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Periodontal dressing after surgical crown lengthening: A randomized clinical trial

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Abstract

Objective. The aim of the present study was to evaluate the effect of periodontal dressing on post-operative pain and swelling after surgical crown lengthening. ***Materials and methods.*** A blind, randomized, clinical trial was carried out with 36 patients. Following surgical crown lengthening, the individuals were randomly allocated to the periodontal dressing group (PDG) and control group (CG, non-placement of periodontal dressing). Pain and discomfort were analyzed using a visual analog scale (VAS), verbal scale (VS) and the number of analgesics consumed in 7 days post-operatively. Post-operative infection, stability of the gingival margin and type of healing were also evaluated. ***Results.*** The PDG had a significantly higher percentage of responses of 'strong pain' on the VS in the first day post-operatively (33.3% vs 5.3%, $p = 0.03$) and greater pain on the first and second days post-operatively based on the VAS. Moreover, a significant difference between groups was found regarding gingival swelling after 7 days. However, gingival recession was found in 57.8% of the sites in the CG and only 5.5% of sites in the PDG. No change in condition was found among individuals with conjunctive tissue/bone exposure in the CG in the immediate post-operative period and 80% of the patients in the PDG had healing by first intention after 7 days. ***Conclusion.*** The use of periodontal dressing seems to be preferable following surgical crown lengthening with connective tissue/bone exposure. However, adequate post-operative analgesic strategies should be employed due to the possibility of intense pain in the first 24 hours.

Key Words: *pain, periodontal surgery, wound healing*

Introduction

The use of periodontal dressing offers the advantage of reductions in infection, pain and root sensitivity as well as stability of the gingival margin. This procedure is also used to protect surgical areas with exposed connective tissue and/or bone, providing greater patient comfort during initial healing by second intention [1].

Ideally, a periodontal dressing should exhibit plasticity, flexibility, sufficient rigidity to avoid displacement, smoothness after setting and bactericidal action and not interfere with the healing process [2]. Most dressings contain zinc oxide and eugenol. Dressings without eugenol contain cyanoacrylate and methacrylate acid and achieve quite satisfactory results with regard to their physical properties [3,4].

Evidence in animal models has demonstrated harmful effects of periodontal dressing, such as cell damage in the subcutaneous connective tissue [5], alveolar bone [6] and the periodontium [7]. In humans [8], greater degrees of inflammation were found with the use of periodontal dressing due to bacterial growth. With regard to pain and discomfort, some studies report similar outcomes with and without the use of periodontal dressing [9,10], whereas others report greater pain among patients submitted to the procedure [4,11]. Considering the methodological limitations of the studies cited and the inconsistency in the findings, divergences remain regarding

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the effect of such dressings on the periodontium healing process, pain and discomfort following periodontal surgery. Moreover, in the specific case of surgical crown lengthening, there is no evidence on the effects of periodontal dressing.

The aim of the present study was to evaluate the effect of periodontal dressing on post-operative pain and swelling after surgical crown lengthening.

Materials and methods

Study design and subjects

A blind, randomized, clinical trial was carried out involving patients treated at the dental clinics of the Franciscan University Center (Brazil) between September 2011 and October 2012. This study received approval from the Human Research Ethics Committee of the university (nº 124.2011.2). All participants received detailed explanations of the objectives, risks and benefits of the study and agreed to participate by signing a statement of informed consent. The registration number is NCT01986 959 and the trial is listed in www.clinicaltrials.gov.

The following were the inclusion criteria: need for surgical crown lengthening on only one tooth with need for proximal osteotomy; aged 18 years or older; absence of systemic disease; absence of periodontal disease at the site of surgical crown lengthening; no restrictions regarding the procedure; and no need for antimicrobial prophylaxis. The following were the exclusion criteria: failure to return for the post-operative evaluations; failure to fill out the charts correctly; occurrence of pulp alteration in the operated tooth following the procedure; occurrence of partial or total loss of the periodontal dressing; and allergic reaction to periodontal dressing.

The sample size was based on an expected difference of 20 ± 19 mm between pain measures on the visual analog scale, an 80% power, 5% significance level and two-tailed hypothesis test. The calculation determined a minimum of 17 individuals in each group.

Experimental procedures

Prior to the surgical procedure, the gingival bleeding index (0 = absence; 1 = presence), probing depth associated with subgingival bleeding and clinical attachment level were recorded at four sites (mesial, vestibular, distal and palatal/lingual) of the teeth involved in the surgery.

Surgery was performed using a proper biosafety protocol. All patients were anesthetized with mepivacaine 2% and epinephrine 1:100.000 (Mepíadre®, DFL Indústria e Comércio S.A., Rio de Janeiro, RJ, Brazil). After folding back the flap and removing the granulation tissue, osteotomy was performed with Fedi chisels (Neumar®, São Paulo, SP, Brazil) and/or carbide burs (KG Sorensen, Cotia, São Paulo, Brazil) under irrigation with saline solution until obtaining a distance of 3 mm from the bone crest to the most cervical portion of the cavity. At the end of the procedure, a simple suture was performed with 4-0 nylon thread (Technew, Rio de Janeiro, RJ, Brazil). The examiner then recorded the distance (in mm) from the gingival margin to a fixed point of reference (cusp or transition angle) on the proximal face of the tooth with greater involvement in the osteotomy using a Williams periodontal probe (Neumar®).

The examiner recorded the duration (minutes) of surgery from the first incision through to the suturing, the amount (mm) of osteotomy and instruments employed (chisel and/or burs). After surgery, the patients were randomly allocated to the periodontal dressing group (PDG) and control group (CG, non-placement of periodontal dressing). Randomization was performed with opaque envelopes containing five cards stipulating 'periodontal dressing' and envelopes containing five cards stipulating 'no periodontal dressing' (block randomization). After the first 10 surgeries, the randomization process was repeated until both groups were completed. Randomization was performed by the surgeons to maintain the examiner blinded to the allocation of the patients. Due to the standardization in the surgical techniques and sequence, all surgeries were supervised by specialists in periodontics (professors R.P.A, F.B.Z. and L.A. W.). Prior to the study, the specialists met to standardize the instructions and procedures.

In the PDG, the dressing was mixed with a sterile spatula on a sterile glass plate following the manufacturer's instructions (2 cm of each paste measured with a sterile endodontic ruler). Coe-Pak™ Regular (GC AMERICA INC, Alsip, IL) was the dressing employed. Mixing and placement were performed only by the specialists in periodontics (R.P.A., F.B. Z. and L.A.W.) to ensure standardization. The dressing was inserted into the surgical wounds and molded to the necessary shape after setting sufficiently.

All patients were instructed to perform plaque control with chlorhexidine 0.12% (15 ml) (Periogard®, Colgate, São Bernardo do Campo, SP, Brazil) every 12 h for 7 days and take acetaminophen 750 mg (Tylenol®, Janssen-Cilag Farmacêutica LTDA, São José dos Campos, SP, Brazil) every 6 h (if needed) for pain control. All participants received both verbal and written instructions regarding post-operative control. A questionnaire for the evaluation of pain and sensitivity on the first, second, third and seventh days post-operatively was given to each patient to fill out at home. All evaluations involved a record of the number of analgesics taken as well as a visual analog scale (VAS, ranging from 0 [absence of pain] to 100 [unbearable pain] mm) and a verbal scale (VS) with the following responses: no pain; mild pain; moderate pain; severe pain; and very severe pain. The

patients were instructed to fill out the scales between 8–9 pm every day.

To ensure the blinding of the examiner regarding the allocation of the patients to the different groups, the removal of the periodontal dressing and suture after 7 days was performed by the surgeons. In cases of partial or complete loss of dressing, the surgeons informed the examiner and the patient was excluded from the analysis. Following removal of the dressing, the examiner (A.R.V.) administered the pain scales (VAS and VS) and determined both the presence of marginal bleeding and the position of the gingival margin. This position was determined individually using the same procedure performed in the immediate post-operative period based on the previously recorded fixed reference points. The determination of gingival recession, position of the gingival margin and gingival swelling were performed categorically, using the gingival margin in the immediate post-operative period for comparison. The examiner also determined the presence/absence of local infection. The healing of the surgical wound was evaluated based on the type of migration of the free edges of the epithelium. Healing by first intention was determined by the migration of the epithelium toward the bed of the wound. Cases in which an area of conjunctive tissue and/or bone was uncovered by epithelium and re-epithelialization by the adjacent epithelium was occurring were classified as healing by second intention [12]. Infection was recorded when persistent signs of redness, tumefaction or spontaneous pain were still present on the seventh day post-operatively [13].

Prior to the onset of the study, the examiner underwent a training exercise with an experienced professional (gold standard) for the evaluation of gingival bleeding, probing for the determination of the position of the gingival margin and type of healing. Training was carried out during surgical crown lengthening for patients who did not participate in the main study, using the same immediate post-operative and Day 7 evaluations until achieving agreement between the evaluator and gold standard on all clinical variables.

Statistical analysis

Pain (VAS and VS) was the main outcome. VS responses were dichotomized as little pain (responses of no pain, mild pain and moderate pain) and strong pain (severe pain and very severe pain). Swelling, infection, type of healing and stability of the gingival margin were the secondary outcomes. The data were tabulated and analyzed using the Statistical Package for Social Sciences (SPSS, version 20.0, IBM). The data were submitted to descriptive statistics (frequency distribution, mean and standard deviation values). Normality was tested and asymmetrical distribution was demonstrated. The variables were analyzed using the chi-squared test, Mann-Whitney, Fisher's exact test, Tukey's post-hoc test and the Bonferroni test ($p < 0.05$).

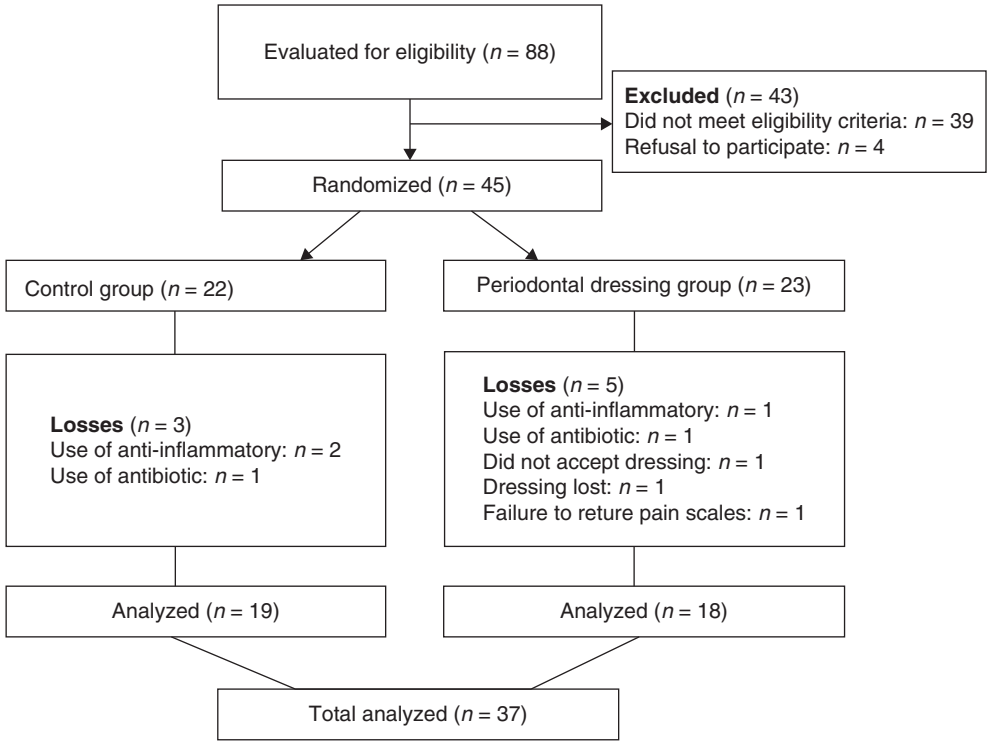

Figure 1. Study flowchart.

Table I. Distribution of demographic and clinical variables in both groups (n = 37).

	CG, n (%)	PDG, n (%)	p
Sex[a]			
Female	14 (73.7)	15 (83.3)	0.379
Male	5 (26.3)	3 (16.7)	
Age (years)[b], $M \pm$ SD	42.57 ± 14.49	43.11 ± 11.45	0.461
PD (mm)[b], $M \pm$ SD	2.53 ± 0.66	2.29 ± 0.57	0.245
CAL (mm)[b], $M \pm$ SD	2.80 ± 1.06	2.34 ± 0.63	0.221

CG, control group; PDG, periodontal dressing group; SD, standard deviation;PD, pocket depth; CAL, clinical attachment level. [a]Fisher's exact test ($p < 0.05$); [b]Mann-Whitney test ($p < 0.05$).

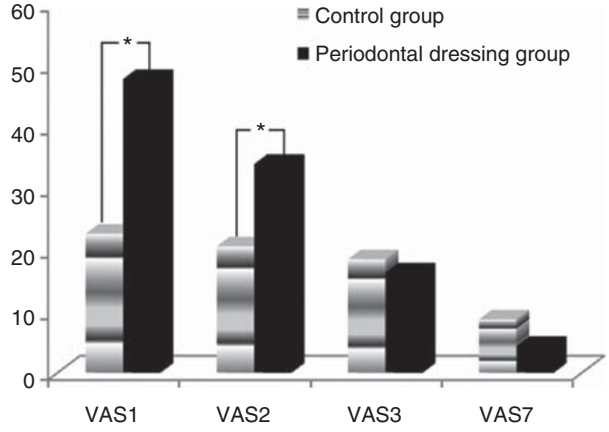

Figure 2. Visual analog scores in groups on days 1, 2, 3 and 7. *Mann-whitney test ($p < 0.05$)

Results

Figure 1 displays the flowchart of the study. Eighty-eight patients with a need for surgical crown lengthening were interviewed and 43 were excluded for not meeting the eligibility criteria. Randomization was performed on 45 individuals. Eighteen patients continued through to the end of the study in the PDG (loss of five patients) and 19 in the CG (loss of three patients). The reasons for the losses are described in Figure 1.

Table I displays the demographic and clinical variables of study participants at baseline. In both groups, the female gender predominated and both mean age and periodontal variables were similar.

The PDG had a significantly higher percentage of responses of 'strong pain' on the VS in the first day post-operatively (33.3% vs 5.3%, $p = 0.03$). However, this pain diminished after 24 h, with no statistically significant difference between groups (Table II).

Figure 2 displays the VAS scores. The PDG experienced significantly greater pain on the first (47.77 vs 22.60, $p = 0.001$) and second (33.94 vs 20.54, $p = 0.009$) days post-operatively. No significant differences between groups were found from Day 3 onward.

Table III displays the surgical and post-operative variables. No significant differences between groups were found regarding the amount of osteotomy, instruments employed, operating time or number of analgesics ($p > 0.05$). A significant difference between groups was found regarding gingival swelling after 7 days (66.6% in the PDG and 5.26% in the CG). However, gingival recession was found in 57.8% of the sites in the CG and only 5.5% of sites in the PDG.

Among individuals with sutures uniting the edges in the immediate post-operative period, an increase of ~ 26% and 23% was found in individuals in the CG and PDG, respectively, who returned with connective tissue and/or bone exposure at the Day 7 evaluation. In contrast, no change in condition was found at the Day 7 evaluation among individuals with conjunctive tissue/bone exposure in the CG in the immediate post-operative period, whereas 80% of the patients in the PDG had healing by first intention after 7 days (Table IV).

No patient in either group exhibited post-operative infection at the surgical site.

Discussion

Considering the controversy regarding the benefits and drawbacks of periodontal dressing, the aim of the

Table II. Percentage of responses of 'little pain' (no pain, mild or moderate pain) and 'strong pain' (severe and very severe pain) in experimental groups throughout the experiment (n = 37).

	Day 1		Day 2		Day 3		Day 7	
	Little pain n (%)	Strong pain n (%)	Little pain n (%)	Strong pain n (%)	Little pain n (%)	Strong pain n (%)	Little pain n (%)	Strong pain n (%)
CG	18 (94.7)	1 (5.3)	18 (94.7)	1 (5.3)	17 (89.5)	2 (10.5)	19 (100)	0
PDG	12 (66.7)	6 (33.3)	18 (100)	0 (0)	18 (100)	0 (0)	18 (100)	0
p*	0.042		0.514		0.257		NA	

CG, control group; PDG, periodontal dressing group.
*Inter-group comparisons: Fisher's exact test ($p < 0.05$).
NA, No applicable statistical test due to lack of individuals in second category.

Table III. Comparison of clinical variables during and after surgery in both groups ($n = 37$).

		CG, $M \pm$ SD	PDG, $M \pm$ SD	p
Operating time (min)*		123.92 ± 26.81	121.2 ± 26.4	0.637
Number of analgesics*		2.14 ± 1.61	2.73 ± 0.70	0.451
Intra-operative probing (mm)*		1.71 ± 0.50	1.60 ± 0.54	0.563
Osteotomy (mm)*		1.53 ± 0.63	1.73 ± 0.79	0.304
Swelling (mm)*		0.60 ± 0.52	0.86 ± 0.61	0.719
Instruments**, n (%)	Chisel	15 (78.94)	13 (72.22)	0.492
	Bur and chisel	4 (21.05)	5 (27.77)	
Position of gingival margin**#, n (%)	Recession	11 (57.89)[a]	1 (5.55)[a]	
	Same position	7 (36.84)[a]	5 (27.77)[a]	< 0.000
	Swelling	1 (5.26)[b]	12 (66.66)[b]	

CG, control group; PDG, periodontal dressing group; SD, standard deviation.
*Mann-Whitney test ($p < 0.05$); **Fisher's exact test ($p < 0.05$); # intra-group comparison, Bonferroni *post hoc* test (different letters in columns denote significant differences [$p < 0.05$]).

Table IV. Connective tissue and/or bone exposure in immediate post-operative period and 7 days following surgical crown lengthening ($n = 37$).

			Day 7		
			Without CT/B exposure	With CT/B exposure	p*
CG	IOP	Without CT/B exposure	11 (57.8)	4 (21.1)	0.018
		With CT/B exposure	0 (0)	4 (21.1)	
PDG	IOP	Without CT/B exposure	10 (55.5)	3 (16.6)	0.701
		With CT/B exposure	4 (22.2)	1 (5.55)	

CG, control group; PDG, periodontal dressing group; IOP, immediate post-operative period; CT/B. connective tissue/bone.
*Fischer's exact test ($p < 0.05$).

present study was to compare post-operative characteristics following surgical crown lengthening with and without the use of dressing. The findings demonstrate that periodontal dressing leads to a significant increase in pain in the first 48 h in comparison to patients not submitted to this procedure. However, the dressing seems to protect the surgical site from gingival recession.

Pain was the main outcome of the present study. Although the pain scales employed are subjective, these tools are routinely used and have been validated for the assessment of pain [14]. The VAS scores demonstrated greater pain in the first 48 h following surgery in the PDG. This finding is in agreement with data reported in previous studies regarding greater pain with the use of periodontal dressing after periodontal flap surgery [4,11]. In contrast, a number of authors report similar degrees of pain in a group submitted to periodontal dressing and a control group following periodontal flap surgery [9,10]. It should be borne in mind that, when pain is not considered very strong, the discomfort generated by the periodontal dressing may be a confounding factor regarding the pain sensation [15]. In the present study, the mean VAS score in the PDG did not surpass 50 and 35 mm in the 24 and 48 h, respectively. Moreover, when pain was evaluated as a dichotomous variable, strong pain was found in 1/3 of the patients who underwent periodontal dressing only in the first 24 h, whereas, after this period, only individuals in the CG reported strong pain (one individual at 48 h and two individuals at 72 h). Therefore, it seems that the greatest difference in pain occurs in the first 24 h, followed by non-significant differences between groups thereafter. Post-operative pain following oral procedures is a normal reaction of the inflammatory response to trauma and is a temporary sensation, with a peak on the first day post-operatively [16]. This is likely related to the greater intensity of the acute inflammatory response caused by the periodontal dressing, as suggested in previous studies [5,7].

Regarding patient satisfaction, previous studies report that patients have some difficulty in eating, but describe a greater psychological feeling of protection and wellbeing [9,10]. The preference does not appear to be based merely on the experience of pain.

Other factors, such as discomfort, appearance, type of surgical procedure and amount of exposed wound surface, also affect the choice [17].

In the PDG, greater swelling of the gingival margin after 7 days was found in ~ 2/3 of the patients. As no significant differences between groups occurred regarding surgical trauma (operating time, amount of osteotomy and instruments employed), this swelling seems to stem from a greater local inflammatory process [16]. The reason for the more acute inflammatory process caused by periodontal dressing remains unclear. The use of periodontal dressing may cause greater heat and bacterial growth on the dressing itself [18,19] and histological analyses reveal a striking inflammatory response [20–22]. However, the antimicrobial components of the Coe-Pack™ seem to be the main substances triggering the acute inflammatory process rather than bacterial proliferation *per se* [21,23].

The intense inflammatory response seems to have an important clinical significance. The present findings show that, paradoxically, while the local inflammatory process influenced by the periodontal dressing caused greater swelling and, consequently, greater post-operative pain in the first 48 h, it seemed to have increased the cell proliferation rate. This hypothesis is supported by fact that 80% of the sites in the PDG with connective tissue/bone exposure in the immediate post-operative period exhibited no exposure after 7 days, whereas such cases in the CG continued exposed at the 7-day evaluation. These findings are in disagreement with data described by other authors, who found that periodontal dressing slowed down the healing process [24] or found no differences in healing with the use of dressing [25]. However, laboratory findings in epithelial cell and fibroblast cultures have demonstrated that the phase in which the periodontal dressing is placed into contact with the gingival tissue appears to influence its effect on healing. It has been demonstrated that when periodontal dressing makes contact with the epithelial cells and fibroblasts before setting, the healing process is slowed down, but when placed after setting has begun, as performed in the present study, its effect on healing is innocuous [21,22,26,27].

Another possible explanation is that many of these older papers employed periodontal dressing after gingivectomy or flap surgery for the treatment of periodontal disease. In such cases, the gingival tissue has a higher degree of inflammation in comparison to sites without periodontal disease that require surgical crown lengthening. This difference in inflammatory status may partially explain the present findings, which underscore the need for periodontal dressing in cases of exposed connective tissue/bone following surgical crown lengthening. However, further evidence is needed to confirm these results.

The CG exhibited a significantly greater percentage of gingival recession and sites of healing by second intention with exposed connective tissue/bone on the 7th day post-operatively. The latter finding may explain the greater pain reported in the CG on the VAS 48 h after surgery, despite the lack of a statistically significant difference between groups. Thus, periodontal dressing seems to exert a protection effect against gingival recession, possibly due to the safeguarding of the sutured tissue against factors related to the oral cavity, such as chewing, brushing, trauma, etc. This hypothesis has been raised by a number of authors, but has not previously been confirmed in controlled experiments [5,7]. This is one of the contributions of the present study, in which the randomized, controlled design was employed using experimental groups with similar characteristics that can affect the outcomes, thereby reducing the chances of bias [28]. Another hypothesis is that sites submitted to periodontal dressing exhibited swelling after 7 days due to the greater inflammatory response, which did not occur in sites without periodontal dressing. As the patients were only followed up for 7 days, it is unknown whether gingival recession similar to that found in the CG occurred in the PDG after the swelling had disappeared.

Coe-Pak™ does not contain eugenol. In its commercial form, (Regular), the product has a base paste containing zinc oxide, an oil (for plasticity), a adhesive resin and a fungicide as well as catalyzing paste containing a coconut oil base thickened with colophony resin and a chlorothymol-based antimicrobial agent. Despite the presence of the antimicrobial agents, it is likely that all periodontal dressings lose this property in less than 7 days [23]. A lesser inflammatory response has been demonstrated in dressings without eugenol in comparison to those that contain this compound [6,29]. Moreover, as Coe-Pak™ has greater adhesiveness than other dressings [30] and more satisfactory clinical results due to its physical properties [2], it is the most often employed dressing in studies [1,3,4,10], which explains the choice of this product in the present investigation.

Conclusion

Based on the present findings, the use of periodontal dressing seems to be preferable in cases of connective tissue/bone exposure following surgical crown lengthening. However, adequate post-operative analgesic strategies should be employed due to the possibility of intense pain in the first 24 h.

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