ISSN

January 2016 ◦ Volume 15 ◦ Issue 1

IN DERMATOLOGY

JDD

DRUGS ◦ DEVICES ◦ METHODS

OFFICIAL JOURNAL OF ODAC

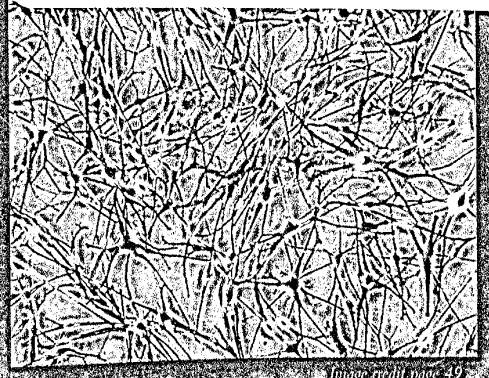

Image credit page 49

SPECIAL TOPIC:
AESTHETIC TREATMENTS

Natural Cosmeceutical Ingredients

Anti-Aging Effects of Probiotics

RF for Abdominoplasty Flaps

FACE-Q Scales

Evolution of Acne Assessments

RESIDENT ROUNDS ◆ NEWS, VIEWS, & REVIEWS ◆ PIPELINE PREVIEWS ◆ CLINICAL TRIAL REVIEW

ANTI-AGING ◦ AESTHETIC ◦ MEDICAL DERMATOLOGY

ORIGINAL ARTICLES

9 **Anti-Aging Effects of Probiotics**
Divya Sharma BS, Mary-Margaret Kober MD, and Whitney P. Bowe MD

14 **Fractional Ablative Laser Followed by Transdermal Acoustic Pressure Wave Device to Enhance the Drug Delivery of Aminolevulinic Acid: In Vivo Fluorescence Microscopy Study**
Jill S. Waibel MD, Ashley Rudnick, Carlos Nousari MD, and Dhaval G. Bhanusali MD

26 **Natural Cosmeceutical Ingredients for Hyperpigmentation**
Noelani Gonzalez MD and Maritza Perez MD

37 **Comparative Study of Professional vs Mass Market Topical Products for Treatment of Facial Photodamage**
Hilary Reich MD, Irmina Wallander BA, Lacie Schulte MS BA, Molly Goodier BS, and Brian Zelickson MD

47 **A Firming Neck Cream Containing N-Acetyl Glucosamine Significantly Improves Signs of Aging on the Challenging Neck and Décolletage**
Joel Schlessinger MD, Barbara Green RPh MS, Brenda L. Edison BA, Lynn Murphy MA, and Yamini Sabherwal PhD

55 **Effects of Subdermal Monopolar RF Energy on Abdominoplasty Flaps**
John Ferguson MD

62 **Assessing Improvement of Facial Appearance and Quality of Life after Minimally-Invasive Cosmetic Dermatology Procedures Using the FACE-Q Scales**
Brian P. Hibler BS, Jonathan Schwitzer MD, and Anthony M. Rossi MD

70 **Safety and Effectiveness of Hyaluronic Acid Injectable Gel in Correcting Moderate Nasolabial Folds in Chinese Subjects**
Yan Wu MD PhD, Jinhua Xu PhD, Yi Jia MD MSc PhD, and Diane K. Murphy MBA

79 **Evolution of Acne Assessments and Impact on Acne Medications: An Evolving, Imperfect Paradigm**
Linda Stein Gold MD, Jerry Tan MD, and Leon Kircik MD

89 **Evaluation of the Appearance of Nail Polish Following Daily Treatment of Ex Vivo Human Fingernails With Topical Solutions of Tavaborole or Efinaconazole**
Tracey C. Vlahovic DPM, Dina Coronado BS, Sanjay Chanda PhD, Tejal Merchant MPharm, and Lee T. Zane MD

ORIGINAL ARTICLES (CONTD)

97 **iPLEDGE Weaknesses: Is It Time to Address the Flaws?**
Amanda A. Cyrulnik MD, Aron J. Gewirtzman MD, Karin Blecher Paz MD, Jaimie B. Glick MD, Anika K. Anam MD, Daniel A. Carrasco MD, Alan R. Shalita MD, and Steven R. Cohen MD MPH

104 **Luliconazole Retention in Stratum Corneum and Prevention of Fungal Infection in a Guinea Pig Tinea Pedis Model**
Hiroyasu Koga PhD, Yasuko Nanjoh, Tetsuo Toga PhD, Radhakrishnan Pillai PhD, William Jo PhD, and Ryoji Tsuboi PhD

CASE REPORTS

111 **A Combination Approach to Perioral Rejuvenation**
Rebecca S. Danhof MD MPH and Joel L. Cohen MD

114 **Horrendous, Treatment-resistant Pediatric Atopic Dermatitis Solved With a Change in Vehicle**
Tejaswi Mudigonda BS, William Kaufman MD, and Steven R. Feldman MD PhD

RESIDENT ROUNDS

117 **The University of Pittsburgh Residency Program in Dermatology: In Memoriam, Dr. Lisa Grandinetti**
Kristen Lo Sicco MD

FEATURED CONTENT

119 **Clinical Trial Review**

Official Publication of
International Society for Dermatologic Surgery
DERM AESTHETIC & CLINICAL
SKIN OF COLOR SEMINAR SERIES

Journal of Drugs in Dermatology (JDD) (ISSN 1545-9616) is published monthly for $300 per year (US subscriptions)/$350 per year (International subscriptions) by the ***Journal of Drugs in Dermatology***, 377 Park Avenue South, 6th Floor, New York, NY 10016. Periodicals postage paid at New York, NY and additional mailing offices.

ADVERTISING: Contact Nick Gillespie at 646-453-5711
e-mail: nick.gillespie@jddonline.com

REPRINTS & PERMISSIONS: Contact Luz Figueroa at 646-736-4338
e-mail: luz.figueroa@jddonline.com

SUBSCRIPTIONS: Log on to www.JDDonline.com or call 212-213-5434

POSTMASTER: Send address changes to the *Journal of Drugs in Dermatology*, 377 Park Avenue South, 6th Floor, New York, NY 10016.

Journal of Drugs in Dermatology (JDD)
is indexed in MEDLINE®/PubMed® and is published monthly by the
Journal of Drugs in Dermatology
377 Park Avenue South, 6th Floor, New York, NY 10016
telephone: 212-213-5434 | fax: 212-213-5435 | JDDonline.com

Evaluation of the Appearance of Nail Polish Following Daily Treatment of Ex Vivo Human Fingernails With Topical Solutions of Tavaborole or Efinaconazole

Tracey C.Vlahovic DPM,[a] Dina Coronado BS,[b] Sanjay Chanda PhD,[b] Tejal Merchant MPharm,[b] and Lee T. Zane MD[b]

[a]Temple University School of Podiatric Medicine, Philadelphia, PA
[b]Anacor Pharmaceuticals, Inc., Palo Alto, CA

ABSTRACT

Introduction: Patients with onychomycosis may mask infected nails with polish. Tavaborole topical solution, 5% is a boron-based, small-molecule pharmaceutical approved for the treatment of toenail onychomycosis caused by *Trichophyton rubrum* and *Trichophyton mentagrophytes*; efinaconazole topical solution, 10% is approved for the same indication. Nail polish appearance after application of tavaborole (dropper) or efinaconazole (brush); respective applicator appearance; presence of color transfer from respective applicators; and color transfer to remaining solutions after dosing of polished nails were evaluated.

Methods: Twelve ex vivo human cadaver fingernails were cleaned, polished with two coats of L'Oréal® Nail Color, Devil Wears Red #420, and mounted on floral foam. Nails were treated with tavaborole or efinaconazole solutions once daily for 7 days. Dropper and brush applicators were applied to white watercolor paper immediately after dosing to evaluate color transfer from polished nails. On day 7, remaining solutions were transferred to clear glass vials to evaluate color transfer from applicators to solutions. Nails, applicators, and papers were photographed daily following application; remaining solutions were photographed after 7 days of dosing.

Results: Tavaborole-treated polished nails showed no polish discoloration, and tavaborole applicators did not change in appearance during treatment. No color transfer from polished nails was evident to applicator, paper, or remaining solution. Efinaconazole-treated polished nails showed substantial polish changes after the first day of treatment, with polish appearance and discoloration progressively worsening over 7 days of treatment. Color transfer from nails was evident to applicator, paper, and remaining solution.

Conclusions: Daily dropper application of tavaborole to ex vivo polished nails did not alter polish appearance. Brush application of efinaconazole produced visible changes in polish appearance and color transfer to applicators, paper, and remaining solution. Tavaborole topical solution, 5% may not alter nail polish appearance; the impact of nail polish on tavaborole clinical efficacy has not been evaluated.

J Drugs Dermatol. 2016;15(1):89-94.

INTRODUCTION

Onychomycosis is a common fungal infection of the nail unit that can cause subungual hyperkeratosis, thickening and discoloration of the nail, and onycholysis.[1,2] The unsightly appearance of the diseased nail can cause social embarrassment and negatively impact patient self-image.[3,4] Even with successful treatment, complete regrowth of healthy toenails can take up to 18 months.[4] During this time, patients may choose to mask discolored infected nails with polish; thus, the compatibility of nail polish with topical antifungal treatments is an important consideration for many patients with onychomycosis.

Treatment of onychomycosis is challenging due to the inability of some drugs to effectively penetrate the nail and reach fungal pathogens located beneath the nail plate.[5] Until recently, the only US Food and Drug Administration (FDA)-approved topical treatment for onychomycosis was ciclopirox nail lacquer, antifungals for the treatment of onychomycosis of the toenails caused by *Trichophyton rubrum* or *Trichophyton mentagrophytes*, including Kerydin™ (tavaborole topical solution, 5%; Anacor Pharmaceuticals, Inc., Palo Alto, CA), a boron-based small-molecule pharmaceutical,[7] and Jublia™ (efinaconazole topical solution, 10%; Valeant Pharmaceuticals, LLC, Bridgewater, NJ).[8]

Findings from in vitro studies have established the effective penetration of tavaborole through full-thickness human nail plates to the nail bed, where the fungal infection resides.[9,10] Importantly, tavaborole has been shown to retain its pharmacologic antifungal activity in the presence of keratin after permeating the nail plate. Similarly, nail-penetration studies in patients with toenail onychomycosis have shown the ability of efinaconazole to penetrate the subungual space between the nail plate and nail bed.[11] In addition, in vitro permeation studies

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.