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### The efficacy of hypnosis compared with the tell/show/do technique for the reduction of anxiety/pain in children undergoing pulpotomies: a randomized controlled trial

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**ORIGINAL RESEARCH** 

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#### Abstract

Anxiety/pain is a combined experience that can hinder dental treatment in children and lead to the development of negative behaviours in any form of surgical treatment. Hypnosis is a suitable option with which to reduce anxiety and pain during dental treatment. In this study, we aimed to evaluate the efficacy of hypnosis compared to the tell/show/do technique for the reduction of anxiety and pain as measured by Face, Legs, Activity, Crying, Consolability (FLACC) scale in children undergoing pulpotomies. We performed a randomized and controlled clinical trial involving 60 children aged 5 to 7 years without previous dental experiences but with clinical and radiographic indications for pulpotomy in the primary mandibular right or left first or second molar. The children were divided into two groups: a control group (treated by conventional behaviour management techniques) and an experimental group (treated by hypnosis). The FLACC scale was used to evaluate anxiety/pain during preoperative, transoperative and postoperative pulpotomy treatment; we also analysed variations in heart rate and skin conductance. The trial was registered at ClinicalTrials.gov (NCT03739346). Statistical analysis was performed in R Studio version 1.2.1335. The FLACC scale was significantly lower in the experimental group (p = 0.022) throughout the entire treatment duration. In addition, heart rate and global skin conductance were both significantly lower in the experimental group when measured at different times (p = 0.005 and p = 0.032, respectively). When compared to conventional behavioural management techniques, the FLACC scale demonstrated that hypnosis was associated with significant reductions in heart rate, skin conductance and anxiety/pain throughout the entire duration of treatment. decreases anxiety/pain during the entire operative procedure. There was clear improvements in anxiety and pain control in patients receiving hypnotic therapy.

#### Keywords

Anxiety; Pain; Behavior; Hypnosis; Randomized controlled clinical trial

#### **1. Introduction**

Anxiety/pain is a combined emotion that a child experiences at the dental surgery which can generate negative behaviours during treatment [1], thus complicating dental care and hindering the possibility of establishing a trusting relationship between the dentist and the patient [2, 3]. Anxiety is an emotional state that precedes an event that may or may not occur. Some of the behaviours associated with anxiety can hinder the treatment of paediatric patients, reduce patient cooperation, increase the duration of procedures, increase the need for specific resources, and generally creates an overall unpleasant experience [4, 5]. The factors that cause dental anxiety can be exogenous previous and direct traumatic dental experiences; endogenous, personality traits; or indirect, negative dental experiences related to family members or the media that arouse fear in a child [1, 6, 7]. In addition, dental anxiety is known to be related to painful stimuli and increases pain perception; therefore, patients who experience this emotion tend to manifest more pain over a longer time period [4, 7, 8].

On the other hand, pain is an unpleasant somatic or visceral sensation that is associated with tissue damage that can be real, potential or perceived. Pain can be associated with anxiety to produce a distorted level of consciousness, along with increased environmental and non-specific reactivity to pain and vegetative reactions [9, 10]. Thus, in paediatric dental care, it is accepted that thoughts and ideas play an important role in dental pain, and that anxiety is likely to be the most important non-sensory component of the pain response [9].

However, anxiety and pain are difficult to assess [11], and

is reliant on the cognitive development of the child [12]; however, it is possible to assess children by monitoring certain physiological parameters, such as heart rate, respiratory rate, skin conductance, oxygen saturation, temperature [4, 13], hormone secretion and hyperglycaemia [11]. It is also possible to apply subjective methods, such as the application of anxiety or behavioural scales that are designed to acquire maximal information about the different dimensions of pain or anxiety perception and to assess cognition and emotional reactions to the painful experience [14]. In this sense, the Face, Legs, Activity, Cry, Consolability (FLACC) scale has adequate reliability and validity to assess anxiety/pain during surgical or medical procedures and other pain-producing processes in children [15]. This scale incorporates five different categories of behaviour that are scored from zero to two; these are then added together to reach scores ranging from zero to ten [15-17]. A score of 0-3 indicates that the child is still and comfortable (no discomfort or pain); a score of 4-7 indicates that the child is experiencing mild discomfort or moderate pain; and a score of 8-10 indicates that the child has severe discomfort or pain [18]. The use of this scale has been recommended for the assessment of pain in children between the ages of 3 and 18 years who are undergoing medical procedures [19, 20].

On the other hand, the most challenging aspect of paediatric dentistry is persuading the patient to readily accept treatment. Most paediatric patients experience great anxiety and fear during routine procedures [21, 22]. Thus, behaviour management problems can be overcome with effective communication, or behaviour management techniques alone or in combination [23, 24], to control the patient's anxiety [25, 26]. The tell/show/do technique is the most commonly used method in paediatric dentistry [24]. This technique is simple and easy to apply, and is effective from one stage to another without interruption and from the moment the child enters until he/she leaves the dental surgery [27]. It is important to familiarize the child with the environment and the instruments that will be used in the dental surgery as this will generate trust with the paediatric dentist [24]. In addition, hypnosis is considered a safe technique that allows the patient to focus on his or her inner world by including cognitive and behavioural components that allow the mind to influence perception and bodily sensation [7, 28]. Hypnotic therapy can be used in a variety of clinical situations to modify the perception of symptoms such as pain, anxiety and fatigue [28, 29]. Children are more receptive to this technique than adults because of their imaginative capacity and cognitive development [7]. Since their critical sensor or conscious minds are not mature, children accept ideas presented to them in a non-critical and indiscriminate manner and easily reach a state of increased susceptibility [22]. This technique is useful in children between 6 and 12 years-of-age, although from the age of 4 years, children can respond adequately to hypnosis [22, 30]. In dentistry, hypnosis has therapeutic applications that can help to reduce anxiety and the fear of dental procedures, increase pain threshold and reduce resistance to anaesthesia and muscle activity, salivation and excessive bleeding [31, 32]. However, hypnosis as an adjunct to paediatric dental procedures is generally underutilized [7, 22].

Therefore, the aim of this study was to evaluate the efficacy of hypnosis compared with the tell/show/do behavioural management technique for the reduction of anxiety/pain, as measured by the FLACC scale during preoperative, transoperative (during anaesthetic infiltration, the placement of absolute isolation, pulp chamber opening and temporary obturation) and postoperative periods, as well as heart rate (HR) and skin conductance (SC) in children undergoing pulpotomies.

#### 2. Materials and methods

#### 2.1 Patients

A randomized and controlled clinical trial was carried out, in which 60 paediatric patients (28 girls and 32 boys) between 5 and 7 years-of-age were selected. The selection criteria were as follows: no previous dental experiences; classification I of the American Society of Anaesthesiologists (ASA I) as determined by clinical history; attending the Paediatric Dentistry Clinic of the Autonomous University of San Luis Potosí, and clinical and radiographic indications for pulpotomy in at least one primary mandibular molar (right or left, first or second). The exclusion criteria were as follows: specific medical conditions; previous experience of hypnosis; allergy to anaesthetics and deafness. The parents of the children provided informed and signed consent, and each child signed a letter of assent. Due to the methodological weaknesses of previous studies with similar characteristics to this present study, we initially proposed to conduct a pilot study that would allow us to estimate an adequate sample size. According to the procedure described by Browne [33], 30 patients were required for each study group, meaning that a total of 60 patients were needed to perform the study.

Two evaluators were responsible for independently judging the FLACC scale [23]; these evaluators were previously trained on the measurement instrument, categories, scores and determinants. A video recording of each patient was used to score the FLACC scale before, during, and after the primary mandibular molar pulpotomy procedure. The evaluators were blinded to the study group to which each patient belonged.

For heart rate and skin conductance measurements, we used Nexus 10 Biofeedback and Biotrace V2015B software. (Mind Media, Louis Eijssenweg 2B6049 CD Herten, Netherlands). A blood volume sensor was placed on the index finger of the child's left hand, while the Ag-AgCL electrodes were placed on the ring and middle finger of the same hand. Skin conductance is an extremely accurate objective method as variations in the measurement of skin electrical conductivity reflects the psychophysiological arousal produced by external stimuli and has been used in several studies to measure anxiety/pain during dental treatment. Skin conductance refers to the variation of electrical properties in the skin when sweating occurs. These variations can be measured by applying a low-intensity direct current in a non-invasive manner [11, 34].

For the 60 patients, measurements were taken at six operative times: the preoperative period, the first three minutes before starting the procedure (time 1, baseline), the time of anaesthetic infiltration (time 2, minute 12–14), the placement of absolute isolation (time 3, minute 17–20), chamber opening pulp (time 4, minute 22–25), temporary filling (time 5, minute 27–28) and postoperative (time 6, minute 30–32).

#### 2.2 Procedure

Patients who met the selection criteria were randomized by symmetrical blocks and divided into two groups: an experimental group and a control group. The conventional behavioural management technique of tell/show/do was used in the control group and hypnosis therapy was performed in the experimental group; this strategy ensured that patients in both groups remained calm, comfortable and responsive during treatment. Both groups were told about the functions of the sensors and electrodes and what they might feel before electrode placement.

Patients that belonged to the control group were seated in the dental chair and received a detailed description of each of the instruments in the work tray and what each part of the dental chair was for. Instruction was given in a simple manner so that the children could understand and assimilate the information being given. We also described what the patient might feel, see and smell. Headphones were fitted to each patient (without any sound) and the patient was told that the headphones were to reduce the sound of the high-speed piece during the procedure. Subsequently, anaesthetic infiltration, absolute isolation with a rubber dam, opening of the pulp chamber and temporary filling were performed. We timed each stage of the procedure from beginning to end, without losing verbal communication with the patient and always applied the "tell/show/do" technique into practice. The objective of providing headphones in the control group was to keep the FLACC evaluators blinded to which group each patient belonged to.

Once patients in the experimental group had been seated in the dental chair, they were given headphones so that they could listen to hypnosis therapy (presented in an audio output device). Prior to this, we explained what the headphones were for and told the patients not to remove the headphones at any point. We also told the patients to listen carefully to the material being played on the headphones. The audio file featuring hypnosis therapy was started, and we began collecting data or signals that would indicate that the patient was following the instructions contained in the audio file. The first stage of dental treatment was carried out at the time when the hypnosis therapy allowed it; each stage of dental treatment was carried out consecutively. The hypnosis therapy was subsequently terminated and we verified that the patient had continued to be attentive, consciously following the instructions given and cooperating with treatment.

#### 2.3 Statistical analysis

Data were analysed using R Studio (version 1.2.1335, R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org). The normality of the data was analysed by the Shapiro-Wilk test. An intraclass correlation coefficient and Lin's correlation coefficient were used to assess the inter-rater reliability of the FLACC scale. Descriptive analysis was performed according to the type of variable and its normality in terms of mean, standard deviation, median and interquartile ranges (IQR). A Student's *t*-test for independent

samples, or its non-parametric equivalent, the Mann Whitney U test, were used to compare the two groups at each operative time;  $p \le 0.05$  was considered statistically significant.

#### 3. Results

A controlled and randomized clinical trial was conducted with sixty children aged 5 to 7 years who were randomly assigned to an experimental group or control group (32 boys and 28 girls). The experimental group featured 14 females and 16 males with a median age of 73 months, while the control group featured 14 females and 16 males with a median age of 71 months. A Consolidated Standards of Reporting Trials (CONSORT) flow diagram of this study is shown in Fig. 1.

Analysis yielded a Lin's concordance correlation coefficient of 0.92 (95% confidence interval (CI): 0.81–0.96), thus providing moderate concordance and an intraclass correlation of 0.92 (95% CI: 0.81–0.97). According to Landis and Koch, there was almost perfect concordance between evaluators with regards to the FLACC scale score.

Table 1 shows baseline measurements for the two study groups; there was a statistically significant difference between the two study groups with regards to the FLACC scale and skin conductance (SC).

With regards to the measurement of anxiety/pain by the FLACC scale, we observed a significant difference in FLACC1 (baseline) and FLACC2 (the time corresponding to anaesthetic infiltration). However, there were no significant differences at any of the other timepoints, although there was a reduction (at one timepoint) in the experimental group (hypnosis therapy), as shown in Table 2.

Table 3 shows the skin conductance measurements for both groups; there was a significant difference in SC1 (baseline), SC5 (temporary filling) and SC6 (postoperative).

In terms of heart rate (HR), we observed a significant reduction in beats per minute (bpm) during the transoperative times (the times of anaesthetic infiltration, placement of absolute isolation, opening of the pulp chamber and temporary obturation) in patients who received hypnosis therapy; this change was attributable to hypnotic therapy, as shown in Table 4.

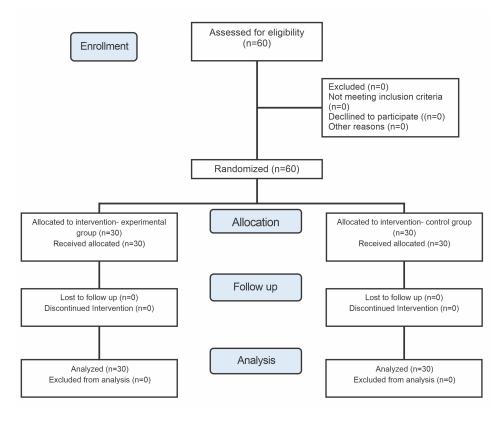
Fig. 2 shows the difference in the medians of the global measurements of the FLACC scale (FLACCGLOB) of both groups, finding statistically significant differences p = 0.022.

Fig. 3 shows that there was a significant reduction in global skin conductance (SCGLOB) throughout the entire duration of observation in the group that received hypnosis therapy when compared to the group that received conventional behavioural management techniques (p = 0.032).

Fig. 4 shows a comparison of HR between the experimental group and the control group throughout the treatment; the mean HR of the experimental group throughout the treatment was 91.0 bpm; this was significantly lower than that in the control group at 99.9 bpm (p = 0.005).

#### 4. Discussion

One of the objectives of paediatric dentistry is to ensure that dental care is pleasant and free of anxiety/pain in children, to improve behavioural management techniques and the impact



#### FIGURE 1. Flowchart of the participants in the clinical trial.

TABLE 1. Baseline characteristics of the study groups.

	Control group		Experimental group		<i>p</i> -value*
	(n = 30)		(n = 30)		
	Median	IQR	Median	IQR	
Age (mon)	71.0	22.2	73.0	20.5	0.529
FLACC1	0.0	1.0	0.0	0.0	0.032
SC1	4.2	4.1	2.0	2.7	0.047
HR1	88.3	27.4	88.5	12.8	0.529

*FLACC1: FLACC scale (baseline); SC1: Skin conductance (baseline); HR1: Heart rate (baseline); IQR: interquartile ranges.* \*: Mann Whitney U test,  $p \le 0.05$ .

TABLE 2	. FLACC scale scores	s in the different	operative times	between groups.

Variable	Control group		Experimental group		<i>p</i> -value*
	(n = 30)		(n = 30)		
	Median	IQR	Median	IQR	
FLACC1	0.0	1.0	0.0	0.0	0.032
FLACC2	2.0	3.0	0.5	2.0	0.001
FLACC3	1.0	3.8	0.5	1.8	0.140
FLACC4	3.0	5.0	1.5	4.0	0.148
FLACC5	0.0	2.8	0.0	1.0	0.245
FLACC6	0.5	1.8	0.0	1.0	0.241
FLACCGLOB	2.2	2.8	0.8	0.8	0.022

*FLACC1: FLACC scale (baseline); FLACC2: FLACC scale (time of anesthetic infiltration); FLACC3: FLACC scale (placement of absolute isolation); FLACC4: FLACC scale (chamber opening pulp); FLACC5: FLACC scale (temporary filling); FLACC6: FLACC scale (postoperative); FLACCGLOB: FLACC global scale; IQR: interquartile ranges.* \*: Mann Whitney U test,  $p \le 0.05$ .

Variable	Control group $(n = 30)$		Experimental group (n = 30)		<i>p</i> -value*
	Median	IQR	Median	IQR	
SC1	4.2	4.1	2.0	2.7	0.047
SC2	5.4	4.6	3.6	4.9	0.253
SC3	5.8	4.7	4.3	3.2	0.077
SC4	5.4	6.2	3.2	2.5	0.063
SC5	5.2	4.7	2.3	1.9	0.028
SC6	4.4	4.2	2.7	2.2	0.032
SCGLOB	4.8	3.8	2.8	3.2	0.032

TABLE 3. Comparison of skin conductance between the study groups.

SC1: Skin conductance (baseline); SC2: Skin conductance (time of anesthetic infiltration); SC3: Skin conductance (placement of absolute isolation); SC4: Skin conductance (chamber opening pulp); SC5: Skin conductance (temporary filling); SC6: Skin conductance (postoperative); SCGLOB: Global Skin conductance; IQR: interquartile ranges. \*: Mann Whitney U test,  $p \le 0.05$ .

	TABLE 4.	Comparison of the hea	art rate of patients bet	ween the groups.	
Variable	Control group		Experimental group		<i>p</i> -value
	(n = 30)		(n = 30)		
	Median	IQR	Median	IQR	
HR1	88.3	27.4	88.5	12.8	0.529‡
HR2	97.9*	16.7**	83.9*	15.9**	$0.001^{\dagger}$
HR3	105.5*	22.1	93.2*	19.8**	$0.026^{\dagger}$
HR4	102.4	23.6	91.8	17.2	$0.014^\dagger$
HR5	100.4	20.8	89.3	25.5	$0.032^{\dagger}$
HR6	97.3*	18.9**	92.8*	18.3**	0.351‡
HRGLOB	99.9*	13.1**	91.0*	10.4**	$0.005^{\dagger}$

HR1: Heart rate (baseline); HR2: Heart rate (time of anesthetic infiltration); HR3: Heart rate (placement of absolute isolation); HR4: Heart rate (chamber opening pulp); HR5: Heart rate (temporary filling); HR6: Heart rate (postoperative); HRGLOB: Global heart rate; IQR: interquartile ranges. \*: mean; \*\*: standard deviation; †: Student t test, ‡: Mann Whitney U test,  $p \leq 1$ 0.05.

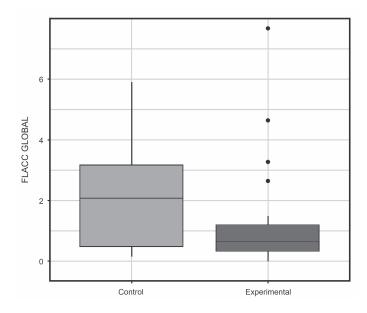


FIGURE 2. FLACC global scale scores throughout the treatment of the study groups. FLACC: Face, Legs, Activity, Crying, Consolability.

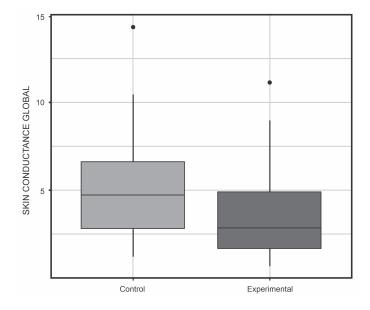


FIGURE 3. Comparison of medians between the study groups of skin conductance during the entire treatment.

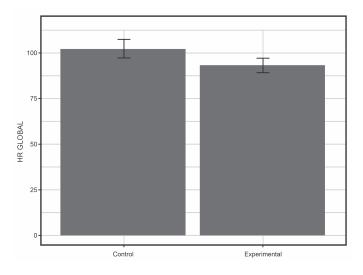


FIGURE 4. Comparison of mean heart rate throughout treatment between study groups. HR: heart rate.

that these have on their behaviour, and to implement new forms of care or modify existing forms of care. Therefore, the purpose of this research was to evaluate the efficacy of hypnosis therapy and the tell/show/do technique as behavioural management tools for the reduction of anxiety/pain in children undergoing pulpotomy procedures. The data collected were evaluated with a validated behavioural scale for the measurement of pain/anxiety and physiological data known to be related to anxiety/pain states were monitored and analysed at six different times during surgery. Pulpotomies are one of the procedures that can induce anxiety/pain in a child. We found that hypnosis significantly reduced the levels of anxiety and pain when used in children undergoing pulpotomies; these children were more relaxed throughout the procedure. This finding was consistent with a previous study which used a modified Yale preoperative anxiety scale (mYPAS), a visual analog scale (VAS), and a modified objective pain score (mOPS), to assess anxiety and pain in children aged 7-12 years who received local anaesthesia [32]. The authors reported that anxiety scores were 50% lower in the group that received hypnosis; furthermore, these children felt no pain or reported only mild pain when compared to the group that did not receive hypnosis; the authors concluded that hypnosis was effective in reducing anxiety and pain [32]. Similar results were reported by Sabherwal et al. [1] who assessed anxiety in children aged 8 to 12 years undergoing primary molar extractions at baseline, after local anaesthesia and after extraction, by measuring the Visual Facial Anxiety Scale (VFAS) and the Wong-Baker Face Pain Scale at pre- and postoperative timepoints [1]. These authors reported a significant reduction in anxiety and pain in the group that received hypnosis therapy. Similarly, Gokli et al. [35] reported that children who were hypnotized showed better behaviour (less crying, hand movement, physical resistance and leg movement) when they received local anaesthesia than those who were not hypnotized. However, Ramírez-Carrasco et al. [2] reported no significant differences when anxiety was assessed with the FLACC scale during local anaesthesia between children who received hypnosis and hypnosis combined with the tell/show/do technique.

In the present study, and despite the differences identified

between the two groups with respect to the FLACC variable, our original hypothesis was rejected. This was because we did not observe the hypothesized difference between the two groups (2 points less on the FLACC scale in the experimental group over the entire treatment). However, it is essential to mention that a reduction of 1 point on the scale represents a major improvement for clinical practice, especially for the operator, who perceived that the children experienced less anxiety/pain anxious/painful and showed more positive behaviour in the experimental group when compared to children in the control group.

Skin conductance is not only affected by the general mood of a patient, it can also be influenced by immediate emotional reactions that are used in psychophysiological experiments to infer the emotional state and cortical arousal in response to stressful situations [36]. These factors have led to skin conductance tests being used in several studies to measure dental anxiety as an objective and precise method [4].

In a previous study, Najafpour *et al.* [11] compared skin conductance against the modified infant dental anxiety scale and the clinical anxiety rating scale and revealed a statistically significant correlation, thus confirming the validity of skin conductance to detect anxiety levels in children during dental treatment.

The results of the present study showed that the median skin conductance reading decreased significantly throughout treatment in the children who received hypnosis, with statistically significant differences being observed at the beginning of the treatment and at the end. The statistically significant differences between the groups in terms of FLACC scale and skin conductance can be attributed to the fact that the children who belonged to the experimental group commenced their treatments under the effect of hypnosis; this modified their behaviour and made them feel more relaxed. These characteristics were very different from those elicited by children in the control group.

Our results can be reinforced by comparing variations in heart rate. We detected statistically significant differences of HR between the experimental group and control group at most of the transoperative times, especially at the time of anaesthetic infiltration and during the opening of the pulp chamber. These results suggest that hypnosis could reduce anxiety/pain at times when procedures are more invasive and painful, such as pulpotomies.

In a similar investigation, researchers observed a reduction in heart rate at the time of anaesthetic infiltration in patients who were hypnotized; this led to a 4 bpm reduction in HR; in comparison, an increase of 10 bpm was detected in nonhypnotized patients [35]. These findings are consistent with those observed by Oberoi *et al.* [22] who found that hypnotized patients showed a reduction in heart rate of 14 bpm and an increase of four bpm in non-hypnotized patients, thus demonstrating that hypnosis is effective for procedures that can cause anxiety and pain, such as anaesthetic infiltration; similar findings were also reported by Ramírez-Carrasco *et al.* [2].

Most previous studies that have measured the efficacy of hypnosis in children during dentistry procedures performed their evaluations at the time of anaesthetic infiltration [2, 22, 32, 35], during extraction procedures, or in the primary molars after extraction [1]. However, in this study, we evaluated 6 operative times and focussed exclusively on hypnosis; our patients did not receive any other form of behavioral management technique [2]. In addition, we observed significant differences in overall measurements during dental procedures, as determined by reductions of the FLACC scale, skin conductance and heart rate in the experimental group.

These differences between children undergoing hypnosis and the tell/show/do technique could be attributed to a child's relaxed mental state, an increasing pain tolerance threshold [22], or the child being too focused on the audio recording instructions (hypnosis therapy). Our data suggest that children became calmer and more relaxed as the treatment progressed.

Hypnosis has significant therapeutic benefits in medicine/psychology. In dentistry, hypnosis has several potential therapeutic and surgical advantages, such as the management of dental phobia, anxiety, behaviour modification, habit modification and analgesia [37]. Furthermore, children are more easily hypnotized than adults, particularly before the age of 12 years. This is because their conscious minds are immature, highly imaginative and generally not dominated by the logic that pervades adult experiences [38].

Hypnosis may represent a relatively safe alternative to general anaesthesia for patients experiencing extreme phobia or anxiety [38]. In our research, we observed that hypnosis can help paediatric patients to feel more comfortable and relaxed during painful or invasive procedures. This may also facilitate subsequent appointments by motivating positive behaviour and by improving patient cooperation. However, its application in paediatric dentistry remains limited [22].

Similar studies should be conducted by following up patients receiving hypnosis to specifically assess their behaviour at subsequent appointments or during less invasive treatments. This research should also include patients who demonstrate disruptive or negative behavior at their first appointment, even if they have never received dental care.

#### 5. Conclusions

We investigated the effect of hypnosis as a behavioural management technique in children undergoing pulpotomies in primary molars. Our analysis showed that hypnosis was a useful tool for managing a child's behaviour during dental treatment, while also increasing cooperation and reducing resistance during pulpotomy procedures. Furthermore, hypnosis led to a considerable reduction in anxiety/pain, heart rate and skin conductance. These changes were observed throughout the entire duration of treatment and not just at operative times associated with greater anxiety/pain, such as local anaesthesia and opening the pulp chamber.

#### AVAILABILITY OF DATA AND MATERIALS

The data that support the findings of this study are available on request from the corresponding author.

#### AUTHOR CONTRIBUTIONS

CBTG—contributed to the study design, interpretation of the data and critically drafting and reviewing the manuscript. ARC—did the procedures, statistical analysis, interpretation of the data and critically drafting and reviewing the manuscript. OSAC—contributed to the interpretation of the data and critically drafting and reviewing the manuscript. APG—contributed to the interpretation of the data and critically drafting and reviewing the manuscript. APG—to the study design, statistical analysis, interpretation of the data and critically drafting and reviewing the manuscript. MPP—contributed to the study design, statistical analysis, interpretation of the data and critically drafting and reviewing the manuscript.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the Ethics and Research Committee of the School of Stomatology of the Autonomous University of San Luis Potosí and assigned the code number CEI-FE-032-017. Informed consent to participate in the study was obtained from the children's parent or their legal guardian.

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#### **CONFLICT OF INTEREST**

The authors declare no conflict of interest. Amaury Pozos-Guillén is serving as one of the Editorial Board members of this journal. We declare that Amaury Pozos-Guillén had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to AS.

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