



Effect of Occlusal Adjustment on Postoperative Pain after Root Canal Treatment: A Randomized Clinical Trial

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The aim of this prospective, randomized, clinical study was to analyze the influence of occlusal adjustment on the prevalence of postoperative pain after endodontic treatment. Seventy-eight patients, diagnosed with symptomatic irreversible pulpitis with indication for endodontic treatment, were selected to participate in the study. The participants were randomized and divided into two groups: in the occlusal adjustment group (OAG), endodontic treatment was performed with subsequent occlusal adjustment. In the control group (CG), endodontic treatment was performed without occlusal adjustment. Treatments were performed by the same operator. Pain occurrence and intensity were recorded on two scales: the verbal rating scale (VRS) and numerical rating scale (NRS). Pain assessment was carried out by a second examiner, blinded to the experiment, 6, 24 and 72 h after endodontic treatment. Data were analyzed using Mann-Whitney, chi-squared, and Fisher's exact tests. In the occlusal adjustment group, 71.1% reported postoperative pain and 67.5% reported pain in the control group. At the 6-hour assessment, 21 individuals reported pain in the occlusal adjustment group and 24 in the control group ($p=0.672$). At the 24-hour assessment, 18 and 19 individuals reported pain ($p=0.991$) and at the 72-hour assessment, 8 and 4 reported pain ($p=0.219$), respectively. Occlusal adjustment did not influence the prevalence of postoperative pain of endodontically treated teeth with symptomatic irreversible pulpitis.

Key Words: clinical trial, postoperative pain, endodontics, occlusal adjustments.

Introduction

The occurrence of postoperative pain is not a rare outcome after endodontic treatment. According to the systematic review by Sathorn et al. (1), it occurs in 3-58% of patients, being more common within the first 24 h and pain reducing to a minimum in 7 days.

Pain intensity following endodontic treatment is frequently mild to moderate, but it may be severe at times. Given the high frequency of postoperative pain, several studies have been carried out in an endeavour to seek treatments using different techniques, substances, instrumentation protocols, and photobiomodulation therapy to minimize pain occurrence (1-5). However, several aspects require elucidation; among them the role of occlusal adjustment after endodontic treatment (6-9). The cause of pain after endodontic treatment is multifactorial, which could be related to the procedures, instruments, medication, and substances used before, during, or after biomechanical preparation of the root canal system, as well as aspects related to the pulp or periapical pathology, which can play an important role in the development of postoperative pain (1,3,10-13).

It is believed that one of the possible causes of pain after endodontic treatment may be the incidence of occlusal

forces in the endodontically treated tooth area that would trigger mechanical allodynia and prolong postoperative pain. Mechanical allodynia can be defined as a reduction in pain threshold, whereas pain occurs in response to innocuous thermal and mechanical stimuli (14-19).

This mechanism is not well established, but it has been suggested that occlusal forces involving asensitized area with activation of pulp and periapical mechano receptive nociceptive neurons and pulp nociceptors may initiate mechanical allodynia (15,16). Few studies have sought to assess the influence of occlusal adjustment on postoperative pain and its role is not clear in the literature. The few existing studies present inconsistent criteria that make it difficult to understand the role of occlusal adjustment for pain prevention and control. Aspects related to the research design concerning selection biases and confounders such as pulpal and periapical pathologies, endodontic instrumentation techniques, intracanal medication, calibration in case of multiple operators, and information on randomization, require further explanation for the results to be fully understood (6-9).

Thus, the aim of this study was to conduct a randomized, controlled, clinical study to assess the influence of occlusal adjustment on postoperative pain after endodontic

treatment in teeth with symptomatic irreversible pulpitis.

Material and Methods

Description of Trial Design

The present study was approved by the Research Ethics Committee of the Federal University of Amazonas (CAAE n°58815116.1.0000.5020) and published in the Brazilian Registry of Clinical Trials - REBEC (UTN U1111-1187-0353). This is a randomized, controlled, double-blinded, parallel-controlled clinical study. The study was conducted at the dental clinic of the Federal University of Amazonas, Manaus, Brazil, from December 2016 to September 2017, with patients needing endodontic treatment. Written consent was obtained from all individuals who participated in this clinical trial.

Sample size was calculated using G*Power, version 3.1.9.2. A total of 78 patients would be required to achieve 90% power, with an α value of 5%, and a difference of 30% in the prevalence of any postoperative pain between the control and experimental group, adopted based on the previous studies conducted by Rosenberg et al. (7) and Lopes et al. (5).

Men and women, aged 18–60 years, diagnosed with symptomatic irreversible pulpitis, without periapical diseases, with indication for endodontic treatment in molar teeth, except for third molars, and with teeth in occlusal contact only by tooth structure, were included in the study. Diagnosis was confirmed by cold thermal testing. The cold spray (Endo-Frost; Coltene-Whaledent, Langenau, Germany) was applied on the occlusal surface of the molar for 5 second with the aid of a cotton swab. If the molar responded positively to the test, occlusal contact was confirmed with articulating paper for the tooth to be eligible for the study (Table 1).

Exclusion criteria included patients at any stage of

pregnancy, who were on anti-inflammatory or antibiotic medication, immunocompromised, hypersensitive to anti-inflammatory drugs, presented previous diagnosis of bruxism or dental clenching, signs and symptoms of temporomandibular disorders, unrestorable teeth, coronal coverage, teeth with endodontic complications or any type of apical periodontitis or severe periodontal diseases, as any of these conditions could interfere with the analysis of the presence of pain after endodontic treatment.

The randomization process was performed using the Sealed Envelope® program (sealedenvelope.com - Exmouth House, London, UK) by a third researcher who was not involved in the research protocol. A list was generated for random allocation of the 78 subjects in the groups, stratified by sex, divided into 4 blocks. Each sequence of randomized numbers was individually placed in opaque, sealed, and sequentially numbered envelopes. After the endodontic protocol, the numbered envelope was opened by the operator to know in which group the patient would be allocated. Patients were unaware of their allocation.

Of the 162 patients considered eligible for the study, 84 did not meet the inclusion criteria. Thus, 78 patients participated in the study and they were divided into two groups: 38 patients in the occlusal adjustment group and 40 patients in the control group (Fig. 1).

Endodontic Treatment Protocol

The endodontic treatment protocol was based on work published by Lopes et al. (5) before endodontic treatment, clinical and periapical radiographic examination was carried out again to confirm the diagnosis of irreversible pulpitis as well as verification of occlusal contact with the aid of articulating paper. As preoperative pain is an important factor that can influence the outcome of the study, it was

E. C. B. Vianna et al.

Table 1. Demographic and clinical data of recruited patients

Variable	OAG (n=38)	CG (n=40)	p-value
Mean age	29.7 ± 9.0	27.4 ± 8.1	0.238
Gender			0.749
Men	12 (31.6%)	14 (35%)	
Women	26 (68.4%)	26 (65%)	
Extrusion of material filling			0.260
Yes	17 (44.7%)	23 (57.5%)	
No	21 (55.3%)	17 (42.5%)	
Systemic diseases	None	None	-
Preoperative pain (VRS)	2.5 ± 0.71	2.3 ± 0.47	0.175

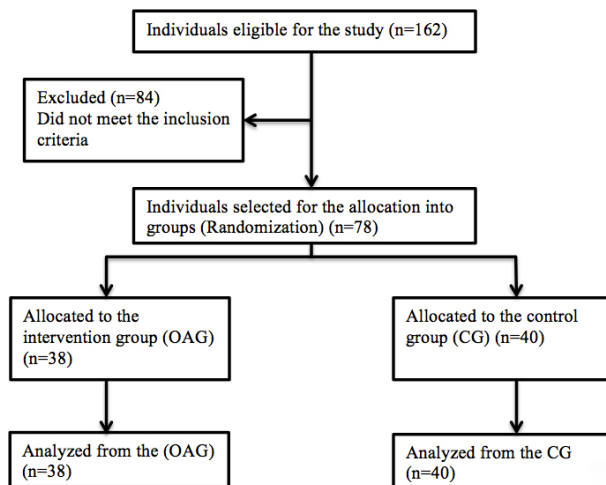


Figure 1 Flow diagram CONSORT for randomized clinical trials

have to return for follow-up evaluation, as they were contacted by telephone. First, the researcher asked the patient to rate pain using the verbal rating scale and then to rank the symptom on the numerical scale from 0 to 10.

Statistical Analysis

The demographic and clinical characteristics of the individuals included in each study group were described. Continuous variables were described by mean and standard deviation and categorical variables by absolute and relative frequencies.

The evolution of postoperative pain throughout the study was also demonstrated by means of line charts. The proportion of individuals with pain was compared by chi-squared and Fisher's exact tests ($p < 0.05$). Multiple nonparametric regression analyzes for the outcomes of postoperative pain at 6h, 24h and 72h were also performed to evaluate the intervention without the effect of possible confounding.

The comparison of pain scores between the two groups at each time interval was performed using Mann-Whitney test (Wilcoxon rank-sum) for non-parametric data ($p < 0.05$). The evolution of pain within each group was assessed by the paired Wilcoxon test. T-tests were further carried out to contribute to the discussion about probability of a type II error in non-parametric analysis. All analyses were performed in software Stata/IC, version 15 (StataCorp, TX).

Results

In the occlusal adjustment group, 71.1% (n=27) of the individuals reported postoperative pain and 67.5% (n=27) in the control group. The number of individuals who reported pain as well as pain intensity decreased over the period analyzed.

Twenty-one individuals in the occlusal adjustment group and 24 individuals in the control group reported

pain within 6 h ($p=0.672$). After 24 h, 18 and 19 individuals reported pain ($p=0.991$) and 8 and 4 individuals reported pain after 72 h ($p=0.219$), respectively.

There were no statistically significant differences in the intensity of postoperative pain between the groups after 6 h (VRS, $p=0.719$, NRS, $p=0.547$), 24 h (VRS, $p=0.906$, NRS, $p=0.987$) and 72 h (VRS, $p=0.178$; NRS, $p=0.176$) on both the VRS and NRS. The mean values of the scales at each time are shown in Figure 3, 4 and Table 2. Only one patient reported taking postoperative medication (Ibuprofen 600mg). Extrusion of filling material also had no relation with postoperative pain in the three evaluated times [VRS, $p=1.000$ (6h), $p=0.588$ (24h), $p=0.150$ (72h); NRS, $p=0.878$ (6h), $p=0.559$ (24h), $p=0.120$ (72h)]. Table 3 shows the adjusted effects of multiple regression analyzes confirming the non-significant effect of the intervention on postoperative pain.

The reduction of pain scores on both scales was significant for both groups between 6h and 72h ($p < 0.001$). However, pain reduction between 6h and 24h was significant only for the group without occlusal adjustment (VRS, $p=0.031$, NRS, $p=0.008$). Stratified analysis according to intervention and extrusion of material filling did not influence the results at 6-72h interval, but at 6-24h pain reduction in group without occlusal adjustment was observed only among individuals without material extrusion (VRS, $p=0.033$, NRS, $p=0.028$). All the results obtained through t-tests were similar.

Only one patient (control group) reported taking postoperative medication (Ibuprofen) for 24h. The results did not differ when the data were reanalyzed without the inclusion of this patient.

Discussion

It was postulated that aggression to the periapical tissues, originating from pulp pathology or endodontic

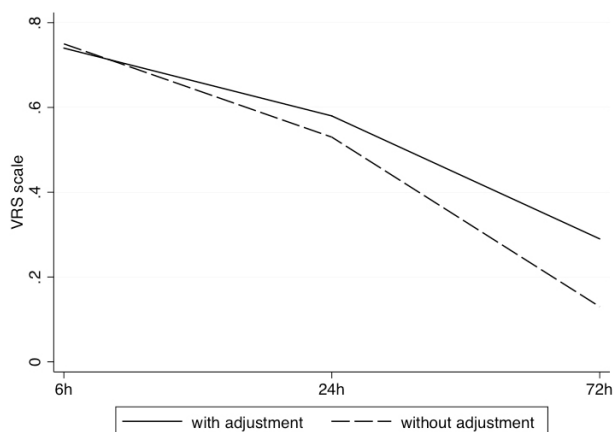


Figure 3 Evolution of pain on the VRS

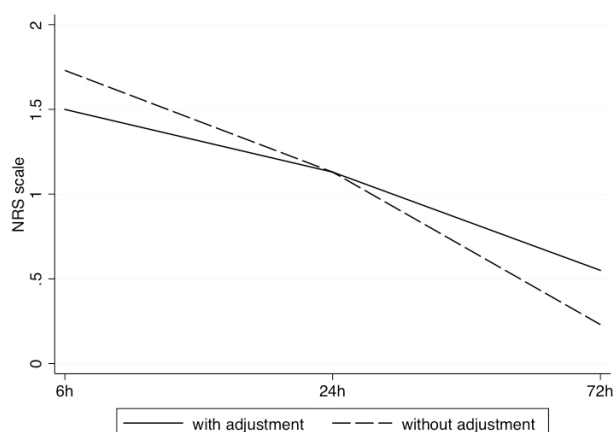


Figure 4 Evolution of pain on the NRS

treatment, would result in the release of chemical mediators, sensitization of voltage-regulated sodium channel molecules and nociceptors, causing a change in the response pattern, among them mechanical allodynia, which is caused by non-painful stimuli. Mechanical allodynia is defined as a reduction in pain threshold, with pain occurring in response to innocuous thermal and mechanical stimuli (15-19).

However, the incidence of occlusal forces after endodontic treatment does not seem to influence the occurrence of postoperative pain when the physiological occlusion of the patient is maintained, which is in

Table 2. Primary outcomes of prevalence of postoperative pain mean (\pm SD)

	VRS		
	6 h	24 h	72 h
With adjustment	0.74 (0.83)	0.58 (0.72)	0.29 (0.65)
Without adjustment	0.75 (0.71)	0.53 (0.60)	0.13 (0.40)
	NRS		
	6 h	24 h	72 h
With adjustment	1.50 (1.75)	1.13 (1.49)	0.55 (1.33)
Without adjustment	1.73 (1.83)	1.13 (1.44)	0.23 (0.77)

Table 3. Multiple nonparametric regressions for the outcomes of postoperative pain, adjusted effect estimates (p-values)

	VRS		
	6 h	24 h	72 h
Group (ref.: without adjustment)	0.01 (0.958)	0.13 (0.423)	0.21 (0.099)
Gender (ref.: female)	-0.31 (0.094)	-0.40 (0.001**)	-0.26 (0.011*)
Extrusion of material filling (ref.: no)	-0.02 (0.922)	0.19 (0.217)	0.22 (0.058)
Age	-0.01 (0.608)	-0.02 (0.076)	-0.01 (0.161)
	NRS		
	6 h	24 h	72 h
Group (ref.: without adjustment)	-0.17 (0.635)	0.10 (0.672)	0.42 (0.086)
Gender (ref.: female)	-0.89 (0.026*)	-0.91 (0.010*)	-0.53 (0.011*)
Extrusion of material filling (ref.: no)	-0.23 (0.581)	0.32 (0.353)	0.33 (0.225)
Age	-0.02 (0.390)	-0.03 (0.180)	-0.02 (0.210)

Effect estimates are averages of derivatives for continuous covariates and averages of contrasts for factor covariates

* $p < 0.05$, ** $p < 0.01$

agreement with the results found by Jostes and Holland (6), Parirokh et al.(8) and Arslan et al.(9).

Another justification for this finding may be the phenomenon of impulse deceleration and parallel sensory adaptive response, which is the inactivation of some isoforms of sodium channels caused by the great activity of these channels in the sensitized tissue, which results in the reduction of the impulse affecting the activation of mechanically sensitive nerve fibers, such as type C fibers. The biophysical process underlying the deceleration of the impulse leads to an increase in the mechanical threshold and probably results in decreased pain perception (20-22).

There are few studies on the influence of occlusal adjustment on postoperative pain after endodontic treatment and they present few comparable criteria, which makes it difficult to understand the role of occlusal adjustment in pain prevention and control. The study by Jostes and Holland (6) found that occlusal adjustment did not influence patient comfort within six (6) days following endodontic instrumentation. The authors included 58 posterior teeth diagnosed with different pulp and periapical pathologies with indication for endodontic treatment. Endodontic instrumentation was performed by several operators and the technique used was not reported. The authors reported failure to detect variables that could hinder or reduce discomfort due to the limited number of individuals and the large number of variables.

The study by Rosenberg et al. (7) found that occlusal adjustment could prevent postoperative pain after endodontic instrumentation in teeth with pulp vitality. The limitations of the study included selection bias, confounders, and limited information about randomization. In addition, the molars presented different pulp and periapical pathologies and the endodontic protocol was performed using the step-back technique with the aid of manual instruments, and patients with bruxism were included in the study.

The study by Arslan et al. (9) did not find any statistically significant differences between the groups with semi-adjustment, complete, and without occlusal adjustment after 1, 3, 5, and 7 days regarding the levels of postoperative pain levels after endodontic treatment. The study was the only one to assess pain after root canal obturation, it included a sample of 35 molars diagnosed with symptomatic apical periodontitis and single-visit treatment was performed using the ProTaper® rotating system (Dentsply Maillefer, Ballaigues, Switzerland). The study used computerized occlusal analysis system (T-Scan II) to quantify force exerted on the endodontically treated tooth.

Differing results may be explained by the influence of preoperative pain on the outcome of studies (7,23). The results of this study also differ from those of Emara et al. (24) who detected differences in postoperative pain levels after endodontic treatment in the occlusal reduction group, which can explain the high levels of preoperative pain in the sample and may exacerbate the allodynia phenomenon.

The mean postoperative pain rates in this study are low in comparison with previous studies, which is explained by the study design as it involves the standardization of the dental group, moderate preoperative pain rate, and single-session endodontic protocol with a single operator. Similar results were observed in the studies of Relvas et al. (4) and Lopes et al. (5) using similar protocols.

One point to be discussed is the method for recording occlusion. Traditionally, occlusion analysis is performed with articulating paper marking the contacts. Recently, computerized occlusal analysis has been used in scientific studies with the purpose of tracing the distribution of forces of occlusion using pressure-sensitive sheets, which is not possible in daily clinical situations using conventional methods. However, this method does not produce any contact markings intraorally for posterior adjustment of occlusion and it has been demonstrated that a combination of methods of computerized occlusion analysis with marking foils would be ideal, which would allow the occlusal contacts described by the computer to be marked intraorally with an even higher accuracy (9,16).

Pain assessment was performed using verbal and numerical scales. According to Williamson and Hoggart (25), patients prefer the verbal rating scale because it is simple, but it is the least sensitive of the scales. The numerical rating scale is more efficient, relatively easy to interpret, and it has greater statistical sensitivity. The protocol of using two scales was also adopted in the study by Lopes et al. (5).

In this clinical study, both scales presented similar values and showed no statistically significant difference in the evaluation within 6, 24 and 72 h after endodontic treatment. The choice of these pain scales was due to their efficiency and ease of evaluation through telephone calls, thus avoiding the need for a second session.

Among the limitations of this study are the inclusion of men and women and a wide window of ages (18-60 years). To eliminate this effect, patients were randomized to ensure comparability between the groups. Another factor is the difficulty in evaluating subjective aspects, such as pain and the presence of other factors that may influence the presence and intensity of pain. In order to minimize this effect, clarifications were provided about pain assessment and the instruments were applied by a single researcher-examiner using a standardized approach.

Regarding baseline factors such as gender, age,

overfilling and preoperative pain, the nonparametric multiple regression analyzes showed no evidence that these factors were confounding. The well-executed randomization of the patients ensured that these variables were equally distributed among the groups and not considered confounding factors.

Future research should include occlusal surface reduction prior to root canal treatment has been advocated to prevent postoperative pain in teeth; however, randomized clinical trials are scarce, which makes it difficult to consolidate clinical protocols that preserve tooth structures. Studies like this should be done on teeth with necrotic pulp with apical periodontitis, periapical lesions represent an increased risk for postoperative pain (26).

In the present study, occlusal adjustment did not influence the prevalence of postoperative pain of endodontically treated teeth with symptomatic irreversible pulpitis.

Resumo

O objetivo deste estudo prospectivo, randomizado e clínico foi analisar a influência do ajuste oclusal na prevalência de dor pós-operatória após o tratamento endodôntico. Setenta e oito pacientes, diagnosticados com pulpíte irreversível sintomática com indicação de tratamento endodôntico, foram selecionados para participar do estudo. Os participantes foram randomizados e divididos em dois grupos: no grupo de ajuste oclusal (GAO), foi realizado tratamento endodôntico com posterior ajuste oclusal. No grupo controle (GC), o tratamento endodôntico foi realizado sem ajuste oclusal. Os tratamentos foram realizados pelo mesmo operador. A ocorrência e a intensidade da dor foram registradas em duas escalas: a escala de classificação verbal (VRS) e a escala de classificação numérica (NRS). A avaliação da dor foi realizada por um segundo examinador, cego para o experimento, 6, 24 e 72 horas após o tratamento endodôntico. Os dados foram analisados utilizando testes de Mann-Whitney, qui-quadrado e exato de Fisher. No grupo de ajuste oclusal, 71,1% relataram dor pós-operatória e 67,5% relataram dor no grupo controle. Na avaliação de 6 horas, 21 indivíduos relataram dor no grupo de ajuste oclusal e 24 no grupo controle ($p=0,672$). Na avaliação de 24 horas, 18 e 19 indivíduos relataram dor ($p=0,991$) e, na avaliação de 72 horas, 8 e 4 relataram dor ($p=0,219$), respectivamente. O ajuste oclusal não influenciou a prevalência de dor pós-operatória após o tratamento endodôntico em dentes com pulpíte irreversível sintomática.

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