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Effect of Oxyflower® Gel as an Adjunct in Pericoronitis Treatment: A Randomized, Triple-Blind Clinical Trial

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: Floral and vibrational therapies represent an emerging field in dental therapy, however, good quality clinical research is still needed. The aim of this research was to investigate the effect of Oxyflower® gel as an adjunct in pericoronitis treatment, evaluating clinical parameters and the impact on the quality of life of patients.

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Methodology: A randomized controlled, triple-blind, longitudinal clinical trial was performed. The sample consisted of 55 participants diagnosed with pericoronitis at the Periodontics and Surgery Clinic of UFVJM. Patients underwent emergency treatment, with local debridement and irrigation with saline solution, followed by topical application of the randomly selected gel: Oxyflower® (OXY, n=19); chlorhexidine gel (CLX, n=17), or placebo (PLC, n=19). In cases of pericoronitis with systemic signs/symptoms, such as fever, malaise, and lymphadenopathy, systemic antibiotic therapy was prescribed one hour before debridement, lasting seven days. Participants received guidance on oral hygiene, and adequacy of the area and were instructed to apply the same gel at home, twice a day for seven days, in addition to being instructed to use analgesics when there was pain. Follow-up was done after 1, 3, 7, 15, 30, 90, and 120 days. After 30 days, the definitive treatment was performed according to the indication: extraction, distal wedge surgery, or follow-up. Participants were followed longitudinally for an additional 90 days, totaling 120 days of follow-up. Pain and quality of life (QOL) were evaluated as primary outcomes. As secondary outcomes: probing depth (PD), bone crest level at the distal of the second molar (BCL), mouth opening (MO), and extent of edema/erythema (EEE) in the pericoronal hood region. Plaque Index (PI), Bleeding Index on Probing (BOP), and lower third molar positioning were also evaluated using panoramic radiography. A comparative analysis was performed between the groups using the chi-square test or Fisher's exact test for categorical variables and ANOVA or Kruskal-Wallis for continuous variables. The Generalized Estimating Equation (GEE) model was used to estimate the differences between groups in pain, QOL, EEE, MO, PI, BOP, PD, and BCL values at each follow-up time. Post-hoc tests of the main effects and interactions were performed using Bonferroni adjustment for multiple comparisons.
Results: The GEE model revealed that there was no statistically significant difference between the groups for pain, QOL, EEE, MO, BOP, and PD ($p>0.05$). However, there was an improvement in clinical parameters and QOL over time, regardless of treatment ($p<0.01$). For the variables PI and BCL, there was an interaction effect between time and intervention.
Conclusion: Oxyflower® gel offered no additional benefit in the treatment of pericoronitis when compared to the chlorhexidine gel or placebo. Local debridement and irrigation with saline solution seem to be sufficient to improve the clinical parameters and QOL of the affected patients.

Keywords: Pericoronitis; quality of life; floral therapy; complementary therapies; randomized controlled clinical trial

1. INTRODUCTION

Pericoronitis is an infectious condition characterized by the occurrence of inflammation in the mucosa of the oral cavity that is located around the crown of an erupted or partially erupted tooth [1,2], presenting a predominantly anaerobic microbial flora [3].

Data regarding the prevalence of pericoronitis are limited [4]. The mean age of affected patients ranges from 21 to 24 years [5,6,4]. Its highest prevalence is related to the eruption of lower third molars [7,1,8], affecting more women, in a proportion of 1:2 [1,9]. Studies show that pericoronitis negatively affects the quality of life (QOL) of affected individuals [1,5,10,11].

The treatment of pericoronitis constitutes an emergency in dentistry and consists of local debridement associated with intense irrigation with saline solution [12,2]. In some cases, local antimicrobial application is used to improve disinfection, such as chlorhexidine [1,13]. In cases of acute symptoms associated with systemic involvement, such as fever, malaise, lymphadenopathy, dysphagia, and limited mouth opening, systemic antibiotic therapy is indicated [12,6,10,14]. In addition, non-steroidal analgesics are prescribed for pain control [1].

Floral and vibrational therapies represent an emerging field in the dental therapeutic modalities. Floral Therapy is defined as a practice that complements patient well-being by utilizing flower essences as a method of treatment, with a focus on the individual rather than the disease. It can be safely used across all age groups, as it has no contraindications and does not produce drug interactions. This therapy offers a broad spectrum of prevention and humanization of treatment [15].

Oxyflower® is a floral gel that modulates frequencies of hydrogen peroxide. Limited scientific evidence supports this compound,

although some of its properties include healing, antimicrobial, and anti-inflammatory actions, attributed to the release of highly reactive oxygen from its formula. These characteristics hold promise for use in dentistry, particularly in the treatment of periodontal diseases.

Considering that floral and vibrational therapies represent an emerging field in the dental therapeutic modalities, the objective of the present study was to evaluate the effect of Oxyflower® gel, used in the adjuvant treatment of pericoronitis in the lower third molar, and its impact on the quality of life of the patient.

2. MATERIALS AND METHODS

This is a randomized, controlled, triple-blind clinical trial, performed according to CONSORT guidelines, lasting 120 days. This study was conducted at the Periodontics and Surgery Clinic of the Federal University of the Jequitinhonha and Mucuri Valleys (UFVJM). The study protocol was registered in an international trials registry (Trial Registry (https://www.clinicaltrials.gov); NCT03919942). The population included in the study consisted of people with symptoms of pericoronitis, treated at the UFVJM dental clinic between May 2017 and January 2019. The diagnosis of pericoronitis was confirmed by the presence of purulent or draining edema, affecting the gingiva of the oral cavity, located over the lower third molar. People with periodontal status level IV, according to the American Academy of Periodontics (American Academy of Periodontology, 2000), people undergoing antibiotic therapy in the last two months, and smokers were excluded from the research.

2.1 Interventions

Under local anesthesia with 2% lidocaine hydrochloride with 1:100,000 epinephrine (2% Lidocaine DFL ®), the region under the pericoronal hood was debrided, using gauze and curettes, with copious irrigation of sterile saline. At this moment, the gel to be applied topically under the pericoronal hood was randomly selected, with a standard volume of 2UI, with the aid of a dosing syringe, as follows: Oxyflower® gel (OXY); chlorhexidine gel (CLX), or placebo gel (PLC). Participants were instructed on oral cavity hygiene and home application of the gel, twice a day, for one week. The home application was performed using a 1ml insulin syringe (Descarpack®), already containing the appropriate volume of gel for each application (2UI), with a blunt-tipped needle. Each participant received 14 pre-dosed syringes and was instructed to apply the gel twice a day, after lunch and after dinner, keep the gel in the mouth for 5 minutes and not ingest water or food in the hour following application. Participants were followed up after 1, 3, 7, 15, 30, 90, and 120 days. Thirty days after the beginning of the study, the patients were evaluated regarding the need for extraction of the mandibular third molar. This procedure was performed for patients who did not have enough space for tooth eruption. In cases of pericoronitis with systemic signs/symptoms, such as fever, malaise, and lymphadenopathy, systemic antibiotic therapy was prescribed one hour before debridement, lasting seven days.

2.2 Clinical Examination

The outcomes evaluated were pain, QOL, the extent of the edema/erythema in the pericoronal hood region, mouth opening (MO), visible plaque index (PI), bleeding on probing index (BOP), probing depth (PD) and level of the bone crest at the distal of the second molar (BCL). Pain and QOL were the primary outcomes of interest, and the others were secondary outcomes. In addition to the physical examination, panoramic radiographs were taken to assess the positioning of the affected third molar.

The pain, extent of the edema/erythema, and MO were measured at baseline and after 1, 3, 7, 15, and 30 days. The pain was measured using the Visual Analogue Scale (VAS) [16,17]. With a millimeter ruler ranging from 0 to 10 cm, the intensity of pain reported by the patient on this scale was measured and recorded. The extent of the edema/erythema in the region of the pericoronal hood was evaluated by measuring the greatest buccolingual and mesiodistal distance from the lesion, using dental floss. The measurements were transferred to a millimeter ruler. By the average of these two distances, the average diameter of the local edema/erythema was obtained [18]. The MO was defined from the average of the values obtained by the double measurement of the distance between the incisal faces of the upper and lower right central incisors, using a millimeter ruler.

PI, BOP, and PD were followed from baseline and for 7, 15, 30, 90, and 120 days. PI was determined by the presence or absence of

biofilm on 4 surfaces of each tooth and expressed in the percentage of faces with biofilm [19]. BOP was determined by the presence or absence of bleeding on probing on four surfaces of each tooth, expressed in the percentage of bleeding surfaces, up to 15 seconds after probing [20]. PD was measured from the gingival margin to the bottom of the gingival sulcus or periodontal pocket at six sites per tooth (three sites per buccal and three sites per lingual or palatal), with the aid of a pressure-controlled computerized probe (Florida Probe Corporation, Gainesville, FL, U.S.A) [21].

BCL at the distal of the second molar was measured at baseline and at 30, 90, and 120 days, from the marginal crest to the alveolar bone crest, with a Williams probe, and measured with a digital caliper, in millimeters. For all clinical measurements, an intra-evaluator calibration was performed, examining ten patients, each patient evaluated twice, with a day of space between the first and second exams. The evaluator was considered calibrated when the percentage of agreement between repeated measurements showed an agreement greater than 90%.

To assess QOL, measured at baseline and at 30 and 120 days of follow-up, a translated and validated Brazilian version of the [22] Oral Health Impact Profile (OHIP-14) questionnaire, covering 14 items distributed in 7 domains (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and social disadvantage), was used.

2.3 Randomization and Blinding

The study used simple randomization to allocate patients to each intervention group. The intervention was randomly selected at the time of debridement of the region affected by pericoronitis, by a person not involved in the research, using opaque and sealed envelopes containing papers with the letters A, B, and C. To ensure the blinding of the participants and the examiner, the packages of the gels were produced in the same size, shape, and quantity of substances, identified by the manufacturer with the codes A, B, or C. All gels were transparent, odorless, and tasteless, making it impossible to distinguish between them. The list containing the identification of the substance according to its coding was kept confidential by a person not involved in the research and was only revealed after the analysis of the data.

2.4 Sample Size

The sample size calculation was performed considering the difference between the means for the pain variable, stipulated at 5mm with a standard deviation of 9.94mm [SHAHAKBARI et al., 2014], a significance level of 5%, and a test power of 80%. The minimum sample size required was 15 participants in each group. To prevent losses, approximately 30% was increased per intervention group.

2.5 Statistical Analysis

Statistical analyzes were performed using the SPSS program (software version 22.0, IBM Corporation, New York, NY). To assess the normality of continuous data, the Kolmogorov-Smirnov and Shapiro-Wilk tests and inspection of histograms were used. Descriptive analysis regarding the three intervention groups (OXY, CLX, PLC) were tabulated as mean (standard deviation, SD), median (interquartile range), or percentages The comparison between groups for categorical data was statistically analyzed using the chi-square test or Fisher's exact test. Continuous data were analyzed using ANOVA or the Kruskal-Wallis test, according to data normality. The Generalized Estimating Equation (GEE) was used to estimate the differences in the values of pain, edema, trismus, PI, BOP, PD, BCL, and QOL at each point between the three groups over the follow-up period. The interaction between treatment and follow-up time was also considered in the analyses. Post-hoc tests of the main effects and interactions were performed using Bonferroni adjustments for multiple comparisons. A p-value of <0.05 was considered statistically significant for all analyses.

3. RESULTS

In total, 55 patients completed the study protocol: 19 in the OXY group, 19 in the PLC group, and 17 in the CLX group (Fig. 1).

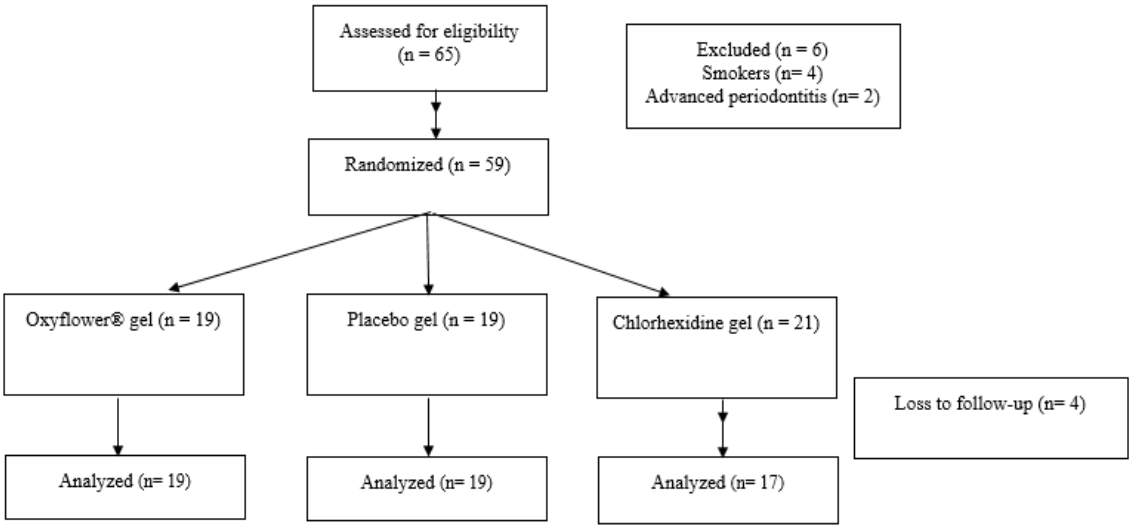

Fig. 1. Flowchart of the selection of the studied sample

Demographic data were similar between groups in terms of gender, age, socioeconomic status, third molar compromised by pericoronitis, and quantity of pain at baseline (Table 1). There was no statistically significant difference in terms of the quantity of analgesics consumed in the postoperative period by the patients allocated to the respective intervention groups (D1: p= 0.586; D2: p= 0.651; D3: p= 0.909; D4: p= 0.227; D5 : p=0.312; D6: p=0.639; D7: p=0.635). The predominant position of the mandibular third molar according to the Pell and Gregory classification was IIB (34.5%), followed by IIA (27.3%) and IA (21.8%). There were no cases involving the lower third molars in the class III position according to the ascending ramus of the mandible or in the C position in relation to the occlusal plane.

Lower third molar extraction was performed in 35 patients (64.8%) after the thirtieth day of the beginning of the study. The GEE model revealed that there was no statistically significant difference between the intervention groups regarding pain, edema, MO, BOP, PD, and QOL (P>0.05). There was a statistically significant temporal trend (differences between individuals or time effect) regardless of the gel used (P < 0.01). Table 2 shows the mean values of the variables over the study period for each intervention group.

Table 1. Patient characteristics at baseline

Variables	OXY	PCL	CLX	P-value
Age (years), Mean ± SD	24 (±4.24)	24.58 (±4.73)	23.47 (±4.90)	0.707
Gender (n, %)				0.368
Male	4 (7%)	3 (6%)	6 (11%)	
Female	15 (27%)	16 (29%)	11 (20%)	
Family income (n, %)				0.072
Up to 250 BRL	1 (2%)	1 (2%)	0	
251 to 500 BRL	0	1 (2%)	3 (7%)	
501 to 1500 BRL	7 (13%)	11 (20%)	6 (11%)	
1501 to 2500 BRL	4 (8%)	5 (10%)	5 (10%)	
2501 to 4500 BRL	6 (11%)	0	1 (2%)	
4501 to 9500 BRL	0	0	1 (2%)	
Pericoronitis (n, %)				0.496
Left third molar (38)	7 (12.7%)	10 (18.2%)	6 (10.9%)	
Right third molar (48)	12 (21.8%)	9 (16.4)	11 (20%)	
Pain, Mean ± SD	5.87 (±2.80)	4.36 (±3.07)	6.20 (±2.02)	0.167
Edema/Erythema	7.60 (±0.66)	6.83 (±6.03)	7.64 (±0.50)	0.502

Table 2. Estimates of the mean of pain, edema, mouth opening, plaque index, bleeding index on probing, probing depth, bone crest level, and quality of life, presented by intervention group and time

		Time trend								p-value†	p-value §	p-value ᴧ
		Baseline	**D1**	**D3**	**D7**	**D15**	**D30**	**D90**	**D120**			
Pain	Oxyflower®	5.87 (0.62)	3.75 (0.61)	3.45 (0.71)	2.27 (0.62)	1.41 (0.48)	2.15 (0.66)	-	-	0.69	<0.01	0.35
	Placebo	4.36 (0.68)	2.79 (0.69)	2.70 (0.60)	1.90 (0.53)	2.31 (0.86)	1.15 (0.65)	-	-			
	Chlorhexidine	6.20 (0.47)	4.81 (0.65)	3.52 (0.60)	1.83 (0.49)	0.68 (0.28)	2.37 (0.51)	-	-			
Edema	Oxyflower®	7.60 (0.66)	6.33 (0.65)	5.77 (0.57)	5.15 (0.65)	3.80 (0.51)	2.40 (0.57)	-	-	0.43	<0.01	0.35
	Placebo	6.83 (6.03)	6.03 (0.40)	5.27 (0.40)	4.72 (0.57)	4.44 (0.61)	2.80 (0.50)	-	-			
	Chlorhexidine	7.64 (0.50)	6.90 (0.53)	6.43 (0.57)	5.44 (0.47)	4.37 (0.65)	3.88 (0.41)	-	-			
Mouth Opening	Oxyflower®	4.65 (0.17)	4.32 (0.11)	4.59 (0.18)	4.80 (0.12)	4.67 (0.11)	4.78 (0.12)	-	-	0.17	<0.01	0.15
	Placebo	4.58 (0.15)	4.72 (0.16)	4.75 (-.12)	4.81 (0.12)	4.92 (0.12)	4.96 (0.10)	-	-			
	Chlorhexidine	4.34 (0.14)	4.52 (0.19)	4.38 (0.16)	4.42 (0.15)	4.69 (0.15)	4.60 (0.21)	-	-			
Plaque Index	Oxyflower®	29.45 (3.82)	-	-	15.81 (2.95)	13.06 (2.38)	14.80 (3.22)	8.63 (1.83)	12.34 (3.01)	0.46	<0.01	<0.01
	Placebo	19.76 (4.22)	-	-	11.56 (1.88)	12.35 (2.14)	12.67 (3.40)	10.08 (2.99)	6.26 (1.37)			
	Chlorhexidine	22.45 (3.41)	-	-	13.40 (2.03)	9.89 (1.44)	10.44 (1.55)	10.90 (1.28)	7.94 (1.04)			
Bleeding Index on Probing	Oxyflower®	8.07 (2.35)	-	-	4.54 (1.61)	5.77 (2.05)	3.35 (1.50)	4.02 (1.99)	4.24 (2.44)	0.29	<0.01	0.28
	Placebo	7.36 (2.57)	-	-	2.52 (0.93)	2.90 (1.14)	3.47 (1.74)	1.06 (0.56)	1.31 (0.55)			
	Chlorhexidine	5.35 (1.43)	-	-	1.96 (0.51)	2.76 (1.05)	3.01 (0.97)	2.63 (0.96)	1.96 (0.70)			
Probing Depth	Oxyflower®	3.25 (0.20)	-	-	3.19 (0.29)	2.93 (0.23)	2.92 (0.25)	2.85 (0.20)	2.25 (0.21)	0.39	<0.01	0.46
	Placebo	3.10	-	-	2.84	2.59	2.70 (0.22)	2.07	2.21			

		Time trend								p-value†	p-value §	p-value ^λ
		Baseline	**D1**	**D3**	**D7**	**D15**	**D30**	**D90**	**D120**			
		(0.22)			(0.19)	(0.16)		(0.31)	(0.31)			
	Chlorhexidine	3.08 (0.18)	-	-	3.03 (0.25)	2.93 (0.32)	2.62 (0.14)	2.80 (0.19)	2.50 (0.23)			
Bone Crest Level	Oxyflower®	5.43 (0.30)	-	-	-	-	4.37 (0.26)	4.19 (0.21)	3.25 (0.18)	0.78	<0.01	<0.01
	Placebo	4.86 (0.43)	-	-	-	-	4.44 (0.36)	3.22 (0.19)	3.71 (0.53)			
	Chlorhexidine	4.45 (0.29)	-	-	-	-	4.05 (0.30)	4.03 (0.39)	3.83 (0.49)			
Quality of Life	Oxyflower®	22.63 (1.39)	-	-	-	-	13.17 (2.13)*	-	11.17 (3.27)	0.03	<0.01	0.45
	Placebo	18.89 (2.27)	-	-	-	-	7.46 (1.03)*	-	8.40 (1.22)			
	Chlorhexidine	22.18 (2.59)	-	-	-	-	10.50 (1.73)	-	14.67 (5.89)			

† Comparison of the variable change between the treatment groups. § Comparison of the behavior of the variable according to the follow-up time. ^λ Interaction between time and treatment.
** Statistically significant difference in the Bonferroni posthoc test when comparing the variable change between the treatment groups (p< 0,05)*

There was no difference in MO values in the group that used the OXY gel at any follow-up period, while MO was significantly higher on the fifteenth day in the PLC (p=0.044) and CLX (p=0.001) groups. The pain reported on the first day of follow-up in the PLC (p=0.025) and CLX (p<0.001) groups was statistically lower compared to the pain reported at baseline, while in the OXY group this difference was only significant on the seventh day (p<0.001). Comparisons of the behavior of each variable over time are shown in Tables 3, 4, and 5.

Table 3. Comparison of the behavior of the Oxyflower® gel in relation to the variables pain, edema, mouth opening, plaque index, bleeding index on probing, probing depth, bone crest level, and quality of life, according to follow-up time

OXY	Time trend							
	Baseline	**D1**	**D3**	**D7**	**D15**	**D30**	**D90**	**D120**
Pain	aaabbb	aaaaba	aaaaaa	baaaaa	bbaaaa	baaaaa	-	-
Edema	abbbbb	baaabb	baaabb	baaaab	bbbaaa	bbbbaa	-	-
Mouth Opening	aaaaaa	aaaaaa	aaaaaa	aaaaaa	aaaaaa	aaaaaa	-	-
Plaque Index	abbbbb	-	-	baaaba	baaaaa	baaaba	bbabaa	baaaaa
Bleeding Index on Probing	aaaaaa	-	-	aaaaaa	aaaaaa	aaaaaa	aaaaaa	aaaaaa
Probing Depth	aaaaab	-	-	aaaaaa	aaaaaa	aaaaaa	aaaaaa	baaaaa
Bone Crest Level	abbb	-	-	-	-	baab	baab	bbba
Quality of Life	abb	-	-	-	-	baa	-	baa

Different letters occupying the same position as the underlined letter indicate a statistically significant difference in the OXY group according to the follow-up time indicated by the column (p< 0,05)

Table 4. Comparison of the behavior of the Placebo gel in relation to the variables pain, edema, mouth opening, plaque index, bleeding index on probing, probing depth, bone crest level, and quality of life, according to follow-up time

PLC	Time trend							
	Baseline	**D1**	**D3**	**D7**	**D15**	**D30**	**D90**	**D120**
Pain	ababab	baaaaa	aaaaaa	baaaaa	aaaaaa	baaaaa	-	-
Edema	abbbbb	bababb	bbaaab	baaaab	bbaaab	bbbbba	-	-
Mouth Opening	aaaaba	aaaaaa	aaaaaa	aaaaaa	baaaaa	aaaaaa	-	-
Plaque Index	abaaab	-	-	baaaab	aaaaab	aaaaaa	aaaaaa	bbbaaa
Bleeding Index on Probing	aaaaaa	-	-	aaaaaa	aaaaaa	aaaaaa	aaaaaa	aaaaaa
Probing Depth	aaaabb	-	-	aaaaba	aaaaaa	aaaaaa	bbaaaa	baaaaa
Bone Crest Level	aabb	-	-	-	-	aaba	bbaa	baaa
Quality of Life	abb	-	-	-	-	baa	-	baa

Different letters occupying the same position as the underlined letter indicate a statistically significant difference in the PLC group according to the follow-up time indicated by the column (p< 0,05)

Table 5. Comparison of the behavior of the Chlorhexidine gel in relation to the variables pain, edema, mouth opening, plaque index, bleeding index on probing, probing depth, bone crest height, and quality of life over time

CLX	Time trend							
	Baseline	**D1**	**D3**	**D7**	**D15**	**D30**	**D90**	**D120**
Pain	abbbbb	baabba	baabba	bbbaaa	bbbaab	baaaba	-	-
Edema	abbbbb	baabbb	baaaab	bbaaab	bbaaaa	bbbbaa	-	-
Mouth Opening	aaaaba	aaaaaa	aaaaaa	aaaaaa	baaaaa	aaaaaa	-	-
Plaque Index	abbbbb	-	-	baaaaa	baaaaa	baaaaa	baaaaa	baaaaa
Bleeding Index on Probing	aaaaaa	-	-	aaaaaa	aaaaaa	aaaaaa	aaaaaa	aaaaaa
Probing Depth	aaabaa	-	-	aaaaaa	aaaaaa	baaaaa	aaaaaa	aaaaaa
Bone Crest Level		-	-	-	-			
Quality of Life	aba	-	-	-	-	baa	-	aaa

Different letters occupying the same position as the underlined letter indicate a statistically significant difference in the CLX group according to the follow-up time indicated by the column (p< 0,05)

For the variables PI and BCL, there was an interaction effect between time and intervention. The three intervention groups showed no significant difference in PI values over the time evaluated. However, the patients evaluated five times (7, 15, 30, 90, and 120 days) had mean PI values different from the values found at baseline, both for treatment with OXY ($p<0.01$) and with CLX ($p<0.01$). In the PLC group, this difference was found between baseline and the seventh day ($p=0.04$) and after 120 days ($p<0.01$). Only the OXY group showed a significant gain in BCL at 30 days compared to the values obtained at baseline ($p=0.009$). This difference was not found at any time of the follow-up among those who used the CLX gel ($p>0.05$). However, at 90 days, the application of the OXY gel was associated with a greater loss of BCL (4.19) when compared to the patients who used the PLC gel (3.22) ($p=0.003$).

4. DISCUSSION

Chlorhexidine has been routinely prescribed to control adverse periodontal conditions as it has been established as an efficient agent against oral biofilms [23,24,25]. However, some studies have demonstrated adverse effects associated with the use of this mouthwash [26,27,28,29]. Alternative and complementary medicine has been increasingly used in an attempt to minimize these events for patients, but it represents a controversial field of knowledge, given the scarcity of studies conducted with scientific rigor. Flower essences have been used to control pain, stress, and fatigue, in addition to being used in the recovery of general surgeries [30,31]. Viola, dog rose and Wedelia vibrational floral essences are the basis of the Oxyflower® gel, a compound evaluated in this research. It has quantum action and acts as a floral frequency modulator, carrying the vibrational information of the oxygen. We did not find additional information about the action of this essence other than those provided by the manufacturer. To the best of our knowledge, this was the first clinical study to investigate the action of Oxyflower® for the immediate treatment of pericoronitis. Despite the promising effect, when compared with chlorhexidine gel and placebo gel, Oxyflower® did not show additional benefits in relation to pain, QOL, the extent of edema/erythema, MO, BOP, and PD.

In this sense, although pain related to pericoronitis can be a severe and continuous condition, this study showed that the tested interventions had no effect on reducing pain and inflammation. It was possible to observe that patients who used the chlorhexidine gel and placebo gel had their pain significantly reduced on the first day of intervention compared to baseline, while the group that used the Oxyflower® gel reported significant improvement in pain on the fifteenth day. Although it is associated with a worsening in the QOL of the patients [4,15,14], the literature indicates that the symptoms presented by young patients with mild to moderate pericoronitis can be reduced only with local irrigation without antibiotics [14,2], which we confirmed with the present study. Paracetamol or ibuprofen may be indicated for persistent pain relief. Studies recommending protocols for pain management, according to its intensity, in pericoronitis are necessary.

Our results show that there was no effect of the interventions on the patient's QOL, once the improvement in QOL was associated with the follow-up time. That is, after 30 days, QOL was significantly better than at baseline regardless of the group. Although data involving QOL in patients with pericoronitis are limited in the literature, it is known that this oral condition can negatively impact the lives of affected people, especially in the pain domain [4,5,11,2]. Thus, in addition to pain and QOL, we also analyzed other variables influenced by pain, such as MO capacity, BOP, PD, and PI.

We found a significant increase in MO 15 days after the start of the study in patients who used the chlorhexidine gel and placebo gel. Patients who used the Oxyflower® gel showed no change in MO measures over time. A study comparing the use of green tea mouthwash with the use of chlorhexidine mouthwash in patients with acute pericoronitis found a significant improvement in MO after three days of green tea mouthwash [32]. Although we did not have satisfactory results like the one presented, the patients included in our study did not have trismus due to pericoronitis, but only impaired MO, according to the diagnostic criteria for trismus: maximum mouth opening less than 35 mm [33,34;2].

BOP was not significantly different between the OXY, PLC, and CLX treatments, as there was no difference in this variable over time in each group. These results suggest that interdental cleaning was avoided in all groups, and the use of the substances in the gel formulation applied through syringe washing did not promote satisfactory antimicrobial effects. It is important to

highlight that persistent gingival bleeding is associated with an increased risk of periodontal collapse and represents an important indicator of stability in the clinical condition of the patients [35]. Thus, maintaining the periodontium in a bleeding state can have a negative impact on the oral health of individuals. Considering that mechanical debridement can substantially contribute to the reduction of PD [35], we recommend performing assisted brushing for patients with acute pericoronitis.

Our results indicate that the PD values found at baseline in patients with pericoronitis were similar to the values found by Sencimen et al. [36] in patients with the same oral impairment. However, none of the interventions tested in the present study had an effect on the reduction of PD, once this reduction could be significantly observed only 30 days after the beginning of the study, regardless of the gel. Studies evaluating clinical outcomes after periodontal surgeries also did not observe additional benefits in periodontal pocket depth after the use of chlorhexidine compared with the placebo group [37,38].

The PI values were significantly lower than the values found at baseline, at all follow-up periods, both for the treatment with Oxyflower® and for treatment with chlorhexidine. As mentioned earlier, chlorhexidine is one of the most used antiseptics for plaque and gingivitis control, and conventionally, it has been recommended during the first week after the debridement of the area affected by pericoronitis, due to its antimicrobial properties [39]. Nevertheless, this study did not detect the superiority of either intervention in reducing the PI. When evaluating the placebo group, the PI values decreased on the seventh day in relation to the baseline and showed an increase at 15, 30, and 90 days. However, they did not differ from those values found at the beginning of the study.

The OXY gel was superior to chlorhexidine in the assessment of BCL gain over the 30, 90, and 120 days of follow-up, while the chlorhexidine had no significant effect on this variable. It is important to highlight that the change in BCL after 90 days may have been temporarily influenced by the extraction of the mandibular third molar since the position of the impacted third molar is generally considered a risk factor for bone loss after its extraction [40].

Based on the results of the present study, the anti-inflammatory properties of the OXY gel have not been proven, and therefore, we do not recommend the use of this compound as an adjunctive therapeutic alternative in the control of pericoronitis [41,42]. However, this study has limitations that must be considered. The first one corresponds to the loss of follow-up of participants for some evaluated outcomes. Another limitation of this study is the lack of assessment of the patients' acceptability in relation to the tested interventions. In this study, we evaluated the QOL of patients at baseline, and after 30 and 90 days. We believe that new longitudinal studies evaluating the impact of pericoronitis from the first day and consecutively until the seventh day of follow-up may contribute to more accurate assessments of this oral condition. Despite these limitations, this study was developed with high methodological rigor, to minimize the risk of bias inherent in randomized clinical trials. In this way, the generation of a randomization sequence, the secret in the allocation, the blinding of the participants and the study team contribute to the reliability of our results [43,44].

5. CONCLUSION

Oxyflower® gel offered no additional benefit in the treatment of pericoronitis when compared to the chlorhexidine gel or placebo. Local debridement and irrigation with saline solution seem to be sufficient to improve the clinical parameters and QOL of the affected patients.

CONSENT AND ETHICAL APPROVAL

The study was approved by the Research Ethics Committee of this institution under the no. 2.253.569. All patients signed the consent form agreeing with treatment.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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