New Compounding Ideas and Marketing Innovation

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Objectives
1. Explain common dental conditions encountered by compounding pharmacists and technicians.
2. Discuss the latest compounded treatment options being prescribed for specific dental conditions.
3. Describe formula examples and clinical applications utilizing various compounded formulations.
4. Understand the mechanism of microneedling and the conditions it can be used for.
5. Describe the procedure when using a microneedling device.
6. Explain the different active ingredients used along with microneedling.

Target Markets
- Dentists
- Dermatologists and Cosmetic Patients
Compounding for Dental Aliments

Common Dental Conditions

- Oral Mucositis
- Dry Mouth
- Lichen Planus
- TMJ

Mucositis

Inflammation of the mucosal membranes which can cause extreme pain, redness, ulcers and infections. Most commonly a complication of chemotherapy and/or radiation treatment.
Mucositis can significantly impact nutritional intake, mouth care and quality of life. Severe cases require a reduction in the chemotherapy dose or a break in the radiation treatment which can negatively influence prognosis.

Treating Mucositis

- Multinational Association of Supportive Care in Cancer (MASCC) Pain Control Recommendations
  - 2% Morphine Mouthwash
  - 0.5% Doxepin Mouthwash
  - Transdermal Fentanyl

"For compounded preparations such as mouthwashes, there are various formulations that pharmacists can use based on the experience and needs of the individual physician and patient, respectively.”
“Magic Mouthwash”

Compounding Pearl - Nystatin

NYSTATIN ORAL SUSPENSION, USP
100,000 units per mL
SHAKE WELL BEFORE USING

Each mL contains: 100,000 USP Nystatin Units in a vehicle containing 50% sucrose. Read more.

Usual dosage for infants: 2 ml, 200,000 units four times daily (1 ml in each sole of mouth).
Usual dosage for children and adults: See package insert.
Commercial Nystatin contains sugar

Sugar Feeds Yeast

Don't use commercial product – use the raw powder

Compounding Pearl - Ethanol

• The metabolism of ethanol (EtOH) by mucosal and/or bacterial alcohol dehydrogenase generates toxic metabolites such as acetaldehyde and free radicals.
  – Acetaldehyde accumulation can damage the oral tissues. It interferes at many sites with DNA synthesis and repair

Make sure your vehicle doesn't contain BOH

Compounding Pearl - Nystatin

Mucositis - Formulas

• Stanford Mouthwash
  – Tetracycline 12.5mg/ml
  – Nystatin 12,000 U/ml
  – Hydrocortisone 0.46mg/ml
  – Diphenhydramine 1.25mg/ml
• Nystatin 12,500 U/ml / Hydrocortisone 0.25 mg/ml / Diphenhydramine HCl 2.5 mg/ml Mouthwash
• Misoprostol 0.0024%/Diphenhydramine HCl 0.1%/Lidocaine HCl 1% Oral Rinse
• Morphine Sulfate 2% Oral Rinse
• Morphine Sulfate 1mg/ml Oral Suspension
• Doxepin HCl 0.5% Mouthwash
Dry Mouth (Xerostomia)

Decreased salivary secretions can cause altered taste, difficulty talking and swallowing, and can lead to dental carries.

Causes of Xerostomia

- Increased Age
- Sjogren’s Syndrome
- Diabetes
- Thyroid Dysfunction
- Dehydration
- Medications
- Chemotherapy/Radiation

Treatment: Pilocarpine

- Cholinergic Agonist
  - Stimulates secretions of the exocrine glands
- When used orally can have systemic effects
  - Hyperhidrosis
  - Nausea
  - Increased urination
Pilocarpine Formulas

- Pilocarpine HCl 2 mg Troche
- Pilocarpine HCl 10 mg/mL Oral Spray
- Pilocarpine HCl 10 mg/mL Oral Drops
- Pilocarpine HCl 5 mg Lollipop

Treatment: Xylitol, Betaine, Olive Oil

- Xylitol 7%/Betaine 4%/Olive Oil 2% Oral Rinse
  - Xylitol: Salivary stimulant
  - Betaine: Decreases the loss of water from the mucus component of saliva
  - Olive Oil: Lubricant, anti-inflammatory
  - Suggested Use: Swish x 1 min and swallow 3-4 x/day

"provided a significant subjective improvement in speech, swallowing, and decreased subjective xerostomia as compared to the control"  
PMID: 26225058
Treatment: Malic Acid

- The dissociation of malic acid generates a stimulation of salivary secretion to dilute the concentration of acids in the oral cavity.

- Malic Acid 1% Oral Spray
  - Suggested use: 3-4 times a day as needed

Treatment: Electrolytes

- Electrolyte troche or oral saliva gel
  - Sodium Chloride
  - Potassium Chloride
  - Calcium Lactate or Calcium Chloride
  - Magnesium Sulfate
  - Sodium Bicarbonate
  - Sodium Phosphate

- Suggested Use: Q 4-6 hours prn
**Treatment: Saliva Substitute**

- Calcium Phosphate Oral Rinse
  - Part A: Calcium Chloride Buffered Solution
  - Part B: Phosphate Buffer Solution

- Recommended directions for use:
  - Mix 15 ml of part A and 15 ml of part B together at time of dose (30 ml total).
  - Swish the mouth thoroughly for 1 min with 1/2 the soln and spit out. Repeat with the remaining 1/2 of the soln and spit out.
  - Use BID up to 10 times a day as needed
  - Avoid eating or drinking x 30 min after dose

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**Oral Lichen Planus**

- Chronic inflammatory disorder of unknown cause
  - Appears to be cell-mediated immune response
  - Presents with white lines or striae on lateral borders of tongue, buccal mucosa and gingiva
  - Atrophic or ulcerative form painful and may need long term pharmacologic therapy
Oral Lichen Planus

Common APIs
- Steroids
- Hyaluronic Acid
- Tretinoin
- Tacrolimus
- Anesthetics

Treatment: Steroids
- Triamcinolone 0.1% Oral Rinse or Adhesive Paste
  - Apply up to QID
- Clobetasol 0.05% Oral Rinse
  - Apply BID for up to 2 weeks

Treatment: Tretinoin
- Topical Tretinoin 0.05% or 0.1% - Apply BID
Treatment: Tacrolimus

• Tacrolimus 0.03%
  Oral Rinse
  – Suggested Use:
    Swish and expectorate ½ tsp BID
  – May add steroid or anesthetic if needed

Treatment: Hyaluronic Acid

“Statistically significant improvements were observed in the objective criteria which involved the degree of erythema and the mean area of the lesions with 0.2% hyaluronic acid application than compared to the control group on placebo.”

PMID: 26894175
Treatment: Hyaluronic Acid

• Hyaluronic Acid Oral Rinse
  – Apply TID, avoid eating or drinking for 30 min after application


Treatment: Combination Formulas

• Tretinoin 0.1%/Clobetasol Propionate 0.05%
  – Oral Rinse
  – Oral Paste
• Clobetasol Propionate 0.05%/Lidocaine Hydrochloride 1% Oral Gel

Temporomandibular Disorders (TMJ)

Pain and compromised movement of the jaw joint and the surrounding muscles.
Treatment: Potassium Complex

“The authors have found that the gel routinely and predictably provides rapid pain relief and patient comfort and speeds restoration of the jaw's functional abilities, usually within 5 minutes after it is applied.”

PMID: 18240797

Potassium Chloride 6%/Potassium Citrate 6%/Potassium Nitrate 6% Topical Gel – Apply to painful areas BID

TMJ Transdermal Treatment

• Ketoprofen 5%/Cyclobenzaprine HCl 0.5% /Lidocaine HCl 5%/Bupivacaine HCl 1% Topical Cream
• Ketoprofen 10%/Cyclobenzaprine HCl 2% Topical Cream

• Suggested Use: Apply BID-TID
Marketing Minute

Microneedling

Microneedling is a procedure that uses small, fine needles to create microinjuries in the skin while leaving the epidermis intact.

AKA: Percutaneous Collagen Induction or Collagen Induction Therapy.
How does it work?

- Needles break old collagen bundles that tether scars or wrinkles
- This controlled skin injury stimulates the healing cascade and the production of collagen and elastin under the epidermis

**Microneedling increases collagen formation**

<table>
<thead>
<tr>
<th>Treatment Duration</th>
<th>Control Biopsy</th>
<th>Biopsy from Needled Skin 6 Weeks Post-op</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 weeks</td>
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<td>Purple collar stained</td>
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</tbody>
</table>


**Microneedling significantly increases epidermal thickness**

Enhanced epidermal thickness after one month and three months of microneedling treatments compared to baseline

Microneedling is used for many cosmetic conditions

- Wrinkles
- Alopecia
- Scars
- Skin Rejv.
- Stretch Marks
- Large Pores

**Devices Used**

- Roller
- Pen

**Needle Length**

- Length of needle selected depends on the indication of the treatment
  - 0.2 mm – 0.5 mm: Alopecia and at home skin care
  - 0.5 mm – 1 mm: Wrinkles/skin rejuvenation
  - 1.5 mm – 2 mm: Scars
Pre-Procedure Treatment

- Use a topical with:
  - Vitamin A (retinol)
  - Vitamin C
  - Palmitoyl pentapeptide or other peptides

- All of these ensure that collagen production will be maximized and that the skin will heal rapidly
- Use a minimum of 3 weeks before but preferably 3 months before microneedling

Pre-Procedure Formulations

- Retinol Molecular 2%/Ascorbic Acid 5% Topical Serum
- Retinol Molecular 2%/Ascorbic Acid 5% Topical Peptide Cream
Procedure

1. Clean the skin
2. Application of topical anesthetic (Not necessary for at-home device usage)
   – Can be applied 2 different ways:
     1. Apply 30-60 minutes prior to the start of procedure
     OR
     2. Apply after a light “rolling” with the microneedling device

Topical Anesthetic Application

• A study demonstrated that after microneedling with 0.5 mm depth and THEN applying Lido 2.5%/Prilo 2.5% pts had better pain control v. topical anesthesia alone when microneedling at a 2.5mm depth was performed.

Formulas:
• Benzocaine 20%/Lidocaine 6%/Tetracaine 4% Topical Cream
• Benzocaine 10%/Lidocaine 5%/Tetracaine 2% Topical Cream

Procedure – Cont.

3. Skin is stretched with one hand and rolling is done in multiple directions (horizontal, vertical, and diagonal)
   – endpoint is identified as uniform pinpoint bleeding
**Post-Procedure**

- Clean face
- Apply serum/topical cream
  - Optimal time of skin penetration when using topical products is at 5 minutes as the tissue starts to close considerably after 30 min
  - Topical Vitamin A, vitamin C, peptides, hyaluronic acid, etc.

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**Post Procedure APIs**

<table>
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<tr>
<th>API</th>
<th>Redness</th>
<th>Inflammation</th>
<th>Anti-Inflammatory</th>
<th>Anti-Wrinkle</th>
<th>Antioxidants</th>
<th>Hyaluronic Acid</th>
<th>Collagenogenesis</th>
<th>Odor</th>
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<td>Beta-glucan (Up to 2%)</td>
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<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>Hyaluronic Acid (1.5%)</td>
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<tr>
<td>Niacinamide (Up to 6%)</td>
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<tr>
<td>Vitamin A (Retinol) (Up to 5%)</td>
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<tr>
<td>Vitamin C (Up to 3%)</td>
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</tbody>
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**Post Procedure Formulations**

**Gels:**
- Sodium Hyaluronate 1% Gel
- Sodium Hyaluronate 2% Gel
- Retinol Molecular 1%/Hyaluronic Acid Topical Gel

**Serums:**
- Niacinamide 5%/Ascorbic Acid 2.5% Topical Serum
- Ascorbic Acid 5%/Sodium Hyaluronate Topical Serum
- Ascorbic Acid 10%/Sodium Hyaluronate Topical Serum
Post Procedure Formulations

**Creams:**
- Ascorbic Acid 5%/Beta Glucan/Hyaluronic Acid Topical Peptide Cream
- Niacinamide 5%/Hyaluronic Acid/Beta Glucan Topical Peptide Cream
- Niacinamide 5%/Retinol Molecular 1%/Hyaluronic Acid/Beta Glucan Topical Peptide Cream

Recovery
- Quick recovery due to epidermis remaining intact
- Minimal side effects
  - Mild redness
  - Irritation
  - Inflammation
- Side effects typically dissipate over 24-48 hours

Counseling Points
- Counsel patient to avoid sun exposure and use sunscreen
- Apply serum/cream daily
- Repeat treatment usually at one month intervals x 4-6 treatments
- Takes approximately 3-6 months for final results.
Contraindications

1. Active acne
2. Herpes labialis or any other local infection
3. Moderate – severe chronic skin conditions (eczema/psoriasis)
4. Patients on anticoagulant therapy
5. Extreme keloidal tendency
6. Patients on chemotherapy/radiation

Results – Fine Lines/Wrinkles

Results – Acne Scars/Hyperpigmentation

Before

After 3 treatments


Results – Androgenic Alopecia

Pre treatment - Baseline
Post treatment 12 weeks
Weekly microneedling + 1ml 5% minoxidil BID


Androgenic Alopecia Formulations

- Minoxidil 5% / Azelaic Acid 5% Topical Foam
- Minoxidil 10% / Finasteride 0.1%Topical Gel
How can microneedling help my practice?

• At home microneedling devices can help increase effectiveness of your formulations
• Dispense with cosmetics/anti-aging/firming formulation
• Many BHRT patients are interested in anti-aging

Are you ready to get started?

Marketing Minute
References


References


References

Thank you!