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Original Article

Effects of an oxygen-releasing mouthwash for peri-implant health management. A pilot randomized controlled clinical trial

Efeitos de um enxaguatório liberador de oxigênio para manutenção da saúde peri-implantar. Estudo piloto clinico, randomizado e controlado

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Resumo

Introdução: O controle do biofilme peri-implantar desempenha um papel importante no sucesso a longo prazo dos implantes dentários. Alternativas de tratamento tópico visando a diminuição ou a prevenção do acumulo de biofilme ao redor dos componentes protéticos do implante é um fator crucial para a sucesso do tratamento. **Objetivo:** Assim, o presente estudo avaliou clinicamente no período de 90 dias, os efeitos de um enxaguatório bucal liberador de oxigênio (BlueM®) após cirurgia de instalação de implante. **Material e método:** Após a instalação dos implantes, os pacientes foram randomizados em dois grupos: grupo controle utilizaram enxaguatório bucal com clorexidina 0,12% e grupo BlueM utilizaram enxaguatório bucal liberador de oxigênio (BlueM). Todos participantes foram orientados a realizarem os bochechos 2 x/dia nos primeiros 10 dias, e 1 x/dia até completar 30 dias da cirurgia. Parâmetros clínicos foram avaliados: índice de placa visível (PV), sangramento marginal (SM), presença de cálculo (PC), presença de supuração (SUP), presença de mucosite (MU), extensão da faixa de gengiva ceratinizada (GC) realizados no ato da remoção da sutura (Baseline). No período de 90 dias do pós-operatório foram realizados os exames de profundidade de sondagem (PS), sangramento à sondagem (SS) e de presença de perimplantite (Pi). **Resultado:** 9 pacientes foram incluídos neste estudo totalizando 38 implantes instalados. O grupo BlueM apresentou redução no SM, maior redução de PV. Os demais parâmetros avaliados foram semelhantes com o grupo controle. **Conclusão:** Pode-se concluir que o enxaguatório BlueM demonstrou benefícios clínicos no controle do biofilme e no controle da inflamação gengival.

Descritores: Implante dental; biofilme dental; peri-implantite; mucosite; enxaguatórios bucais.

Abstract

Introduction: The control of peri-implant biofilm plays a crucial role in the long-term success of dental implants. Topical treatment alternatives aimed at reducing or preventing biofilm accumulation around the implant's prosthetic components are critical for the success of the treatment. **Objective:** The present study has clinically evaluated the effects of an oxygen-releasing mouthwash (BlueM®) over a 90-day period, following implant placement surgery. **Material and method:** Inclusion and exclusion criteria allowed for the selection of participants who, after implant placement, were randomized into two groups: the control group, which used a 0.12% chlorhexidine mouthwash, and the BlueM group, which received the oxygen-releasing BlueM mouthwash. All participants were instructed to rinse twice daily for the first 10 days and once a day up to 30 days post-surgery. Clinical parameters were evaluated, including the visible plaque index (VP), marginal bleeding (MB), presence of calculus (PC), suppuration (SUP), mucositis

(MU), and the extent of keratinized gingiva (KG). These data were collected at the time of suture removal (baseline). At 90 days postoperative, in addition to the aforementioned parameters, probing depth (PD), bleeding on probing (BOP), and the presence of peri-implantitis (PI) were evaluated. **Result:** Nine patients were included in this study, with a total of 38 implants. The BlueM group demonstrated a reduction in MB and an even greater reduction in VP. The other assessed parameters showed similar results to those in the control group. **Conclusion**: BlueM mouthwash has clinical benefits for biofilm control and gingival inflammation reduction.

Descriptors: Implants; biofilm; periimplantitis; mucositis; mouthwash.

INTRODUCTION

Dental caries and periodontal disease are two major conditions that affect the global population. If left untreated and uncontrolled, they can lead to tooth loss. According to a systematic review of observational studies[1] it was found that in a population of approximately 3.9 billion people, 291 oral conditions and injuries were the most prevalent. Among these, dental caries in permanent molars was the most common condition, while tooth loss ranked as the 36th most serious condition affecting global dental health, making them significant public health concerns[1].

The consequences of tooth loss extend beyond aesthetics, as they affect the physiology of the masticatory system, emotional and psychological well-being, as well as patients' quality of life. In the past, the treatment option for the rehabilitation of partially edentulous areas was the fabrication of removable partial dentures, which often caused unfavorable aesthetics and discomfort for patients. However, with the advent of osseointegrated implants a new range of treatment options has emerged, providing a solution for various clinical conditions.

Osseointegrated implants have revolutionized the possibility of aesthetic and functional rehabilitation for both partially and fully edentulous patients, regardless of whether they have lost teeth in one or both arches. Initially, according to the original clinical protocol, osseointegrated implants were placed in a two-stage surgical procedure, with a minimum healing period of 3 to 6 months prior to the installation of a prosthesis on the implants[2,3]. However, studies on the histophysiology of bone tissue have provided a better understanding of the osseointegration process[2], leading to a reduction in the time between implant placement and prosthesis installation[4].

Research has shown that implants placed in the mandible with immediate loading yield clinical outcomes similar to those of implants with delayed loading (3-4 months) during the first five years of evaluation[5]. With advancements in implant macro- and microstructures and the development of various surface treatments, the practice of immediately loading implants after placement has gained greater clinical usage, showing positive results in patients' health[6]. This approach is particularly beneficial for fully edentulous patients, since it reduces the number of surgeries and shortens the rehabilitation period.

However, one of the major challenges in implant rehabilitation is controlling the biofilm that forms on the prosthetic components, gingival tissue and on the installed prosthesis. If not managed, this biofilm can trigger a local immune-inflammatory response and interfere with the healing and health of peri-implant tissues, which can lead to peri-implant diseases[7]. Patients may struggle to maintain proper oral hygiene, due to a lack of manual skills or difficulty in accessing certain areas, thus compromising bacterial control. In such cases, the selection of an appropriate agent to control bacterial biofilm becomes necessary.

Various chemical agents have been developed for this purpose, in the form of gels, toothpaste or mouthwashes. The main active agents include stannous fluoride, triclosan, citric acid, phenolic compounds, cetylpyridinium chloride, essential oils (thymol, menthol, eucalyptol, and methyl salicylate extracts), sodium lauryl sulfate, oxygenating compounds, and bis-biguanides[8-11]. Based on systematic reviews, only two chemical agents are considered the most effective in controlling biofilm: 0.12% chlorhexidine digluconate and essential oils[12,13]. It should

be noted that the prolonged use of chlorhexidine should be approached with caution, as research has shown it can cause staining of restorations, supragingival calculus formation, mucosal erosion, taste alteration, fungal growth, and parotid gland swelling[14].

In implant dentistry, the use of chemical agents to control the peri-implant biofilm for the prevention of post-surgical transient bacteremia, favoring soft and hard tissue healing, as well as disease prevention, is scarce. Recently, a new product has been introduced to the market that, according to the manufacturer, releases active oxygen (O_2). This product, commercially known as BlueM, is available in different formulations. The benefits of oxygen at various levels—cellular, tissue, and for life itself—are undeniable. Studies have shown that oxygen plays critical roles in the body, such as the production of energy needed for the daily cellular metabolism[15]. O_2 is also involved in several host processes, including oxidative bacterial killing, angiogenesis, collagen formation, wound re-epithelialization, and cell differentiation[16-18]. These processes also occur in implant dentistry, during surgical wound healing, and in the maintenance therapy and control of the peri-implant biofilm. This new oxygen-releasing agent was recently introduced in the Brazilian market. Its effects on peri-implant health have not been extensively studied using randomized controlled clinical trials.

Therefore, the present study aims to clinically evaluate the effectiveness of the oxygen-releasing mouthwash BlueM on peri-implant health in patients with dental implants subjected to immediate-load prosthesis installation. The primary hypothesis of the research is that the use of BlueM will improve peri-implant health, based on the periodontal parameters evaluated.

MATERIAL AND METHOD

The present research is a controlled, prospective, randomized clinical trial, designed in accordance with the CONSORT statement guidelines for randomized clinical trials. It was submitted to the Research Ethics Committee of Ilapeo College and received approval on Nov 07, 2019.

Sample

Nine participants, each requiring the placement of 4 or more osseointegrated implants for the construction of a fixed protocol-type prosthesis, were selected for the study. All participants were recruited at the Implantology Clinic at Ilapeo College. Initially, the participants were informed about the nature of the study, its benefits and potential risks of participation. Any questions were answered accordingly. Next, the patients completed a comprehensive health questionnaire to assess their eligibility for the study. Those who qualified for the study signed an informed consent form (ICF) priorly approved by the Research Ethics Committee of Ilapeo College.

Inclusion and Exclusion Criteria

The inclusion criteria were as follows: participants had to be aged between 40 and 70 years old; be fully edentulous in one of the arches; require the placement of 4 or more osseointegrated implants for the construction of a fixed protocol-type prosthesis in one arch; no need for any prior regenerative procedures; and have sufficient bone quantity and quality to allow for the placement of implants of at least 3.75 mm in diameter and 10 mm in length.

The exclusion criteria were: participants with a history of chemotherapy or radiotherapy to the head and neck; medical conditions that could affect treatment response; the use of bisphosphonates within the last 12 months; uncontrolled diabetes; blood disorders; diseases affecting inflammation or bone metabolism; a history of alcoholism or drug use; smokers; ex-smokers who had quit for less than 3 years; a prior history of implant placement in the area; immunocompromised individuals (HIV, immunosuppressive medication, etc.); and finally, individuals who had lost teeth less than 4 months prior to the study.

Randomization of Participants

A total of nine participants were divided into 2 groups using an online randomization system (www.sealedenvelope.com). After randomization, a professional who neither treated nor evaluated the participants prepared individual envelopes with the identification number of each patient. Inside each envelope was information on the group to which the participant would be assigned: the control (C) or BlueM group.

Immediately after the surgical procedure, another professional who was not involved in the randomization or clinical data collection opened the envelopes to determine which group the participant belonged to. All participants were unaware of the group to which they were assigned.

Placement of Osseointegrated Implants and Prosthesis

All surgical and prosthetic procedures were performed by specialists at the Implantology Clinic of Ilapeo. Following clinical and radiographic diagnoses, each case underwent surgical and prosthetic planning. Pre-surgical procedures were performed where needed (periodontal preparation, surgical and prosthetic planning, obtaining a multifunctional guide). The same implant model (characteristics and size) was used for each participant.

The implant placement followed conventional surgical techniques. Immediately after implant placement, the insertion torque of each implant was measured using a torque wrench (Neodent, Curitiba, PR, Brazil), followed by impression for the construction of the fixed protocol-type prosthesis.

Mouthwash Treatments

After the implant surgery and with the prostheses installed, the participants were submitted to one of the following treatments: Control group (n=3), participants were instructed to use a mouthwash containing 0.12% chlorhexidine digluconate; whereas BlueM group (n=6) participants were instructed to use the BlueM mouthwash. Mouthwashes were recommended to be used twice daily, with a 12-hour interval, during the first 10 days post-surgery, and then once a day until 30 days post-surgery.

Clinical Evaluation

The clinical evaluations were carried out by a calibrated examiner blinded to the treatments. Evaluations were conducted at predetermined intervals during the study. Clinical parameters were assessed at 4 sites of each implant (mesial, distal, buccal, and lingual/palatal), at baseline (after suture removal, which occurred 10 days post-surgery) and again at 3 months post-surgery when the prosthesis was removed for cleaning.

The following clinical parameters were evaluated using a dichotomous criterion (0 = absent, 1 = present): Visible Plaque (VP); Presence of Calculus (PC); Marginal Bleeding (MB); Bleeding on Probing (BoP); Presence of Mucositis (MU); Presence of Peri-implantitis (Pi); and suppuration (SUP). The width of keratinized gingiva (KG) and probing depth (PD) were measured with a periodontal probe and expressed in millimeters. Furthermore, participants' satisfaction with the mouthwash was noted. Data collection for the clinical parameters was conducted using a calibrated periodontal probe (UNC-15, Hu-Friedy, Chicago, Illinois, USA), and the measurements were recorded in a specially designed clinical form.

Evaluation of Participant Satisfaction with Mouthwash

To assess satisfaction with the mouthwash all participants responded, free from any input from the researchers, to a Visual Analog Scale (VAS) with scores from 0 to 10. Scores 0–2 represented a totally unpleasant experience, 3-7 partially pleasant, and 8-10 totally pleasant.

Statistical Analysis

The program GraphPad Prism was used to perform the statistical analysis. The width of keratinized gingiva and probing pocket depth (measured in millimeter) were subjected to the following statistical tests: normality test (Shapiro-Wilk test), intragroup analysis (Wilcoxon test), and intergroup analysis (Mann-Whitney test), with a significance level of 80% and $P < 0.05$.

RESULT

Demographic Data

Demographic data of the 9 included participants demonstrated that 6 were assigned to the BlueM group and 3 to the control group (chlorhexidine). Of them, five individuals were male and 4 females. A total of 38 implants were installed in the maxilla (3 patients) and in the mandible (6 patients). All placed implants were Helix® Grand Morse® (GM) implants with an Acqua® hydrophilic surface (Neodent Curitiba, PR, Brazil), with a diameter and length ranging from 3.75 to 4.00 mm and 10.0 to 16.0 mm, respectively. Additionally, the primary insertion torque varied from 45 to 60 Nm.

Clinical Parameters

Results of the VP parameter indicate that participants in the BlueM group showed a greater reduction in sites with visible plaque (17.70%) compared to the control group over a 90-day period (Figure 1A). The PC results showed that both groups were effective in reducing the number of surfaces with calculus presence during the same 90-day period (Figure 1B). MB results point to the fact that the BlueM group had a greater reduction in sites with marginal bleeding over the 90-day period (Figure 1C). SUP results revealed that none of the participants in either group showed a presence of suppuration during the 90-day period (Figure 1D). MU results demonstrated that no participants in either group exhibited mucositis during the 90-day period (Figure 2A). PI results indicated that none of the participants in either group exhibited peri-implantitis during the 90-day period (Figure 2B).

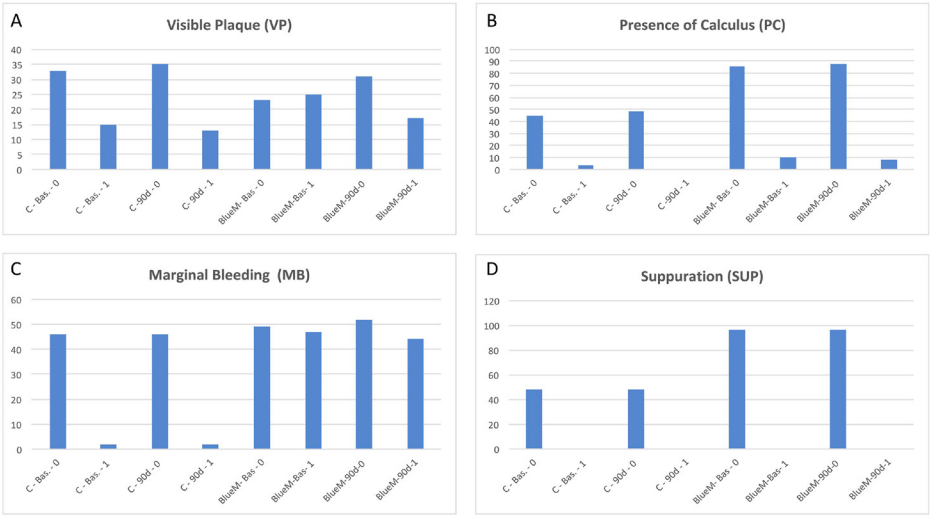

Figure 1. (A) Graphics representing the presence of visual plaque, (B) presence of calculus, (C) marginal bleeding, and (D) suppuration between control (C) and BlueM groups at baseline (day 0) and 90 days postoperative, using a dichotomous criterion (0 = absent, 1 = present).

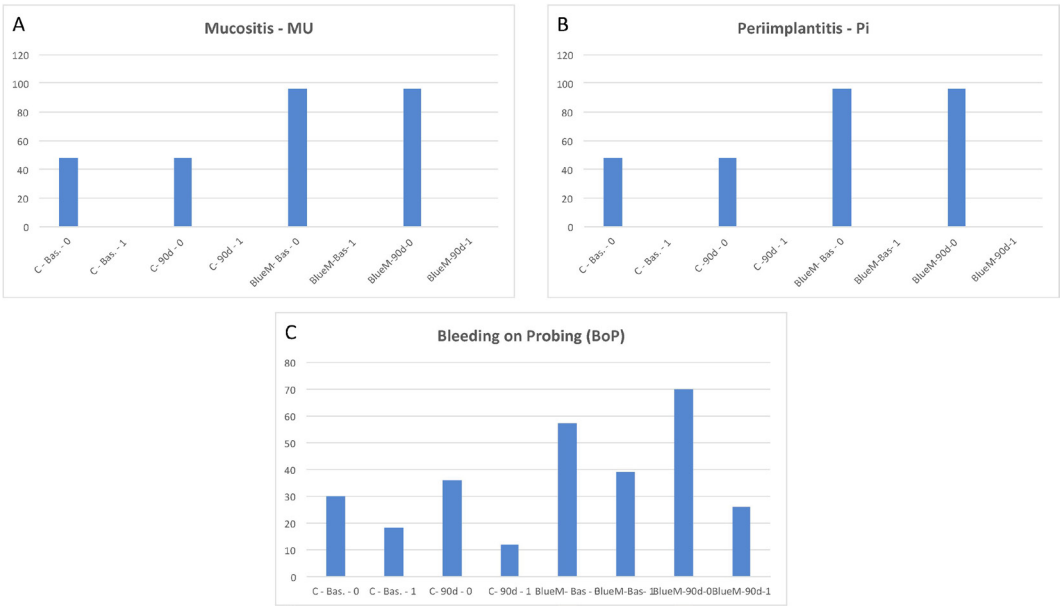

Figure 2. (A) Graphics representing mucositis index, (B) periimplantitis index, and bleeding on probing (C), comparing the control (C) and BlueM groups at baseline (day 0) and 90 days postoperative, using a dichotomous criterion (0 = absent, 1 = present).

BOP results showed a reduction in the number of sites with bleeding on probing in both groups (Figure 2C). The results regarding the extent of KG and PD (measured in millimeters) demonstrated that neither treatment was effective in reducing the extent of keratinized gingiva, maintaining it stable after 90 days postoperatively, with an average of 6.1 mm in the Control group and 4.55 mm in the BlueM group (Figure 3A). The PD assessment indicated that both mouthwashes significantly reduced probing depth (Figure 3B). Participant satisfaction was higher in the BlueM group, with 5 out of 9 reporting totally(55.5%), compared to the Control group (Figure 3C).

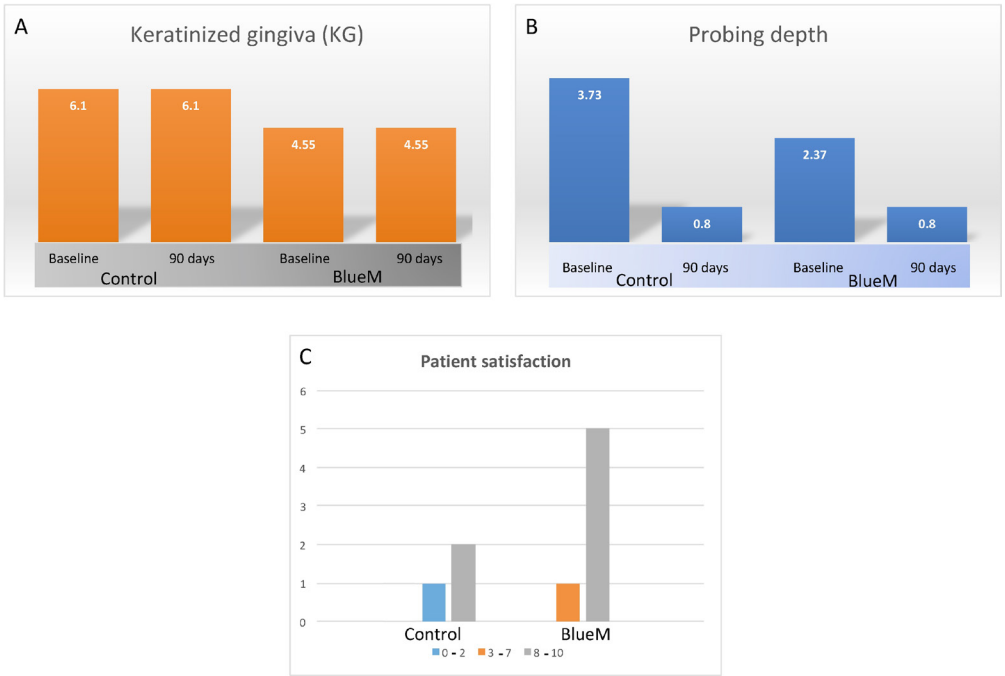

Figure 3. (A) Graphics (expressed in millimeters) representing the width of keratinized gingiva, and (B) probing depth, comparing the control (C) and BlueM groups at baseline (day 0) and 90 days postoperative. Figure 3C is a graphic representative of patient satisfaction using the Visual Analog Scale (VAS).

DISCUSSION

This study has clinically evaluated the effectiveness of the oxygen-releasing mouthwash, commercially known as BlueM®, on peri-implant health in patients receiving the placement of implants subjected to immediate loading and fixed prosthesis installation. The results of this study have indicated that BlueM as mouthwash is as good as chlorhexidine in preventing biofilm formation and might be considered a viable alternative to use after prosthesis installation to maintain the peri-implant health.

Mouthwash use has garnered attention from clinicians, specialists and researchers, due to its effectiveness in controlling bacterial biofilm. While various agents have been proposed for biofilm control, only two have proven efficacy: 0.12% chlorhexidine digluconate and essential oils[12,13]. Chemical agents for biofilm control are widely used in periodontology, particularly in combination with mechanical therapies. The literature shows notable differences between periodontal and peri-implant biofilms, with the peri-implant biofilm being far more complex than the one seen in periodontitis[19]. Although there are common bacterial genera between the two, some species are unique to the peri-implant biofilm, such as *Butyviribrio, Campylobacter, Eubacterium, Prevotella, Selenomonas, Streptococcus, Actinomyces, Leptotrichia, Propionibacterium, Peptococcus, Campylobacter* and *Treponema*[20]. Additionally, research has shown differences in biofilm composition on various implant surfaces[21]. These findings support the use of mouthwash as an adjunct therapy to conventional mechanical biofilm control. It is also important to note that periodontal pathogens such as *Porphyromonas gingivalis, Porphyromonas intermedia, Aggregatibacter actinomycetemcomitans, Tannerella forsythiae,* and *Treponema denticola* have been identified in peri-implant diseases like peri-implantitis[22].

The results of the present study have indicated that, over a 90-day period, both chlorhexidine and BlueM mouthwash had beneficial effects on peri-implant tissue repair, without causing adverse effects. Those using BlueM mouthwash showed a greater reduction in the percentage of visible plaque (17 out of 96 = 17.70%), dental calculus (8 out of 96 = 8.33%), gingival bleeding (44 out of 96 = 45.83%), and bleeding on probing (26 out of 96 = 27.08%). Both mouthwashes were effective in reducing probing depth, although they did not alter the extent of keratinized tissue and helped prevent the onset of suppuration, mucositis, and peri-implantitis.

The benefits of chlorhexidine in periodontal and peri-implant health are well-documented in the literature[12,13,23-25]. However, despite its effectiveness, chlorhexidine has been associated with several undesirable effects, such as tooth staining, calculus buildup, taste alteration, oral mucosa changes, fungal growth, and parotid gland edema[14,26]. Although the exact action mechanism of BlueM mouthwash is not fully understood, it contains various components, including water, honey, sodium lauryl sulfate, polyvinylpyrrolidone, hydrogenated castor oil, sodium citrate, flavoring, cellulose gum, sodium perborate, sodium methylparaben, xylitol, methyl salicylate, lactoferrin, magnesium sulfate, linalool, PEG-40, and coloring agents, according to the manufacturer. The beneficial results observed in this study from participants using BlueM mouthwash likely stem from its components, which promote oxidative activity (sodium perborate), antimicrobial action (honey, linalool), neutrophil and lymphocyte proliferation, macrophage activation, nitric oxide and cytokine production (lactoferrin), and analgesic and anti-inflammatory effects (methyl salicylate, linalool), in addition to the release of oxygen peroxide in the area (linalool).

The results have underscored the benefits of using BlueM mouthwash on peri-implant health, making it a viable alternative that can be applied from the time of osseointegrated implant placement and throughout maintenance therapy. It controls biofilm formation, prevents dental calculus formation and manages the peri-implant inflammatory response, as evidenced by the reduction of visible plaque, dental calculus, marginal bleeding, and bleeding on probing. Additionally, BlueM mouthwash was well accepted by patients, with around 55% of participants reporting favorable experiences (5 out of 9 = 55.5%).

Despite the promising results of using BlueM, the present study does have some limitations that should be acknowledged. As a pilot study with a small sample size, the findings may not be generalizable to a broader population. Additionally, the short follow-up period has limited our ability to draw conclusions about the long-term effects of BlueM. Therefore, further clinical studies with larger sample sizes and longer evaluation periods are necessary before a definitive conclusion can be reached.

CONCLUSION

Based on the results, it can be concluded that BlueM mouthwash is effective in controlling biofilm formation, reducing dental calculus, and decreasing gingival inflammation. The evaluated clinical parameters have shown comparable results to chlorhexidine.

AUTHOR CONTRIBUTIONS STATEMENT

Conceptualization: CPC, RMF, EMJr, RSdM, VGG; Methodology: CPC, RMF, EMJr, RSdM, VGG; Validation: CPC, RMF, EMJr, RSdM, VGG; Formal analysis: CPC, RMF, EMJr, RSdM, VGG; Investigation: CPC, RMF, EMJr, RSdM, VGG; Data curation: CPC, RMF, EMJr, RSdM, VGG; Writing—original draft preparation: RSM and VGG: Writing—review and editing: CPC, RMF, EMJr, RSdM, VGG; Supervision: VGG. All authors have read and agreed to the published version of the manuscript.

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CONFLICTS OF INTERESTS

The authors declare that there is no conflict of interest related to this study.

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