Formulas to Grow Your Practice

Nat Jones, RPh, FIACP
PCCA Marketing and Sales Symposium
San Diego, CA
May 12-14, 2016
Areas of Interest

- DENTAL
- DERM
- ENT
- GI
- GYN
Dental

• Oral too!
  – Halitosis
  – Dry socket
  – Xerostomia
  – Burning mouth
  – Ulcers
  – Gingivitis
  – Herpes Labialis
  – Angular Cheilitis
Halitosis

- Commonly caused by bacteria present below the gum line and on the back of the tongue
- Other conditions, including disorders in the nasal cavity, sinuses, throat, lungs, esophagus, stomach or tonsilloliths
- Can be serious underlying medical condition such as liver failure
Halitosis

• Volatile sulfur compounds (mainly hydrogen sulfide and methyl mercaptan) are mostly responsible for intra-oral halitosis

• Bacteria produced by enzymatic reactions of sulfur-containing amino acids; L-cysteine and L-methionine.

Halitosis

- 90% of cases, problem is in the mouth
- Fix: better brushing or gently scraping the back of the tongue and improving the health of the gums by using dental floss
Halitosis

• Chlorhexidine effective at killing oral bacterial and decreasing volatile sulphur compounds
• Formula #10892
  – Chlorhexidine Gluconate 0.2% Oral Rinse, Alternate (MucoLox™)

* J Clin Periodontol. 2004 Dec;31(12):1128-34. Comparative effects of different chlorhexidine mouth-rinse formulations on volatile sulphur compounds and salivary bacterial counts. Roldán S1, Herrera D, Santa-Cruz I, O’Connor A, González I, Sanz M.
Halitosis

• Formula #11137
  – Chlorophyllin Sodium Copper 0.2% Mouthwash (MucoLox™)
  – Alcohol free

• This formula is requested sometimes but... it doesn’t work – sorry!

  * Rev Laryngol Otol Rhinol (Bord). 1951 May-Jun;72(5-6):397-408. [Considerations on the use of chlorophyllin in otorhinolaryngology; study on its deodorizing action in halitosis]. MASSON, LEVIER. PMID: 14865411
Chlorophyllin Sodium Copper

- Chlorophyllin treatment demonstrated no deodorization in comparison to the control
- Successful treatments may be due to enzymatic, polyphenolic, or acid deodorization

Halitosis

• Formula #11929  NEW

  – Green Tea Extract 10% Mouth Rinse
  – Swish 1-2 ml BID for 1 month
  – Good oral hygiene

Halitosis

• References


Halitosis

• Use probiotics regularly

Dry Socket (Alveolar Osteitis)

- Post extraction a blood clot should form in the socket to protect the bone and nerves below.
- If it is dislodged (usually by eating) or dissolves a couple of days after the extraction that leaves the bone and nerve exposed to air, food, fluid, etc.
- May lead to infection and severe pain.
Dry Socket

Blood clot forms after tooth extraction which leads to healing and new bone formation.

If the blood clot doesn't form or is lost too early, a painful 'dry socket' occurs.
Dry Socket

• Dental alveoli (singular alveolus) are sockets in the jaws in which the roots of teeth are held
Dry Socket

• Happens in 0.5% - 5% of general extractions and 25 - 30% of impacted wisdom teeth extractions
Dry Socket Packing

• Common ingredients include:
  – Eugenol (extract of clove oil, an antiseptic analgesic)
  – Guaiacol or Balsam of Peru (compounds related to Eugenol)
  – Benzocaine (an anesthetic)
  – Iodoform (an antimicrobial agent)
  – Chlorobutanol (an anesthetic)
Eugenol

- Oily liquid extracted from certain essential oils (clove oil, nutmeg, cinnamon, basil and bay leaf)
- A local antiseptic and anesthetic

1-Allyl-3-methoxy-4-hydroxybenzene
Dry Socket

- Old school formulas
  - Formula #2349
    - Benzocaine / Eugenol Dressing
  - Formula #1438
    - Benzocaine 4% Compound Socket Liquid
  - Formula #5560
    - Guaiacol / Chlorobutanol / Eugenol Compound Dry Socket Paste
Formula #2349

- Benzocaine USP
- Flavor, Eugenol USP
- Lanolin USP (Anhydrous)
- Petrolatum, White USP

* Getz® Surgical Dressing, Alternate
Dry Socket – New School

• Formula #11385
  – Benzocaine 16.7% Dry Socket Gel (MucoLox™)
  – For pain from dry socket

• Formula #11541
  – Tranexamic Acid 4.8% / Phenytoin 2% / Clindamycin 1% / Sodium Hyaluronate 0.5% Poloxamer Dental Gel
  – To help prevent dry socket
Dry Socket – New School

• Formula #11777
  – Beta Glucan 0.5% / Phenytoin 2% / Lidocaine HCl 5%
    Dry Socket Gel (MucoLox™)
  – Beta Glucans trigger activity in immune cells: white blood cells
  – A side effect of phenytoin is gingival hyperplasia stimulating growth of epithelial cells
Xerostomia (Dry Mouth)

• Associated with a change in the composition of saliva, or reduced production of saliva, or often no identifiable cause
• A common symptom, or a side effect of many drugs
• More common in older people because they take more drugs and in mouth breathers
• Dehydration, radiation, chemotherapy and Sjögren's syndrome are common causes
Xerostomia Formulae

• Formula #11149
  – Artificial Saliva Gel (MucoLox™)
• Formula #11150
  – Electrolyte Saliva Gel (MucoLox™)
• Formula #11151 (BUD)
  – Pilocarpine HCl 10 mg/mL Oral Rinse (MucoLox™)
• Formula #11400
  – Calcium Phosphate Mouthwash (MucoLox™)
Xerostomia Formulae

• Formula #11754
  – Xylitol 7%, Betaine 2%, Olive Oil 2% Mouth Rinse (MucoLox™)

• Formula #11768
  – Xylitol 10%, Beta Glucan 0.5%, Olive Oil 2% Mouth Rinse (MucoLox™)
  – Sig: 1 - 2 ml Q4-6h, swish (hold) and gradually swallow
Burning Mouth Syndrome

• Types:
  – *Primary* - no known cause. Believed to be caused by damage to the nerves that control pain and taste
  – *Secondary* - caused by medical problem and treating the problem will fix the symptom
## Burning Mouth Syndrome

- **Secondary BMS causes include...**
  - Hormonal changes (diabetes or thyroid)
  - Allergies to dental products, or foods
  - Dry mouth, such as Sjögren’s syndrome and treatments (certain drugs and radiation therapy)
  - Certain high blood pressure medicines
  - Nutritional deficiencies (low B vitamins or iron)
  - Infection in the mouth (yeast)
  - Acid reflux
Burning Mouth

- Formula #11127
  - Amitriptyline HCl 2% / Gabapentin 6% / Lidocaine HCl 0.5% Oral Rinse (MucoLox™)

- Formula #10893
  - Salicylic Acid 0.3% Mouthwash (MucoLox™)
Burning Mouth

• **Formula #11128**
  - Doxepin HCl 0.5% Mouthwash (MucoLox™)

• **Formula #11412**
  - Ketamine HCl 3% / Amitriptyline HCl 2% / Gabapentin 6% / Lidocaine HCl 0.5% Oral Rinse (MucoLox™)
Burning Mouth

• Formula #9959
  – Amitriptyline HCl 2% / Gabapentin 6% / Lidocaine HCl 0.5%
  – Oral Rinse
  – Use 4 or 5 times a day (swish and spit)

• Formula #3327
  – Capsaicin 0.25 mg Base A Troche

• Formula #3399
  – Capsaicin 0.25 mg Base A Troche (Capsicum Oleoresin)
Aphthous Ulcer (Canker Sore)

- Formula #1833
  - Camphor / Phenol / Eugenol Topical Paste
- Formula #3210
  - Triamcinolone 0.1% Oral Adhesive Paste
Formulae

- Formula #11438
  - EDTA 0.12% / Tetracycline / Deoxy-d-glucose 2% / Lidocaine HCl 2% / Bupivacaine 0.5% Oral Adhesive Paste

- Formula #11157
  - Acyclovir 5% / Lidocaine HCl 1% / Deoxy-D-Glucose (2) 2% Oral Rinse (MucoLox™)

- Formula #0522
  - Tetracycline HCl 125 mg / Nystatin 60417 units / Diphenhydramine HCl 12.5 mg / Hydrocortisone 2.3 mg Base A Troche
Gingivitis

• Formula #11130
  – Coenzyme Q-10 1% Oral Rinse (MucoLox™)
  – As an alternative to or in conjunction with Co-Q10 toothpaste use
Herpes Labialis

• Formula #11413
  – Acyclovir 5% / Lidocaine HCl 5% / Deoxy-D-Glucose 2% Vaginal Gel (MucoLox™)
  – Apply 4 to 6 times a day

• Formula #4963
  – Acyclovir 2% / Deoxy-D-Glucose (2) 0.2% Lip Balm
  – Apply 4 to 6 times a day
Herpes Labialis

• Formula #7416
  – Alaskan Red Algae 1% Lip Balm with SPF 15
  – Antiviral properties


Angular Cheilitis

Can be due to nutritional deficiencies of B vitamins, Fe and Zn (25% of cases)
Angular Cheilitis

- Sometimes caused by bacteria (staph)
- Once the corners are fissured, saliva accumulation and contamination can lead to infection... most commonly, candida albicans
- Formula #11156
  - Clotrimazole 2% / Ibuprofen 2% / Tea Tree Oil 1%
  - Topical Gel (MucoLox™ / VersaBase®)
Angular Cheilitis

• Formula #11450
  – Mupirocin 2% / Nystatin 30,000 un/gm / Lidocaine 1% Ointment
  – Contains 20% PracaSil™-Plus in Plasticized Base

• Start treatment early so that it doesn’t lead to this...
Miscellaneous Oral Problems

• Oral thrush (Candidiasis)
  – Formula #11141
    • Nystatin 100,000 u/mL Oral Suspension (MucoLox™)
    • Swish and swallow QID - Sugar Free

• Lichen Planus
  – Formula #11749
    • Tacrolimus 0.03% Oral Rinse (MucoLox™)
Areas of Interest

DERM
Derm

- Atopic Dermatitis
- Eczema
- Psoriasis
- Rosacea
- Keratosis Pilaris
Get Rid of the Inflammation Source

• Diet - eliminate as many pro-inflammatory foods as possible
• Gut repair - probiotics, prebiotics, Glutamine
• Supplements
  – Optimize Vit. D, Fish oil, Vitamin C, Digestive enzymes
Barrier Repair

- When the stratum corneum moisture content of skin drops below 10%, it is perceived as dry
- A moisturizer is any material that helps skin retain moisture
- Fix the lipid barrier - key!
Atopic Dermatitis (AD)

- AD is an itchy, hereditary skin disorder that is the most common form of eczema
- Approximately 10 to 20% of people will exhibit this condition and many cases will be infants
- 20 to 40% of those patients will have it as an adult
AD

- Commonly has multiple clinical patterns, characterized histologically by a spongiotic tissue reaction pattern
- Intracellular fluid build up
Dermatitis

• The cause of dermatitis is unclear
• One possibility is a dysfunctional interplay between the immune system and skin
• Dermatitis can occur at any age, but atopic dermatitis usually begins in infancy
Mast Cells (MC)

- Play an important role in our innate immune response
- Key roles in wound healing and defense against pathogens, but are also often associated with allergy and anaphylaxis
- Type of white blood cell known as a Granulocyte (granules in cytoplasm)
Mast Cells (MC)

- Once activated they rapidly release granules rich in histamine and heparin
- Also various other inflammatory stimulators (cytokines and interleukins) are released
- Histamine dilates blood vessels, causing the characteristic signs of inflammation, and recruits WBC’s
Mast Cells (MC)

Resting mast cell

Activated mast cell
Mast Cells

- Dermal layer
- Located close to blood vessels and sensory nerve endings and can react when triggered
Tranilast for AD

- Patients with AD have increased IL-2*
- Severity of AD is worse with higher IL-2 production
- Tranilast decreased IL-2 production to normal by stabilizing mast cells

Tranilast for AD

• Formula #11881
  – Tranilast 1% Topical Cream (XemaTop™)
  – Apply three times a day as needed
### Natural Mast Cell Stabilizers

- Quercetin
- EGCg (green tea)
- Silymarin (active component in Milk Thistle)
- Resveratrol
- Curcumin
- Theanine

Natural Mast Cell Stabilizer Cream

• Formula #11963
  – Theanine 0.5% / Quercetin 1% / Green Tea Extract 0.5% Topical Cream (XemaTop™)
  – Can be used twice daily to treat AD or as a preventative for those subject to outbreaks
Melatonin Response

- IL-10 prevents inflammatory cytokine production
- Melatonin increases IL-10 which decreases inflammation

Melatonin for AD

• Formula #9871
  – Melatonin 2.5% Topical Cream (VersaBase®)
  – Apply 2 to 3 times a day
• Formula #12094 (NEW)
  – Melatonin 2.5% / Naltrexone 1% / Tranilast 1% topical Cream (XemaTop™)
Tacrolimus

- Is an immunosuppressive agent (transplant rejection use) that is classified as a Calcineurin inhibitor
- Anti-inflammatory properties, decreasing cytokine production (IL-2)
- FDA approved topically for adults and children for treatment of atopic dermatitis
Tacrolimus for AD

• Tacrolimus 0.1% was better than low-potency corticosteroids, pimecrolimus 1%, and tacrolimus 0.03%

Tacrolimus in AD

- Decreases mast cell stimulators
- Decreases allergic reaction and down-regulates the entire inflammatory cascade
- Topically; does not inhibit collagen synthesis and cause skin thinning like steroid therapy

* Clinical Pharmacology – Online 2016
Commercial Tacrolimus Ointment

• Inactive ingredients
  – Mineral oil
  – Paraffin
  – Petrolatum
  – White beeswax
Tacrolimus for AD

• Formula #11882
  – Tranilast 1% / Tacrolimus 0.1% Topical Cream (XemaTop™)
  – Apply a thin layer to the affected areas three times a day
Tacrolimus for AD

- Formula #11515
  - Tacrolimus 0.1% Topical Gel (PracaSil™-Plus)
  - Apply a thin layer every 12 hours to affected area
  - Anhydrous (180 day BUD)
Commercial Tacrolimus for AD

- Tacrolimus 0.1% ointment

  Topical directions for use:
  - Adults and adolescents > 15 years: apply a thin layer to the affected areas twice daily. Rub in gently and completely. Treatment should continue for one week after clearing of signs and symptoms. Do not use under occlusive dressings. A European study revealed that topical tacrolimus (0.03%, 0.1%, and 0.3%) every 12 hours for 3 weeks was an effective treatment for atopic dermatitis.
Montelukast

- Montelukast (oral) was found to be a safe and effective alternative or steroid-sparing therapy in the management of patients with atopic dermatitis.

• One animal study on burn wounds where it was used topically [1] and another with nasal use [2]


Ketotifen

- The patients in the ketotifen (oral) group improved significantly during the treatment by all the clinical assessments...overall efficacy of treatment was significantly increased in the ketotifen group.

Montelukast and Ketotifen - AD

• Formula# 11962 (NEW)
  – Montelukast 1% / Ketotifen 0.05% XemaTop™ Cream
  – Apply BID to affected area(s)
Ginseng

- Ginsenosides Rh2 and Rg3 were found to exert an anti-inflammatory effect in vivo and proved to be beneficial in an animal model of AD
- Suggesting have potential as a topical agent for the treatment of AD

Ginseng for AD

• Formula #11944 (NEW)
  – Milk Thistle 5% / Panax Ginseng 2% / Tranilast 1%
  – XemaTop® Cream
  – Light brown color
  – Apply 2-3 times a day
Naltrexone for AD

• Study showed a “significant advantage of topically applied naltrexone over the placebo”
• More than 70% of the patients using the 1% naltrexone cream experienced a significant reduction of pruritus

Naltrexone for AD

• Formula #11934 (NEW)
  – Naltrexone HCl 1% Topical Cream (XemaTop™)
  – Apply twice daily
  – Labeled for “pruritus” so it can be used for itching from other causes as well

Eczema vs. AD

- Eczema comes from a Greek word that means to effervesce or bubble or boil over and is commonly used to describe atopic dermatitis also known as atopic eczema.

- In some languages, dermatitis and eczema are synonyms, while in other languages dermatitis implies an acute condition and eczema a chronic one.
Eczema
Eczema
Eczema

Scratch → Itch → Damaged Skin → Release of Inflammatory Chemicals → RED, DRY SKIN → Scratch

© 2016 PCCA. All Rights Reserved.
Eczema

- Symptoms
  - Very itchy
  - Red
  - Dry
  - Swollen
  - Sore
Standard Eczema Treatments

- Corticosteroids
- Topical Calcineurin Inhibitors (TCI’s)
  - Tacrolimus
- Narrowband ultraviolet B (UVB)
- Immunosuppressant's - Cyclosporine, Methotrexate
Eczema Formulas

• Formula #11882
  – Tranilast 1% / Tacrolimus 0.1% Topical Cream (XemaTop™)
  – Tacrolimus is effective in treating the itch and rash of eczema without causing thinning of the skin, stretch marks, spider veins or discoloration of the skin
Eczema Formulas

• Formula #8907
  – Cyanocobalamin 0.07% Topical Cream (VersaBase®)

• Formula #10132
  – Zinc Pyrithione 0.2% / Clobetasol Propionate 0.05% / Cyanocobalamin 0.07% Topical Cream (Oclusaderm® and VersaBase® Cream)
Eczema Formulas

• Formula #11780
  – Cyanocobalamin 0.07% Topical Cream (XemaTop™)
• Formula #11781
  – Cyanocobalamin 1% Topical Cream (XemaTop™)
Eczema Formulas

• Formula #11795
  – Tranilast 1% / Cyanocobalamin 0.07% Topical Cream (XemaTop™)
• Formula #11792
  – Cyanocobalamin 0.07% / Urea 2% Topical Cream (XemaTop™)
Eczema

• Formula #11934
  – Naltrexone HCl 1% Topical Cream (XemaTop™)
  – Apply BID to affected area(s)
Eczema

• Formula #11940
  – Naltrexone 0.5% / Diphenhydramine HCl 2% / Vitamin D3 5000 IU/Gm Topical Cream (XemaTop™)

• Formula #11881
  – Tranilast 1% Topical Cream (XemaTop™)
Psoriasis

• Life long autoimmune disease characterized by patches of abnormal skin that are typically red, itchy, and scaly
• Is genetically transmitted but environmentally triggered
Psoriasis

- Inflammatory skin disease affecting all major human populations with the greatest prevalence of 2% - 3% in those of northern European ancestry
Psoriasis

• 16 types including: light sensitive, scalp, palms & soles, penis, digits, nails, arthritis
• Five main types: plaque, guttate, inverse, pustular, and erythrodermic
• “Heartbreak” emotionally and physically disabling, erodes self image, forces a life of concealment
Psoriasis

- Because immunosuppressive drugs can help improve symptoms this suggest the involvement of an immunologic mechanism
- Cyclosporine and methotrexate were used earlier in the treatment of psoriasis, but caused severe adverse effects due to down regulation of immune system
Psoriasis Treatment on <20% of Body

Compounding standard TX options

• Formula #0318
  – Salicylic Acid 6% / Coal Tar Topical Solution 6% Topical Ointment (petrolatum)

• Formula #0217
  – Anthralin 0.25% / Salicylic Acid 2.4% / Coal Tar Topical Solution 50% Topical Lotion

• Formula #1032
  – Anthralin 1% / Coal Tar 1% Topical Ointment

• Formula #11794
  – Anthralin 1%/Coal Tar 1% Topical Cream (XemaTop™)
Cyanocobalamin Topical Use


XemaTop™ Psoriasis Formula #’s

• Formula #11780
  – B-12 0.07%

• Formula #11781
  – B-12 0.1%

• Formula #11783
  – Zinc Pyrithione / Pyridoxine

• Formula #11784
  – Salicylic Acid / LCD

• Formula #11785
  – Salicylic Acid / Resorcinol / LCD

• Formula #11786
  – Pentoxifylline 5%

• Formula #11787
  – Pentoxifylline 10%
XemaTop™ Psoriasis Formula #’s

- Formula #11788
  - Clobetasol / B-12 / Zinc Pyrithione
- Formula #11789
  - Clobetasol / Zinc Pyrithione
- Formula #11790
  - Salicylic Acid / LCD
- Formula #11791
  - B-12 / Zinc Pyrithione / Tacrolimus
- Formula #11792
  - Urea / Cyanocobalamin
- Formula #11793
  - Salicylic Acid / Anthralin
- Formula #1794
  - Anthralin / LCD
XemaTop™ Psoriasis Formula #’s

• Formula #11795
  – Cyanocobalamin / Tranilast
• Formula #11796
  – Salicylic Acid / LCD / Shea Butter
• Formula # 11797
  – Betamethasone Dipropionate / LCD

© 2016 PCCA. All Rights Reserved.
XemaTop™ Psoriasis Formula #’s

• Formula # 11798
  – Clobetasol Propionate / Aloe Vera / Vitamin D3 / Tranilast

• Formula #11804
  – Mometasone Furoate 0.1% Topical Cream
Psoriasis

• Formula #9557 and #9558
  – Pentoxifylline 10 and 15% in Lipoderm™
  – Topical application of Pentoxifylline has... (shown) reductions in (psoriatic) epidermal thickness

Psoriasis

- Formula #11979
  - Sulfasalazine 5% / Pentoxiphylline 5% XemaTop™
  - Apply to affected area BID

Supplements for Psoriasis

- Folic Acid [high dose (50-150mg) with vitamin C]
- Omega-3 fatty acids
- Vitamin D₃ - optimize dosage
- Riboflavin (doses range 5 to 50mg, old studies)
- Chromium 600mcg/day
- Zinc 17-34mg/day (symptoms improved only) Cu⁺
- Possibly: Vitamin A, Selenium, B-12 IM
  
  * Gaby A, Nutritional Medicine 2011, p.719 - 721

© 2016 PCCA. All Rights Reserved.
Supplements for Psoriasis

- Folic Acid [high dose (50-150mg) with vitamin C]
- **Omega-3 fatty acids**
- **Vitamin D₃ - optimize dosage**
- Riboflavin (doses range 5 to 50mg, old studies)
- Chromium 600mcg/day
- Zinc 17-34mg/day (symptoms improved only) Cu⁺
- Possibly: Vitamin A, Selenium, B-12 IM

* Gaby A, Nutritional Medicine 2011, p.719 - 721
Mast Cells

• Increased numbers in the dermis of rosacea patients
• Have critical functions during the development of skin inflammation in rosacea

Rosacea

- Chronic inflammatory skin disease that affects ≈16 million people in North America
- Flares often occur without specific triggers, and when left untreated, can take weeks to subside
Rosacea

• > 75% of people with rosacea feel the condition has affected their self-esteem or made them uncomfortable in public settings and avoid social activities (National Rosacea Society)
Rosacea

- Characterized by facial redness, small and superficial dilated blood vessels on facial skin, papules, pustules, and swelling.
Rosacea

- Three times more common in women
- Patients often between the ages of 30 to 50 & usually Caucasians
Rosacea

• Primary features
  – Flushing (transient redness)
  – Non-transient redness
  – Papules and pustules
  – Telangiectasia
Telangiectasia

- Telangiectasia
  - Dilated superficial vessels
  - Thinning epidermal layer
Phymatous Rosacea

- It is a myth that rosacea is a disease of alcoholics

Hyperplasia of sebaceous glands
Rosacea

- Typically begins as redness on the central face across the cheeks, nose, or forehead, but can also less commonly affect the neck, chest, ears, and scalp
Triggers

• Triggers that cause episodes of flushing and blushing play a part in its development
  – Foods, beverages, emotional influences, skin care products, temperature, weather related, drugs, medical conditions, physical exertion
Most Common Triggers

- Sun exposure 81%
- Emotional stress 79%
- Hot weather 75%
- Wind 57%
- Heavy exercise 56%
- Alcohol consumption 52%
- Hot baths 51%

- Cold weather 46%
- Spicy foods 45%
- Humidity 44%
- Indoor heat 41%
- Certain skin-care products 41%
- Heated beverages 36%
- Certain cosmetics 27%
Causes…A Long List of Possibilities

- Demodex Mites
- Chlamydia pneumoniae
- H. Pylori
- Immune initiated skin inflammation
- Increased levels of enzymes
- Sun exposure, genetic predisposition, topical steroids are risk factors
Demodex Mites
Demodex

- Demodex mites are a normal part of the human microbiome but have often been found in more than four times greater numbers on the facial skin of rosacea sufferers than in the normal population.
Demodex Treatment Options

- Ivermectin reduces inflammation and kills the Demodex
- A compound, ivermectin 1% cream, which is currently under review by the US FDA
- If approved by the FDA, this new compound will be the first medication to address a key component of papulopustular rosacea
Ivermectin for Rosacea

• Formula #11991
  – Ivermectin 1% / Niacinamide 4% Topical Cream (Clarifying™)
  – This combination is not commercially available

Is Treatment Effective?

• Clinical research has demonstrated that rosacea patients who continue therapy on a long-term basis are substantially more likely to maintain remission


Compounds for Rosacea

• Formula #10723
  – Brimonidine Tartrate 0.5% Topical Gel
    • Apply once daily
  – Manufactured Mirvaso Gel (Brimonidine 0.33%)

* Clin Cosmet Investig Dermatol. 2015 Apr 7;8:159-77. Update on the management of rosacea. Weinkle AP, Doktor V, Emer J.
Oxymetazoline for Rosacea

• Data suggest improvements in these symptoms with chronic use
• Formula #11711
  – Oxymetazoline HCl 0.06% Topical Cream (Clarifying™)
Compounds for Rosacea

• Formula #11883
  – Metronidazole 1% / Niacinamide 4% Topical Cream (XemaTop™)
Compounds for Rosacea

• Formula #11936
  – Milk Thistle 10% / MSM 5% Compound Topical Cream (XemaTop™)

Compounds for Rosacea

• Formula #11881
  – Tranilast 1% Topical Cream (XemaTop™)
Compounds for Rosacea

• Formula #4712
  – Ivermectin 1% Topical Lotion

• Formula #11710
  – Niacinamide 5% / Glycosaminoglycans 5% / Dimethyl Sulfone 2% / Biotin 0.2% Topical Cream (Clarifying™)

• Formula #11711
  – Oxymetazoline HCl 0.06% Topical Cream (Clarifying™)
Rosacea, the Real Answer

• Fix the gut
• Fix the diet
• Treat the inflammation, put out the fire (decrease IL-6, histamine & mast cells production of cytokines)
• Fix the barrier
• Normalize the Demodex count if needed
Keratosis Pilaris

- Is a common, harmless skin condition that causes dry, rough patches and tiny bumps, usually on the upper arms, thighs, cheeks or buttocks, that generally don't hurt or itch
Keratosis Pilaris

• It can't be cured or prevented but you can treat the appearance
• It often becomes more exaggerated at puberty but usually disappears by 30yr
• Affects nearly 60% of all adolescents and approximately 40% of young adults
Keratosis Pilaris

• Is a genetic disorder of keratinization of hair follicles of the skin. It is often described as chicken bumps, chicken skin, or goose bumps, usually on the outer-upper arms and thighs.
Keratosis Pilaris (KP)

• The study demonstrated that 10% Lactic Acid and 5% Salicylic Acid are beneficial to treat KP with the significantly clearance and marked improvement as by instrumental evaluation

Keratosis Pilaris

- Formula #12043 (NEW)
  - Lactic Acid 10% / Salicylic Acid 5% / Plukenetia Volubilis 5% Topical Cream (XemaTop™)
  - Apply twice daily
Plukenetia Volubilis

- Native to much of tropical South America as well as some of the Windward Islands in the Caribbean
- Great source of omega-3,6,9
- Uses as a humectant, protectant and moisturizer in cosmetic products
Start Treatment Early

Before it gets out of hand.......
Areas of Interest

ENT
Areas of Interest

- Eustachitis
- Polyps
- Nasosinus infections
- Eosinophilic Esophagitis
- Otitis
- Excess wax
- Vertigo
Eustachitis Suggestion

- MucoLox™ 70% as an instillation or 15% as a spray are options
- Formula #11375
  - Mometasone Furoate 50 mcg / 0.1 mL Nasal Spray (MucoLox™)
- Formula #11376
  - Fluticasone Propionate 50 mcg / 0.1 mL Nasal Spray (MucoLox™)
Eustachitis Suggestion

- Formula # 11756
  - Tranilast 1% Nasal Spray (MucoLox™)

- Formula # 11757
  - Tranilast 1 mg/0.1 mL / Mometasone Furoate 50 mcg/0.1 mL Nasal Spray (MucoLox™)

- Formula # 11758
  - Tranilast 1 mg/0.1 mL / Mometasone Furoate 50 mcg/0.1 mL / Chlorpheniramine Maleate 1 mg/0.1 mL Nasal Spray (MucoLox™)
  - One spray in each nostril bid
Nasal Polyps

- Formula #11375
  - Mometasone Furoate 50 mcg / 0.1 mL Nasal Spray (MucoLox™)
  - One spray in affected nostril(s) q12h
- Formula #11378
  - Mometasone Furoate 50 mcg / 0.1 mL Poloxamer Nasal Spray
- Formula #10344
  - Mometasone Furoate 0.6 mg Capsules (Size #1) (LoxaSperse™)
Nasal Polyps

- Formula #11756
  - Tranilast 1% Nasal Spray (MucoLox™)
- Formula #11757
  - Tranilast 1% / Mometasone Furoate 50mcg/0.1ml Nasal Spray (MucoLox™)
- Formula #11758
  - Tranilast 1% / Mometasone 50mcg/0.1ml / Chlorpheniramine 1% Nasal Spray (MucoLox™)
  - Directions for use: 1 spray in each nostril twice daily as needed
Nasal Mast Cell Stabilizer

• Formula #11877
  – Quercetin Dihydrate 0.5% Nasal Spray (Base C)
  – Mast cell stabilizer (allergy), antioxidant
Nasal Polyps

• Formula #11439
  – Furosemide 1 mg LoxaSperse™ Capsule
  – 1 cap via nasal nebulization every 12 hours

• Formula #10552
  – Amphotericin B 10 mg Capsules (Size #1) (LoxaSperse™)
  – 1 capsule via nasal nebulization twice daily
MRSA Nasal Applications

• Formula #11428
  – Mupirocin 0.2% Nasal Spray (MucoLox™)
  – Instill 2 sprays in each nostril TID

• Formula #3406
  – Mupirocin 0.2% Nasal Spray
Nasal Mupirocin Combination

• Formula #10761
  – Itraconazole 0.2% / Mupirocin 0.2% / Triamcinolone 0.03% / Xylitol Nasal Spray (BUD Study)
  – Aqueous, benzalkonium chloride preserved
Anti-Viral Nasal Compounds

• Formula #11880
  – EGCg 0.4% Nasal Spray

• Formula #3756
  – Deoxy-D-Glucose 0.2% Nasal Solution

• Formula #9355
  – Tranilast 1% / Deoxy-D-Glucose (2) 0.19% / EGCg 1% / Shea Butter
Eosinophilic Esophagitis

Eosinophils invade the epithelium of the esophagus, possibly in response to allergens in food and the air, in a process mediated by type 2 helper T cells, which release the cytokines interleukin 5, interleukin 13, and eosinophils.
Eosinophilic Esophagitis

- Eosinophils are within the lining of the esophagus causing inflammation and narrowing of the esophagus
- Some patients have no symptoms or symptoms of reflux...a sensation of the food becoming stuck in the esophagus or even blocking the esophagus causing inability to even swallow one’s own saliva
Eosinophilic Esophagitis

• Treatment often includes:
  – Food elimination diet
  – Proton pump inhibitors
  – Steroids
Eosinophilic Esophagitis

• Formula #11107
  – Budesonide 1 mg/10 mL Oral Suspension (MucoLox™)
  – Gargle & swallow 3-5 ml once a day for children and twice a day for adults and adolescents
Eosinophilic Esophagitis

• Formula #12049 (NEW)
  – Montelukast Sodium 1 mg/mL / Ketotifen 0.5 mg/mL
  / Budesonide 0.5 mg/mL Oral Suspension
    (MucoLox™)
  – Gargle & swallow 3 ml twice a day for adults
Otitis Externa

• Formula #11443
  – Ketoconazole 2% Otic Poloxamer Gel
  – Instill 0.25 to 0.5ml in affected ear canal(s) once every 3 days for 5 doses
  – Forms a gel at 78 degrees Fahrenheit
Otitis Externa

• Formula #11444
  – Ketoconazole 2% / Ciprofloxacin 2% Otic Poloxamer Gel

• Formula #11445
  – Ketoconazole 2% / Ciprofloxacin 2% / Triamcinolone 0.5% Otic Poloxamer Gel
Kitchen Sink Powder Formula 2.0

• Formula #11440
  – Chloramphenicol 50mg / Sulfacetamide 50mg / Amphotericin B 5mg Otic Insufflation Powder Capsules (Size #4)
  – Instill one puff in affected ear(s) twice daily for 2 weeks
Otitis Media

- Prevention
- Formula #5417
  - Xylitol 2 Gm Sorbitol Lollipop Base
  - Daily dose of 8 to 10g
Otic MRSA

- Formula #11938
  - Vancomycin 250 mg/Gm Poloxamer Otic Gel
- Formula #11939
  - Mupirocin 2% / Vancomycin 250 mg/Gm Poloxamer Otic Gel
Local Anesthetics

- Formula # 10010 (alternates for Benzotic®, Americaine®, Oticaine®)
  - Benzocaine 20% Otic
  - Adults: instill 2 - 4 drops into ear canal(s); insert a saturated cotton plug. Repeat 3 - 4 times per day or up to once every 1 or 2 hours.
  - Children: fill ear canal; insert a saturated cotton plug. Repeat every 1 - 2 hours as needed for ear pain.
Local Anesthetics

• Formula #11846
  – Benzocaine 10% / Ibuprofen 2% Otic Solution

• Formula #11848
  – Benzocaine 10% / Ibuprofen 2% / Hydrocortisone 1% Otic Solution

• Both formulas use Base C
  (Polyethylene Glycol 300 MW, NF Liquid)
Cerumenolytics

- Cerumenex® discontinued by manufacturer
- Formula #1270
  - Trolamine Oleate Otic Solution
    - Trolamine NF
    - Oleic Acid NF
    - Base, PCCA Gelatin™
    - Propylene Glycol USP

© 2016 PCCA. All Rights Reserved.
• Formula #1270
  – Trolamine Oleate Otic Solution
  – Fill ear canal while the patient's head is tilted at a 45° angle. Insert cotton plug and allow to remain 15-30 minutes. Then gently flush with lukewarm water using a soft rubber syringe (avoid excessive pressure). May repeat. Exposure of skin outside the ear to the drug should be avoided.
Cerumenolytics

• Formula #10691
  – Docusate Sodium 2% Otic Solution
    • Docusate Sodium USP (WAX-LIKE) 2 g
    • Glycerin USP (NATURAL) 80 ml
    • Purified Water, USP q.s. 100 ml
  – Tilt head, fill ear canal once a day as needed. May be used 2 days in a row.
Vertigo and Meniere’s Disease

- Formula #10963
  - Betahistine Dihydrochloride 16 mg Capsules (Size #1) (LoxOral™)
- Formula #10962
  - Betahistine Dihydrochloride 12 mg Capsules (Size #1) (LoxOral™)
- The usual recommended dose of betahistine for adults is 24 mg to 48 mg given in 2 or 3 divided doses. To prevent stomach upset, it is recommended that this medication be taken with food.
Areas of Interest

GI
• Radiation proctitis
• Perianal Crohn's
• Fissures
• Gut recovery
Radiation Proctitis (RP)

• Radiation therapy causes production of MMP’s and ROS, causes tissue degradation and damage lining

• Commonly occurs after radiation treatment for cancers such as those of the cervix, prostate, and colon

Radiation Proctitis (RP)

• Symptoms include:
  – Inflammation
  – Pain
  – Bleeding
  – Diarrhea

• Diarrhea usually treated with oral opioids
Radiation Proctitis (RP)

• Formula #11425
  – Loperamide HCl 1 mg/Gm Rectal Gel (MucoLox™ / VersaBase®)
  – Alternative to opioid therapy, potentially providing symptomatic relief without the systemic side effects

Clinical Pharmacology: “Loperamide interferes with peristalsis by a direct action on the circular and longitudinal muscles of the intestinal wall to slow motility”
Radiation Proctitis (RP)

• Formula #11928
  – Lidocaine HCl 1% / Beta Glucan 0.5% / Dexpanthenol 1% / Glutamine 2% Rectal Enema (MucoLox™)
  – Glutamine helps provide energy, Dexpanthenol helps with hydration, Beta Glucan induces macrophage activity and Lidocaine helps with pain
  – Potentially helps recovery of the lining
Perianal Crohn Disease

• Presentation can include tags, fissures, abscesses, fistulae, or stenosis
• Associated with symptoms such as incontinence of stool, pain, itching, bleeding, and purulent discharge

* de Zoeten EF, Pasternak BA, Mattei Peter, Kramer RE, Kader HA. Diagnosis and Treatment of Perianal Crohn Disease: NASPGHAN Clinical Report and Consensus Statement. JPGN Volume 57, Number 3, September 2013
Articles have been published on the use of topical tacrolimus as a non-surgical option for the treatment of PCD

MucoLox™ Rectal

• Formula #11933
  – Tacrolimus 0.1% Rectal Gel (MucoLox™/ VersaBase®)

MucoLox™ Rectal

• Formula #11373
  – Tacrolimus 4 mg/60 mL Rectal Enema
* A Multi-centre Double Blind Randomised Placebo-controlled Study of the Use of Rectal Tacrolimus in the Treatment of Resistant Ulcerative Proctitis. Sponsor: The University of Western Australia, 2012 ClinicalTrials.gov Identifier: NCT01418131 (results not yet published)
Hemorrhoids & Fissures

- Formula #11491
  - Lidocaine 2% / Hydrocortisone 1% Base MBK / Wax / MucoLox™ Suppository (Rectal Rocket)

- Formula #11124
  - Nifedipine 0.2% Rectal Gel (MucoLox™ / VersaBase® gel)

Short Chain Fatty Acids (SCFAs)

• Made by bacteria when digesting dietary fiber and resistant starch
• Particularly important as the preferred fuel of the cells that line the colon to maintain healthy GI mucosal structure and function

• SCFA deficiency is associated with colitis and in ulcerative colitis

• Although SCFA enemas were not of major value in this study, the results suggest efficacy in subsets of patients with distal ulcerative colitis

• Comment: “Prolonged contact with rectal mucosa seems to be necessary for therapeutic benefit”

• What does MucoLox™ do?

Gut Recovery

• Formula #12053 (NEW)
  – Sodium Butyrate 100 mM/Liter Enema (MucoLox™)
  – 60cc rectally daily
Areas of Interest

GYN
• Lichen Sclerosus
• Vulvodynia
• Vaginal infections
• Vulvar lesions
• Topical tacrolimus is a promising novel agent in the treatment of lichen sclerosus of the anogenital area. A major advantage over topical corticosteroids is the lack of skin atrophy. Further clinical trials are warranted to confirm our findings.

* Arch Dermatol. 2003;139(7):922-924. doi:10.1001/archderm.139.7.922. Successful Treatment of Anogenital Lichen Sclerosus With Topical Tacrolimus. Markus Böhm, MD; Uta Frieling, MD; Thomas A. Luger, MD; Gisela Bonsmann, MD
Lichen Sclerosus

• Formula #11583
  – Tacrolimus 0.1% / Tranilast 1% VersaBase® Cream
    • Apply BID (forever and ever...)
Vulvodynia Treatment Options

- Vehicle / dosage form
  - Suppository (MBK)
  - VersaBase® Cream
  - Poloxamer 30%
  - MucoLox™ cut with VersaBase® Gel
  - Mini-troche
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazepam</td>
<td>5 - 10mg/dose</td>
</tr>
<tr>
<td>Baclofen</td>
<td>2%</td>
</tr>
<tr>
<td>Amitriptyline</td>
<td>2%</td>
</tr>
<tr>
<td>Gabapentin</td>
<td>6%</td>
</tr>
<tr>
<td>Ketamine</td>
<td>2% (0.5% - 5%)</td>
</tr>
<tr>
<td>Lidocaine</td>
<td>1% - 5%</td>
</tr>
</tbody>
</table>
Vulvodynia

• Formula #11110
  – Gabapentin 6% Vaginal Gel (MucoLox™/ VersaBase®)

• Formula #11108
  – Amitriptyline HCl 2% / Baclofen 2% Vaginal Gel
    Carboxymethylcellulose Sodium 1.75% Gel
    (MucoLox™)
Vulvodynia / Pelvic Floor Dysfunction

• Formula #11109
  • Ketamine HCl 0.5% / Diazepam 1% / Baclofen 2%
    Vaginal Gel (MucoLox™ / VersaBase®)

• Formula #11114
  • Diazepam 10 mg/Gm Vaginal Gel (MucoLox™ / VersaBase®)
Vaginal Infections

• Antiviral
  – Formula #11415
    • Deoxy-D-Glucose 0.2% / Acyclovir 5% / Imiquimod 2.5% / Tea Tree Oil 2.5% Vaginal Gel (MucoLox™ / VersaBase®)
  – Formula #11416
    • Cimetidine 5% / Deoxy-D-Glucose 2% / Tea Tree Oil 2.5% Vaginal Gel (MucoLox™ / VersaBase®)
Vaginal Infections

• Acidifier
  – Formula #11368
    • Boric Acid 30% Vaginal Gel (MucoLox™)
  – Formula #11367
    • Boric Acid 600 mg Base MBK / MucoLox™ Vaginal Suppository (Pink Mold)
Vaginal Infection

- Yeast
  - Formula #11122
    - Miconazole Nitrate 2% / Acidophilus 15% / Lidocaine HCl 1% Vaginal Gel (MucoLox™ / VersaBase®)
Vulvar Lesions

• Formula #11424
  – Lidocaine HCl 1% / Beta Glucan 1% / Tranilast 1% / Nystatin 100,000 U/Gm Topical Gel (MucoLox™)
  – Apply to lesion 5 times a day???
Thanks!