wondering if it is time to get a business card? Do you need an update on business card etiquette? If either or both of your answers are “yes,” this article will enhance your professional image. Let’s discuss five common questions related to business cards.

Why do you need a business card?

Business cards are a great way to capture essential information in a quick and user-friendly manner. Every professional needs a business card to network. Recently, a colleague at a luncheon was asked if she wanted to run in a 5K race to support breast cancer research. When asked for race details, the website was written on the back of a business card. Isn’t that better than writing on a table napkin?

Most people love to get a business card. It gives them a sense of being an important part of a team and having access to key personnel. Business cards can be clipped to a report, a note, or anything you are sending to someone. This lets the person know that you are the sender and gives your contact information

What information should be on a business card?

This will depend on the purpose of the card. Some basics include your name, degrees, position, and contact information – address, phone, email, and fax. If your full name is ambiguous (such as, “Pat”), add a title (for example, “Mr.” Pat Sweeney or “Ms.” Pat Sweeney). If you are trying to promote something, like a consulting business, make sure you have consultant on the card and include a web address if you have one.

It is a great idea to have more than one business card if this will help target your business to a specific audience. Business cards can also be designed for purely social situations. When a new family moved into a neighborhood, they gave everyone they met a business card with their names (parents and children) and contact information. Everyone was really impressed and quickly learned their names.

Business cards can benefit by the personal touch. For example, you may add your cell phone number on the back if you will be traveling and tough to get hold of during a certain time period. That is a thoughtful gesture that will be appreciated.

Every professional needs a business card to network.

The business card is one of the first graphic statements we make about ourselves.

Can I make my own business card?

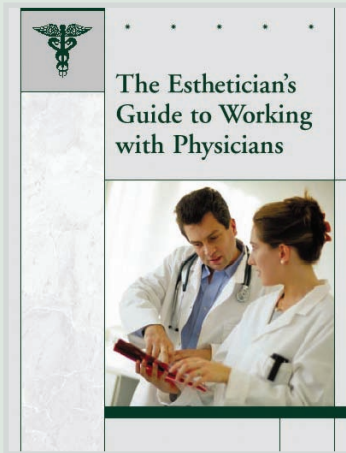
Yes, if this is the only way that you will get a card. This will give you an opportunity to test out what you have written on the card. Usually these home-made cards are readily detected by the perforations around the edges. As soon as you can afford something better, get the cards printed professionally. The business card is one of the first graphic statements we make about ourselves.

Consider asking your employer to provide a card so you can network more effectively. This will improve your image and the image of your facility. Make sure the card is in good condition. Don’t use a card if it is soiled, bent, or ripped because the card will not reflect a positive impression or memory of you. It is better to give no card than to give one in a bad condition. The business card is sometimes described as “the handshake you leave behind.” Men should not remove a warm and mushy card from their back pocket and present it to someone.

What are some common mistakes people make with business cards?

Here are five mistakes with some suggestions.

Passing out your cards like you are dealing a deck of cards. (It is better to have a person ask for your card. One way to do this is to ask for his or her card.)

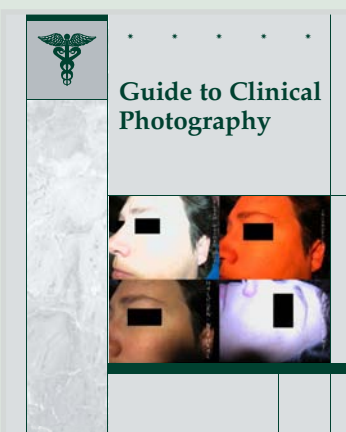


Guide to Working with Physicians By Susanne S. Warfield

Price: \$ 54.95

Chapters include:

- Examining your Career Options
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Guide to Clinical Photography By Deborah Sinclair Black Reed, RNC

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Price: \$ 42.95

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- A Brief History of Photography
- Basic Digital Camera Parts
- Choosing the Best Equipment
- Technique, Legal Implications of Photographing
- Appendix I HIPAA
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Not presenting the card.

(Business cards should be presented with the content face up and readable to the receiver. The receiver should look at the card and make a comment. For example, "I see you are a Computer Specialist.")

Writing on the card without asking permission.

(In some parts of the world, such as Japan, you deface the card if you write on it without asking permission.)

Not having your business cards with you at all times.

(Keep some cards in your wallet or purse at all times. You never know when someone will ask you for one. A business card holder will keep your cards looking professional.)

Not having a card and asking for someone else's card to write on the back.

(This is rude. You should jot your information on a piece of paper. Then, make sure this doesn't happen again.)

Does business card etiquette differ around the world?

Yes, it does. So, if you are traveling for business to a foreign country, check into this before you travel. Some countries (for example, Germany) are impressed by education and like to see all degrees and titles above the bachelor's degree. Other countries have a particular way to present the card. For example, in China, the card is held in both hands when it is presented. In Saudi Arabia, the card should be printed in English on one side and Arabic on the other side. When traveling to Poland, bring plenty of cards and give one to everyone you meet. For more tips on business etiquette for international travel, see www.executive-planet.com.

These questions and answers clearly show the need and importance of having a business card. If you don't have a business card, when are you going to get one?

Dr. Kathleen D. Pagana, RN, is a teacher and speaker, specializing in Momentum Leadership techniques for individuals and companies that want to reposition themselves to maximize their leadership potential. She draws on her experience of more than 25 years in healthcare, college teaching, administration, clinical practice, and business management. Among the 18 books Dr. Pagana has written, she has co-authored the best-selling book on healthcare diagnostic and laboratory testing. She began her professional career in the Army Nurse Corps, and received her PhD from the University of Pennsylvania in Nursing Research. For more information, please visit www.kathleenpagana.com.



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Meetings Calendar

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- Aug. 1-5

American Academy of Dermatology
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Contact: (866) 503-SKIN or
www.aad.org
- Aug. 4-5

Dermatology Nurses' Association
New York, NY.
Contact: (856) 256-2330 or
www.dnanurse.org
- Aug. 25-27

Face & Body Healthy Aging
San Francisco, CA.
Contact: (630) 653-2155 or
www.faceandbody.com

August 27th, 2007
4th Annual Medical Esthetic Conference
Sponsored by PCI Journal
Moscone South - San Francisco, CA

- Sept. 9

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Continuing Education**
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www.spaandresortexpo.com
- Sept. 8-10

**Medical Spa Expo & Conference
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New York, NY.
Contact: (800) 363-3631 or
www.spaandresortexpo.com
- Sept. 29-Oct. 1

**International Esthetics, Cosmetics
& Spa Conference,**
Orlando, FL.
Contact: (800) 624-3248 or
www.iecsc.com
- Oct. 7-8

**International Congress of Esthetics
& Spa**
Philladelphia, PA.
Contact: (800) 471-0229 or
www.lneonline.com
- Oct. 26-31

Plastic Surgery 2007
Baltimore, MD.
Contact: (800) 766-4955 or
www.plasticsurgery.org

- Nov. 12-15

ISPA Conference & Expo
Kissimmee, FL.
Contact: (888) 651-ISPA or
www.experienceispa.com
- 2008

Jan. 28-29

**National Coalition of Estheticians,
Manufacturers/Distributors &
Associations (NCEA) Meeting**
New Orleans, LA.
Contact: (201) 670-4100 or
www.ncea.tv

Feb. 1-5

**American Academy of Dermatology
Annual Meeting**
San Antonio, TX.
Contact: (866) 503-SKIN or
www.aad.org

Feb. 4-7

**6th Annual Society of Dermatology
SkinCare Specialists Meeting**
San Antonio, TX.
Contact: (201) 670-4100 or
www.sdss.tv

Feb. 23-25

**Medical Spa Expo & Conference
Spa and Resort Expo & Conference**
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www.spaandresortexpo.com

Apr. 2-6

**American Society for Laser
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Conference**
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Contact: (800) 363-3631 or
www.aslms.org

April 13-14

**International Congress of Esthetics
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Dallas, TX.
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www.lneonline.com

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