EARLY RECOVERY AFTER IMPACTED MANDIBULAR THIRD MOLAR SURGERY WITH BLUE M HEALING GEL

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Impacted mandibular third molar surgery is commonly followed by pain, facial swelling, trismus, and delayed soft-tissue healing, which can affect patient comfort and oral function. This controlled clinical interventional study with longitudinal follow-up evaluated Blue M gel as an adjunctive local therapy after impacted mandibular third molar removal. Eighty-six eligible patients were randomly assigned to the Blue M gel group or the control group, with 43 patients in each group. Baseline demographic, clinical, and tooth-related characteristics were comparable. Postoperative outcomes included facial swelling, pain, trismus, gingival coverage of the extraction socket, and early wound healing. Both groups showed gradual reduction in swelling over time, but the Blue M gel group had significantly less postoperative swelling after adjustment. Pain scores were also significantly lower in the Blue M gel group from day 1 to day 7. No significant between-group difference was observed for trismus. At day 7, the Blue M gel group showed better gingival coverage of the extraction socket and more favorable wound healing (OR = 5.22 [95% CI: 1.57 - 17.43], p < 0.001) than the control group. These findings suggest that Blue M gel may improve early postoperative recovery after impacted mandibular third molar surgery, particularly by reducing swelling and pain and enhancing gingival coverage and soft-tissue healing.

Keywords: Impacted mandibular third molar; Blue M gel; postoperative pain; facial swelling; wound healing.

I. INTRODUCTION

Surgical removal of impacted mandibular third molars is one of the most frequently performed procedures in oral and maxillofacial surgery.[1] Despite its routine nature, the early postoperative period is still commonly characterized by pain, facial swelling, trismus, and delayed soft-tissue recovery, all of which may impair mastication, oral hygiene, and short-term quality of life. Although multiple pharmacologic and non-pharmacologic strategies have been proposed to mitigate these sequelae, no single approach has consistently optimized all major postoperative outcomes without practical limitations or unwanted effects.[2,3]

In recent years, topical oxygen-based therapy has attracted increasing interest in oral wound care because oxygen availability is closely linked to fibroblast activity, angiogenesis, epithelial migration, collagen organization, and local microbial control. Blue® M gel, an oxygen-releasing topical agent, has shown promising effects in oral soft-tissue healing and postoperative pain reduction in other dental settings, and contemporary reviews have highlighted its potential role as an adjunct in oral surgery and periodontology.[4,5] However, clinical evidence specifically addressing its

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use after impacted mandibular third molar surgery remains limited, and, to the best of our knowledge, published data from Vietnam are still lacking. Against this background, the present controlled study was conducted to evaluate whether adjunctive Blue® M gel could improve postoperative swelling, pain, trismus, gingival coverage, and early wound healing after impacted mandibular third molar surgery.

II. OBJECTS AND METHODS

1. Study population

Patients with an indication for surgical removal of an impacted mandibular third molar who presented for examination and treatment at Kien Giang General Hospital were considered eligible for recruitment.

The inclusion criteria

Patients aged 18 years or older who had an indication for surgical removal of an impacted mandibular third molar. Eligible participants were those with impacted mandibular third molars classified as Pell and Gregory class IIA or IIB. In addition, only patients who voluntarily agreed to participate in the study were included.

The exclusion criteria

Patients who were undergoing treatment for periodontal disease; or had previously undergone extraction of the mandibular second molar or had a fractured distal surface of this tooth; and individuals with a history of allergy to local anesthetics or to any medications used during or after the surgical procedure. Patients with uncontrolled systemic conditions, including hypertension, cardiovascular disease, diabetes mellitus, or coagulation disorders, were also excluded. In addition, patients receiving treatment for other medical conditions that required anticoagulant therapy, or were pregnant or breastfeeding, and/or unable or unwilling to comply with the follow-up schedule were not eligible for inclusion in the study.

2. Methods

Study design

A controlled clinical interventional study with longitudinal follow-up.

Sample size and sampling method

The sample size was calculated based on the primary outcome of postoperative pain intensity measured by the visual analogue scale. The reference standard deviation was derived from the study by Alenazi et al., which evaluated intra-socket hyaluronic acid application after lower impacted third molar extraction. In that study, postoperative VAS scores on day 3 were 5.20 ± 1.62 in the intervention group and 5.90 ± 1.79 in the control group; therefore, an SD of approximately 1.6 was used for sample size estimation.[6] A minimum clinically meaningful between-group difference of 1.0 point in VAS score was assumed. With a two-sided α of 0.05 and 80% power, the required sample size was 41 patients per group.

Eligible patients who met the study criteria were recruited consecutively from July 2025 to January 2026. After written informed consent and confirmation of eligibility, participants were randomly allocated according to a pre-prepared random number list. Patients assigned an odd number were allocated to the intervention group, in which Blue M gel was used during impacted mandibular third molar surgery, whereas those assigned an even number were allocated to the control group, in which the same surgical procedure was performed without Blue M gel. Because the intervention was applied intraoperatively, the surgeon was aware of group allocation and was not involved in postoperative outcome assessment. Postoperative pain, facial swelling, trismus, gingival coverage of the extraction socket, and wound healing were evaluated by an independent examiner who

was not involved in the surgical procedure. The primary outcome was postoperative pain intensity measured using the visual analogue scale on postoperative day 1. Secondary outcomes included facial swelling, trismus, gingival coverage of the extraction socket, and overall wound healing and recovery. In total, 86 patients were enrolled and equally distributed between the two groups.

Study variables

Baseline characteristics included age, gender, chief complaint, tooth position, clinical visibility of the impacted mandibular third molar, gingival coverage, angulation on panoramic radiography, vertical position according to the Pell and Gregory classification, and distal bone loss of the mandibular second molar. Chief complaint was categorized as pain/swelling, trismus or difficulty eating, prophylactic extraction, or other reasons. Tooth position was recorded as tooth 38 or 48. Clinical visibility was classified as partially visible or not visible, while gingival coverage was categorized as the gingival margin at or below the occlusal plane, partial occlusal surface coverage, or complete occlusal surface coverage. Angulation was assessed on panoramic radiographs by tracing the long axes of the mandibular second molar and the impacted mandibular third molar and measuring the angle formed between them. Vertical position was classified as Class A or Class B according to Pell and Gregory. Distal bone loss of the mandibular second molar was categorized as normal, mild, moderate, or severe based on the level of the alveolar crest relative to the cementoenamel junction and root length.

All patients underwent surgery and postoperative follow-up according to a standardized protocol. Postoperative assessments were performed on days 1 (T1), 3 (T3), 5 (T5), and 7 (T7) to evaluate pain intensity using the visual analogue scale (VAS), facial swelling based on the AC, AD, and BE facial measurements, and trismus, defined as a maximum mouth opening of less than 35 mm. In these measurements, A represented the earlobe attachment, C the corner of the mouth, D the pogonion, B the angle of the mandible, and E the lateral canthus of the eye. On postoperative day 7, additional evaluations included gingival coverage over the extraction socket and overall wound healing and recovery. Gingival coverage was classified as incomplete coverage with the socket filled by a blood clot, early granulation tissue formation, complete epithelialization, or bone remodeling. Postoperative healing and recovery were graded as good, fair, or poor. Good healing was defined by the absence of pain and swelling, normal local findings, a clean surgical wound, no numbness or pain in the mandibular second molar, and good masticatory function. Fair healing was defined by the presence of at least two mild symptoms, including mild pain or swelling, mouth opening limitation, pseudomembrane formation at the surgical site, and the ability to tolerate soft food. Poor healing was defined by the presence of at least one adverse sign, such as inflammation at the extraction site, purulent discharge, possible ipsilateral lip numbness, or marked limitation of mouth opening.[7]

Study protocol

At enrollment, patients underwent history taking, clinical examination, and panoramic radiography. The study was explained, written informed consent was obtained, and required preoperative laboratory tests were completed before surgery. Group allocation was performed using block randomization by drawing lots. Before recruitment, 22 blocks of four lots, each containing two 1 labels and two 2 labels were prepared to obtain equal allocation of

86 participants. Eligible patients were enrolled consecutively and drew one concealed lot after completion of baseline assessment and immediately before surgery. Label 1 corresponded to the Blue M gel group, whereas label 2 corresponded to the control group. In the intervention group, impacted mandibular third molar surgery was performed with adjunctive Blue M healing gel, whereas the control group underwent the same procedure without Blue M gel. All surgeries were performed by the same surgeon who had formal training in oral and maxillofacial surgery and experience in impacted mandibular third molar removal, under standardized antiseptic conditions using 10% povidone-iodine and sterile draping. Local anesthesia was achieved with lidocaine 2% with epinephrine 1:100,000 by inferior alveolar nerve block with supplementary buccal and lingual infiltration. A mucoperiosteal flap was raised using a No. 15 blade, followed by buccal bone removal under continuous saline irrigation, tooth sectioning when necessary, tooth extraction, socket inspection, and debridement as indicated. In the intervention group, Blue M gel was applied to fill the extraction socket for approximately 2 minutes and then rinsed with normal saline; this step was omitted in the control group. The wound was closed with 3-0 silk sutures in a standardized manner. Postoperatively, all patients received the same antibiotics, analgesics, and anti-inflammatory drugs for 5 to 7 days, together with standardized postoperative instructions. Follow-up visits were scheduled on postoperative days 1, 3, 5, and 7, and all findings were recorded in the data collection form.

Data analysis and processing

Data were processed and analyzed using R software version 4.5.0. The primary analysis was performed using a complete-case/per-protocol approach, including participants who received the allocated intervention and completed postoperative follow-up. If no participants were lost to follow-up or crossed over between groups, all allocated participants were included in the final analysis. Continuous variables were summarized as mean ± standard deviation, whereas categorical variables were presented as frequencies and percentages. Comparisons of continuous variables were performed using the independent-samples t test, while categorical variables were compared using the chi-square test, Fisher's exact test, or the Fisher-Freeman-Halton test, as appropriate. Adjusted p values for continuous outcomes, including changes in the AC, AD, and BE measurements at postoperative time points relative to baseline (T0), were obtained using analysis of covariance (ANCOVA) with adjustment for baseline covariates selected based on clinical relevance or a univariable p value < 0.20. Effect sizes were reported with 95% confidence intervals. Mean differences with 95% confidence intervals were used for continuous outcomes, whereas odds ratios or risk ratios with 95% confidence intervals were used for categorical outcomes. For binary categorical outcomes, such as wound healing and recovery at postoperative day 7, multivariable logistic regression was used to obtain adjusted estimates. A p value < 0.05 was considered statistically significant.

3. Ethics approval

The study was approved by the Scientific Research Council and the Biomedical Research Ethics Committee of Can Tho University of Medicine and Pharmacy on June 30, 2025, under Approval No. 25.550.HV/PCT-HĐĐĐ.

III. RESULTS

A total of 86 patients indicated for mandibular impacted third molar extraction who met the eligibility criteria were randomly allocated to either the Blue M gel group or the non-Blue M gel group, with 43 patients in each group (Figure 1). Selected baseline characteristics of the study population in the two groups are presented in Table 1.

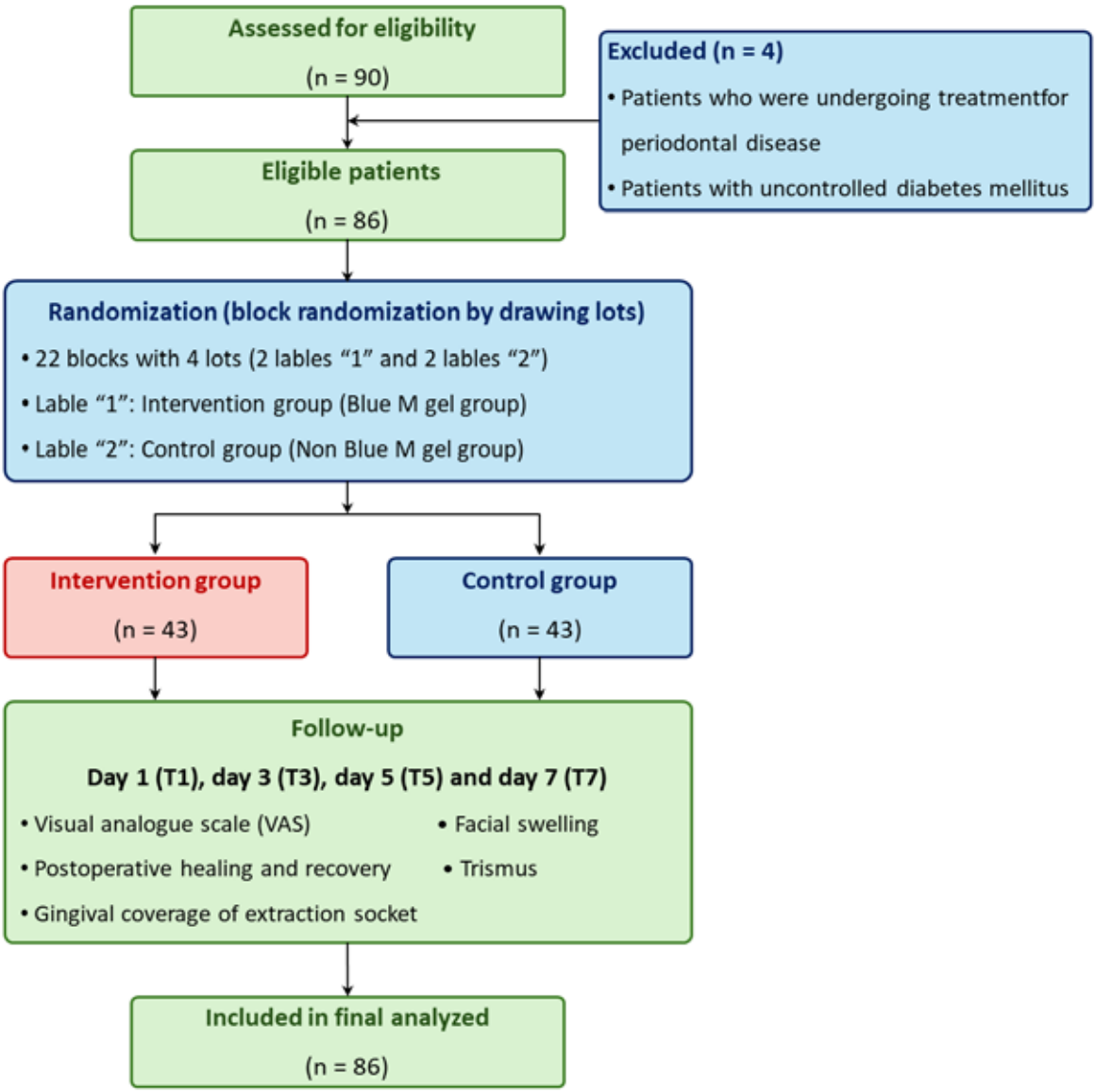

Figure 1. Flowchart of study

Table 1. Baseline characteristics of the study population

Characteristics	Using Blue M gel	Non-using Blue M gel	Total	p
Gender				
- Male	21 (48.8)	19 (44.2)	40 (46.5)	0.665[a]
- Female	22 (51.2)	24 (55.8)	46 (53.6)	
Age (years), mean (SD)	26.9 (7.1)	29.3 (8.3)	28.1 (7.8)	0.161[b]
Chief complaint				
- Pain/swelling	5 (11.6)	6 (14.0)	11 (12.8)	0.233[c]
- Trismus/difficulty eating	7 (16.3)	3 (7.0)	10 (11.6)	
- Prophylactic extraction	18 (41.9)	13 (30.2)	31 (36.0)	
- Other	13 (30.2)	21 (48.8)	34 (39.5)	
Tooth position				
- Tooth 38	18 (41.9)	18 (41.9)	36 (41.9)	1.000[a]
- Tooth 48	25 (58.1)	25 (58.1)	50 (58.1)	
Impacted mandibular third molar visibility				
- Partially visible	35 (81.4)	37 (86.0)	72 (83.7)	0.559[a]
- Not visible	8 (18.6)	6 (14.0)	14 (16.3)	
Gingival coverage over third molar				
- Gingival margin at/below the occlusal plane	5 (11.6)	5 (11.6)	10 (11.6)	0.839[a]
- Partial occlusal surface coverage	30 (69.8)	32 (74.4)	62 (72.1)	
- Complete occlusal surface coverage	8 (18.6)	6 (14.0)	14 (16.3)	
Angulation				
- ≤ 30^{o}	0 (0.0)	3 (7.0)	3 (3.5)	0.372[c]
- 30^{o} - ≤ 45^{o}	9 (20.9)	8 (18.6)	17 (19.8)	
- 45^{o}- ≤ 60^{o}	10 (23.3)	9 (20.9)	19 (22.1)	
- 60^{o} - ≤ 90^{o}	24 (55.8)	23 (53.5)	47 (54.7)	
Vertical Pell and Gregory classification				
- Class A	36 (83.7)	42 (97.7)	78 (90.7)	0.058[d]
- Class B	7 (16.3)	1 (2.3)	8 (9.3)	

Characteristics	Using Blue M gel	Non-using Blue M gel	Total	p
Distal bone loss of the second molar				
- Normal	4 (9.3)	3 (7.0)	7 (8.1)	0.391[c]
- Mild bone loss	14 (32.6)	16 (37.2)	30 (34.9)	
- Moderate bone loss	22 (51.2)	24 (55.8)	46 (53.5)	
- Severe bone loss	3 (7.0)	0 (0.0)	3 (3.5)	
Surgical time (minutes), mean (SD)	21.3 (7.3)	20.5 (6.9)	20.9 (7.1)	0.601[b]
Intraoperative complications				
- Absent	32 (74.4)	39 (90.7)	71 (82.6)	0.043[b]
- Root fracture	11 (25.6)	4 (9.3)	15 (17.4)	

[a]Chi-square, [b]Independent Sample T, [c]Fisher Freeman Halton Exact, [d]Fisher's exact

For baseline characteristics were shown in Table 1, no statistically significant differences were observed between the Blue M gel and non-Blue M gel groups across demographic, clinical, and tooth- and surgery-related variables, except for intraoperative complications (p = 0.043), indicating that the two groups were comparable at baseline.

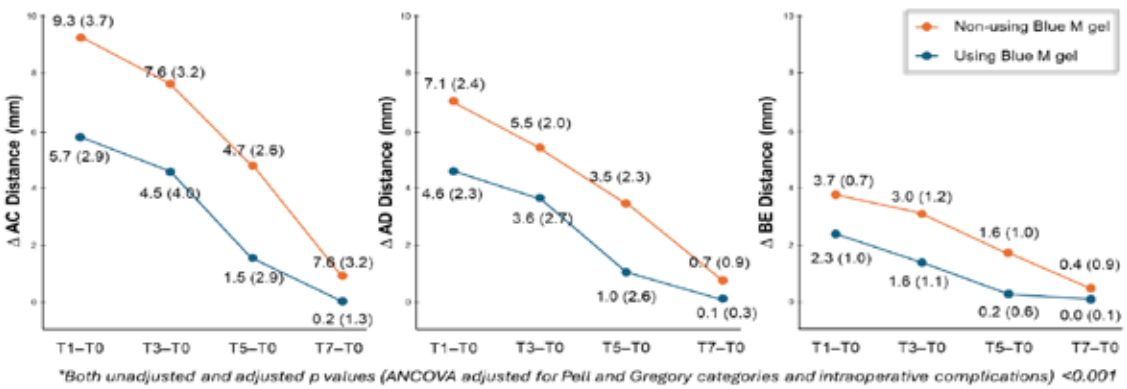

Figure 2. Changes in facial swelling measurements over time between the Blue M gel and non-Blue M gel groups

Figure 2 shows the changes in facial swelling at each postoperative time point relative to the preoperative baseline progressively decreased in both groups, with consistently smaller mean changes in the Blue M gel group than in the non-Blue M gel group. These between-group differences remained statistically significant after adjustment (p < 0.001).

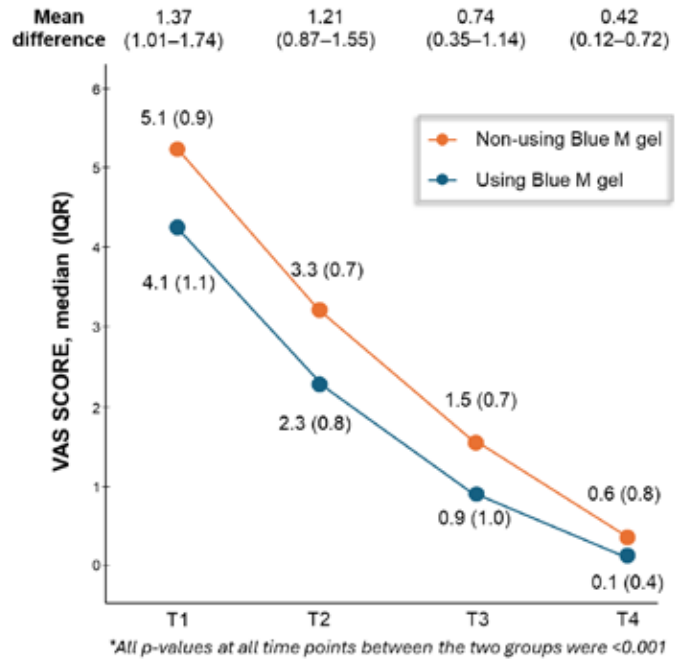

Figure 3. Comparison of VAS scores over time between the Blue M gel and non-Blue M gel groups

Figure 3 shows a progressive decrease in VAS scores over time in both groups, with consistently lower scores in the Blue M gel group than in the non-Blue M gel group at all time points (all $p < 0.001$).

Table 2. Postoperative trismus and gingival coverage status

Characteristics	Using Blue M gel	Non-using Blue M gel	p
Trismus, n (%)			
- Day 1	1 (2.3)	1 (2.3)	0.999[a]
- Day 3	0 (0.0)	0 (0.0)	-
Gingival coverage of extraction socket after 7 days, n (%)			0.032[b]
- Initial granulation tissue formation	0 (0.0)	6 (13.9)	
- Complete epithelialization	43 (100)	37 (86.1)	

[a]Fisher's exact, [b]Fisher Freeman Halton exact

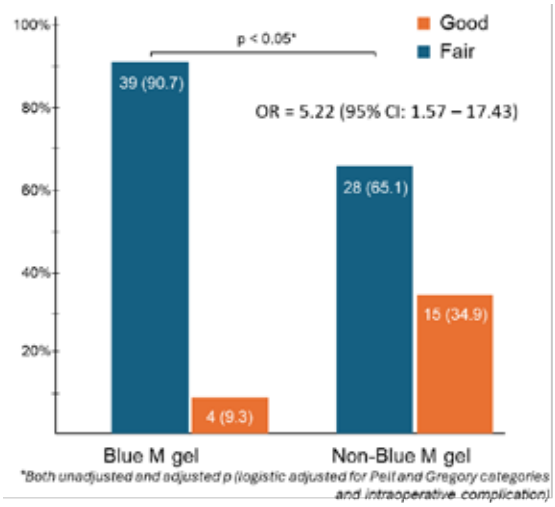

Figure 4. Postoperative healing and recovery assessment

Table 2 and Figure 4 show that the Blue M gel group had better gingival coverage of the extraction socket at day 7, and more favorable wound healing and recovery than the non-Blue M gel group. In contrast, postoperative trismus did not differ significantly between the two groups.

IV. DISCUSSION

In this randomized controlled study, adjunctive Blue® M gel was associated with a more favorable early postoperative course after impacted mandibular third molar surgery. Compared with the non-Blue® M group, patients receiving Blue® M gel experienced less postoperative swelling and pain, together with better gingival coverage of the extraction socket and more favorable early wound healing, whereas postoperative trismus did not differ meaningfully between groups. From a clinical perspective, these findings suggest that Blue® M gel may serve as a simple local adjunct to improve patient comfort and soft-tissue recovery during the first postoperative week, particularly in situations where clinicians wish to enhance local healing without increasing systemic medication burden.

The findings regarding swelling, pain, and trismus are broadly consistent with previous work on topical adjuncts used after third molar surgery, although the magnitude and pattern of benefit have not been uniformed across studies. In a split-mouth trial involving 60 patients with bilateral impacted mandibular third molars, Kazancioglu et al. found that ozone therapy significantly reduced postoperative pain and analgesic consumption, but did not produce significant differences in mouth opening or swelling between sides.[8] By contrast, Sivalingam et al, in a randomized controlled trial including 33 patients, reported significant reductions in postoperative pain, swelling, and trismus, together with lower analgesic requirements in the ozone-treated group.[9] Glória et al, in a triple-blind randomized trial of 20 patients, similarly observed satisfactory postoperative control with ozonized irrigation, yet found no significant between-group difference in oedema or trismus.[10] A comparable pattern has also been reported with hyaluronic acid-based adjuncts. Yilmaz et al studied 25 patients with bilaterally impacted lower third molars and found significantly lower pain scores with 0.8% hyaluronic acid, but no significant change in swelling or maximal mouth opening.[11] In contrast, Al-Saadi and Al-Quisi reported in 66 patients that 1% hyaluronic acid gel significantly reduced pain, swelling, and trismus compared with the control group.[12] Taken together, these studies suggest that local adjuncts may more consistently attenuate nociception and superficial inflammatory edema than trismus. This is biologically plausible because trismus after third molar surgery is not driven solely by inflammation, but also by masticatory muscle trauma, flap reflection, extent of bone removal, surgical difficulty, and individual muscular reactivity.

The soft-tissue findings in the present study are particularly noteworthy because they align well with the proposed biologic rationale of oxygen-based wound modulation. In a split-mouth randomized clinical trial of 20 patients undergoing gingival depigmentation, Juliana and Tarek showed that Blue® M gel produced significantly lower pain scores during the first 5 postoperative days and significantly better re-epithelialization during the first 3 postoperative weeks than Coe-Pack dressing.[5] In a case series of 11 oral surgery patients, Mattei et al also reported lower pain and less postoperative inflammatory burden on the Blue® M-treated side, suggesting a favorable influence on early tissue recovery.[13] Findings from third molar studies using other bioactive topical materials point in the same general direction. Gocmen et al included 40 patients and found that hyaluronic acid was associated with less leukocyte infiltration and greater angiogenesis at 1 week, even though VAS pain and mouth opening were not significantly different between groups.[14] More recently, Alenazi et al reported in 40 dental patients that intra-socket hyaluronic acid promoted more favorable socket healing and reduced postoperative pain and swelling, while interincisal opening remained statistically similar between groups.[6] Collectively, these data support the interpretation that improvements in gingival coverage and early wound appearance may arise from modulation of the local healing microenvironment, including enhanced angiogenesis, more efficient re-epithelialization, better moisture balance, and reduced microbial burden. These effects may become clinically visible earlier in the soft tissues than in muscle-related functional recovery such as mouth opening.

Several limitations should be acknowledged. First, this was a single-center study with a relatively modest sample size, which may limit generalizability and reduce power for outcomes that are less frequent or less sensitive to local topical therapy, particularly trismus. Second, follow-up was limited to the early postoperative period, so the findings primarily reflect short-term symptom control and early soft-tissue healing rather than longer-term socket maturation or bone healing. Finally, the study relied on clinical outcome measures without biochemical or histologic assessment, so the underlying mechanisms of Blue® M gel in this surgical setting remain inferential rather than directly demonstrated. Future multicenter studies with longer follow-up, more objective wound-healing metrics, and mechanistic endpoints would help clarify the durability and biologic basis of these early clinical benefits.

V. CONCLUSION

Within the limitations of a single-center controlled clinical interventional study with longitudinal follow-up, adjunctive Blue M gel provides short-term clinical evidence of improved early postoperative recovery after impacted mandibular third molar surgery. Its use was associated with lower postoperative pain and swelling and more favorable gingival coverage and wound healing during the first postoperative week, whereas no meaningful benefit was observed for trismus. Clinically, Blue M gel may be considered as a local adjunct to standard surgical and postoperative care in selected patients to support early comfort and soft-tissue healing. However, it should not replace established postoperative management. Larger multicenter studies with longer follow-up are needed to confirm these findings and to better define its role in routine clinical practice.

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