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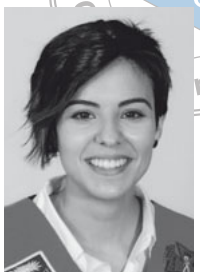

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A randomized split-mouth clinical trial comparing pain experienced during palatal injections with traditional syringe versus controlled-flow delivery Calaject technique

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Objective: To compare the pain experienced by patients during injections of local anesthesia in the palate using the traditional syringe and the controlled flow technique with the Calaject system. **Method and Materials:** A single-blind, split-mouth, randomized controlled trial was performed. Twenty-five volunteers were recruited in the Dental Hospital of the University of Barcelona, Spain. Each participant received two injections (0.3 mL of mepivacaine 3%), one with the traditional syringe (control side) and another with the Calaject system (experimental side), both during the same session. Pain intensity was evaluated after each injection with a 100-mm visual analog scale (VAS). A descriptive and bivariate statistical analysis was made. **Results:** The mean pain experienced was 44.8 mm (standard deviation [SD] 19.0, range 8–72) with the traditional injection and 28.8 mm (SD 19.7, range 8–72) with the Calaject system ($P < .001$). Moderate/severe pain was more frequently referred in the control side (68%) in comparison with the experimental side (28%). **Conclusion:** Given the parameters of this study's design, the injection of local anesthetics in the palatal area with the Calaject controlled-flow system seems to reduce pain, in comparison to the use of a traditional syringe. *(Quintessence Int 2016;47:797–802; doi: 10.3290/j.qi.a36566)*

Key words: Calaject system, computer-delivery anesthesia, dental anesthesia, local anesthesia, pain

Pain control is one of the main concerns to dentists during dental treatments. Most patients fear pain and refer anxiety during local anesthetic injections. One of the most developed strategies of the recent years is the technology of injecting anesthesia by means of a computer. When flow and pressure are accurately controlled during injection of a local anesthetic, pain can be significantly reduced.[1] Primosch and Brooks[2] revealed that injecting 0.3 mL of local anesthetic solution at a slow rate with a constant flow (161 s/mL) is less painful than with a faster infiltration (29 s/mL). Other authors reported that to minimize pain and anxiety, it is important for dentists to start to inject anesthesia at a pressure below 306 mm Hg. Nonetheless, they also indicated that some other variables, such as

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the injected volume and tissue integrity, could also have an impact on pain perception.[3]

The aim of this study was to compare the pain experienced by volunteers during injections of local anesthesia in the palate area using the traditional syringe and the controlled-flow technique with the Calaject system (Ronvig, Daugaard, Denmark).

METHOD AND MATERIALS

A single-blind, split-mouth, randomized controlled trial involving 25 dental students was performed. The study was conducted at the Dental Hospital of the University of Barcelona between April and May 2015 after approval from the local Institutional Review Board (Ethics Committee for Clinical Research of the Dental Hospital of the University of Barcelona) (EUDRACT number 2015-06). This study was designed complying with the CONSORT guidelines for clinical trials. Before enrolment, all subjects were explained the objectives, implications, and possible complications of this clinical trial and agreed to participate by signing an informed consent. The Helsinki declaration guidelines for research were followed.

A sample of 25 dental students was calculated on the basis of the values published by Hochman et al[1] and the formula $N = 2\,\sigma^2\,Z^2_{\alpha;1-\beta} / \delta^2$ where N is the number of subjects for each technique, σ the standard deviation (17.9 mm),[1] Z the coefficient for unilateral tests with an alpha risk .05 and power 80% whose value is 6.183, and δ the difference between means expected to be obtained and established at 35 mm. The N value obtained was 20 subjects, which was increased to 25 to mitigate any losses.

The inclusion criteria were: healthy subjects or patients with mild systemic disease without substantial functional limitations, who were 20 to 30 years old. Exclusion criteria were: pregnancy or suspected pregnancy, allergy or intolerance to mepivacaine or amide-like anesthetics, volunteers under treatment with analgesics or psychotropic drugs, and presenting any kind of pathology in the injection site. Mepivacaine 3% without vasoconstrictor (0.3 mL; Normon) was used in all cases. Short needles 30G 0.3 × 25 mm (Jet Plus, Normon) were used.

UnijectK (Hoechst) syringes were employed for the traditional injection, and the Calaject system (Ronvig) for the controlled-flow techniques.

Both assignation of the applied technique sequence (T, traditional; C, Calaject) and the intervention side (R, right; L, left), were randomized by means of a random sequence generated using the website http:/www.randomization.com. Thirteen patients received first the Calaject injection and then the one with the traditional syringe, while in the remaining 12 patients the sequence was inverted.

The decision of enrolling patients in the trial was made before randomization (allocation concealment).

Before the injection, the subjects were notified about the duration of the study (5 minutes) and were asked to complete the Corah dental anxiety scale. They then received two injections, one for each different system. They were blindfolded during the entire procedure and the Calaject system was also activated during the traditional injection since it produces an acoustic signal that cannot be cancelled.

The pain felt by individuals during infiltration (rather than at the time of the needle entry) was recorded on a horizontal 100-mm visual analog scale (VAS), with no inside markings, ranging from "no pain" to "maximum pain imaginable". VAS values ranging from 40 to 70 mm were considered as moderate pain and values over 70 mm were classified as severe.[5,6]

In all cases, the patient was placed in a supine position with the head tilted backwards. The same researcher (JRG) performed all techniques in approximately 40 seconds (time necessary to infiltrate 3 mL of anesthetic with the Calaject system) for both groups. The time factor was therefore limited to prevent a possible confounding effect in the patients' pain perception. Injections were performed in the palatal area, between the first and second maxillary premolars, at a distance of approximately 3 mm below the papilla (Fig 1). The needle was always inserted with a 45-degree inclination with the bevel towards the palatal tissue. After each injection, a time interval of approx-

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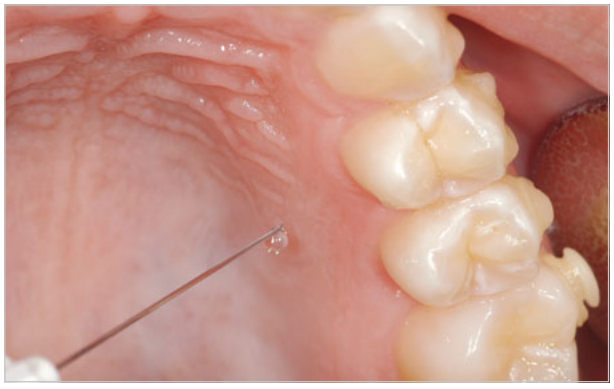

Fig 1 Palatal injection. The location was similar for both systems.

imately 1 minute was left for the patients to rinse their mouth and complete the pain intensity evaluation in the record sheet.

The statistical analysis was performed using the SPSS statistics 22.0 software (IBM). A descriptive (mean, standard deviation [SD], and ranges) and bivariate analysis (student *t* tests for paired samples to compare groups) was conducted. Statistical significance was set as $P \leq .05$.

RESULTS

The mean age of subjects was 23.6 (SD 1.85) years old, and 21 (84%) were female and only 4 (16%) were male. The mean Corah anxiety scale score was 4.8, and all cases were below the cut-off point for moderate anxiety (range 4 to 8; Table 1). Pain intensity values obtained in the VAS are shown in Table 1 and Fig 2. Most subjects (84%) referred more pain with the traditional system.

With the traditional technique, 15 (60%) and 2 (8%) subjects experienced moderate and severe pain, respectively, while with the Calaject system these values were reduced to 6 (24%) and 1 (4%).

Mean pain intensity was 44.8 mm (SD 19.0, range 8 to 72) for the traditional method and 28.8 mm (SD 19.7, range 2 to 72) for the Calaject system. The difference between means (16.0 mm, 95% confidence interval [CI] 8.2 to 23.8) was statistically significant ($t = 4.217$; df = 24; $P < .001$).

Table 1 Pain intensity values obtained in the VAS

Subject	Corah scale	First injection	VAS (0–100)	
			Traditional (mm)	Calaject (mm)
#1	4	T	60	18
#2	4	C	54	25
#3	6	C	33	2
#4	4	T	23	6
#5	4	T	66	42
#6	4	C	58	20
#7	5	C	17	9
#8	8	C	44	63*
#9	4	T	51	39
#10	4	C	72	30
#11	4	C	71	50
#12	5	T	49	58*
#13	4	T	21	2
#14	5	C	23	9
#15	4	C	65	26
#16	4	C	56	23
#17	4	T	47	11
#18	7	T	54	72*
#19	6	T	63	56
#20	4	T	51	29
#21	7	T	41	42*
#22	4	C	19	16
#23	7	T	8	28*
#24	5	C	56	33
#25	4	C	19	12

*Patients that reported more pain in the experimental side.
C, Calaject system injection; T, traditional syringe.

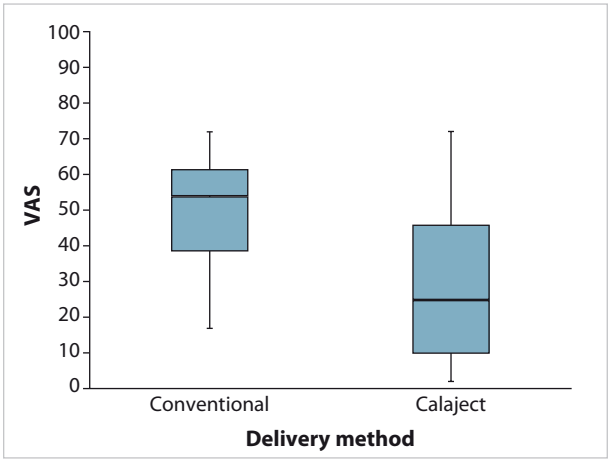

Fig 2 Boxplot with pain intensity values (VAS) comparing both groups.

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DISCUSSION

The results of the present study show that the application of the Calaject system seems to reduce pain during local anesthesia infiltration techniques in the palate. Although this trial yielded statistically significant differences between the two groups, additional studies with larger samples are required to confirm the clinical relevance of this system, since pain rating (VAS score) varied considerably between subjects (Fig 2). To our knowledge, no clinical trials have been published evaluating this system, and therefore these results add new information to the literature.

In general, most papers comparing traditional versus computer injection systems show beneficial results for the latter. However, these studies must be assessed individually since many of them have different designs and evaluate different injection locations and techniques (combination anesthetic techniques,[6-14] intraligamentary injections,[7,8,15-17] or inferior alveolar nerve blocks[13,18-22]).

The palatal area is often studied since the needle entry and injection are usually more painful.[1,8-13,19,23,24] Nonetheless, several variables vary considerably in these reports. For example, some samples only included adult healthy volunteers (dentists[1] and dental students[13]). In general, throughout the literature, the gender ratio is usually balanced, but in the present case most subjects were healthy young women (dental students of the University of Barcelona). Although this might slightly compromise the generalization of the results, sex is unlikely to be considered a distorting factor based on the findings of other authors such as Gibson et al[9] and Allen et al.[12]

Another interesting variable is patient's anxiety, since it affects pain perception.[22] In the present trial, all volunteers had low levels of anxiety (Table 1), probably due to the sample features (ie, dental students).

Although the sample size might be considered limited, the power calculation made before the study showed that 20 patients would be sufficient to complete the trial. In fact, the sample was increased to 25 to mitigate possible drop-outs that did not occur during the study. Therefore, we believe that this sample size is adequate. Furthermore, a split-mouth design was employed to reduce the variability and increase the statistical power of the analysis. In our opinion, this study design, also used by other authors,[1,10,14] seems to be ideal because it permits both procedures to be done in a single session, allowing a more direct comparison by the patient. On the other hand, some reports[22,23,25] perform the techniques in different appointments, which adds confounders (time and different wash-out periods among others), and compromises the reliability of the results. Nevertheless, split-mouth designs might lead to some limitations. Indeed, if the first stimulus produces intense pain, this factor could amplify the patient's response to the second injection. Also, when patients are given preparatory information without control instructions, as in the present trial, pain perception to the second stimulus can be enhanced. According to Williams et al,[26] preparatory information and control (ie, subject's ability to stop a painful stimulus) should be provided to patients before the injections. However, we think that the effect of these factors in our trial was limited since the sequence of the applied techniques was balanced (Table 1).

In some studies, especially in pediatric patients, topical anesthesia was applied prior to injection.[6,7,11,20,21,23,24,27] In this situation, pain perception can be significantly altered and might justify why the observed differences were not significant.[24,27]

It is also important to have information on the amount and type of anesthetic solution injected; perhaps it is even more critical to ascertain whether measures were taken to equal the injection time between the traditional and the controlled flow techniques. The impact of a shorter or longer injection time on pain perception is unknown, although one might expect fast infiltrations to be more painful, especially in an area like the palate. In most studies, this parameter is simply recorded with a general observation of a higher duration for the controlled flow system.[7,21] Nonetheless, some authors preferred to control this variable,[6] as in the present case, in which a similar time of 40 seconds was required to inject 0.3 mL of anesthetic solution. In

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four patients (case #21 was not considered because VAS pain ratings between sides were very similar), pain perception was higher when the Calaject system was employed (Table 1). The fact that injection rates were similar in both sides could have reduced the benefits of the controlled-flow system. The injection sequence can also partially explain these cases, since in three of these four patients the traditional syringe was used first and might have enhanced the response to the Calaject system injection. Needle insertion can also produce pain during dental anesthesia. However, in the present study, this parameter was not measured since both the experimental and control sides used the same needles.

Although pain is usually considered the main outcome measure in dental anesthesia trials, evaluation systems vary substantially, making comparisons among studies risky. In our opinion, VAS is the most appropriate tool to measure pain perception, since it is more sensitive than other tests. According to the criteria of Breivik et al[28] and Brailo and Zakrzewska,[5] the mean pain intensity values observed in the present trial could be classified as moderate (44.8 mm) for the traditional technique and mild (28.8 mm) for the controlled-flow injection system.

CONCLUSIONS

Given the parameters of the study's design, the injection of local anesthetics in the palatal area with the Calaject controlled-flow system seems to reduce pain, in comparison to the use of a traditional syringe. Well-designed prospective large sample randomized clinical trials are required to confirm this conclusion.

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