Non Injectable Local Anesthesia (NILA) for Periodontal Debridement: A Review and Discussion for Subgingival Application

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(Part 1 of a 2 part series)

Introduction

Oral health professionals have long used local anesthetic in conjunction with non surgical periodontal debridement with an objective to achieve maximum clinical outcomes while providing optimal patient comfort. For decades, clinicians have been using either injectable or topical anesthetics when pain control is needed for scaling and root planing procedures. The use of “topicals” in this instance has been especially alluring as the needle free anesthesia without the classic numbing effects of injectable anesthesia is extremely desirable for the clinician and the patient. However, the traditional topical application of local anesthetics often fails to provide the effect needed to carry out debridement procedures comfortably. To improve clinical effectiveness, manufacturers have recently expanded the delivery methods of local anesthetics beyond traditional topical and injectable applications. Clinicians now have options to choose products that allow for the placement of local anesthesia drugs directly into periodontal pockets. In these instances, a blunt tipped canula, not a needle, is indicated as the “non injectable” local anesthetic is placed in a sulcus or pocket to be systemically absorbed. (See Figure 1). With the abundance of product choices now available, it is important for practitioners to have an up to date understanding of non injectable local anesthetics (NILA) for maximum effectiveness and safety. This article, presented as a two part continuum, will examine the classifications, formulations, maximum recommended dosage (MRD) and dosage control of NILA. It will also explore considerations specific to subgingival application.

Classifications and Formulations

In dentistry, local anesthesia is classified as either ester type or amide type compounds. Today, all injectable anesthetics, available in cartridge form, are amides. Those not for injection, are available in amides or esters and depending on the manufacturer and application methods that include traditional mucosal delivery (non subgingival) or subgingival delivery. (See figure 2).

Esters

For intraoral use, benzocaine and tetracaine are the most common compounds found within the ester classification. Products can be purchased in various formulations including gels, liquids, sprays, creams, ointments and patches. Familiar brand names include Hurricane, Cetacaine, Ultracare and Topex. Practitioners should consult each manufacturer to determine if traditional supragingival “topical” applications or non injectable subgingival applications are available. (See figure 3).

Benzocaine has effective concentrations in dentistry at 6–20%. A 2% concentration is recommended for topical applications of tetracaine. Tetracaine is the most potent, not for injection, dental anesthesia; excessive doses and too frequent administration should be avoided. Tetracaine is typically used in combination with other drugs; some products include combinations of two or more drugs as this can provide a much more useful range of anesthesia to any of the individual drugs acting alone.
Cetacaine (Cetylite Industries Inc.) and Hurricane (Beutlich Pharmaceuticals LLC) are available as a traditional topical local anesthetic and for subgingival placement. Cetacaine is an example of a combination ester type and contains 14% benzocaine, 2% tetracaine and 2% butamben. According to the product insert, Cetacaine is “a topical anesthetic indicated for the production of anesthesia of all accessible mucous membrane except the eyes.” Although the product is not specifically indicated for application in periodontal pockets during periodontal debridement, with the Cetacaine liquid kit, the manufacturer provides armamentarium and instructions for subgingival delivery and indicates that the maximum dose when using the syringe provided is 0.4 ml per office visit. Recently, from the makers of Hurricane, HurriPak has become available in Canada. HurriPak is a liquid containing 20% benzocaine; it comes in a jar and is packaged with disposable syringes and plastic tips that allow placement of the liquid into the periodontal pocket. The maximum recommended dose of HurriPak is 3 ml.

### Amides

For those preferring amide type compounds, lidocaine or lidocaine and prilocaine, eutectic mixtures are available. Effective concentrations in dentistry are 2–5%. As with the esters, the purpose of the combination of drugs is to enhance clinical effectiveness. Amide products for intraoral use can be purchased in ointments, sprays, gels, liquids and liquid gel—liquid at room temperature, gel at body temperature. (See figure 4.)

For practitioners wanting an amide packaged with armamentarium for subgingival application, choice is more limited than within the ester classification. Available in Canada since 2010, and specialized for subgingival application is Oraqix (DENTSPLY Pharmaceutical), a thermosetting liquid gel containing 2.5% prilocaine and 2.5% lidocaine that is packaged in a 1.8 g cartridge. In addition to providing excellent tissue anesthesia and occasional pulpal anesthesia, this system has wide margins of safety, a known maximum safe dose and easily quantified volumes dispensed due to its packaging in cartridge form. According to the product monograph MRD of Oraqix is 5 cartridges. With the exception of Oraqix, all NILA products used introrally—including those that are packaged with armamentarium for subgingival application—carry indications for general use on all accessible mucous membrane. Oraqix is indicated specifically for application in periodontal pockets for moderate pain during scaling and/or root planing and has received Health Canada approval for this indication.

### Adverse Effects

Adverse effects may result from hypersensitivity or allergy. Esters are associated with a higher incidence of allergic reactions but allergies to amides have been described as virtually unknown. More often, adverse effects are dose related, caused by excessive dosage or rapid absorption of the drug. Products void of an exact indication for use in periodontal pockets may require greater deliberation to ensure maximum effectiveness and safe practice.

The next article in this series will cover adverse effects in more detail as it examines maximum recommended dosage (MRD), dosage control and considerations specific to the subgingival application of NILA.

### References

9. DENTSPLY Canada Product monograph for Oraqix. revised Apr 30, 2009
ORAQIX® (lidocaine and prilocaine periodontal gel) is indicated for topical application in periodontal pockets for moderate pain during scaling and/or root planning. ORAQIX® should not be injected.

**INDICATIONS AND CLINICAL USE**

**Adults**

ORAQIX® (lidocaine and prilocaine periodontal gel) is indicated for topical application in periodontal pockets for moderate pain during scaling and/or root planning. ORAQIX® should not be injected.

**CONTRAINdications**

- **Cardiovascular**
  - Patients with cardiovascular disease, especially those with a history of angina pectoris, congestive heart failure, or myocardial infarction
  - Patients with a history of severe allergic reactions to topical anesthetics

- **Pregnancy**
  - Pregnancy category C. ORAQIX® is not recommended for use during pregnancy due to the potential for adverse effects on the fetus.

- **Lactation**
  - Nursing women should avoid or discontinue breastfeeding if they use ORAQIX®.

- **Children**
  - ORAQIX® is not recommended for use in children or adolescents.

**Adverse Reactions**

- **Systemic reactions**
  - Hypersensitivity reactions, including anaphylaxis
  - Methemoglobinemia

- **Local reactions**
  - Application site reactions (e.g., pruritus, erythema, edema)

**Warnings and Precautions**

- **Hypersensitivity**
  - ORAQIX® should be used with caution in patients with a history of hypersensitivity to lidocaine or prilocaine.

- **Pregnancy**
  - Pregnancy category C. ORAQIX® is not recommended for use during pregnancy due to the potential for adverse effects on the fetus.

- **Lactation**
  - Nursing women should avoid or discontinue breastfeeding if they use ORAQIX®.

**Administration**

**Dosing Considerations**

- ORAQIX® is for topical use only. Do not inject ORAQIX® and should not be used with standard dental anesthetics.

**Dosage and Administration**

**SENTIPS CANADA**

Conditions where dosing may require adjustment:

- In patients who are administered other local anesthetics or are atypical local anesthetics (e.g., procaine or mepipvacaine).

**Recommended Dose**

Typically, one cartridge (1.7 g or less of ORAQIX®) will be sufficient for one quadrant of the mouth. However, if the ORAQIX® at one treatment session is five cartridges, i.e., 8.5 g containing 212.5 mg lidocaine base and 212.5 mg prilocaine base.

**Additional local anesthesia is needed in combination with ORAQIX®.**

The use of ORAQIX® in children and adolescents has not been assessed and therefore its use is not recommended in patients less than 18 years old.

**Administration**

Apply ORAQIX® on the gingiva margin around the selected teeth using the blunted-tip applicator included in the package. Then fill the periodontal pockets with ORAQIX® using the blunted-tip applicator until the gel becomes visible at the gingival margin. Wait for 30 seconds before starting treatment. A longer waiting time decreases the risk of aspiration. For aspiration, as assessed by probing of pocket depths, has a duration of approximately 20 minutes (individual overall range 14 - 27 minutes). If the anesthesist is not prepared to use ORAQIX® may be re-applied if needed.

**Adverse Drug Reaction Overview**

The clinical safety database included 559 subjects, 391 of whom were exposed to ORAQIX® (lidocaine and prilocaine periodontal gel) and 168 to placebo gel. In a crossover study, 170 patients exposed to ORAQIX® also received an injection of 2% lidocaine with epinephrine.

The most frequent adverse reactions in clinical trials were local reactions in the oral cavity. The frequency and type of reactions were similar for ORAQIX® and placebo- and treatment-placebo patients. The treatment-emergent adverse events observed in three placebo-controlled parallel studies (N = 83) are summarized in Table 1.

**Table 1: Treatment-Emergent Adverse Events for ORAQIX® in placebo controlled parallel studies (B1 – B3) (1% or more frequent than placebo)**

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>ORAQIX® n (%)</th>
<th>Placebo n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Site Reaction</td>
<td>25 (15)</td>
<td>20 (12)</td>
</tr>
<tr>
<td>Headache</td>
<td>4 (2)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Tissue Perforation</td>
<td>4 (2)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Accident and/or Injury</td>
<td>2 (1)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Application Site Reaction</td>
<td>2 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Respiratory Infection</td>
<td>2 (1)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

**Allergic Reactions**

In rare cases, local anesthetics have been associated with allergic reactions and in the most severe instances, anaphylactic shock (see WARNINGS AND PRECAUTIONS, Sensitivities, Allergy). Allergic reactions were not reported during clinical trials. Very rare cases of anaphylactic or anaphylactoid reactions associated with the use of ORAQIX® have been reported.

For more details on adverse events reported during clinical trials, see ADVERSE REACTIONS in the Clinical Product Information.

To report a suspected adverse reaction, please contact DENTSPLY Canada Inc. by Toll-Free Number: (800) 263-1437 or visit the website at DENTSPLY Canada Inc. 161 Vinyl Court, Woodbridge.