COMPARISON OF PAIN LEVELS BETWEEN THE CONVENTIONAL AND THE COMPUTERIZED ANESTHETIC INJECTION WITH MORPHEUS® FOR THE NASOPALATINE NERVE BLOCK: A DOUBLE-BLIND RANDOMIZED CLINICAL TRIAL

COMPARAÇÃO DOS NÍVEIS DE DOR ENTRE A INJEÇÃO ANESTÉSICA CONVENCIONAL E COMPUTORIZADA COM MORPHEUS® PARA O BLOQUEIO NERVOSO NASOPALATINO: UM ENSAIO CLÍNICO ALEATÓRIO EM DUPLA OCULTAÇÃO

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ABSTRACT: Objective: To compare pain levels between the conventional injection and the Morpheus® device for the nasopalatine nerve block concerning the puncture, needle introduction, and local anesthetic (LA) deposition. Methods: A crossover, double-blind, randomized clinical trial was carried out involving 32 participants. Group I comprised the conventional syringe (control group), while Group II comprised the Morpheus® device (experimental group). The study was developed in two sessions, two weeks apart. The pain was assessed using a 100-mm Visual Analog Scale (VAS). The intragroup analyses were performed using Friedman’s test and Durbin-Conover’s post hoc test. The Wilcoxon test was used for intergroup analyses. The significance level was set at p < 0.05. Results: Intragroup analyses showed statistical differences within both groups (Group I, p < 0.001; Group II, p = 0.003). All the evaluated moments of both injection techniques differed statistically, except between the needle introduction and LA deposition within Group II (p = 0.526). In the intergroup analyses, participants of Group I presented higher pain levels, experiencing the highest pain at the LA deposition moment (median 58; 46 - 62). Pain levels were statistically significant between all the corresponding moments of the groups.
Conclusion: Computerized injection with the Morpheus® can be effectively employed to increase comfort during anesthetic injections and patient compliance with dental treatments.

KEYWORDS: Dental Anesthesia, Local Anesthesia, Pain.

1. Introduction

Minimal discomfort during dental anesthetic injection is crucial to increasing patient compliance with dental treatment. Patients often fear
more the anesthetic injection than the dental treatment itself [1,2]. Several elements may influence the pain perception upon anesthetic injection, such as tissue puncture, injection site, drug temperature, needle penetration, and practitioner’s experience [3,4]. For this reason, the application of topical anesthetic, the use of small diameter needles, or the application of laser to the injection site have been recommended to decrease pain during anesthetic injection [5–7]. The most effective method to decrease pain, however, seems to be the injection speed slowdown².

Several computerized local anesthetic delivery systems (CLADS) have been developed since the mid-1990s aiming to reduce pain focus by controlling the dose and deposition velocity of the local anesthetic (LA). When the dose and speed of LA deposition are controlled during anesthetic injection, pain can be significantly reduced [8]. However, manually controlling the dose and the speed of LA deposition for painless injection is complex, for injection sites vary in tissue resistance and depth of needle introduction. Most CLADS, on the other hand, can control precisely the flow rate of LA [7], and in Brazil, this technology started in 2005 with the Morpheus® device (Meibach Tech Ltda, SP, Brazil). This use of CLADS results in a highly effective and comfortable anesthetic injection even in resilient tissues, such as the palate or periodontal ligament.

The perception of pain on anesthetic injection into the oral cavity varies according to the injection site and injection speed. The injection site is a determining factor in the patient’s pain perception [9–11]. Aminabadi et al. (2009) [12] showed that maxillary injections produced statistically higher pain levels than mandibular ones (p < 0,05), and nasopalatine nerve block produced the highest pain levels (median 10). Regarding the relationship between the anesthetic injection speed and pain, Primosch and Brooks (2002) [8] reported less pain when 0.3 mL of a LA was injected into the palatal mucosa at a low rate (161 s/mL) than at a high rate (29 s/mL).
This study aimed to compare pain levels between the conventional injection technique and the Morpheus® device for the nasopalatine nerve block during the puncture, needle introduction, and LA deposition. The null hypothesis was that the pain levels during nasopalatine nerve block using the Morpheus® device equal the pain levels using the conventional syringe.

2. Methods

2.1 Ethical Aspects and Study Design

A crossover, double-blind, randomized clinical trial was carried out including 32 participants. The research was approved by the Research Ethics Committee of the Federal University of Sergipe (CAAE: 26828514.0.0000.5546) and the Brazilian Registry of Clinical Trials (RBR-9h2kdm9). The Declaration of Helsinki and its later amendments, as well as the recommendations of the Consolidated Standards of Reporting Trials (CONSORT) were followed throughout. After a clear explanation of the objectives, risks, and other information, the participants that agreed to participate in the study signed a consent form.

2.2 Eligibility Criteria

A sample containing 32 participants was calculated based on values published by Hochman et al (1997) [13].

Inclusion criteria were healthy individuals, aged between 18 and 30 years old; previous uneventful dental anesthesia; no palatal anesthesia in the two weeks before the study; and no use of any medication capable of altering pain perception in the two weeks before the study.
Exclusion criteria consisted of pregnancy; breastfeeding; allergy to the drugs proposed in the study; history of alcohol abuse or drug dependence; psychiatric disorders or systemic diseases; treatment in course with central nervous system drugs; use of drugs capable of altering pain perception in the two weeks preceding the study; and moderate or high anxiety (>9) [14].

The participants’ degree of anxiety was assessed to verify their eligibility using Corah’s Dental Anxiety Scale [14]. This scale is reliable and has predictive validity [15], consisting of a multiple-choice questionnaire to assess the degree of anxiety associated with dental treatment, ranging from 4 (no anxiety) to 20 (high anxiety).

2.3 Randomization, Blinding, and Allocation Concealment

A researcher (researcher #1), with no direct participation in the procedures or pain assessments, randomized the injection techniques using the website www.sealedenvelope.com. Group I comprised the anesthetic injection using the conventional syringe (control group), while Group II comprised the computerized anesthetic injection using the Morpheus® device (experimental group). Allocation concealment was ensured by utilizing sequenced, opaque, and sealed envelopes where the randomization information was deposited. For each participant, researcher #1 opened an envelope and informed a second researcher (researcher #2), assigned solely to perform the procedures, about the injection technique to be performed.

Given the crossover design, each participant received both injection techniques and served as their own control. The study was developed in two sessions, two weeks apart. One of the techniques was performed according to the randomization in the first session, and in the second session, the other technique was used. A third researcher (researcher #3), assigned solely to the pain assessment, had no access to the randomization and stayed outside
the research environment during the anesthetic injections, entering the clinic for the pain assessment only after authorization.

Blinding of all participants was obtained visually and audibly. To prevent visual identification of the anesthetic injection technique, a model of glasses with opaque lenses was used. Since the Morpheus® emits a characteristic sound during the injection, the use of a noise damper aimed to avoid audible interferences in the blinding.

2.4 Anesthetic Procedures

The anesthetic procedures were performed by an experienced operator (researcher #2). For conventional injection, a metallic, side-loaded, aspirating syringe was used (Quinelato, Rio Claro, SP). For all cases, benzocaine 20% gel (Benzotop® DFL Ind. Com. SA, Rio de Janeiro, RJ), lidocaine hydrochloride 2% associated with epinephrine 1:100,000 (Alphacaine 100® - DFL Ind. Com. SA, Rio de Janeiro, RJ), and short 30G needles (Unoject® DFL Ind. Com. AS, Rio de Janeiro, RJ) were utilized.

To perform the anesthetic procedures, all patients were positioned similarly (supine position, with the head slightly extended backward). The incisive papillae were previously dried with sterile gauze, and Benzotop® was applied to the area for two minutes. The conventional anesthetic injection was performed according to the standard technique, and the computerized injection according to the manufacturer’s instructions. Regardless of the injection technique, the total volume of LA administered was 06 mL.

2.5 Pain Assessment

The pain was assessed using the Visual Analog Scale (VAS). The VAS is a continuous scale composed of a horizontal line, 100 mm long, exhibiting
the phrase “no pain” at the left endpoint and “worst possible pain” at the right endpoint. Immediately after each anesthetic injection, participants were instructed to make a perpendicular stroke at the location on the scale that represented pain intensity. The pain was assessed concerning three moments of the injections: the puncture, needle introduction, and LA deposition. A digital caliper was employed to measure the distance from the end of the marking “0” to the marking made by the participant on the scale. The instruction on filling out the VAS and measuring the pain levels was performed by a third researcher (researcher #3), blinded to the injection techniques.

2.6 Data Analysis

For the distribution of categorical variables, absolute and relative frequency were applied, and for continuous variables, mean and standard deviation. The measurements from the VAS were tabulated in millimeters and treated as ordinal qualitative variables. The descriptive analysis was performed using median accompanied by the 1st and 3rd quartiles. The intragroup analyses were performed using Friedman’s test, followed by Durbin-Conover’s post hoc test. The intergroup analyses between the corresponding moments were performed using the Wilcoxon test. Statistical tests were performed using Jamovi v.1.6.4.0 software (The Jamovi Project, 2021) with a significance level set at p<0.05.

3. Results

The sample of this study consisted of 32 participants (n = 32). Seventeen participants (53.1%) were women and 15 (46.9%) were men,
with a mean age of 20.5 ± 1.61 years old (Table 1). No adverse events or dropouts of participants occurred.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>17 (53.1%)</td>
</tr>
<tr>
<td>Male</td>
<td>15 (46.9%)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>20.5 ± 1.61&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup>Years old.

Source: the authors

In the intragroup analysis, Friedman’s test revealed statistically significant differences within both groups (Group I, p < 0.001; Group II, p = 0.003). Durbin-Conover post hoc analysis revealed differences between the evaluated moments of both injection techniques, except between the needle introduction and LA deposition within Group II (p = 0.526) (Table 2).

In the intergroup analysis, Group I presented higher pain levels (Table 3). Participants felt the highest pain at the LA deposition moment of the conventional injection (median 58; 46 - 62). Group I had a lower level of pain at the time of puncture (median 2; 0 - 3); group II had no pain during puncture. Similarly, the moment of insertion of the needle showed low levels of pain in both groups. The differences in pain levels were statistically
significant between all the corresponding moments of the groups (p < 0.001).

Table 3. Intergroup comparison of pain levels between the corresponding moments of the anesthetic injections

<table>
<thead>
<tr>
<th>Moments</th>
<th>Group I Conventional Syringea</th>
<th>Grupo II Morpheus® Devicea</th>
<th>p-valueb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Puncture</td>
<td>2 (0 – 3)</td>
<td>0 (0 – 0)</td>
<td>&lt;.001*</td>
</tr>
<tr>
<td>Introduction</td>
<td>6 (4 – 8)</td>
<td>1 (0 – 2)</td>
<td>&lt;.001*</td>
</tr>
<tr>
<td>LA deposition</td>
<td>58 (46 – 62)</td>
<td>0 (0 – 2)</td>
<td>&lt;.001*</td>
</tr>
</tbody>
</table>

Abbreviation: LA, Local Anesthetic.

aMedian (1st quartile – 3rd quartile); in millimeters on the VAS.
bWilcoxon test.

*Statistical significance at p < 0.05.
Source: the authors

Detailed demographic characteristics and raw pain levels according to groups and moments are available in Table 4.

Table 4. Participants’ demographic characteristics and raw pain levels according to groups and moments.

<table>
<thead>
<tr>
<th>Participants</th>
<th>Sex</th>
<th>Age</th>
<th>Group I Pain levelsa</th>
<th>Group II Morpheus® Deviceb</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Conventional Syringe</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Punc  Intro  Depo</td>
<td></td>
</tr>
<tr>
<td>#1</td>
<td>F</td>
<td>21</td>
<td>0      3    62</td>
<td>0    2    0</td>
</tr>
<tr>
<td>#2</td>
<td>F</td>
<td>18</td>
<td>0      0    36</td>
<td>0    0    0</td>
</tr>
<tr>
<td>#3</td>
<td>M</td>
<td>19</td>
<td>0      6    45</td>
<td>0    3    4</td>
</tr>
<tr>
<td>#4</td>
<td>F</td>
<td>21</td>
<td>0      6    55</td>
<td>0    0    4</td>
</tr>
<tr>
<td>#5</td>
<td>M</td>
<td>23</td>
<td>0      7    58</td>
<td>0    0    0</td>
</tr>
<tr>
<td>#6</td>
<td>F</td>
<td>21</td>
<td>0      10   62</td>
<td>0    0    0</td>
</tr>
<tr>
<td>#7</td>
<td>F</td>
<td>21</td>
<td>0      6    71</td>
<td>0    0    3</td>
</tr>
<tr>
<td>#8</td>
<td>F</td>
<td>19</td>
<td>3      4    46</td>
<td>0    2    0</td>
</tr>
<tr>
<td>#9</td>
<td>M</td>
<td>23</td>
<td>5      12   72</td>
<td>0    0    0</td>
</tr>
<tr>
<td>#10</td>
<td>F</td>
<td>21</td>
<td>0      4    45</td>
<td>0    2    0</td>
</tr>
<tr>
<td>#11</td>
<td>M</td>
<td>22</td>
<td>2      6    50</td>
<td>0    0    0</td>
</tr>
<tr>
<td>#12</td>
<td>F</td>
<td>19</td>
<td>5      7    67</td>
<td>0    0    0</td>
</tr>
<tr>
<td>#13</td>
<td>M</td>
<td>21</td>
<td>0      5    62</td>
<td>0    3    3</td>
</tr>
<tr>
<td>#14</td>
<td>M</td>
<td>19</td>
<td>5      8    63</td>
<td>0    3    0</td>
</tr>
<tr>
<td>#15</td>
<td>F</td>
<td>19</td>
<td>1      6    58</td>
<td>0    0    0</td>
</tr>
<tr>
<td>#16</td>
<td>M</td>
<td>19</td>
<td>0      3    46</td>
<td>0    0    0</td>
</tr>
<tr>
<td>#17</td>
<td>F</td>
<td>19</td>
<td>3      11   50</td>
<td>0    0    0</td>
</tr>
<tr>
<td>#18</td>
<td>M</td>
<td>22</td>
<td>3      7    48</td>
<td>0    0    4</td>
</tr>
<tr>
<td>#19</td>
<td>F</td>
<td>20</td>
<td>5      8    35</td>
<td>0    2    1</td>
</tr>
<tr>
<td>#20</td>
<td>M</td>
<td>22</td>
<td>5      22   60</td>
<td>2    4    2</td>
</tr>
<tr>
<td>#21</td>
<td>M</td>
<td>21</td>
<td>5      14   56</td>
<td>0    3    2</td>
</tr>
</tbody>
</table>
4. Discussion

This study aimed to compare pain levels between the conventional injection technique and the Morpheus® device for the nasopalatine nerve block during the puncture, needle introduction, and LA deposition moments. The results of the present study reject the null hypothesis that the pain levels during nasopalatine nerve block using the Morpheus® device equal the pain levels using the conventional syringe. The findings indicate that participants experienced statistically lower pain levels during nasopalatine nerve block with the Morpheus® device in all evaluated moments — puncture, needle introduction, and LA deposition. Despite the evidence on the efficacy of Morpheus® on pain perception for inferior alveolar nerve blocks [16,17], this clinical trial appears to be the first to evaluate the Morpheus® device for the nasopalatine nerve block.

Although conventional syringes are still the most commonly used method for dental anesthetic injection [18,19], computerized injection offers the advantage of precisely controlling the dose and speed of LA delivery. When manually performed, the resistance of the palatal tissue influences the control of digital pressure, increasing the difficulty to achieve a painless injection. On the other hand, CLADS can stabilize the flow of LA release at a...
pre-set dose and speed, irrespective of tissue resistance [7]. This aspect is particularly relevant for the nasopalatine nerve block, considering the tightly adhered tissue and the pressure applied to inject the LA [20]. Investigating palatal injections with another CLADS (The Wand®), researchers also found lower pain levels with the computerized injection [3,21,22]. Our findings support that maintaining a slow and continuous flow of LA delivery contributes to decreasing discomfort during the injection. This lesser discomfort is due to the injection speed (flow rate) of the anesthetic solution, which prevents detachment of the periosteal tissue and, consequently, avoids tissue trauma. This is especially advantageous in regions where the tissue is firmly adhered, such as the mucosa of the hard palate.

Another aspect influencing pain perception during an anesthetic injection is anxiety. Anxiety and fear appear to increase pain perception during anesthetic injection and discomfort during dental treatment, extending operative time and difficulty [23,24]. Using a CLADS (The Wand®. Milestone Scientific, Livingston, NJ) to administer 0.5 mL of a LA at a low speed (94.6 ± 1.6 seconds) and a high speed (16.7 ± 0.5 seconds), Kudo (2005) [25] found positive correlations between the pressure at the beginning of the injection and pain intensity and anxiety. As highly anxious patients tend to have lower pain thresholds, slow injection also helps to prevent high pain levels by not stimulating anxiety.

Additionally, fear represents a considerable barrier to successful dental treatment. Especially in children and adolescents, fear is the most common reason for not visiting the dentist because of its association with pain, discomfort, and anxiety [2,5]. The use of the Morpheus® demonstrated to be a safe and effective device to minimize pain perception for the nasopalatine nerve block, differing statistically from the conventional injection. Therefore, computerized LA injections can favor greater comfort and compliance with dental treatments.
To control confounding variables related to pain, all injections in the present study were performed by the same operator and using the same needle gauge, anesthetic solution, and LA volume. We employed Corah’s Dental Anxiety Scale [14] to include only participants with mild or absent anxiety, favoring variability reduction and statistical power increase. Our methodology included no comparisons between pain levels and gender since gender does not seem to influence pain perception [26,27]. Besides, instead of a split-mouth design and a single-appointment research, we opted for a crossover design and a two-appointment research. The crossover design was chosen especially because of the reduction in the variability and increase in statistical power found in paired comparisons. As for the performance of the injection technique in different appointments, we believe that waiting two weeks as the wash-out period to perform the second anesthetic injection technique was an adequate and safe measure to prevent any influence concerning the pain perception of the first technique over the second one.

A limitation, however, was the use of Benzotop® before anesthetic injections. Considering the characteristic pain of the nasopalatine nerve block, we accepted to include Benzotop® in the procedures, such as previous works [22,28]. Despite its use, statistical analyses detected significant differences. The explanation for this difference comes from the initial puncture procedure using the Morpheus device, where the needle is introduced as superficially as possible (above the nerve endings), with an inclination almost parallel to the tissue plane. The anesthetic volume is then injected, ensuring that the next step (needle insertion) is painless. Furthermore, the manual technique is subject to human variations and lack of precise control of the anesthetic flow. All of these factors result in a positive scenario for the Morpheus® device, even when applying topical anesthetic to both groups of participants in this research. Given the scarcity of published studies, the results found and the stated limitations, future trials
should include larger samples and add the anxiety variable to the study design. Given the scarcity of published studies, the results found, and the limitations stated, future trials should include larger samples and add the anxiety variable to the study design.

5. Conclusion

The findings of this study showed that computerized injection with the Morpheus® device elicited lower pain levels compared with conventional injection in the nasopalatine nerve block. Thus, computerized injection with the Morpheus® can be effectively employed to increase comfort during anesthetic injections and patient compliance with dental treatments.

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References


