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Pimecrolimus and Tacrolimus: The US FDA Public Health Advisory

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In February of this year, the US FDA issued a public health advisory to inform healthcare providers and patients about a potential cancer risk from the topical use of pimecrolimus (Elidel[®], Novartis), approved by the FDA in December 2001, and tacrolimus (Protopic[®], Astellas, formerly Fujisawa), approved in December 2000. As well, the Therapeutic Product Directorate of Health Canada has recommended that a "Dear Doctor" letter be sent to all physicians in Canada outlining these concerns.

These drugs are topical calcineurin inhibitors that are applied to the skin and are the only approved drugs in this class. Since their approval, the FDA has received reports of lymphoma and skin cancer in children and adults treated with these drugs; whether the reported cancers are associated with these products has not been established.

Basis for Decision

The decision to issue an advisory was based on data from animal studies, case reports from a small number of patients, and information about their mechanism of action that were presented to a hearing of the FDA Pediatric Advisory Committee.¹ It may take 10 years or longer to determine if the use of these calcineurin inhibitors is linked to cancer in humans. In the meantime, because this risk is uncertain, the FDA advised that these drugs should be used only as labeled for patients who have failed treatment with other therapies.

US FDA Recommendations

The FDA recommended that healthcare providers, patients, and caregivers should consider

- using pimecrolimus and tacrolimus only as second-line agents for short-term and intermittent treatment of atopic dermatitis in patients who are unresponsive to or intolerant of other treatments.
- avoiding use of these drugs in children younger than 2 years of age. Their effect on the developing immune system in infants and children is not known. In clinical studies, infants and children younger than 2 years old treated with pimecrolimus had a higher rate of upper respiratory infections than did those treated with placebo cream.²
- using these drugs only for short periods of time, not continuously. Their long-term safety is unknown.
- not using these drugs in children and adults with a weakened or compromised immune system.
- using the minimum amount of pimecrolimus and tacrolimus needed to control the symptoms. In animals there was a dose-related response, i.e., increasing the dose and duration reportedly resulted in higher rates of cancer.²

Data from Animal Studies and Human Case Reports

Animal studies presented at the hearing included data from three species (mice, rats, and monkeys) that developed cancer following exposure to these drugs applied orally or topically. These studies were conducted at doses ranging from 1.5-340 times higher than that generally used by humans.¹ The warning is also based on 29 reports of cancer including 12 lymphomas and 8 skin malignancies (e.g., basal cell carcinomas, squamous cell carcinomas, and Kaposi's sarcoma) in adults and children previously treated with these immunomodulators. In total there were six reports of cancer in children, the youngest being 2 years of age. Cause and effect have not been established.^{1,3}

On the basis of the advice from the Pediatric Advisory Committee, the FDA will require labeling changes for pimecrolimus and tacrolimus, including the placement of a boxed warning about the potential cancer risk. In addition, the FDA will work with the commercial sponsors of the drugs to develop and implement a Medication Guide (MedGuide) to provide this information as well as instructions about appropriate use of these drugs to patients, their families, and caregivers. MedGuides are intended to be distributed by pharmacists with each prescription or refill of a medication.

Dermatologist Comments at the Hearings

At the hearing, dermatologist Robert A. Silverman, MD, of Fairfax, Virginia, spoke on behalf of the Academy of American Dermatology (AAD), urging the FDA not to impose a black box warning or other labeling restrictions because such steps could limit access to these medications, or limit treatment options if qualified patients decide not to use these medications because of fear of a cancer risk.⁴

Lawrence Eichenfield, MD, also addressed the Committee, stating that atopic dermatitis places a tremendous burden on individuals and families, and that calcineurin inhibitors have had a great impact on improving their quality of life. Patients and physicians now have a choice in addition to emollients and topical corticosteroids. These products have allowed the ability to mix and match medications and allowed tailoring of treatment to disease severity.¹

AAD Response

After the FDA decision was announced, Clay J. Cockerell, MD, president of the American Academy of Dermatology responded, "The Academy is disappointed that the FDA has taken this action, despite the fact that there is no data that proves proper topical use of these drugs is dangerous in humans. Because these medications are applied to the skin, virtually none of it gets inside the body. It's not the same as taking a pill. These are valuable medications, and if used properly, they significantly reduce the debilitating impact of eczema and allow millions of our patients to live normal lives."⁴

CDA Response

The Canadian Dermatology Association (CDA) reported that these drugs have been studied collectively in more than 38,000 subjects, including 14,000 children under the age of 17 years. To date there have been 2 cases of malignancy reported with pimecrolimus (no lymphoma) and no cases reported with tacrolimus in the clinical trials programs. In the spontaneous reporting programs, 6 cases have been reported with pimecrolimus (4 lymphomas) and 19 cases with tacrolimus (10 lymphomas). None of the cases of malignancy were reported in children younger than 2 years of age. The number of lymphomas observed in treated patients is below the expected number of lymphomas in both adult and pediatric populations and for cases where enough information was available they were assessed by external experts as unlikely to be linked to the use of topical calcineurin inhibitors. Thus, the current available information does not support an increased risk for lymphoma development associated with the use of topical calcineurin inhibitors. The CDA believes that topical calcineurin inhibitors are an important therapeutic class for the treatment of atopic dermatitis in children and adults and that the FDA and TPD recommendation for a warning of this nature is not supported by clinical evidence and experience.⁵

Skin Therapy Letter® Poll

In an effort to provide clarification to clinicians and their patients, Skin Therapy Letter® conducted a poll of some of the world's leading dermatologists:

Has the recent US FDA decision to add a black box warning label for pimecrolimus and tacrolimus altered the way in which you prescribe these drugs?

YES: 3 NO: 13

In the absence of convincing evidence, most of those polled said that these warnings will not alter their prescribing habits. Some stated that they had not changed the way in which they prescribed these drugs, but spent extra time counseling patients.⁶⁻⁸

Would you restrict their use in children?

YES: 3 NO: 13

The majority of respondents said they would not restrict their use in children.

Would you limit their use below 2 years of age?

YES: 7 NO: 9

A slight majority would not limit their use. Some noted that they would limit use of these calcineurin inhibitors to those children whose eczema could not be maintained adequately with topical corticosteroid use.⁶⁻⁸

Have many of your patients expressed concern about using calcineurin inhibitors?

YES: 9 NO: 7

Because their patients had asked about it, they took the time to reassure them and provide reports of the safety data seen in human clinical trials.

Have pharmacists in your area demonstrated reluctance in filling prescriptions for these drugs?

YES: 1 NO: 15

Only one dermatologist has experienced reluctance on the part of the pharmacists to fill his prescriptions.⁶

Conclusion

After assessing the results of the Skin Therapy Letter® survey and reviewing the reports by the American Academy of Dermatology and the Canadian Dermatology Association, I would suggest that both of these drugs should be monitored and periodic reappraisals of any untoward reports be published. However, new warnings without new evidence will only serve to increase doubt in the minds of the prescriber and reduce patient access to worthwhile drugs.

Experts Polled

Kenneth A. Arndt	Harvard Medical School, Boston, MA, USA
Jim Bergman	University of British Columbia, Vancouver, BC, Canada
Hugo Degreef	Catholic University, Leuven, Belgium
Lawrence Eichenfield	University of California at San Diego, San Diego, CA, USA
Boni Elewski	University of Alabama, Birmingham, AL, USA
Steven R. Feldman	Wake Forest University School of Medicine, Winston-Salem, NC, USA
Herald P. Gollnick	Otto von Guericke University, Magdeburg, Germany
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J. H. Saurat	University of Geneva, Geneva, Switzerland
Robert Silverman	Georgetown University, Washington, DC, and University of Virginia at Charlottesville, Charlottesville, VA, USA
Bruce Strober	New York University School of Medicine, New York, NY, USA
Klaus Wolff	University of Vienna, Vienna, Austria

Acknowledgment

I am very grateful to these world-recognized authorities on calcineurin inhibitors for providing answers to the above questions.

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Surgical Techniques for Scar Revision

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ABSTRACT

Patients frequently seek cosmetic improvement for existing scars. While no scar can be completely erased, dermatologic surgeons can employ a variety of approaches to achieve more esthetically pleasing scars. Classification of a scar abnormality guides the choice of treatment technique. Lasers and injectables are useful tools; however, for certain scar abnormalities, scalpel-based surgery remains the mainstay. This review focuses on common incisional surgical methods for scar revision.

Keywords: scars, excision, scar revision

Scar Classification

Scar formation is a necessary process for the healing of tissue after insult. However, abnormal or disturbed collagen production can cause poor restoration of the cutaneous surface and textural irregularities. A cosmetically acceptable scar is often level with the surrounding skin, a good color match, soft, and narrow. Favorable lines of closure are usually within or parallel to relaxed skin tension lines (RSTLs): lines due to dynamic action of the underlying musculature.¹ Preoperative planning and prevention are critical to achieving scar cosmesis.²

Abnormal scars usually fall into four etiologic categories: traumatic, poorly designed, poorly healed, and disease-related (Table 1). It is important to keep in mind the original etiology of poor scar cosmesis as this may influence the result of any revision attempt.

The resulting scar abnormality will guide the choice of treatment technique. A summary of treatment approaches

is presented in Table 2. The surgical strategy selected should be based on a thorough evaluation of the scar's characteristics: size, color, thickness, texture, position and orientation, type and timing of previous therapy, and quality of the surrounding skin. In addition, while any scar with a suboptimal appearance can be revised, greatest patient satisfaction is achieved with realistic expectations. Patients must be counseled preoperatively that a scar can never be completely removed but, exchanged for a more cosmetically pleasing one.

Treatment Techniques

Excisional Techniques

Shave Excision

Indications:

- Elevated scars
- Hypertrophic scars or Keloids

Category	Examples of Causes
Traumatic or irregular wound creation	Burn Debris Laceration
Poorly designed	Not parallel or within RSTLs Lack of respect for facial landmarks Distortion of free margin e.g., lip or eyelid Long linear design Depressed scar from lack of evertional closure
Prior poor healing	Infection Excess tension Necrosis or slough
Disease-related	Acne Varicella Keloidal

Table 1: Abnormal scars: etiologic categories

Adapted from Choi JM, Rohrer T, Kaminer M, Batra RS. Surgical approaches to patients with scarring. In: Arndt, KA, ed. Scar Revision—Procedures in Cosmetic Dermatology. East Sussex: Elsevier Science. In press.

Scar Abnormality	Possible Causes	Surgical Techniques	Other Therapies
Elevated	Wound closure under tension Inadequate apposition of edges Full-thickness grafts (oversized)	Shave excision Fusiform excision	Intralesional corticosteroids Dermabrasion Laser Resurfacing
Hypertrophic scars/ Keloids	Genetic predisposition Area of motion or tension Nidus of prolonged inflammation (e.g., infection or foreign body reaction)	Shave excision Fusiform excision	Intralesional immunomodulators Radiation Cryosurgery Lasers Compression therapy
Depressed scar	Deep shave biopsy Electrodesiccation/curettage Deficient wound eversion Prior hematoma or infection	Fusiform excision Subcision/ subdermal undermining	Fillers Lasers
Widened scars	Wound closed under tension	Excision & suture with buried vertical mattress intradermal sutures	Lasers
Long linear scar	Laceration Preoperative poor planning	W-plasty Geometric broken line closure (GBLC)	Dermabrasion
Contracted/webbed	Traverse concavities	Z-plasties	Intralesional corticosteroids
Ice pick/pitted	Prior acne Trauma	Punch excision	Punch grafting Dermal pocket grafting Dermabrasion
Boxcar scars	Prior acne Varicella	Punch excision Punch elevation	Lasers
Rolling scars	Prior acne	Subcision	Fillers Lasers

Table 2: Scar abnormalities and treatment approaches

Adapted from Choi JM, Rohrer T, Kaminer M, Batra RS. Surgical approaches to patients with scarring. In: Arndt, KA, ed. Scar Revision—Procedures in Cosmetic Dermatology. East Sussex: Elsevier Science. In press.

The scar is tangentially shaved with a flexible razor blade/scalpel until it is level with the surrounding skin avoiding entry into the deep dermis. When using a scalpel, it is often helpful to score the periphery of the elevated scar initially to ensure there is no extension beyond the intended area. The wound is allowed to heal by secondary intention.

Fusiform/Elliptical Excision

Indications:

- Elevated scars
- Hypertrophic scars or Keloids
- Depressed scars
- Widened scars

Regardless of width and depth, complete removal of scar tissue is the goal. The scar is removed as the center of an ellipse with opposing angles of 30 degrees or less. Adequate undermining is necessary to produce wound edges in an even and tension-free manner. Buried vertical mattress sutures are critical for wound edge eversion, especially for deep defects.³

For keloids, avoid areas of high tension since they have a high rate of recurrence. All potential sources of persistent inflammation should be excised, including epithelial cysts, sinus tracts, or trapped hair follicles.⁴ The overlying uninvolved epidermis and upper dermis can be used as a flap or graft by dissecting out the underlying keloidal collagen and replacing the upper dermis and epidermis over the site. With this technique, only epidermal sutures are used and subcutaneous sutures are avoided to prevent a subsequent inflammatory reaction.⁴

Serial Partial Excision

Indications:

- Large scars with insufficient surrounding tissue laxity for a single excision

This technique is helpful when the size, location, and elasticity of the scar and surrounding skin prevent primary closure or when closure will yield distortion of nearby structures. Using conventional excision methods, the scar is partially excised and the adjacent skin advanced by undermining sufficiently. If more than two procedures are

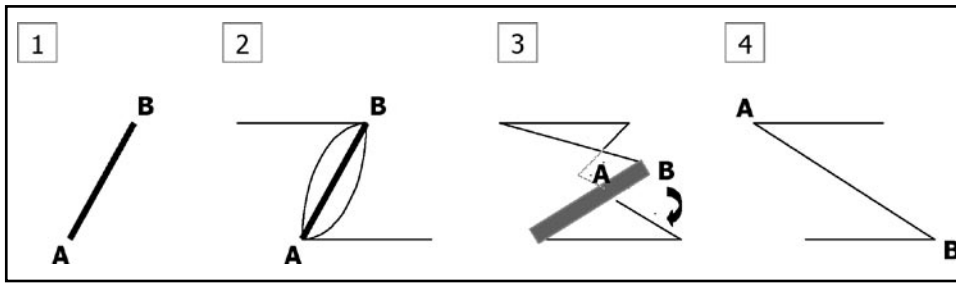


Figure 1: Z-Plasty

1=Scar oriented A-B; 2=Scar excised and creation of flaps with two limbs parallel to RSTLs; 3=Movement of the flaps; 4=Resultant scar with reorientation of A-B

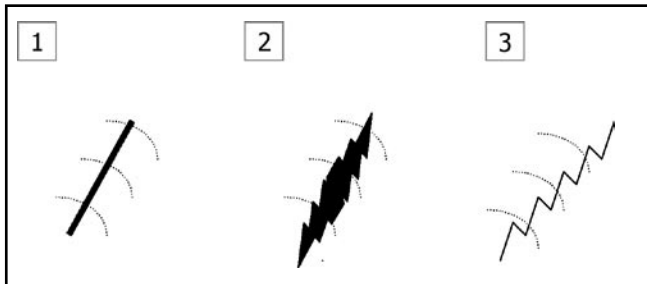


Figure 2: W-Plasty

1=Straight line scar oriented perpendicularly to RSTLs; 2=Excision of scar with pattern of interdigitating W's on either side; 3=Resultant zig-zag line with interposition of the W's after scar excision

required, consider tissue expansion as a complementary tool to reduce the number of necessary excisions.⁵

Scar Irregularization

Z-Plasty

Indications:

- Long linear scars
- Contracted or webbed scars
- AVOID in keloid revision as the keloid may recur along the lengthened scar

This technique diffuses tension by transposing triangular skin flaps, changing the direction of an abnormal scar to lie within RSTLs. The lateral limb lengths are marked before excising the scar. Removal of the main portion of the scar creates the central limb, and the triangular flaps are cut to the same length as the central limb, although they may need to be lengthened depending on skin laxity. The final position of the central limb on the new "Z" can be predicted by connecting the two free ends of the original Z (Figure 1).^{6,7} The final scar will be approximately three times longer than the original scar, and multiple Z-plasties can be combined in series to reduce tissue contraction. The surrounding tissue is undermined, and the two triangles are then transposed. It is important to release the flaps adequately to allow the tips to have little tension and avoid tip necrosis.

W-Plasty

Indications:

- Long linear scars
- Contracted scars
- Scar perpendicular to RSTLs

This technique does not lengthen the scar. Careful preplanning is essential, as a series of small interdigitating triangular skin flaps (several small "Ws") are positioned on either side of the original scar so that the two sides will interpose after scar excision and local undermining.^{1,3,8} Triangle limbs should be 3-5mm long and ends should be less than 30 degrees in order to avoid a standing cone or "dog ear" effect. Components should parallel RSTLs as much as possible to yield optimal camouflage (Figure 2).

Geometric Broken Line Closure (GBLC)

Indications:

- Long linear scars
- Scars perpendicular to RSTLs

Rather than employing "w's", the GBLC involves a series of varying geometric shapes designed to interlock precisely with their mirror images on the other side of the wound. The irregularly irregular pattern camouflages the scar to an observer.^{1,3} Geometric shapes should vary irregularly and be 3-7mm in size placed 3-6mm from the scar margin.⁸ As with the W-plasty, wide undermining is essential for a tension-free closure and ends should be less than 30 degrees or an M-plasty employed to avoid dog ears.

Atrophic Scar Revision^{4,9}

Punch Excision

Indications:

- Icepick scars
- Deep boxcar scars

Depending on the size of the scar, a 1.5-3mm punch tool can be used to remove the entire defect. Outward traction perpendicular to RSTLs during the excision creates an ellipse and allows closure parallel to RSTLs.

Punch Elevation

Indications:

- Wide boxcar scars (>3mm) without significant color or textural irregularities

The punch size is matched to the inner diameter of the crateriform scar. A quick, rotating punch motion is used to release the bound-down scar. The scar is then elevated with forceps so that it lies slightly higher than the surrounding skin. The plug is secured with Dermabond® (2-Octyl Cyanoacrylate, Ethicon) and paper tape such as Steri-Strips® (3M Pharmaceuticals).

Subcision

Indications:

- Rolling scars
- Depressed scars

This procedure releases subcutaneous fibrotic strands that tether the overlying tissue. The controlled trauma creates new connective tissue formation under the defect for additional support. A sterile 18-gauge, 1½ inch NoKor™ Admix needle (Becton-Dickinson) on a 3cc syringe is inserted at a shallow angle, with the blade parallel to the skin surface into the superficial subcutaneous layer, and occasionally, the deep dermis. The free hand should be used to stabilize the site while the needle moves in a lancing and fanning motion to release the subcutaneous fibrotic strands. Multiple puncture sites are used. Firm pressure should be applied postoperatively to achieve hemostasis.

Conclusion

A successful scar revision can dramatically improve a patient's quality of life. Dermatologists can employ a number of surgical scar revision techniques. While some are better suited to treat specific types of scars, they can

be used in combination with each other or with adjunctive therapies to achieve optimal results.

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Class	Name/Company	Approval Dates and Comments
<i>Corticosteroid</i>	Fluocinonide 0.1% Cream <i>Vanos™</i> Medicis/Patheon	The US FDA approved this Class I corticosteroid in February 2005, for the treatment of plaque-type psoriasis. It is a super high potency cream for once or twice daily application.
<i>Antibacterial Agent</i>	Dalvancin Vicuron Pharmaceuticals	The US FDA granted Priority Review status in February 2004, for this investigational agent, a novel once-weekly antibiotic for the treatment of complicated skin and soft tissue infections including the most difficult to treat strain of Staphylococcus-methicillin-resistant Staphylococcus aureus.
<i>Antipruritic Agent</i>	Epinastine Hydrochloride <i>Alesion® Dry Syrup 1%</i> Nippon Boehringer Ingelheim/Sankyo	Japan's regulatory authority approved this antiallergy dry syrup in January 2005, for the treatment of allergic rhinitis, urticaria, and pruritus associated with skin diseases such as eczema and dermatitis. It is the first once-daily administrative antiallergy dry syrup for pediatric use in Japan.
<i>Antifungal Agent</i>	Griseofulvin Oral Suspension USP Glades Pharmaceuticals	The US FDA approved this systemic antifungal agent in March 2005, for the treatment of tinea barbae, tinea capitis, tinea corporis, tinea pedis, and tinea unguium (onychomycosis). This product is the first and only AB rated generic version of Grifulvin V® (Johnson & Johnson).

Drug News

<i>Drug Warning</i>	Eli Lilly and the US FDA notified health care professionals, in January 2005, that there have been reports of medication dispensing or prescribing errors between the antihistamine ZYRTEC® HCl (cetirizine, Pfizer) which is indicated for the treatment of allergic rhinitis or chronic urticaria, and atypical antipsychotic ZYPREXA® (olanzapine, Eli Lilly), indicated for the short-term and maintenance treatment of schizophrenia and for the short-term treatment of acute mixed or manic episodes associated with bipolar I disorder. These reports include instances where ZYRTEC® was incorrectly dispensed for ZYPREXA® and vice versa, leading to unnecessary adverse events or potential relapse in patients suffering from schizophrenia or bipolar disorder. They recommend that these products be stored in different locations, that prescribers print both the brand and generic names of medication on all prescriptions, and that healthcare professionals discuss medications, their indications, and their proper use when counseling patients.
<i>Oncology News</i>	Researchers at Stanford University have discovered that a fragment of the collagen VII protein, which normally helps hold the skin intact, is also needed by skin cancer cells as they spread to other regions of the body. Studies were done in mice <i>in vivo</i> and in human skin cells <i>in vitro</i> , and the investigators found that when the subjects/cells were treated with the collagen VII-blocking antibody that the skin cancer failed to spread, though the cancer remained. Furthermore, it appears that the antibody blocks only the cancer-spreading aspect of collagen VII. The protein is still able to perform its normal job of keeping the skin intact. Despite this optimism, the lead investigator Paul Khavari, MD, PhD, the Carl J. Herzog Professor in Dermatology at Stanford, cautioned that many further experiments are needed before this work could lead to any cancer treatment.

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