



SUCCESSFULLY TREATING ATOPIC DERMATITIS IN CHILDREN

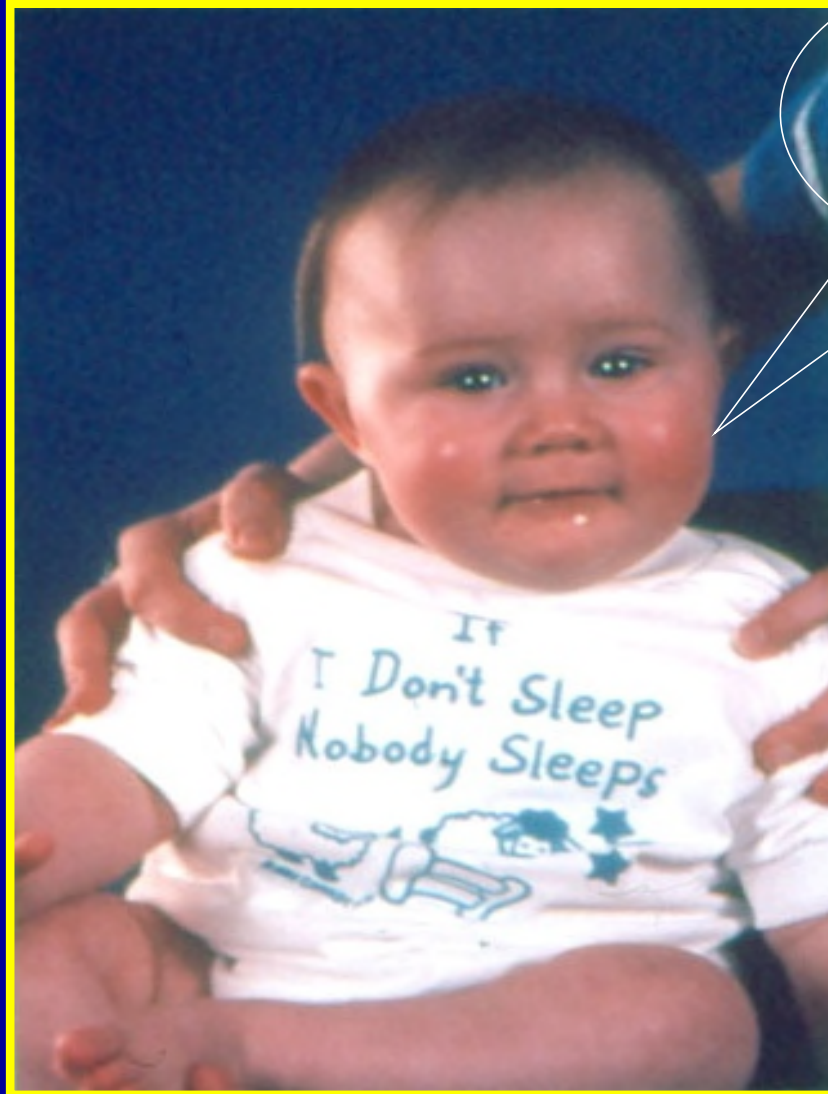
Lawrence A. Schachner, M.D.
Professor, Chair Emeritus and Stiefel Laboratories Chair
Director of the Division of Pediatric Dermatology
Department of Dermatology & Cutaneous Surgery
Professor, Department of Pediatrics
Leonard M. Miller School of Medicine
University of Miami

Disclosures of relevant relationships with industry

- **Lawrence A. Schachner, MD**
- *Investigator:* Astellas, Berg Pharma, Celgene, Ferndale Labs, Lilly, Medimetrics, Novartis, Organogenesis Inc., Pfizer, Stiefel Laboratories
- *Consultant:* Beiersdorf, Cutanea, Hoth, Lexington, Mustela, TopMD

Atopic Dermatitis

1. A disease of the whole family
2. No patient should leave the office without an instructional handout with the therapeutic ladder
3. If your stable atopic patient is flaring, think:
 - STAPH
 - STAPH
 - STAPH
4. New therapies



*If I don't Sleep
Nobody Sleeps!!*



Associated Comorbidities with Atopic Dermatitis:

- Cochrane systemic review and meta-analysis
- Patients with **vitiligo and alopecia areata** had SS greater odds of atopic dermatitis than control patients, $p < .001$
- Recent literature discussed morbidity
 - E.g. **Obesity** and increased **blood pressure** in atopic dermatitis children
- 2018 study discussed **suicidality** in pediatric patients:
 - Korean children with AD were at a significantly higher risk of suicidal ideation (OR 1.23, 95% CI 1.13-1.35) and suicide attempts (adjusted OR, 1.31; 95% CI, 1.12-1.52)
 - Female pediatric patients with AD also had an increased risk of suicidal ideation (adjusted OR, 1.114; 95% CI, 1.046-1.186) and suicide attempts (adjusted OR, 1.188; 95% CI, 1.065-1.325) compared with healthy controls

Mohan G.C and Silverberg J. JAMA Dermatology 2015(5) 522-528
Sandhu J, Wu KK, Bui T, Armstrong AW. JAMA Dermatology 2018

Avoiding Treatment Pitfalls

- **Printed regimen goes home: NO HANDOUT, NO COMPLIANCE**
- Atopic Dermatitis Made EZ: Easy sliding scale treatment tree
 - 2 minutes of education
 - 2 minutes of treatment explanation
- When in doubt: Dx/Rx infection.
- Give adequate volumes of medication.
- Supply and refills for **ACUTE AND MAINTENANCE** treatment.
- Remember the whole family is the patient: psychosocial intervention when necessary.









































Therapy

Therapeutics

PATIENT INSTRUCTIONS

ATOPIC DERMATITIS: TREATMENT MADE E.Z.SM:

THE SIMPLE SLIDING SCALE

Created by Lawrence A. Schachner, M.D.

- Basic Rules:
 - Short nails, short bath (3 minutes), cotton clothing, and cool environment
 - Laundry: Hypoallergenic detergent with no bleach or fabric softener.
- Bath care:
 - If previous Staph infection, use antibacterial soap from the neck down (do not use on face) for three minutes before bath
 - If history of Staph infections, ¼ cup of bleach in 1 ft of water; bleach in a bottle
 - After bath, **pat dry**. Do not rub!
 - **Emollient** to ENTIRE body.

ATOPIC DERMATITIS: TREATMENT MADE

E.Z.SM:

The Simple Sliding Scale For Mild to Moderate AD

- Morning:

- Emollient to entire body, even if no inflammation (nothing *pink* or *red*).

AND

- Medium strength topical steroid and/or Topical Calcineurin Inhibitors (TCI) and/or Phosphodiesterase inhibitors (PDI) to *red* areas on *body*.
- Hydrocortisone and/or Topical Calcineurin Inhibitors (TCI) and/or PDI to *slightly red* or *pink* areas on *body*.
- Hydrocortisone and/or Topical Calcineurin Inhibitors (TCI) and/or PDI to *pink* or *red* areas on *face, groin, and armpits*.

ATOPIC DERMATITIS: TREATMENT MADE

E.Z.SM:

The Simple Sliding Scale For Mild to Moderate AD

- Afternoon: Emollient to all skin.
- Evening:
 - Emollient to entire body, even if no inflammation (nothing *pink* or *red*).
 - AND
 - Medium strength topical steroid and/or Topical Calcineurin Inhibitors (TCI) and/or PDI to *red* areas on *body* (**emollient to other areas**).
 - Hydrocortisone and/or Topical Calcineurin Inhibitors (TCI) and/or PDI to *slightly red* or *pink* areas on *body* (**emollient to other areas**).
 - Hydrocortisone and/or Topical Calcineurin Inhibitors (TCI) and/or PDI to *pink* or *red* areas on *face, groin, and armpits* (**emollient to other areas**)

ATOPIIC DERMATITIS: TREATMENT MADE

E.Z.SM:

The Simple Sliding Scale

Other Instructions:

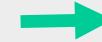
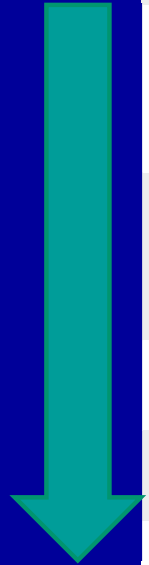
- Antibiotics
 - Oral or Topical
- Topical Calcineurin Inhibitors (TCI)
 - Tacrolimus (Protopic 0.03%, 0.1%)
 - Pimecrolimus (Elidel)
- Phosphodiesterase inhibitors
- Antihistamines & Bedtime
 - Non-sedating in a.m.
 - Sedating at bedtime
 - **Doxepin** – the secret weapon
 - Additional pearl: use of **melatonin** in infants and children in AD
- Scalp care:
 - Shampoo
 - Topical Steroid

A 3-day Rate of Efficacy of a
Moderate Potency Topical Steroid in
the Treatment of Atopic Dermatitis in
Infancy and Childhood

**Lawrence A. Schachner, M.D.
Pediatric Dermatology, 1996;13(6):513-514**

The Schachner Ladder

Severity	Topical Treatment	Schedule
If Severe:	Clobetasol (high potency CS) + TCI or PDI + emollients	Twice daily for 3-5 days
If Moderate:	Triamcinolone (medium potency CS) + TCI or PDI + emollients	Twice daily for 3-5 days
If Mild:	Alclometasone (low potency CS) + TCI or PDI + emollients	Twice daily for 3-5 days
Controlled:	TCI or PDI or TS + emollients	Twice daily for 2 weeks
Maintenance (to areas of predilection):	TCI or PDI or TS + emollients	Twice weekly for 6 months
Long-term Maintenance & Prevention:	Emollients	Twice daily




- * Antihistamines as needed
- * Antibiotics as needed

*Abbreviations: CS: Corticosteroid. PDI: Phosphodiesterase inhibitor. TCI: Topical Calcineurin Inhibitor

Oberlin KE, Nanda S. Atopic dermatitis made easy: The Schachner Ladder. *Pediatr Dermatol.* 2019;36(6):1017-8.

Algorithm For The Treatment Of Moderate To Severe Atopic Dermatitis

- If successful:
 - Titrate down 
 - TCI's 2x a week or
role for PDI or
topical steroid
 - Emollients only
- If unsuccessful:
 - 1) Patch testing
 - 2) Tar
 - 3) Class I-II topical steroids
 - 4) Prednisone
 - 5) **DUPILUMAB**
 - 6) IVPS
 - 7) UVA, UVB, narrowband UVB
 - 8) Cytotoxic and Biologic agents: cyclosporine, cellcept, cyclophosphamide, azathioprine, methotrexate
 - 9) INF α or γ subcutaneously
 - 10) IVIG
 - 11) Relaxation / Massage therapy / Behavioral/
Probiotics

Phototherapy in the management of atopic dermatitis: a systematic review

Meduri NB *et al* Photodermatol Photoimmunol Photomed 2007; 23:106-112

- Results:
- Three studies showed that UVA1 is both faster and more efficacious for treating acute AD.
 - Two trials used medium dose (50J/cm²) UVA1 for treating acute AD with success
- Two trials revealed that combined UVAB was superior to UVA alone in the management of AD
- Two studies demonstrated the narrow-band UVB is more effective than either broadband UVA or UVA1 for managing chronic AD

Prednisone My Way – 16 day cycle

e.g. – 20 kg child with severe atopic dermatitis

- 1mg/kg/day x 4 days = 20 mg/day
- .75 mg/kg/day x 4 days = 15 mg/day
- .50 mg/kg/day x 4 days = 10 mg/day
- .25 mg/kg/day x 4 days = 5 mg/day



Cyclosporine in the treatment of patients with atopic eczema-a systematic review and meta-analysis

Schmitt J, Schmitt N, Meurer M et al. JEADV 2007; 21: 606-619

- Methods: search on MEDLINE, Cochrane and hand search for atopic dermatitis and cyclosporine
- 15 studies, 602 patients, were included for review
 - Included: all languages, only human studies
 - Excluded: reviews, studies with $n < 3$
- **Three studies included only children**, 4 included both children and adults, and 8 included only adults
- Duration of treatment varied from 6 weeks to 12 months

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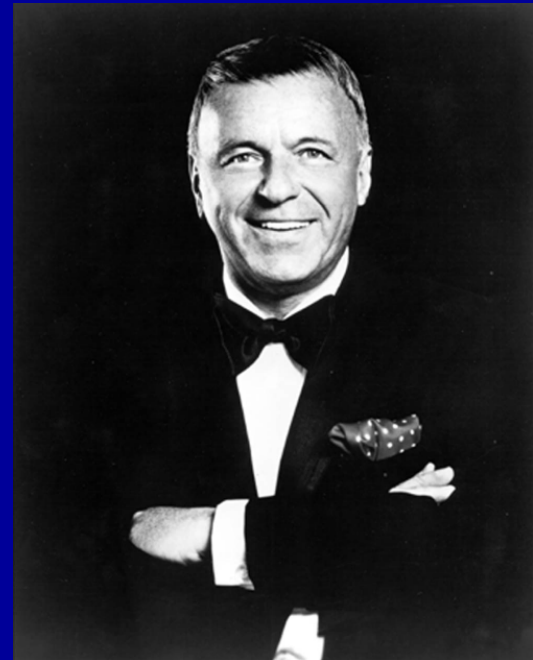
- Nine studies used higher cyclosporine doses (4-5mg/kg) and 4 studies used 2.5-3mg/kg
- In the **higher** cyclosporine dosage (4-5mg/kg) groups, there was an average of **40% change** in mean disease severity after 2 weeks compared to an average of **20% change** in disease severity in the studies using **lower** dose 2.5 - 3mg/kg

Cyclosporine My Way

1. Check blood pressure, BUN, Creatinine pre-treatment and each month.

2. Cyclosporine

- 5mg/kg/day - First Month
- 4mg/kg/day - Second Month
- 3mg/kg/day - Third Month
- 2mg/kg/day - Fourth Month
- 1mg/kg/day - Fifth Month



Oral CyA Weekend Therapy

- 5 patients, Mean age 12 yo (range 10-14)
- SCORAD >40
- CyA (5mg/kg/d) for longer than 1 year with SCORAD \leq 30
- Weekend dose kept same
- Examined at 12 and 20 weeks
- Results showed less relapse
 - 4/5 maintained SCORAD \leq 30
 - 1/5 had to return to daily CyA
 - BP and Cr stable

Mycophenolate mofetil for severe childhood atopic dermatitis: experience in 14 patients

Heller M, Shin HT, Orlow SJ, Schaffer JV. Br J Dermatol. 2007 157(1): 127-32

- Retrospective analysis of 14 pediatric patients with severe AD
- MMF was used as systemic monotherapy at doses of 40-50mg/kg in younger children and 30-40mg/kg in adolescents
- 4 patients had complete clearance, 4 had > 90% improvement, 5 had 60-90% improvement, and 1 failed to respond; thus, 13 of 14 had 60-100% clearance
 - Maximal effects were seen at 8-12 weeks
- Medication was well tolerated in all patients
 - No infectious complications, no anemia, leukopenia, thrombocytopenia or elevated aminotransferases

Dermatological Uses Of High-dose Intravenous Immunoglobulin

Stephen Jolles, MSc, MRCP

Jenny Hughes, MRCP

Sean Whittaker, MD, MRCP

Archives of Dermatology Jan 1998; 134 : 80-86.

Crisaborole

- First topical Phosphodiesterase 4 inhibitor (PDE-4)
- U.S. FDA approved in December 2016 for **mild-moderate** atopic dermatitis in patients **2 years** of age and older
- Mechanism of action: by inhibition PDE-4, results in increase intracellular cAMP levels which is suppression the release of pro-inflammatory cytokines
- Crisaborole ointment 2% apply twice daily supplies in 60 g and 100 g tube.

Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults

- Two identically designed multicenter, randomized, double-blind, vehicle-controlled phase III

EFFICACY	AD-301 ($p=0.038$)		AD-302 ($p<0.001$)	
	EUCRISA (N=503)	Vehicle (N=256)	EUCRISA (N=513)	Vehicle (N=250)
Success in ISGA	32.8%	25.4%	31.4%	18.0%

ISGA: Investigator's static Global Assessment score

- More crisaborole-treated patients achieved improvement in ISGA score at day 29 and achieved earlier success than those treated with vehicle ointment

Paller et al. J Am Acad Dermal 2016;75:494-503

Efficacy and safety of crisaborole ointment continued...

- Improved disease severity by decreasing pruritus, erythema, exudation and lichenification at day 29
- Pruritus improvement earliest at day 8 (58 vs 42%, $p < 0.001$)
- Safety end point
 - No reported of series adverse event.
 - Burning or stinging at application site 4.4%, which 76.7% report on first day and resolve within one day.
 - No available data in pregnancy & lactation

PDI application site pain: frequency and clinical relevance

- There are reports of application site pain, described as a “burning or stinging” sensation¹⁻⁴
- Randomized controlled clinical trial (RCT) conducted in Australia on adults resulted in 4% of subjects experiencing pain³
- RCTs from the US found a frequency of 4.4% in children
- A 48 week extension study was conducted in which the incidence of pain was 2.3% of patients and noted to decrease over time⁴
- A retrospective study conducted at Tufts Medical Center in adults found a frequency of 31.7%²
- Clinical relevance:
 - May decrease patient compliance and use in **AD**
- Efficacy without stinging in intertriginous and facial **psoriasis** in adults: difference in barrier function may explain the total lack of application site reaction⁵

1. Paller AS, Tom WL, Lebwohl MG, Blumenthal RL, Boguniewicz M, Call RS, et al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. *J Am Acad Dermatol*. 2016;75(3):494-503 e6.
2. Pao-Ling Lin C, Gordon S, Her MJ, Rosmarin D. A retrospective study: Application site pain with the use of crisaborole, a topical phosphodiesterase 4 inhibitor. *J Am Acad Dermatol*. 2019;80(5):1451-3.
3. Murrell DF, Gebauer K, Spelman L, Zane LT. Crisaborole Topical Ointment, 2% in Adults With Atopic Dermatitis: A Phase 2a, Vehicle-Controlled, Proof-of-Concept Study. *J Drugs Dermatol*. 2015;14(10):1108-12.
4. Eichenfield LF, Call RS, Forsha DW, Fowler J, Jr., Hebert AA, Spellman M, et al. Long-term safety of crisaborole ointment 2% in children and adults with mild to moderate atopic dermatitis. *J Am Acad Dermatol*. 2017;77(4):641-9 e5.
5. Hashim PW, Chima M, Kim HJ, Bares J, Yao CJ, Singer G, et al. Crisaborole 2% ointment for the treatment of intertriginous, anogenital, and facial psoriasis: A double-blind, randomized, vehicle-controlled trial. *J Am Acad Dermatol*. 2020;82(2):360-5.

Mitigation strategies for PDI application-site pain

- Burning and stinging may decrease patient compliance and use
- *Potential strategies*
 - Begin TCS for 3 days before adding PDI to treatment regimen
 - Can utilize a slow introduction approach (e.g. TCS or emollient and PDI together in a 5:1 ratio and titrate
 - Very thin application with or without TCS or emollient
 - Can cool the PDI by placing in refrigerator at 2 - 8°C
 - Modify formulation

DUPIXENT

Dupilumab is a successful currently available biologic treatment of a **moderate to severe** Atopic Dermatitis (AD)

- It is a fully human monoclonal antibody directed against the shared alpha subunit of the IL-4 receptor resulting in signaling blockade of IL-4 and IL-13, which are key drivers of Th2-mediated inflammation of AD
- Suppresses the expression of genes related to the activation of Th2 cells and related inflammatory pathways, a major driver in AD clinical disease

Indications:

- Moderate to severe AD not responding to topical treatment (as monotherapy or in combination with topical steroids) in 12 year olds and up.
- **Current studies are being conducted in 6 month – 11 year old patients with AD**

DUPIXENT

Dose: 300 mg subq/ 200 mg subq...60 kg

- Dupixent comes in a pre-filled syringe and can be self-administered as a subcutaneous injection every other week after an initial loading dose (600mg) . It can be used with or without topical corticosteroids.
- An open label multicenter extension study revealed a favorable long-term (> 1 year) safety and efficacy profile in adults²
- Dupixent has been used off-label in children < 12 years old and demonstrated success with good tolerability but weight-based dosing must be optimized³

¹ Clark et al. Cutis. 2018 Sep;102(3):201-204.

² Deleuran M, et al. J Am Acad Dermatol. 2020 Feb;82(2):377-88.

³ Igelman S, et al. J Am Acad Dermatol. 2020 Feb;82(2):407-11.

Safety and Efficacy Studies

- Deleuran et al. recently conducted an open label multicenter extension study to determine long-term (76 weeks) safety and efficacy profile in adults
 - Loading dose of 600 mg with 300 mg maintenance dose given weekly
 - Overall, there were 420 adverse events (AEs) per 100 person-years (Pys) and 8.5 serious AEs per 100 Pys
 - Most AEs were mild to moderate and most commonly included nasopharyngitis, upper respiratory tract infections, AD, and headache
 - Injection site reactions and conjunctivitis-related side effects diminished in incidence over time
 - Only 1.8% of patients overall discontinued the study before data cutoff
 - By week 76, most patients showed significant improvement in pruritus, quality of life, and AD disease activity

Deleuran M, et al. J Am Acad Dermatol.
2020 Feb;82(2):377-88.

Safety and Efficacy Continued...

- A retrospective review assessed patients with moderate to severe AD from birth to 17 years old receiving dupixent
- Mean loading dose was 8.7 mg/kg and mean maintenance (q 2 wks) was 5.1 mg/kg
- Of 111 treated patients, mean age of dupixent initiation was 13 years old
- This study included 24 patients who were < 11 years old
 - 18 patients 6-11 years old
 - 6 patients < 6 years old
- Over a mean follow-up period of 9 months, 64% of patients demonstrated at least a 2 point improvement in IGA score
- Adverse events, which included 10 cases of conjunctivitis, 6 facial eruptions, 3 injection site reactions, and 2 upper respiratory tract infections, did NOT lead to discontinuation of treatment

Igelman S, Kurta AO, Sheikh U, McWilliams A, Armbrrecht E, Jackson Cullison SR, et al. Off-label use of dupilumab for pediatric patients with atopic dermatitis: A multicenter retrospective review. J Am Acad Dermatol. 2020;82(2):407-11.

New & Emerging Therapies

New:

- Crisaborole (Eucrisa): topical 2016
- Dupilumab (Dupixent): systemic 2017
- Dupilumab (Dupixent) approved for adolescents 12-17 in 2019

Emerging:

- Monoclonal antibodies against IL-13 and 31RA
- Phosphodiesterase- 4 inhibitors
- JAK inhibitors
- Transient receptor potential (TRPV1) antagonist
- T-cell inhibitors
- Prostaglandin/leukotriene inhibitors

Alternative Therapies

Atopic Dermatitis Symptoms Decreased In Children Following Massage Therapy

Schachner LA, Field T, Hernandez-Reif M,
Duarte A, Krasnegor J

Pediatric Dermatology, 1998; 15 (5): 390-395.

Atopic dermatitis symptoms decreased in children following massage therapy

Prior to study: Per mothers, their child's skin condition impacted their appearance 1) **hardly at all** in 11% of patients, 2) **somewhat** in 67% of patients, and 3) **considerably** in 22% of patients.

Methods: 20 children (7 girls) 2-8 years old

- 10 received standard of care* + massage therapy 20 min/day
- 10 in control group: standard of care* alone
- Oral antibiotics were supplemented for superinfection with Staph if needed

Visits: 1) Day 1
2) Day 30

*Standard of care: Topical 1 % hydrocortisone (face and groin) + 0.1% TAC (trunk) BID or PRN + Aquaphor BID

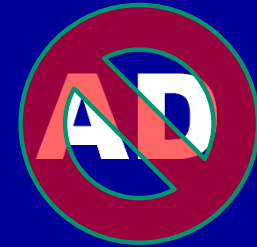
Atopic dermatitis symptoms decreased in children following massage therapy

Results:

- Children in massage group:
 - affect, anxiety, and activity level **significantly improved** by day 30.
 - **improved significantly** on all clinical measures including redness, scaling, lichenification, excoriation, and pruritus.
- Control group:
 - improved significantly on the scaling measure.
- Parents of massaged children:
 - anxiety decreased **immediately** after the massage therapy sessions.
 - reported lower anxiety levels in their children.

Low cost measure such as massage therapy with appropriate emollient offers a significant adjuvant therapy for AD.

Emollients Prevent Atopic Dermatitis in Neonates at Risk



- Two prospective, randomized controlled trials demonstrated that the **daily use of a moisturizer prevented AD** in 32% of Japanese and 50% of Anglo-American **high-risk newborns**

(Horimukai et al. J Allergy Clin Immunol., 2014; Simpson et al. J Allergy Clin Immunol., 2014)

- Daily use of emollients in high risk neonates may serve as a novel and simple approach to **primary prevention** of AD

Melatonin and Atopic dermatitis

- Randomized, double blind, placebo controlled crossover study in a Taiwan tertiary hospital
- 48 patients, 1 to 18 years old (Mean 7 yo)
- **Melatonin 3mg/day** for 4weeks, followed by 2 weeks wash out, crossover to alternate treatment for 4 weeks
- **SCORAD reduced by 9.1** ($p < 0.001$) versus placebo from a mean of 49.1
- **Sleep latency reduced by 21 minutes** ($p = 0.02$) versus placebo from a mean of 44 minutes
- No adverse events were reported

Emollients & Barrier Repair Products: A Brief Review

Can they be valuable tools in the treatment of AD?

Yes!



Product	100 grams
Petroleum	\$1.25
Aquaphor ointment jar	\$4.82
Cetaphil Basic	\$3.53
Cerave Moisturizing cream	\$3.82
Eucerin Basic	\$3.48
Vanicream	\$3.75
Stelatopia- CVS	\$14.23
Stelatopia- Amazon	\$13.68
Atopiclair - CVS	\$144.99
Atopiclair - Walgreens	\$143.99
Eletone - CVS	\$101.99
Eletone - Walgreens	\$107.99
EpiCeram- Walgreens	\$208.88
Hylatopic Plus - Walgreens	\$129.99
Mimyx - CVS	\$105.71
Mimyx - Walgreens	\$118.56
Neosalus - CVS	\$138.99
Neosalus - Walgreens	\$155.99

PATIENT INSTRUCTIONS

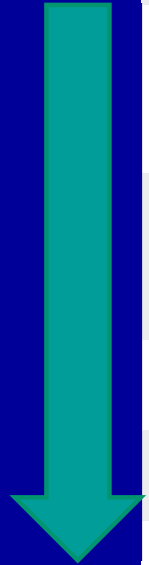
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- Bath care:
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 - If history of Staph infections ¼ cup of bleach in 1 ft of water
 - After bath, **pat dry**. Do not rub!
 - **Emollient** to ENTIRE body.

The Schachner Ladder

Severity	Topical Treatment	Schedule
If Severe:	Clobetasol (high potency CS) + TCI or PDI + emollients	Twice daily for 3-5 days
If Moderate:	Triamcinolone (medium potency CS) + TCI or PDI + emollients	Twice daily for 3-5 days
If Mild:	Alclometasone (low potency CS) + TCI or PDI + emollients	Twice daily for 3-5 days
Controlled:	TCI or PDI or TS + emollients	Twice daily for 2 weeks
Maintenance (to areas of predilection):	TCI or PDI or TS + emollients	Twice weekly for 6 months
Long-term Maintenance & Prevention:	Emollients	Twice daily



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Oberlin KE, Nanda S. Atopic dermatitis made easy: The Schachner Ladder. *Pediatr Dermatol.* 2019;36(6):1017-8.

Dr. Schachner's email

lschachner@med.miami.edu

Pediatric Dermatology Fellows

- Chulaporn Pruksachatkunakorn, 1991-1992 –Thailand
- Ana Margarita Duarte, 1991-1995 – USA
- Abdallah Huneiti, 1998-1999 – Jordan
- Jan Izakovic, 1999-2000 – Switzerland
- Julie Greenberg, 2000-2002 – Israel
- Andrea B. Trowers, 2001-2003 – USA
- Latanya Benjamin, 2003-2005 – USA
- Cheryl Aber, 2005-2006 – USA
- Cynthia Burke Price, 2006-2007 – USA
- Mercedes Gonzalez, 2007-2008 – USA
- Susan Bard, 2008-2009 – USA
- Jessica Simon, 2009-2010 – USA
- Daniele Torchia, 2009-2011 – Italy
- Carol Lattouf, 2010-2011 – USA
- Jasem Al-Shaiji, 2011-2012 – Kuwait
- Marc Z. Handler, 2011-2012 – USA.
- Pajaree Thitthiwong, 2012-2013 – Thailand.
- Leelawadee Techasatian, 2013-2014 – Thailand
- Ingrid HersHKovitz-2013-2014-Brazil
- Osama Alsharif – 2014-2015 – Saudi Arabia
- Shanna Ng- 2015-2016- Singapore
- Hanadi Alsatti, 2016-2017 – Saudi Arabia
- Weena Phuthongkam, 2016-2017 - Thailand
- Khalid Alwunais, 2017-2018 – Saudi Arabia
- Penelope Hirt 2017-2019- Venezeula
- Sonali Nanda, 2018-2019 – USA
- Stephanie McNamara, 2019 – present – USA
- Eran Gwillim, 2019-present – USA