DISCOMFORT REDUCTION DURING MAXILLARY ANESTHESIA:
A Clinical Split-Mouth Study using a High Frequency Oscillating Device

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Discomfort Reduction during Maxillary Anesthesia: A Clinical Split-Mouth Study using a High Frequency Oscillating Device.

Abstract

Fear of pain is the primary reason for missed dental appointments, while delivery techniques and technologies have been introduced with the goal of reducing discomfort and making it possible to deliver painless local anesthesia. A number of devices have been introduced that are intended to improve patient comfort. This study of 62 subjects assessed the patient experience when local anesthesia procedures were accompanied by use of a pulsed, micro-oscillating device for patient comfort.

Learning Objectives

The overall goal of this article is to provide the reader with information on the management of pain and discomfort during local anesthesia. On completing this article, the reader will be able to:

1. Describe the gate-control pain theory;
2. Review the study design and study hypotheses;
3. Describe anxiety and discomfort as reported in published data; and,
4. Review the results of the clinical study and any implications for local anesthesia procedures.

ABOUT THE AUTHORS

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Introduction

Existing data states that the primary reason for missed dental appointments is fear of pain,1-3 and administering local anesthesia is often the first procedure dentists and dental hygienists perform prior to delivery of care.4 Receiving injections is one of several factors that cause apprehension and anxiety in patients5-7 and may lead to systemic complications such as syncope or blood pressure elevation.8 If the patient is not adequately anesthetized, or experiences pain during the administration of anesthetic, the remaining procedure can be difficult and anxiety-ridden for both the patient and the clinician.7 This is of great concern as this anxiety may be passed down from generation to generation, leading to poor oral health and fewer dental visits.7,9-12

Patient comfort during the administration of anesthesia provides a foundation for productive and successful treatment outcomes, which in turn impacts the likelihood of patients returning to the oral healthcare setting.13,14

The introduction of topical anesthesia, improvements in needles and other novel delivery technologies have previously been reported.14,15 Delivery techniques and innovative instrumentation have been developed in efforts to make injections of local anesthetic more comfortable for the patient.14-17 In 2010, a cordless, rechargeable, handheld device that delivers pulsed, micro-oscillations to the site where the injection is to be administered, was introduced to the dental market18 (Figure 1). The reported mechanism of action of this device is based on the gate-control theory of pain. The Gate control theory, first described by Melzack and Wall,18-22 indicates that the spinal cord has a “gate” that allows pain signals to travel to the brain if carried on small nerve fibers, but does not allow pain signals to pass if carried on larger fibers. Hence, pain transmission though A-delta and C nociceptive fibers is depressed in the dorsal horn if nerve impulses are simultaneously transmitted via A-beta fibers.21

The intensity of pulsations can be increased as needed and the latex-free tips are designed with a pressure-sensing feature that shuts off temporarily if excessive force is applied. An LED positioned within the handle adds illumination to the injection site and an audible buzzing sound acts as an additional distractor for the patient. According to the manufacturer, this device is designed to eliminate pain when administering local anesthesia in pediatric and adult patients.18

The purpose of this split-mouth clinical study was to assess the reduction in discomfort achieved by using a high-frequency oscillating unit during the administration of maxillary local anesthesia. Multiple factors such as

Figure 1. Test device
discomfort, anxiety, pain, and overall satisfaction were measured. The primary hypothesis of this clinical study was that there is a significantly lower anxiety and pain level when the device is used, compared to the use of a mirror retraction, when administering dental local anesthesia.

Materials and Methods

For this IRB-approved study (clinical trials ID: NCT02414620), 62 patients were enrolled (35 female and 27 male). Operators in the study had successfully completed their local anesthesia curriculum and worked under the direct supervision of the approved principal investigator (faculty). Informed consent was signed by all subjects, advising them of any risks and benefits related to the study. Participation in the study was voluntary and occurred within an OSHA-compliant clinical setting.

Local Anesthesia Technique and Agents

Infiltrations are considered supraperiosteal injections to only anesthetize the terminal branches innervating pulps and surrounding tissue limited to one or two teeth. In contrast, a nerve block, such as the anterior superior alveolar (ASA), is delivered close to the main nerve trunk and can produce anesthesia to a larger surface area. The principal investigators chose the ASA block technique in the maxillary arch to gauge “numbness” for a larger surface area while using the two different retraction modalities. The decision was made to use 2% Lidocaine with 1:100,000 epinephrine so that we could focus on patients’ perceptions with a common anesthetic along with the test device. Studies have concluded that 4% articaine produces a more significant response in the maxilla when used for buccal infiltration in comparison to 2% Lidocaine HCL with 1:100,000 epinephrine. However, we wanted patients to focus on “numbness” related to the comfort from the retraction methods applied in the study. In addition, 4% solutions when used in a block have minimal, but some, risk associated with paresthesia.

Local Anesthesia Administration

Each patient received two injections, one on the control side and one on the contralateral device side. A standard syringe, twenty-seven gauge short needle, and a 1.8 ml cartridge of 2% lidocaine with 1:100,000 epinephrine was used for delivery of the local anesthetic. Prior to the injection, operators felt for the infraorbital foramen extraorally for both the control site and the contralateral device site (test).

Firstly on the control side, gauze was used to dry the injection site and a small amount of topical anesthetic (20% benzocaine) was applied for one minute. Using the mouth mirror retraction technique, the operator delivered an ASA injection. The insertion site for the ASA was the mucobuccal fold above the maxillary first premolar. After initial penetration into the soft tissue, the needle was slowly advanced apically towards the infraorbital foramen. Once at the deposition site, 0.9 ml of anesthetic solution was administered after an aspiration test was performed. If aspiration was positive (visible blood in cartridge), the cartridge was replaced.

The soft tissue was prepared at the test site (device side) in the same manner as on the control side, including topical application of 20% benzocaine. The ASA injection was delivered by the operator using the device for retraction, again after performing an aspiration test. The same syringe and remaining anesthetic solution was administered after an aspiration test was performed. If aspiration was positive (visible blood in cartridge), the cartridge was replaced.

The soft tissue was prepared at the test site (device side) in the same manner as on the control side, including topical application of 20% benzocaine. The ASA injection was delivered by the operator using the device for retraction, again after performing an aspiration test. The same syringe and remaining anesthetic solution was administered after an aspiration test was performed. If aspiration was positive (visible blood in cartridge), the cartridge was replaced.
Discomfort Reduction during Maxillary Anesthesia

Figure 2. Questionnaire

Evaluation of ASA Injections using Mirror Retraction versus Pulsed, Micro-oscillating Device

1. Gender: Male ☐ Female ☐

2a. Please rate any discomfort experienced on right injection (Mirror)

2b. Please rate any discomfort experienced on left injection (DV)

3a. Did you have any preconceived notions of the injection using the mirror for retraction?
   Yes ☐ No ☐
   If yes, was the anxiety level: Low ☐ Medium ☐ High ☐

3b. Did you have any preconceived notions of the injection using the Dental Vibe for retraction?
   Yes ☐ No ☐
   If yes, was the anxiety level: Low ☐ Medium ☐ High ☐

4a. Was there penetration pain on “Mirror” side?
   Yes ☐ No ☐
   If yes, was the pain: Low ☐ Medium ☐ High ☐

4b. Was there penetration pain on “DV” side?
   Yes ☐ No ☐
   If yes, was the pain: Low ☐ Medium ☐ High ☐

5a. On a scale of 1-4 rate your experience on any post op sensation you felt after the needle was removed. (Mirror)
   No discomfort 1 ☐ 2 ☐ 3 ☐ 4 ☐ Highly uncomfortable

5b. On a scale of 1-4 rate your experience on any post op sensation you felt after the needle was removed. (DV)
   No discomfort 1 ☐ 2 ☐ 3 ☐ 4 ☐ Highly uncomfortable

6a. How long did it take you to experience
   Tingling: [ ] sec
   Feeling Fat: [ ] sec
   Profound Anesthesia: [ ] sec

6b. How long did it take you to experience
   Tingling: [ ] sec
   Feeling Fat: [ ] sec
   Profound Anesthesia: [ ] sec

7. How was your experience from the two different injection methods?
   ☐ A) The injection felt the same on both sides (No significant differences)
   ☐ B) The injection was better (more comfortable) using the Dental Vibe
   ☐ C) The injection was worse (more pain experienced) using the Dental Vibe

8. On a scale of 1-4, 1 being extremely satisfied and 4 being very dissatisfied, please rate your experience of having the DV used on you:
   Extremely Satisfied 1 ☐ 2 ☐ 3 ☐ 4 ☐ Extremely Dissatisfied

9. Would you recommend or ask your dentist to use the Dental Vibe during the administration of local anesthesia?
   ☐ D) Yes, I would want my dentist to use the Dental Vibe for all anesthetics.
   ☐ E) Yes, I would want my dentist to use the Dental Vibe but not for all anesthetics.
   ☐ F) No, I would not want my dentist to use the Dental Vibe during local anesthesia.
   ☐ G) No, I was so traumatized when the Dental Vibe was used
and in place for an additional five seconds as instructed by the manufacturer.

**Anxiety and Pain measurement**

All patients received instructions and completed the questionnaire that included the Wong-Baker\(^{28}\) pain rating scale as it related to the injection experience (Figure 2).

**Statistical Analysis**

Paired t-tests and Chi-square tests were performed for statistical analyses, with a confidence interval of 95% (p<0.05). Statistical analysis was performed using open source statistical software R from the Free Software Foundation’s GNU General Public License, USA, 2014.

**Results**

Question two asked about discomfort level during the injection of local anesthesia. There was a statistically significant difference in the discomfort level during the administration of local anesthesia on the control side compared with the device side, based on the Wong-Baker Faces Pain Rating Scale (p= 0.02). More discomfort was experienced on the control side than on the device side (Figure 3). No statistically significant differences in discomfort between the control side and device side were reported by female subjects (p=0.216). Male subjects reported significantly greater discomfort on the control side than the device side (p=0.012).

The third question enquired about preconceived notions regarding the injection on the respective sides. Based on the Chi-square analyses, subjects who answered that they did have preconceived notions regarding the use of mouth mirror retraction for the control side (42 out of 62) were highly likely to also report that they had preconceived notions regarding the use of the device on the contralateral side (39 out of 62). A similar pattern was observed for those who reported no preconceived notions for the control or device side. Comparing the control with the device side, the paired t-test found a statistically significantly greater level of anxiety in those with preconceived notions of the injection on the control side (p=0.017).

All subjects answering that they had preconceived notions were asked in a follow-up question about their anxiety level and asked to rate it as “low”, “medium” or

**Figure 3. Level of discomfort experienced by subjects**

<table>
<thead>
<tr>
<th>Control Side</th>
<th>Device Side</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of Patients</strong></td>
<td><strong>Number of Patients</strong></td>
</tr>
<tr>
<td><strong>0</strong></td>
<td><strong>0</strong></td>
</tr>
<tr>
<td><strong>4</strong></td>
<td><strong>6</strong></td>
</tr>
<tr>
<td><strong>1</strong></td>
<td><strong>9</strong></td>
</tr>
<tr>
<td><strong>2</strong></td>
<td><strong>4</strong></td>
</tr>
<tr>
<td><strong>5</strong></td>
<td><strong>4</strong></td>
</tr>
<tr>
<td><strong>4</strong></td>
<td><strong>23</strong></td>
</tr>
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<td><strong>6</strong></td>
<td><strong>18</strong></td>
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<td><strong>10</strong></td>
<td><strong>11</strong></td>
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<tr>
<td><strong>25</strong></td>
<td><strong>8</strong></td>
</tr>
</tbody>
</table>
Discomfort Reduction during Maxillary Anesthesia

On the control side, 64% of subjects experienced low anxiety, while 31% and 5% experienced medium and high anxiety levels, respectively. On the device side, 77% and 23% of subjects reported low and medium anxiety levels, respectively, with none reporting high anxiety.

The fourth question inquired about pain during needle penetration. It was found that subjects who reported no pain during needle penetration on the control side were highly likely to report the same for the device side (p=0.006; Figure 5). A paired t-test was conducted to compare both sides for subjects answering “yes.”

In question seven, patients were asked about their experience with both injection methods and whether there was any difference in the level of discomfort. 27 of 62 subjects experienced no difference with or without use of the device, 21 reported that local anesthesia was more comfortable on the device side, and 14 reported that it was more comfortable on the control side. Table 1 shows the distribution by gender.

In question eight, subjects were asked to rate their overall satisfaction with the device. Findings were that 38 of 62 subjects were either extremely satisfied or satisfied, 19 were dissatisfied and 5 were extremely dissatisfied (Figure 6). In question nine, subjects were asked to report their preferences based on their experience of local anesthesia on the control and device sides during the study and whether they would choose device-assisted injections for future local anesthesia procedures. 44 of 62 subjects reported that they would prefer to have the device used either all or some of the time (Table 2).

Discussion

This split-mouth study demonstrated that using a high-frequency oscillating unit may decrease the discomfort associated with the delivery of local anesthesia in dental procedures. The first hypothesis that anxiety level can be lowered using the device has been confirmed, while the second hypothesis that the pain level can be reduced with the device was rejected. Interestingly, several subjects preferred the device-assisted injections for future local anesthesia procedures.

Table 1. Distribution of discomfort experience by gender

<table>
<thead>
<tr>
<th>Gender Experience</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>14</td>
<td>13</td>
<td>8</td>
<td>35</td>
</tr>
<tr>
<td>Male</td>
<td>13</td>
<td>8</td>
<td>6</td>
<td>27</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>21</td>
<td>14</td>
<td>62</td>
</tr>
</tbody>
</table>

A: The injection felt the same on both sides  
B: The injection was more comfortable on the device side  
C: The injection was less comfortable on the device side
eral factors contribute to the results that were observed, such as the gender of the patient, what the anxiety level of the patient was before the device was used and his/her pain threshold. Using the device resulted in no significant discomfort level for females, yet males experience more discomfort on the control side (Figure 3), while studies have reported that women try to avoid pain, accept it less, and fear it more than men.29 Figure 4 breaks down anxiety levels prior to the delivery of the injections. For both injection methods, the majority of subjects reported low anxiety with only 5% reporting high anxiety on the control side.

Published data have also reported lower percentages (8-15%) of surveyed populations to have high dental anxiety.11,30,31 A statistically significant proportion of subjects reported a lower level of anxiety related to receiving the injection on the device side. This might be partially attributed to the fact that all subjects in the study had recently experienced a local anesthetic injection (within the prior 6 months). If any pain or discomfort was associated with their past experience, it would follow that a device that may contribute to pain reduction might be a welcome addition to the injection protocol (Figure 5).

Published data have also reported lower percentages (8-15%) of surveyed populations to have high dental anxiety.11,30,31 A statistically significant proportion of subjects reported a lower level of anxiety related to receiving the injection on the device side. This might be partially attributed to the fact that all subjects in the study had recently experienced a local anesthetic injection (within the prior 6 months). If any pain or discomfort was associated with their past experience, it would follow that a device that may contribute to pain reduction might be a welcome addition to the injection protocol (Figure 5).

It is hard to quantify through a small randomized trial to what degree the improvements in patient comfort were related to physiologic reduction in actual pain transmission attributed to the Gate control theory of pain. When subjects were asked if the injection was better (more comfortable) on the device side, 20 answered that the device side felt more comfortable, 27 felt no comfort difference between the device and control sides and only 14 of the 61 patients reported the injection was more painful on the device side. Results suggest that the Gate theory to block the transmission of the sensation of pain might indeed be confirmed using the device during anesthesia delivery, thus supporting our hypothesis, but this is inconclusive. The results from Table 2 suggest that most subjects would prefer to have the option of using the device for future injections, but that the ultimate preference would depend on the injection site. Interestingly, two patients reported being traumatized by the device and indicated a preference for not using the device again.

When satisfaction was surveyed (Figure 6), only 5 patients were very dissatisfied with their experience with the device. Administration of dental anesthesia is often the first procedure performed, and can set the tone for the entire appointment.3,32,33

Dentists and hygienists use dental anesthesia to satisfy the goal of eliminating pain and an unpleasant experience for the patient. As previous studies have shown, despite an increase in general anxiety within the United States during the past 50 years, dental anxiety seems to have remained stable throughout that time, which might

<table>
<thead>
<tr>
<th>Gender Experience</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
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<td>9</td>
<td>15</td>
<td>10</td>
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<tr>
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<td>15</td>
<td>29</td>
<td>14</td>
<td>2</td>
<td>60</td>
</tr>
</tbody>
</table>

D: Yes, I would want my dentist to use the device for all anesthetics
E: Yes, I would want my dentist to use the device but not for all anesthetics
F: No, I would not want my dentist to use the device during local anesthesia
G: No, I was so traumatized when the device was used
be attributed in part to advances in dental technologies and delivery. Any modality that may prove to reduce or eliminate the pain associated with dental injections, reduce the associated anxiety or improve the efficiency of anesthesia, is worthy of evaluation.

The authors staged this study with several key points in mind:

- Standardization of test and control subjects in the randomized trial by virtue of split-mouth design.
- Elimination of subject attrition via immediate response design.
- Survey questions designed to not only evaluate pain perception via Wong-Baker faces pain rating system, but also to gauge possible placebo effect related to anxiety reduction by virtue of using a “pain reduction device.”
- Reduction of expertise bias via novice test delivery (operators with minimal and relatively equal injection experience delivered the injections, none of whom had any experience with the oscillating unit).

Innovative technologies that enhance the delivery of dental anesthesia have many benefits for both patient and operator. Further studies are needed to determine whether the oscillating device is advantageous for all dental injections.

Clinical Implications

When a pulsed, oscillating device was used, results were mixed. Twenty-one subjects perceived less discomfort when the device was used during local anesthesia infiltration, however 14 experienced more discomfort and 27 perceived no difference in the level of discomfort. The application reduced anxiety. Technologies that improve patient experience, related to dental anesthesia, can serve to eliminate one of the obstacles in patient care.

References


Webliography


1. Receiving injections is one of several factors that can ________.
   a. significantly lengthen treatment time
   b. cause apprehension and anxiety in patients
   c. significantly decrease mobility
   d. none of the above

2. The Gate control theory indicates that the spinal cord has a “gate” that allows pain signals to travel to the brain if ________.
   a. carried on small nerve fibers
   b. carried on large nerve fibers
   c. supplemented by auxiliary fibers
   d. a and b

3. Pain transmission though A-delta and C nociceptive fibers is depressed in the dorsal horn if nerve impulses are simultaneously transmitted via C-delta fibers.
   a. True
   b. False

4. In the current study, statistically significant differences in discomfort were found between the control side and the device side in ________.
   a. female subjects
   b. male subjects
   c. older adults
   d. children

5. When asked to report their preferences for future local anesthesia procedures, ________ subjects reported that they would prefer to have the device used either all or some of the time.
   a. 24 of 42
   b. 24 of 62
   c. 34 of 62
   d. 44 of 62

6. In the current study, it was found that subjects who reported no pain during needle penetration on the control side were highly likely to report the same for the device side.
   a. True
   b. False

7. The findings from this split-mouth study demonstrated that using a high-frequency oscillating unit ________.
   a. may decrease the discomfort associated with the delivery of local anesthesia
   b. may lower a patient’s anxiety level
   c. can reduce the pain level
   d. a and b

8. According to the authors, modalities that may ________ associated with dental injections, are worthy of evaluation.
   a. prove to reduce or eliminate the pain
   b. reduce the anxiety level
   c. improve the efficiency of anesthesia
   d. all of the above

9. Reduction of expertise bias in this study was obtained by using ________ for dental anesthetic injection.
   a. operators with minimal and relatively equal injection experience
   b. operators with no injection experience
   c. recent post-graduates
   d. operators with experience using the test device

10. When a pulsed, oscillating device was used, there was ________ for dental anesthetic injection with no adverse effects.
    a. an overall negative response
    b. no response
    c. an overall positive response
    d. no positive response
Anesthesia Paper – Clinical Split Mouth Study

CE ANSWER FORM (E-mail address required for processing)

Name:

*Address:

*City:  *State:  *Zip:

*Telephone:

A score of 70% will earn your credits.

EDUCATIONAL OBJECTIVES
- Define the elements of the chain of infection;
- Delineate and describe the differences in the processing of critical, semicritical and noncritical instruments;
- Review the use of presoaks and cleaning of instruments;
- List and describe heat sterilization options and appropriate sterilization packaging; and
- Review the uses and purposes of chemical and biological indicators.

COURSE EVALUATION
Please evaluate this course using a scale of 3 to 1, where 3 is excellent and 1 is poor.

1. Clarity of objectives ...........................................  ⬜  ⬜  ⬜  ⬜
2. Usefulness of content ...........................................  ⬜  ⬜  ⬜  ⬜
3. Benefit to your clinical practice ...............................  ⬜  ⬜  ⬜  ⬜
4. Usefulness of the references .................................  ⬜  ⬜  ⬜  ⬜
5. Quality of written presentation ..............................  ⬜  ⬜  ⬜  ⬜
6. Quality of illustrations .......................................  ⬜  ⬜  ⬜  ⬜
7. Clarity of quiz questions .....................................  ⬜  ⬜  ⬜  ⬜
8. Relevance of quiz questions .................................  ⬜  ⬜  ⬜  ⬜
9. Rate your overall satisfaction with this course .........  ⬜  ⬜  ⬜  ⬜
10. Did this lesson achieve its educational objectives? Yes No
11. Are there any other topics you would like to see presented in the future? ____________________________

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3. Mark only one answer for each question.
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