A Supplement to
Skin & Allergy News®

Skin Disease
Education Foundation

Roundup on Cosmetic Dermatology

WINTER 2006

TOPIC HIGHLIGHTS:

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Produced in affiliation with the 30th Hawaii Dermatology Seminar and the Cosmetic Dermatology Seminar.


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ELSEVIER

INTERNATIONAL MEDICAL NEWS GROUP

Evolving Clinical Roles for LED, Fillers, Botulinum Toxin

The field of cosmetic dermatology continues to explore, expand, and define the clinical utility of many commonly used tools, including light-emitting diode (LED) therapy, fillers, and botulinum toxin.

In the United States, LED therapy traditionally has consisted entirely of yellow light. The light has been used as an adjunct to laser therapy and light therapy for treatment of a variety of conditions. Recently, other colors of LED therapy have become available, including blue, red, and near-infrared.

David J. Goldberg, M.D., J.D.

"The impact of LED therapy on the skin is related to its effect on basic cellular structures," said David J. Goldberg, M.D., J.D., Clinical Professor of Dermatology and Director of Laser Research and Mohs Surgery at Mount Sinai School of Medicine in New York City. "Each color of LED light penetrates to a different depth in the skin and has a potentially different effect on different portions of the cell structure. Thus, it should come as no surprise that different LED therapies are optimally used for different applications. Sometimes, the best approach is to use more than one LED therapy for the same patient."

The role of LED therapy has yet to be fully defined, Dr. Goldberg added, but the modality's popularity results from its ease of use, the ability to use it on people with all ethnic skin colors, and the lack of pain resulting from treatment.

Recently Dr. Goldberg spearheaded a multicenter United States/United Kingdom study that explored the roles of combining 633-nm and 830-nm LED therapy for the treatment of early photoaged skin: "The combined treatment led to overall improvement in the quality of skin, with electron microscopic ultrastructural changes suggesting the formation of new collagen after treatment." Traditionally, collagen fillers have been the treatment of choice, but over the past few years newer fillers have entered the market to expand treatment options. The newer fillers consist of hyaluronic acid, poly (L-lactic acids), and calcium hydroxyapatite. Each of the fillers has advantages and disadvantages, and the scope of application for individual products has yet to be defined. In some cases, different types of fillers are used together to achieve desired results.

"The era of fillers is just beginning in the United States," said Dr. Goldberg. "If you look at Europe, many more short-acting, intermediate-acting, and long-acting fillers are available than in the United States." Over the next several years, the United States can expect to see a variety of hyaluronic fillers. Some will be shorter-acting and others will last longer than currently available agents.

Development of new fillers continues, and clinical options in the United States should continue to evolve in the future, added Dr. Goldberg.

The role of botulinum toxin in cosmetic dermatology in the United States continues to expand. At present, the material is used to soften wrinkles around the forehead, eyes (crow's feet), lower eyelids, lip, chin, and neck. Both botulinum toxin A and botulinum toxin B have been used in the United States, but botulinum toxin B is no longer readily available for cosmetic purposes, leaving cosmetic dermatologists with the Botox brand of botulinum toxin type A (Allergan Inc.). That could change in the future.

"Currently, US Food and Drug Administration sponsored studies are ongoing, involving the use of two newer types of botulinum toxin A," said Dr. Goldberg. "These studies will lead to newer and potentially different botulinum toxins that can be offered to our patients." ■

Dr. Goldberg has received funding for clinical grants from Photo Therapeutics, Cynosure, Inc., Neocutis Swiss Technology, Inamed Corporation, Thermage, Inc., and Cutera Inc. He is also a consultant to BioForm Medical Inc., Lumenis Ltd., and Juva Medical Inc. He discusses the off-label use of Mentor Corporation, Inamed, and Juva products.

Please see brief summary on following page.

Sculptra®

injectable poly-L-lactic acid

Brief Summary. Please see complete product information.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed physician, or properly licensed practitioner.

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DEVICE DESCRIPTION

SCULPTRA™ is an injectable implant that contains microparticles of poly-L-lactic acid, a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family. **SCULPTRA** is reconstituted prior to use by the addition of Sterile Water for Injection, USP (SWFI) to form a sterile non-pyrogenic suspension.

INTENDED USE / INDICATIONS

SCULPTRA is intended for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus.

CONTRAINDICATIONS

- **SCULPTRA** should not be used in any person who has hypersensitivity to any of the components of the product.

WARNINGS

- Use of **SCULPTRA** in any person with active skin inflammation or infection in or near the treatment area should be deferred until the inflammatory or infectious process has been controlled.
- Do not overcorrect (overfill) a contour deficiency because the depression should gradually improve within several weeks as the treatment effect of **SCULPTRA** occurs (see **IMPORTANT CONSIDERATIONS**).
- Injection procedure reactions to **SCULPTRA** have been observed consisting mainly of hematoma, bruising, edema, discomfort, inflammation, and erythema. The most common device related adverse effect was the delayed occurrence of subcutaneous papules, which were confined to the injection site and were typically palpable, asymptomatic and non-visible. Refer to **ADVERSE EVENTS** for details.
- Special care should be taken to avoid injection into the blood vessels. An introduction into the vasculature may occlude the vessels and could cause infarction or embolism.

PRECAUTIONS

- **SCULPTRA** should only be used by health care providers with expertise in the correction of volume deficiencies in patients with human immunodeficiency virus after fully familiarizing themselves with the product, the product educational materials, and the entire package insert.
- **SCULPTRA** vials are for single patient use only. Do not reuse or resterilize the vial. Do not use if package or vial is opened or damaged.
- Long-term safety and effectiveness of **SCULPTRA** beyond two years have not been investigated. Dermik® is conducting a post approval study to evaluate the safety and effectiveness of **SCULPTRA** beyond two years.
- **SCULPTRA** should be used in the deep dermis or subcutaneous layer. Avoid superficial injections. Special care must be taken when using **SCULPTRA** in areas of thin skin. Refer to **PATIENT TREATMENT** for instructions regarding injection techniques.
- Safety and effectiveness of treatment in the periorbital area have not been established.
- As with all transcutaneous procedures, **SCULPTRA** injection carries a risk of infection. Standard precautions associated with injectable materials should be followed.
- As with all injections, patients treated with anti-coagulants may run the risk of a hematoma or localized bleeding at the injection site.
- Universal precautions must be observed when there is a potential for contact with patient body fluids. The injection session must be conducted with aseptic technique.
- After use, treatment syringes and needles may be potential biohazards. Handle accordingly and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements.
- The safety of **SCULPTRA** for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established.
- No studies of interactions of **SCULPTRA** with drugs or other substances or implants have been made.
- The safety and effectiveness data from clinical trials of **SCULPTRA** in non-Caucasians and women with human immunodeficiency virus are limited. Dermik® will conduct a post approval study in non-Caucasians and women with human immunodeficiency virus.
- The safety of using **SCULPTRA** in patients with increased susceptibility to keloid formation and hypertrophic scarring has not been studied. Dermik® will conduct a post approval study to determine the likelihood of keloid formation and hypertrophic scars in patients with human immunodeficiency virus receiving **SCULPTRA** injections.
- The patient should be informed that he or she should minimize exposure of the treatment area to excessive sun and UV lamp exposure until any initial swelling and redness has resolved.

ADVERSE EVENTS

Adverse event data from four clinical studies that included 277 patients are summarized in Tables 1 & 2 below.

TABLE 1:
NUMBER OF PATIENTS WITH TREATMENT-RELATED ADVERSE EVENTS OBSERVED IN CLINICAL STUDIES WITH TWO-YEAR FOLLOW-UP

	VEGA STUDY 50 Patients	C&W STUDY*** 29 Patients	AVERAGE DURATION (DAYS)
INJECTION PROCEDURE RELATED ADVERSE EVENTS			
Bruising	3(6%)	11(38%)	6
Edema	2(4%)	2(7%)	3
Discomfort	0	3(10%)	3
Hematoma	14(28%)	0	17
Inflammation	0	3(10%)	3
Erythema	0	3(10%)	3
DEVICE-RELATED ADVERSE EVENTS			**AVERAGE ONSET** (Months)**
Injection site subcutaneous papule*	26(52%)	9(31%)	7

*Subcutaneous papules refer to lesions of 5 mm or less, typically palpable, asymptomatic and non-visible.
**Onset data available from VEGA study only. Duration not noted for subcutaneous papules because most were ongoing at study completion.
*** Safety data were collected *post hoc* for 27 of the patients at approximately two years from study start.

TABLE 2:
NUMBER OF PATIENTS WITH TREATMENT-RELATED ADVERSE EVENTS OBSERVED IN CLINICAL STUDIES WITH ONE-YEAR FOLLOW-UP

	APEX 002 STUDY 99 Patients	BLUE PACIFIC STUDY 99 patients
INJECTION PROCEDURE RELATED ADVERSE EVENTS		
Bruising	1(1%)	30(30%)
Edema	3(3%)	17(17%)
Discomfort	19(19%)	15(15%)
Erythema	0	3(3%)
DEVICE RELATED ADVERSE EVENTS		
Injection site subcutaneous papule	6(6%)	13(13%)

The duration of the adverse events in Table 2 was not collected. The most common device related adverse effect was the delayed occurrence of subcutaneous papules, which were confined to the injection site and were typically palpable, asymptomatic, and non-visible. The study protocols did not include evaluation of treatment for subcutaneous papules, therefore, no information is available on how the papules were treated. In the VEGA study, the average onset of subcutaneous papules was 7 months after initial injection (range 0.3 – 25 months). Subcutaneous papules resolved spontaneously in 6/26 patients (24%) during the study. No information of onset and duration of papules is available from the Chelsea & Westminster study.

Treatment related adverse events, not included in Table 1 & 2, observed in clinical studies with a frequency of less than 5% were: injection site tenderness, injection site lesion, injection site bleeding, injection site induration, injection site infection and fever.

The following adverse events, which were not observed in the clinical studies, were detected from post-marketing surveillance outside of the US and literature reports: visible nodules with or without inflammation or dyspigmentation, malaise, injection site abscess, allergic reaction, injection site atrophy, Quincke's edema, injection site fat atrophy, photosensitive reaction, fatigue, injection site granuloma, hypersensitivity reaction, skin rash, skin roughness, lack of effectiveness, injection site reaction, hypertrophy of skin, hair breakage, colitis not otherwise specified, brittle nails, application site discharge, angioedema, aching joints, ectropion, and telangiectasias.

IMPORTANT CONSIDERATIONS

Post-treatment care. Immediately following an injection session with **SCULPTRA**, redness, swelling, and/or bruising may be noted in the treatment area. Refer to **ADVERSE EVENTS** for details. After the injection session, an ice pack (avoiding any direct contact of the ice with the skin) should be applied to the treatment area in order to reduce swelling. It is important to thoroughly massage the treatment area to evenly distribute the product. The patient should periodically massage the treatment area for several days after the injection session to promote a natural-looking correction.

Treat, Wait, Assess. During the first injection session with **SCULPTRA**, only a limited correction should be made. Do not overcorrect (overfill). The patient should be evaluated no sooner than two weeks after the injection session to determine if additional correction is needed. The original skin depression may initially reappear, but the depression should gradually improve within several weeks as the treatment effect of **SCULPTRA** occurs. The patient should be advised of the potential need for additional injection sessions at the first consultation.

STORAGE

SCULPTRA can be stored at room temperature, up to 30ºC (86ºF). DO NOT FREEZE.
Refrigeration is not required.

STERILITY

Each vial of **SCULPTRA** is packaged for single-use only. Do not resterilize.

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Reference: 1. Sculptra™ Product Information.

Combining New and Traditional Techniques Provide Maximal Benefits to Patients

While looking ahead in anticipation of continued technologic advancement, cosmetic dermatologists should continue to make good use of the capabilities of older technologies, which still have much to offer.

"If people have extensive photodamage, they can see dramatic improvements with both traditional and current techniques," said Christopher B. Zachary, M.D., Chair of Dermatology at the University of California, Irvine. "We should not forget about the real benefits of chemical peels, nor the significant benefits people might derive from dermabrasion. We should certainly not forget the excitement created about 10 years ago with the high-energy, short-pulsed CO_2 laser, typified by the UltraPulse (Lumenis Ltd.)."

Christopher B. Zachary, F.R.C.P.

Older technologies can still provide good cosmetic results, and Dr. Zachary continues to rely on some of the older technologies on a regular basis. However, he notes that "anything that causes dramatic improvement also has the potential to cause dramatic side effects, such as prolonged healing, persistent redness, delayed onset permanent hypopigmentation, and scarring." Typical cosmetic dermatology patients today are unwilling to take time off from work or otherwise alter their normal routines and schedules to accommodate potential side effects of rejuvenation procedures.

Many of the newer devices that have become available in recent years combine modest cosmetic improvement with minimal downtime related to after-effects of treatment. That trend will likely continue in the future.

"I don't know where we will be in 5 years, but I can guarantee that things will look very different," said Dr. Zachary. "We are living in very exciting times. While the perfect device for facial rejuvenation does not exist at this point in time, there will indeed be new devices available to us in the near future."

Current technology has much to offer in the way of nonablative rejuvenation. Devices such as the SmoothBeam (Candela Corp.), CoolTouch (CoolTouch Inc.), and ThermaCool (Thermage, Inc.) can tighten and rejuvenate the skin with considerably less downtime compared to older technologies, said Dr. Zachary.

Fractionated therapy with the Fraxel device (Reliant Technologies, Inc.) also has made inroads by providing the ability to rejuvenate skin with minimal surface damage. The 1550-nm device creates a myriad of three-dimensional areas of cylindrical damage affecting 5% to 10% of the skin surface. The cylinders of damage penetrate the skin to a depth of 200 to 400 microns, creating microthermal zones that rejuvenate the epidermal component of photodamaged skin, tighten the dermis, and induce significant improvement in acne scarring with a minimal amount of erythema and swelling and no exudate.

"We're still in the early days with fractionated therapy, but I believe that fractionated therapy (treating only part of the surface of the skin with multiple microthermal zones), is as important to laser surgery as was the development of the selective photothermolysis and dynamic cooling, the latter protecting the skin during laser surgery," said Dr. Zachary.

The intense pulsed light also has brought substantive benefits to cosmetic dermatology. The device selectively filters out light with a wavelength below that specified. The end result is the delivery of light that is well absorbed by pigment and blood vessels, leading to improved color, vascularity, and general tone of the skin.

The reduced skin damage associated with newer technologies does not mean that rejuvenation procedures have become trouble-free, Dr. Zachary cautions.

"It would be a mistake to think that these procedures can be performed without discomfort, without swelling, without redness," he said. "Pret-

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Combining Techniques

Continued from page 7

ty much anything that's going to give you any benefit is going to have some side effects, albeit on a temporary basis."

Though cosmetic dermatologists have a leadership role in the use of rejuvenation techniques that are both safe and effective, they also have a responsibility to educate the public about the need to protect children from the potentially harmful effects of ultraviolet (UV) light (UVA and UVB). Dermatologists should lead the way in educating parents, teachers, and government officials about the need to provide children with adequate protection from UV light.

"Given what we know today, it is disturbing that approximately 90% of the population in the United States has had excessive sun exposure," said Dr. Zachary. Besides the ultimate effects on patient health and quality of life, he points out that this "leads to millions of dollars in treatment costs annually for skin cancers and other conditions directly related to excessive sun exposure. It is imperative that our children get adequate protection. During childhood, we receive about 50% of our entire lifetime sun exposure."

Continuing with the theme of responsibility, Dr. Zachary urged laser manufacturers to develop and distribute product information that is both accurate and well considered. Unsupported claims regarding technologic capabilities should be avoided in every case. When those claims get widespread distribution, physicians in general, and dermatologists in particular, are left with the responsibility for responding to unrealistic patient expectations created by misleading or inaccurate information.

"We can do very good work these days, and we can do it in a safe manner," said Dr. Zachary. "But our expectations need to be carefully controlled, and that includes the expectations of physicians, of manufacturers, and particularly of the public."

Dr. Zachary has nothing to disclose.

Laser Technique Zaps Focal Areas of Excess Fat

Laser lipolysis without fat suction appears safe and effective for the removal of small volumes of focal fat, according to data presented at the annual meeting of the American Society for Laser Medicine and Surgery.

Based on MRI, patients who underwent laser lipolysis alone showed an average of 17% reduction in fat, said Karen H. Kim, M.D., a dermatologist in New York. Those treated under the chin showed the greatest average loss (25%); other areas averaged a 13% reduction.

In this study, 10 patients were treated with laser lipolysis using a Nd-YAG laser (Cynosure Inc.), and 12 were treated with laser lipolysis and the Tri-Active therapeutic laser massage device (12 treatments). There were also 10 control volunteers. The patients had unwanted fat less than 120 cc in volume. Cynosure provided equipment and funding for the study.

Treatment involves the use of a 1,064-nm Nd:YAG laser with a 100-mm optic fiber and 1-mm microcannula. The low-power laser produces a photothermal effect when in contact with fat, Dr. Kim said. Treated fat was allowed to drain naturally in the patients. The Tri-Active device was used on 10 patients to facilitate drainage.

Of the 30 patients enrolled, 29 completed treatment. The area under the chin was the most commonly treated area. Total energy ranged from 758 J to more than 7,000 J. Greater energy was used at larger treatment sites, Dr. Kim said.

At 3 months, patients who received treatment considered the treated area to have improved 37% on average, based on observation. For those treated with the Tri-Active device and for the laser lipolysis only group, the figures were 47% and 33%, respectively. The most common side effects were bruising, swelling, and tenderness. The technique seems to be well suited for the treatment of focal areas of excess fat, Dr. Kim said. She and her colleagues are planning a larger multicenter trial using the technique.

This technique has been used in South America, Europe, and Japan. Previous studies have shown that it destroys more adipocytes than cannulation alone.

By Kerri Wachter, IMNG News Service. Reprinted from Skin & Allergy News, *June 2005. Based on a presentation at the annual meeting of the American Society for Laser Medicine and Surgery.*

Is a Cosmetic Practice for You? Consider These Tips

Cosmetic dermatology is a rapidly moving and rewarding area of dermatology for those with the right mind set, Gerald N. Bock, M.D., said at the American Academy of Dermatology's Academy 2005 meeting.

An elective procedures practice offers the gratification of learning new procedures, recognition as having specific expertise, and less stress as a result of upfront payments and fewer insurance hassles. Staff can be used to amplify income, and fewer patients can generate the same or greater income, he said.

"We're in the golden age of minimally invasive procedures," reported Dr. Bock.

That being said, a cosmetic practice is not for everyone.

"If you don't enjoy working with these patients, who can sometimes be more demanding, don't do it," he said. "If your sole motivation is financial gain, don't do it. This will lead you to make bad decisions. And if you just don't have the flexibility or want to learn new things or take risks, this is not for you."

New patients should be seen 2-3 weeks after their first treatment to make sure they're satisfied or to offer them additional treatments if the result is less than satisfactory.

Dr. Bock acknowledged that his views are colored by the fact that he established a private elective procedures practice in the unlikely Central Valley location of Stockton, Calif., a conservative agricultural community far from the aesthetically obsessed hills of Hollywood. He offered the following tips from his experiences:

- **Set realistic expectations.** It's best to underpromise and overdeliver on your services. Have a humble attitude and offer great service. "You really want to be Wal-Mart with Nordstrom practices," Dr. Bock said. Put everything in writing to avoid misunderstandings. Explain that retreatment may be necessary and failures can occur. Consent forms should list the worst-case scenario for each procedure. Dr. Bock's Botox disclosures note that death can occur.
- **Follow-up and photographs are essential.** New patients should be seen 2-3 weeks after their first treatment to make sure they're satisfied or to offer them additional treatments if the result is less than satisfactory. Photograph all patients, every time. Photographs improve patient satisfaction and can resolve issues that may arise later. One patient complained of eyelid ptosis from her Botox injections until she was shown pretreatment photographs that helped her to realize the ptosis was there beforehand.
- **Proper positioning is key.** Pricing your services below what people expect is one way to exceed their expectations. Start out with very reasonable pricing. You can always raise your prices later. At lower prices, patients will want more frequent and extensive treatments, leading to better results and earlier retreatment. You'll get bigger and better faster, and this may intimidate potential competitors. "Just because you're better doesn't mean people will pay more for your services," he explained. "I've had patients in the past who've had their Botox done by the plastic surgeon's nurse, even though they know I was doing a better job."
- **Little details are important.** Dr. Bock strongly recommends using Air-Tite SteriJect 31-gauge needles for Botox injections. "Everybody tells us that our Botox injections are significantly less painful than injections they get elsewhere, and that's because of these needles," he said. Consider using vibration anesthesia, a technique developed by dermatologist Kevin Smith (*Dermatol. Online J.* Oct 15, 2004;10:1) to reduce discomfort during dermatologic procedures, particularly for needle-phobic patients.
- **Consider used equipment.** There are a lot of good machines available if you're willing to do the research. One source is the Aesthetic Buyers Guide (www.miinews.com), which offers direct product comparisons and product roundtables. One exception may be microdermabrasion machines; Dr. Bock recommends buying a new, nonparticle system. These machines get a fair amount of wear and tear, but "once you've got a noncrystal machine, nobody will go back to using a crystal machine; that's been our experience," he said.
- **Keep up your training.** Botox, microdermabrasion, and hair removal generate the greatest revenue in Dr. Bock's practice. But patients will demand what they can't get elsewhere. Dr. Bock gained an edge, albeit temporary, by becoming the only practice in his area to offer soft tissue augmentation with Sculptra. ■

By Patrice Wendling, IMNG News Service. Reprinted from SKIN & ALLERGY NEWS, *October 2005. Based on a presentation at the American Academy of Dermatology's Academy 2005 meeting.*

For the temporary treatment of moderate to severe glabellar lines

Trusted tool of aesthetic artistry

BOTOX® Cosmetic is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in patients 18 to 65 years of age.

Important Safety Information: BOTOX® Cosmetic is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any ingredient in the formulation. Serious and/or immediate hypersensitivity reactions have been rarely reported. These reactions include anaphylaxis, urticaria, soft-tissue edema, and dyspnea. Patients with neurological disorders such as ALS, myasthenia gravis, or Lambert-Eaton syndrome may be at increased risk of serious side effects. The most common side effects following injection include headache, respiratory infection, flu syndrome, temporary eyelid droop, and nausea.

Please see brief summary of full prescribing information on following page.

BOTOX® Cosmetic
Botulinum Toxin Type A

By prescription only

BOTOX® COSMETIC (Botulinum Toxin Type A) Purified Neurotoxin Complex

INDICATIONS AND USAGE

BOTOX® COSMETIC is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤ 65 years of age.

CONTRAINDICATIONS

BOTOX® COSMETIC is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any ingredient in the formulation.

WARNINGS

BOTOX® and **BOTOX® COSMETIC** contain the same active ingredient in the same formulation. Therefore, adverse events observed with the use of **BOTOX®** also have the potential to be associated with the use of **BOTOX® COSMETIC**.

Do not exceed the recommended dosage and frequency of administration of **BOTOX® COSMETIC.** Risks resulting from administration at higher dosages are not known.

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been rarely reported. These reactions include anaphylaxis, urticaria, soft tissue edema, and dyspnea. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent, and consequently the causal agent cannot be reliably determined. If such a reaction occurs further injection of **BOTOX® COSMETIC** should be discontinued and appropriate medical therapy immediately instituted.

Pre-Existing Neuromuscular Disorders

Caution should be exercised when administering **BOTOX® COSMETIC** to individuals with peripheral motor neuropathic diseases (e.g., amyotrophic lateral sclerosis, or motor neuropathy) or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome). Patients with neuromuscular disorders may be at increased risk of clinically significant systemic effects including severe dysphagia and respiratory compromise from typical doses of **BOTOX® COSMETIC**. Published medical literature has reported rare cases of administration of a botulinum toxin to patients with known or unrecognized neuromuscular disorders where the patients have shown extreme sensitivity to the systemic effects of typical clinical doses. In some of these cases, dysphagia has lasted several months and required placement of a gastric feeding tube.

Dysphagia

Dysphagia is a commonly reported adverse event following treatment of cervical dystonia patients with all botulinum toxins. In these patients, there are reports of rare cases of dysphagia severe enough to warrant the insertion of a gastric feeding tube. There is also a case report where a patient developed aspiration pneumonia and died subsequent to the finding of dysphagia.

Cardiovascular System

There have also been rare reports following administration of **BOTOX®** of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease.

Human Albumin

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

PRECAUTIONS

General:

The safe and effective use of **BOTOX® COSMETIC** depends upon proper storage of the product, selection of the correct dose, and proper reconstitution and administration techniques. Physicians administering **BOTOX® COSMETIC** must understand the relevant neuromuscular and/or orbital anatomy of the area involved, as well as any alterations to the anatomy due to prior surgical procedures and avoid injection into vulnerable anatomic areas. Caution should be used when **BOTOX® COSMETIC** treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

Reduced blinking from **BOTOX® COSMETIC** injection of the orbicularis muscle can lead to corneal exposure, persistent epithelial defect and corneal ulceration, especially in patients with VII nerve disorders. In the use of **BOTOX®** for in the treatment of blepharospasm, one case of corneal perforation in an aphakic eye requiring corneal grafting has occurred because of this effect. Careful testing of corneal sensation in eyes previously operated upon, avoidance of injection into the lower lid area to avoid ectropion, and vigorous treatment of any epithelial defect should be employed. This may require protective drops, ointment, therapeutic soft contact lenses, or closure of the eye by patching or other means.

Inducing paralysis in one or more extraocular muscles may produce spatial disorientation, double vision or past pointing. Covering the affected eye may alleviate these symptoms.

Caution should be used when **BOTOX® COSMETIC** treatment is used in patients who have an inflammatory skin problem at the injection site, marked facial asymmetry, ptosis, excessive dermatochalasis, deep dermal scarring, thick sebaceous skin or the inability to substantially lessen glabellar lines by physically spreading them apart as these patients were excluded from the Phase 3 safety and efficacy trials.

Needle-related pain and/or anxiety may result in vasovagal responses, (including e.g., syncope, hypotension) which may require appropriate medical therapy.

Injection intervals of **BOTOX® COSMETIC** should be no more frequent than every three months and should be performed using the lowest effective dose (See Adverse Reactions, Immunogenicity).

Information for Patients

Patients or caregivers should be advised to seek immediate medical attention if swallowing, speech or respiratory disorders arise.

Drug Interactions

Co-administration of **BOTOX® COSMETIC** and aminoglycosides[1] or other agents interfering with neuromuscular transmission (e.g., curare-like nondepolarizing blockers, lincosamides, polymyxins, quinidine, magnesium sulfate, anticholinesterases, succinylcholine chloride) should only be performed with caution as the effect of the toxin may be potentiated.

The effect of administering different botulinum neurotoxin serotypes at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Pregnancy: Pregnancy Category C

Administration of **BOTOX® COSMETIC** is not recommended during pregnancy. There are no adequate and well-controlled studies of **BOTOX® COSMETIC** in pregnant women. When pregnant mice and rats were injected intramuscularly during the period of organogenesis, the developmental NOEL (No Observed Effect Level) of **BOTOX® COSMETIC** was 4 U/kg. Higher doses (8 or 16 U/kg) were associated with reductions in fetal body weights and/or delayed ossification.

In a range finding study in rabbits, daily injection of 0.125 U/kg/day (days 6 to 18 of gestation) and 2 U/kg (days 6 and 13 of gestation) produced severe maternal toxicity, abortions and/or fetal malformations. Higher doses resulted in death of the dams. The rabbit appears to be a very sensitive species to **BOTOX® COSMETIC**.

If the patient becomes pregnant after the administration of this drug, the patient should be apprised of the potential risks, including abortion or fetal malformations that have been observed in rabbits.

Carcinogenesis, Mutagenesis, Impairment of fertility

Long term studies in animals have not been performed to evaluate carcinogenic potential of **BOTOX® COSMETIC**.

The reproductive NOEL following intramuscular injection of 0, 4, 8, and 16 U/kg was 4 U/kg in male rats and 8 U/kg in female rats. Higher doses were associated with dose-dependent reductions in fertility in male rats (where limb weakness resulted in the inability to mate), and testicular atrophy or an altered estrous cycle in female rats. There were no adverse effects on the viability of the embryos.

Nursing mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **BOTOX® COSMETIC** is administered to a nursing woman.

Pediatric use: Use of **BOTOX® COSMETIC** is not recommended in children.

Geriatric use

The two clinical studies of **BOTOX® COSMETIC** did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. However, the responder rates appeared to be higher for patients younger than age 65 than for patients 65 years or older. (See: CLINICAL STUDIES)

There were too few patients (N=3) over the age of 75 to allow any meaningful comparisons.

ADVERSE REACTIONS

General:

BOTOX® and **BOTOX® COSMETIC** contain the same active ingredient in the same formulation. Therefore, adverse events observed with the use of **BOTOX®** also have the potential to be associated with the use of **BOTOX® COSMETIC**.

The most serious adverse events reported after treatment with botulinum toxin include rare spontaneous reports of death, sometimes associated with anaphylaxis, dysphagia, pneumonia, and/or other significant debility. There have also been rare reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease. (See: WARNINGS). New onset or recurrent seizures have also been reported, typically in patients who are predisposed to experiencing these events. The exact relationship of these events to the botulinum toxin injection has not been established. Additionally, a report of acute angle closure glaucoma one day after receiving an injection of botulinum toxin for blepharospasm was received, with recovery four months later after laser iridotomy and trabeculectomy. Focal facial paralysis, syncope and exacerbation of myasthenia gravis have also been reported after treatment of blepharospasm.

In general, adverse events occur within the first week following injection of **BOTOX® COSMETIC** and while generally transient may have a duration of several months or longer. Localized pain, infection, inflammation, tenderness, swelling, erythema and/or bleeding/bruising may be associated with the injection.

Glabellar Lines

In clinical trials of **BOTOX® COSMETIC** the most frequently reported adverse events following injection of **BOTOX® COSMETIC** were headache*, respiratory infection*, flu syndrome*, blepharoptosis and nausea.

Less frequently occurring (<3%) adverse reactions included pain in the face, erythema at the injection site*, paresthesia* and muscle weakness. While local weakness of the injected muscle(s) is representative of the expected pharmacological action of botulinum toxin, weakness of adjacent muscles may occur as a result of the spread of toxin. These events are thought to be associated with the injection and occurred within the first week. The events were generally transient but may last several months or longer.

(* incidence not different from Placebo)

The data described in Table 4 reflect exposure to **BOTOX® COSMETIC** in 405 subjects aged 18 to 75 who were evaluated in the randomized, placebo-controlled clinical studies to assess the use of **BOTOX® COSMETIC** in the improvement of the appearance of glabellar lines (See: CLINICAL STUDIES). Adverse events of any cause were reported for 44% of the **BOTOX® COSMETIC** treated subjects and 42% of the placebo treated subjects. The incidence of blepharoptosis was higher in the **BOTOX® COSMETIC** treated arm than in placebo (3% vs. 0).

In the open-label, repeat injection study, blepharoptosis was reported for 2% (8/373) of subjects in the first treatment cycle and 1% (4/343) of subjects in the second treatment cycle. Adverse events of any type were reported for 49% (183/373) of subjects overall. The most frequently reported of these adverse events in the open-label study included respiratory infection, headache, flu syndrome, blepharoptosis, pain and nausea.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not be predictive of rates observed in practice.

TABLE 4.

	Percent of Patients Reporting Adverse Events	
Adverse Events by Body System	**BOTOX® Cosmetic (N=405) %**	**Placebo (N=130) %**
Overall	44	42
Body as a Whole Pain in Face	2	1
Skin and Appendages Skin Tightness	1	0
Digestive System Nausea Dyspepsia Tooth Disorder	3 1 1	2 0 0
Special Senses Blepharoptosis	3	0
Musculoskeletal System Muscle Weakness	2	0
Cardiovascular Hypertension	1	0

Adverse Events Reported at Higher Frequency (>1%) in the BOTOX® COSMETIC Group Compared to the Placebo Group

Immunogenicity

Treatment with **BOTOX® COSMETIC** may result in the formation of neutralizing antibodies that may reduce the effectiveness of subsequent treatments with **BOTOX® COSMETIC** by inactivating the biological activity of the toxin. The rate of formation of neutralizing antibodies in patients receiving **BOTOX® COSMETIC** has not been well studied.

The critical factors for neutralizing antibody formation have not been well characterized. The results from some studies suggest that botulinum toxin injections at more frequent intervals or at higher doses may lead to greater incidence of antibody formation. The potential for antibody formation may be minimized by injecting the lowest effective dose given at the longest feasible intervals between injections.

Rx Only

Based on package insert 71711US13S revised January 2005

Manufactured by: Allergan Pharmaceuticals Ireland
a subsidiary of: Allergan, Inc., 2525 Dupont Dr., Irvine, CA 92612

Reference:

1. Wang YC, Burr DH, Korthals GJ, Sugiyama H. Acute toxicity of aminoglycoside antibiotics as an aid in detecting botulism. *Appl Environ Microbiol* 1984; 48:951-955.

Ferulic Acid

Ferulic acid (4-hydroxy-3-methoxycinnamic acid) is pervasive in the plant world. It is present in the cell walls of grains, fruits, and vegetables, where it is conjugated with mono-, di-, and polysaccharides and other compounds (*Biochem. Biophys. Res. Commun.* 1998;253: 222-7; *Biomed. Pap. Med. Fac. Univ. Palacky Olomouc Czech Repub.* 2003;147:137-45; *J. Sci. Food Agric.* 2004;84:1261-9; *Free Radic. Biol. Med.* 1996;20:933-56).

Leslie S. Baumann, M.D.

Derived from the metabolism of phenylalanine and tyrosine (*Biochem. Biophys. Res. Commun.* 1998;253:222-7; *Free Radic. Biol. Med.* 1992;13:435-48), ferulic acid is prevalent in whole grains, spinach, parsley, grapes, and rhubarb. Dietary ferulic acid is now considered a significant antioxidant substance (*Appl. Environ. Microbiol.* 2004;70:2367-72). This potent herbal constituent also has been incorporated into cosmetic lotions and other topical products for the photoprotection it confers (*Free Radic. Biol. Med.* 1992;13:435-48).

Ferulic acid belongs to the polyphenolic compounds known as hydroxycinnamic acids, which also includes caffeic acid, *p*-coumaric acid, and cinnamic acid. These molecules are known to confer cutaneous benefits (*J. Cosmet. Sci.* 2002;53:321-35). Hydroxycinnamic acids are typically included in sunscreen formulations. In terms of direct benefit to the skin, ferulic acid is one of the more promising botanical ingredients. It is a potent antioxidant, protecting skin from UVB-induced erythema (*Biomed. Pap. Med. Fac. Univ. Palacky Olomouc Czech Repub.* 2003;147:137-45). It also strongly absorbs UV, like its related compounds (*Int. J. Pharm.* 2000;199:39-47). And phospholipid membranes are protected by ferulic acid from UV-induced peroxidation as the lipid peroxidative chain reaction is interrupted (*Biomed. Pap. Med. Fac. Univ. Palacky Olomouc Czech Repub.* 2003;147:137-45; *J. Sci. Food Agric.* 1999;79:476-80).

Antineoplastic Action

In a study of the inhibitory effects of three phenolic compounds on benzo[*a*]pyrene- and 7,12-dimethylbenz[*a*]anthracene-induced neoplasia in mice, ferulic acid and chlorogenic acid were active—although less so than ellagic acid—against lung carcinogenesis, but were ineffective against skin tumor formation (*Carcinogenesis* 1983;4:1651-3). Since that study, the literature has added strong evidence of ferulic acid's oral and topical benefits, particularly its protective effects against cancer.

The inhibitory effects of the topical application and oral administration of *Ixora javanica* flower extract on the growth and delayed onset of various kinds of tumors in mice were attributed, in a study nearly 15 years ago, to the active compound in the extract, namely ferulic acid (*Cancer Lett.* 1991;60:253-8). The phenolic nucleus and extended side chain conjugation of ferulic acid account for the compound's facility in forming a resonance-stabilized phenoxy radical, to which its antioxidant activity is attributed (*Free Radic. Biol. Med.* 1992;13:435-48).

Previously, the topical application of ferulic acid was found to inhibit by 46% the induction of ornithine decarboxylase activity by 12-*O*-tetradecanoylphorbol-13-acetate (TPA) in female CD-1 mice. Similar treatment of mice with ferulic acid together with TPA also inhibited the number of TPA-induced tumors per mouse in a dose-dependent manner (*Cancer Res.* 1988;48:5941-6). And in a study a decade ago, the topical application of a dehydrogenation polymer of ferulic acid inhibited TPA-induced tumor promotion, although a monomeric ferulic acid failed to exhibit the same inhibitory effect in female ICR mice (*Carcinogenesis* 1994;15:2069-71).

Phenolic antioxidants, including ferulic acid, fed to male F344 rats significantly lowered the incidence of tongue neoplasms (squamous cell papilloma and carcinoma) and preneoplastic lesions (hyperplasia and dysplasia). The researchers concluded these compounds show promise as chemopreventive agents in the tongue, skin, and other organs (*Carcinogenesis* 1993;14:1321-5).

In a study evaluating the potential of dietary polyphenols as anticarcinogenic agents, ellagic acid, tannic acid, caffeic acid, and ferulic acid were combined with phorbol-12-myristate-13-acetate or mezerein and were topically applied to mice. The results showed significant protection against skin tumors induced by 7,12-dimethylbenz[*a*]anthracene under in vivo and in vitro conditions (*Nutr. Cancer* 1998;32:81-5).

Sun Protection

The vitamin E/ferulic acid compound alpha-tocopheryl ferulate (alpha-TF) has the capacity to absorb UV radiation, thereby maintaining tocopherol in a stable state. Thus, researchers investigated whether alpha-TF can act as a depigmenting agent and antioxidant to improve and prevent UV-induced facial hyperpigmentation.

The researchers studied the effects of alpha-TF on cultured human melanoma cells and normal human melanocytes in vitro, and found that alpha-TF inhibited melanization significantly better than arbutin, kojic acid, ascorbic acid, and tranexamic acid. The investigators suggested that alpha-TF has potential as a whitening agent, and hypothesized that it acted by indirectly inhibiting tyrosine hydroxylase activity (*Anticancer Res.* 1999;19:3769-74).

In related studies, most of the same researchers determined alpha-TF inhibits the biologic responses prompted by reactive oxygen species (*Br. J. Dermatol.* 1999;141:20-9) and may mitigate damage induced by active oxygen species, thus helping to suppress or decelerate skin carcinogenesis (*Anticancer Res.* 1999;19:3769-74).

Based on in vitro tests of the capacity of ferulic and caffeic acids to permeate excised human skin, researchers evaluated the capacity of the same organic acids to reduce UVB-induced

Continued on page 14

Ferulic Acid

Continued from page 13

erythema in healthy human volunteers. Dissolved in saturated aqueous solution (pH 7.2), both compounds conferred significant cutaneous protection. Ferulic acid—which is more lipophilic and thus better able to penetrate the stratum corneum—and caffeic acid were assessed as worthy photoprotective agents in topical formulations and judged to be unaffected by the pH of the product into which they might be incorporated (*Int. J. Pharm.* 2000;199:39-47). In a recent study of the free-radical scavenging abilities of ferulic acid and eugenol that may summarize current thinking on this potent phenolic compound, ferulic acid was deemed an effective antioxidant (*Anticancer Res.* 2002;22:2711-7). The investigators concluded it may be useful in preventing cell damage by free radicals.

Buttressing such claims is a just-published study showing the addition of 0.5% ferulic acid to a solution of 15% l-ascorbic acid (vitamin C) and 1% alpha-tocopherol (vitamin E) stabilized the formulation and, more significantly, rendered the topically applied formulation a much better skin-protective agent, doubling photoprotection to skin from fourfold to eightfold (*J. Invest. Dermatol.* 2005;125:826-33).

The authors of this study found the addition of ferulic acid conferred a synergistic effect, greatly enhancing the existing synergistic effects seen in the combination of vitamins C and E, and further supporting research published by other investigators last year, which highlighted synergistic relationships between ferulic acid, vitamins C and E, and b-carotene (*J. Agric. Food Chem.* 2004;52:2411-20).

Authors of the more recent study speculate that a topical antioxidant formulation combining vitamins C and E with ferulic acid in a broad-spectrum sunscreen would be an optimal way to protect skin from sun damage via a topically applied product (*J. Invest. Dermatol.* 2005;125:826-33).

Ferulic acid is found in SkinCeuticals C E Ferulic and in small amounts in Murad Raspberry Face Wash.

Conclusion

Significant antioxidant, photoprotective, and anticarcinogenic properties have been seen with ferulic acid. The cutaneous benefits associated with this phenolic compound continue to be borne out by research. Given advances in combining antioxidant ingredients for optimal effects, I am optimistic ferulic acid will be a significant component in the armamentarium against photoaging and skin cancer. ■

Dr. Leslie S. Baumann is director of cosmetic dermatology at the University of Miami. Reprinted from Skin & Allergy News, *October 2005.*

Examine Patient Motivation For Cosmetic Surgery

Six simple words stop Rona Z. Silkiss, M.D., in her tracks after she greets a cosmetic surgery patient by asking, "What can I do for you?" Those words are the response: "I don't know, you're the doctor." Within this seemingly innocuous exchange lies a warning that the balance of power between doctor and patient is already skewed, setting the scene for an unhappy outcome. In cosmetic procedures, the doctor-patient relationship must be bilateral, with each person coming to the table with a defined role and measurable expectations, Dr. Silkiss said at a facial cosmetic surgery symposium.

Don't bite when a patient says, "Take a look at me and tell me what you can do," Dr. Silkiss advised. The patient is not taking responsibility for the initial objectives of his or her cosmetic surgery, she explained. "The environment is wide open and ill defined. As a result, it is impossible for the surgeon to meet the patient's expectations" because they have not been clearly established, she said.

Maintaining a balance of power was just one of a series of tips offered by Dr. Silkiss, chief of the division of ophthalmic plastic, reconstructive, and orbital surgery at California Pacific Medical Center in Oakland.

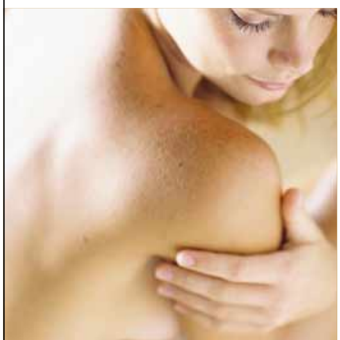
Another patient to watch out for is one who presents at a young age with a very minor problem, saying she has read articles advocating early cosmetic surgery. "This is what I call surgery in search of a problem," Dr. Silkiss said at the meeting, which was sponsored by the Multi-Specialty Foundation for Facial Aesthetic Surgical Excellence. Such a patient may be giving in to media pressure fueled by fashion magazines and reality TV shows such as "Nip and Tuck" and "Extreme Makeover." Reassuring such a patient that she does not need surgery exemplifies surgical integrity that will be rewarded later, she said.

Patients who arrive in the traumatic aftermath of a divorce or job loss might be well advised to come back in a few months, when life has stabilized for them. "The patient is at a stressful juncture in his or her life. What you do not want to do is give the patient the opportunity to transfer his or her unhappiness to the recent surgery and surgeon," she said.

Dr. Silkiss described a scenario in which a 50-year-old man, recently divorced, came to her because his new girlfriend told him he needed blepharoplasty. "Actually, he didn't notice he had a problem." This patient, she said, had insufficient motivation to undergo an elective surgical procedure. "The patient is not personally committed to the surgery. This is his body and he has to want the surgery himself." Such patients often come to a consultation hoping that the surgeon will agree that surgical correction for such an issue is purely optional. "They are trying to reestablish their self-esteem. Reassurance alone may be the best medicine," she said. ■

By Betsy Bates, IMNG News Service. Reprinted from Skin & Allergy News, *September 2005. Based on a presentation at a meeting sponsored by the Multi-Specialty Foundation for Facial Aesthetic Surgical Excellence.*

FOR DRY SKIN THAT JUST WON'T GO AWAY



OMEGA-6 FORMULAS PROVIDE RELIEF FOR CHRONIC SKIN PROBLEMS

If you suffer from recurring skin problems, it may be because your cells have a shortage of an important *omega*-6 fatty acid called GLA. It is known that many people (infants, children, teens and adults) have a deficiency of GLA and experience skin problems of one sort or another as a result.

- steroid-free
- non-prescription
- dermatologist recommended
- clinically proven (with 82% success)
- natural and fragrance-free

SHIKAI Borage Dry Skin Therapy™ addresses this condition by supplying GLA directly to the cells in the form of borage oil. Borage is the world's richest source of GLA and has been proven in clinical studies to help relieve serious skin disorders such as cradle cap, atopic eczema and other forms of dermatitis.

Dry, itchy and inflamed skin which is caused by a deficiency of GLA can be relieved with daily use of SHIKAI Borage Dry Skin Therapy™

"This is the first non-prescription lotion that has really helped my dry skin."
K.Smith - Healthcare Technician

"I used this lotion as I have extremely dry skin myself. I think it is an excellent product."
L.Langley, RN - Diabetes Educator

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BORAGE OIL, A RICH SOURCE OF THE *OMEGA*-6 FATTY ACID, GLA

Borage (borago officinalis), commonly called "starflower", is a well known herb which can be found in almost all temperate regions of the world.

Borage is commercially grown for the valuable oil found in its seeds. The great value of this oil is that it produces the highest yield (up to 26%) of the omega-6 fatty acid, GLA.

*GLA is essential for the formation and maintenance of healthy skin cell membranes. In clinical studies borage has been shown to have beneficial effects on chronic dry skin as well as on other skin disorders.**

* British Journal of Dermatology

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Fillers: Beyond the Mythic 'Ideal'

Many speakers include a slide on "the Ideal Filler" in their talks at cosmetic dermatology seminars.

I don't have such a slide for my presentations, because there is no ideal filler. There is not now; there never will be. Every time you consider using a filler, you are in a unique clinical situation. The face is going to be different, and the person attached to that face is going to be different.

Alastair Carruthers, M.B.

Let's say a woman who is concerned about her aging appearance comes to see you. Are you going to use the same filler in areas that need a little stiffening as you would use to fill out deep lines around her mouth? What if she doesn't want to come back every 3-6 months for a retouch?

What we have today—and what I predict will increasingly become the norm—is an array of fillers, each with its own advantages, drawbacks, and, once in a while, a special niche in the cosmetic armamentarium. In Canada and certainly in the United States, a host of new fillers will soon be available. Some that currently sit on your shelf may not survive in this competitive market.

In my personal view, cadaveric facial fillers are as dead as the donors. Furthermore, I would not invest money in Isolagen, which uses a patient's own cultured fibroblasts to produce a filler substance. I'm unconvinced that something that involves this much of a procedure, this much expense, and this much time is something that my patients will buy into.

On the other hand, I didn't see the rationale for Sculptra (poly-L-lactic acid), and yet Sculptra clearly works. I was wrong about that and I could be wrong about Isolagen, too.

Artecoll, which may be approved by the Food and Drug Administration by the end of the year, will offer less potential for allergenicity than do collagen products we use now, as well as permanence. This and other future permanent fillers that are injected subdermally work by fibroblast proliferation. There are definite risks associated with this. Lumps are common and are technique related. Granulomas can and do occur, and they may be very difficult to treat effectively (SKIN & ALLERGY NEWS, August 2005, p.1).

I expect to see remarkably similar problems in other permanent-type fillers that are on the horizon, including Dermalive and probably Silskin as well. In addition, I am concerned that we do not yet know the true complication potential in normal individuals of fillers that are tested on and approved for HIV-associated lipoatrophy. My suspicion is that HIV patients, because of their altered immune systems, may be protected from many problems, such as infection.

My impression is, you can throw anything at patients with HIV-associated lipoatrophy; I have yet to see a significant complication. I would be very cautious about applying findings in these patients to patients in the general population seeking cosmetic improvement through the use of fillers. This is especially true for permanent fillers.

I think most cosmetic dermatology patients are satisfied with long-term temporary correction. People accept the concept of maintenance. They know they have to keep going to the gym, maintaining a healthy diet, and returning to the hairdresser. They will accept maintenance visits for filler touch-ups as long as the correction is "long-term."

So how long is long-term? We're pushing the envelope here. Certainly the longer-term the correction, the longer the risk of complications will last. For example, with Restylane, the complications are reduced because the product is immunologically simple. The duration of action is at least as long as that of Zyplast and CosmoPlast, but this and products like it aren't dermal fillers; they're volume replacers. They're easy to inject and tolerant of mistakes.

Can these be made safer and longer lasting by changing the particle size? I am unimpressed that there is a difference in duration. Will there be fewer adverse events with smaller or larger particles? We have no evidence of that yet.

Sculptra seems destined to have a place in the future of fillers. I'm convinced it works. Designed for the subcutaneous space, it's all about volume. Obviously, the injection technique is crucial to avoid nodules. There is a problem with the number of injection sessions required, and also with its inconsistency in terms of longevity. In some people, the correction lasts years; others lose the volume in 1-2 years. I like things that are very predictable, but I must say I am impressed with the results achieved with Sculptra. It's not approved yet in Canada, but I look forward to the day when it will be.

Radiesse also works, but it is also unpredictable, albeit to a lesser extent. Some people get long-lasting correction, but the results can be more variable in others. Another problem with Radiesse is the cost. I am currently involved in a study of Radiesse for HIV-associated lipoatrophy, and the volumes I am using would be extremely expensive.

So what is my concept of an ideal filler? I look for long-term temporary correction, which I define as something that achieves good filling of the lips for 6-12 months. Something that induces fibroplasia is okay, but not if it produces individual results so varied that the filler becomes unpredictable. I think an acceptable filler is one that can be used with a 30-gauge needle.

Beyond these basic criteria, I think we need an array of fillers, to be mastered one at a time for the many varied types of volume correction sought by many different types of patients. ■

This editorial is based on remarks delivered by DR. CARRUTHERS, *who practices in Vancouver, B.C., at the annual Hawaii Dermatology Seminar sponsored by the Skin Disease Education Foundation. Dr. Carruthers disclosed that he has received funding for research and/or consulting fees from a number of manufacturers of fillers, including Q-Med, Medicis Aesthetics, Artes Medical, Richard-James, BioForm Medical, and Inamed.*

Reprinted from SKIN & ALLERGY NEWS, *September 2005.*

Injectable Silicone Called a Safe, Elegant Filler

Liquid injectable silicone can be a highly effective means of tissue augmentation, especially for acne scarring and HIV-related lipoatrophy, Derek Jones, M.D., said at a cosmetic dermatology seminar sponsored by the Skin Disease Education Foundation.

"This can be an ideal filler that is long lasting and cosmetically elegant," said Dr. Jones of the department of dermatology at the University of California, Los Angeles.

A "wealth of anecdotal data" indicates that liquid injectable silicone is safe and effective, but the following critical rules are key to its safe usage, he said:

- Use only pure, Food and Drug Administration–approved, injectable-grade liquid silicone; in the United States that means only Silikon-1000, made by Alcon Laboratories. The product has FDA approval for intraocular injection to treat retinal detachment, but it may be legally used off label, under the 1997 FDA modernization act that allowed medical devices to be used off label.

It's important to note, however, that the law prohibits advertisement of off-label uses, and malpractice insurance carriers have different policies regarding such uses.

- Adhere to a strict serial puncture microdroplet technique, defined as 0.01 cc injected into the immediate subdermal plane or deeper at 2- to 4-mm intervals, with no double pass in the same plane. Intradermal injection should be strongly avoided except among the most skilled practitioners.

The technique is necessary to allow a fibroproliferative response that develops around each microdroplet between treatments, not only causing each droplet to become anchored and less likely to drift but contributing to further augmentation, Dr. Jones said.

"This is an oil, and if you inject a lot all at once, it's like throwing olive oil on the floor—it's going to spread out and track tissue planes along the path of least resistance," he said. "But the microdroplet technique addresses this problem."

- Inject only small volumes—2 cc or less for lipoatrophy, or 0.5 cc or less for other indications. "Avoid the temptation to use larger volumes," Dr. Jones said, adding that injections should be spread out at intervals of at least 4 weeks.

In addition to these three critical rules, important considerations for silicone use include informing patients that liquid injectable silicone is permanent, and that its use is still investigational and likely to remain so for years. And, while patients can resume a normal routine immediately, they are advised to avoid activities that could predispose them to blunt trauma.

Dr. Jones demonstrated the injection technique on a patient with HIV-related facial lipoatrophy at the conference and said that most patients are highly pleased with the results.

Liquid silicone injections "really give an extraordinarily natural-appearing correction," he said. "When you touch the cheeks of these individuals, they feel nice, soft, and supple, and the injections really can restore subtle and refined facial contours."

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By Nancy Melville, IMNG News Service. Reprinted from Skin & Allergy News, *August 2005. Based on a presentation at a cosmetic dermatology seminar sponsored by the Skin Disease Education Foundation.*

Pain-Relief Options Available For Cosmetic Procedures

Ice, vibrators, "talk-esthesia," and sundry topical anesthetic creams and gels were advocated as safe and effective options for relieving pain during a mini-symposium at the annual Hawaii Dermatology Seminar sponsored by the Skin Disease Education Foundation.

"How much is a happy patient worth? If you hurt them, they won't come back," said Kevin C. Smith, M.D., a dermatologist practicing in Niagara Falls, Ont.

The discussion focused on patients undergoing cosmetic procedures, but the techniques, listed here, can be used on medical dermatology patients as well:

- **Ice.** It's effective and about as cheap as pain relief gets. "We use it a lot," said Alastair Carruthers, M.B., a dermatologist in practice in Vancouver, B.C.
- **Vibrators.** Snickers aside, the Hitachi Magic Wand with a Wonder Wand attachment provides excellent pain relief when applied under a patient's chin during facial procedures by blocking pain signals to the brain, said Dr. Smith. The devices can be found at the Web site www.drugstore.com.
- **Talk therapy.** "It's not enough to put some cream on a patient," Dr. Smith said. From the time a patient first calls the office, the staff and the physician should convey calm reassurance. Patients will have less pain if they feel "confident of your skill and your care."He said he always uses "talk-esthesia" to talk patients through procedures, even when other forms of pain relief are used.
- **Analgesics.** Some procedures call for up-front pain relief. Dr. Smith sometimes advises patients to take an NSAID in combination with acetaminophen for an additive effect. Patients who do not have asthma may be prescribed propranolol, which provides analgesia but does not interfere with a patient's ability to drive.
- **L.M.X. 4.** This 4% lidocaine cream (formerly ELA-Max 4%) is sold over the counter, does not require occlusion, and provides anesthesia 30 minutes after application, Dr. Carruthers explained. He tested it against a vehicle cream in 24 patients receiving Botox (botulinum toxin type A) injections for crow's feet.

"I like to think this is not a very painful procedure, so in order to reduce the discomfort, this stuff has to work very well," he said.

'How much is a happy patient worth? If you hurt them, they won't come back.'

The study showed a significant difference in patient visual analogue scale scores and observer ratings of discomfort when L.M.X. 4 was used, with P values in the range of .005.

- **L.M.X. 5.** This anorectal anesthetic cream is more appropriate for use in the mouth than alcohol-containing topical gels, which can cause sloughing of mucous membranes and irritation and stinging if they get in the eyes, Dr. Smith said.

For lip procedures, optimal anesthesia can be obtained by numbing the mucosal surface of the lips, including the anterior mucosae of the anterior labioalveolar sulci down to the gingival sulcus as well as the vermilion and a 1-cm margin around the vermilion border.

To achieve this without getting anesthetic all over the inside of the patient's mouth, he cuts a Telfa pad to mimic a plastic laser shield designed to protect the teeth from laser work performed around the mouth. He cuts a 3-by-4-inch Telfa pad in half, lengthwise, then folds it over and cuts a slit in the middle (to allow the patient to breathe) and slits at the top and bottom to accommodate the frenula.

He inserts the pad into the patient's mouth, against the teeth. He then uses a tongue depressor to apply L.M.X. 5 thickly over the lips and gums and attends to other patients for 30-45 minutes, until his watch alarm sounds to remind him to return to perform the procedure.

At that time, he can inject lidocaine painlessly or, for simple filler procedures, move directly to injections of Restylane (nonanimal stabilized hyaluronic acid gel).

Dr. Smith noted that previous research has determined that the anesthetic mixture in L.M.X. 5 does not produce toxic blood levels, even when applied to mucous membranes.

Dr. Carruthers disclosed that he has financial ties to Allergan Inc., which distributes Botox. Dr. Smith received L.M.X. 5 samples from Ferndale Laboratories Inc. for his research.

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By Betsy Bates, IMNG News Service. Reprinted from SKIN & ALLERGY NEWS*, June 2005. Based on a presentation at a mini-symposium at the annual Hawaii Dermatology Seminar sponsored by the Skin Disease Education Foundation*

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