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## **Original Research Article**

# New age oxygen therapy for enhanced recovery: BLUE®M oral gel in post-extraction socket healing

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#### **Abstract**

**Background:** Tooth extraction initiates a cascade of healing events in both soft and hard tissues. Various dressings had been used to optimize healing and minimize post-extraction complications such as dry socket. Blue®M oral gel, an oxygen-releasing de-novo dressing have shown promising results in enhanced healing in different dimensions of dentistry but role in post-extraction socket healing is not very well demonstrated in literature. The study aimed at studying its clinical efficacy in post-extraction alveolar sockets.

Materials and Methods: A prospective randomized controlled comparative study was conducted on 30 patients requiring tooth extraction. Patients were assigned into two groups: Group A (Blue®M oral gel) and Group B (placebo - KY jelly). Visual Analogue Scale (VAS) for pain and Landry Healing Index were assessed on postoperative days 3 and 7.

**Results:** On postoperative day 3, the mean VAS score for pain was significantly lower in Group A  $(4.00\pm0.93)$  compared to Group B  $(5.40\pm0.51)$  (p=0.0002). By day 7, pain scores were similar in both groups. The Landry Healing Index score was significantly better in Group A on both day 3 (p=0.0124) and day 7 (p<0.0001), indicating faster healing.

Conclusion: Blue®M oral gel significantly enhanced post-extraction healing and reduced pain in early postoperative days. It presented a promising alternative to conventional dressings for optimizing alveolar healing.

Keywords: Blue®M oral gel, Wound healing, Post-Extraction alveolar socket, Oxygen therapy

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# 1. Introduction

Despite substantial progress in restorative and preventive dentistry, tooth extraction remains a fundamental procedure. Exodontia involves the careful removal of a tooth or root with minimal trauma to surrounding structures to ensure uneventful healing and prevent post-procedural complications. The healing of the extraction socket is a well-coordinated biological process involving both soft and hard tissues, culminating in the regeneration of new bone and full socket closure. <sup>1</sup>

Socket healing occurs in distinct stages unfolding over a period of 12 to 24 weeks, though individual biological factors can influence the duration.<sup>2</sup> Various animal and human studies have provided insight into the typical timeline and mechanisms of repair.<sup>3</sup>

Following extraction, the healing cascade initiates with clot stabilization, this clot in the first week, is replaced by granulation tissue, and initial mineralized tissue is deposited. By 2–4 weeks, provisional matrix formation occurs and over the following 6–8 weeks, woven bone formation predominates. In the final healing stage (12–24 weeks), woven bone transitions into lamellar bone, completing the remodelling phase.<sup>1</sup>

Despite the natural healing process, complications such as alveolar osteitis (dry socket) can arise, characterized by premature clot disintegration, severe pain, and delayed healing.<sup>4</sup> This manifests as exposed bone accompanied by necrotic tissue breakdown and persistent discomfort.

Post-extraction complications can be immediate, delayed, or long-term. Immediate complications include anesthesia failure, root fractures, alveolar bone fractures, and

\*Corresponding author: Muskan Grover Email: muskangrover5@gmail.com nerve damage. Delayed complications may involve excessive pain, soft tissue infections, swelling, and alveolar osteitis. In the long term, complications such as chronic osteomyelitis and neuropathic pain can develop, affecting overall oral health.<sup>5</sup>

The primary mechanism underlying alveolar osteitis is increased fibrinolytic activity, leading to clot degradation. Studies have identified the plasminogen pathway as a key player in clot lysis, with systemic fibrinolysis further exacerbating the condition.<sup>6</sup> Bacterial colonization has also been implicated, as elevated microbial loads prior to extraction have been correlated with a higher incidence of alveolar osteitis.<sup>7</sup>

The oral cavity presents a unique environment for wound healing, characterized by high vascularization, rapid cellular turnover, and fluctuating oxygen levels. Hypoxic conditions can hinder recovery by increasing infection susceptibility and slowing nutrient transport to regenerating tissues.<sup>8</sup> Oxygen plays a pivotal role in cellular metabolism, protein synthesis, and overall tissue repair.<sup>9</sup>

Oxygen therapy has been employed in medicine for over a century, dating back to its discovery by Joseph Priestley in 1774. <sup>10</sup> Recently, topical oxygen therapy has gained attention in oral- soft tissue and wound care, with emerging evidence supporting its role in enhancing the healing and controlling microbial imbalances that may delay recovery. <sup>11,12</sup>

One such topical oxygen-releasing agent is Blue®M oral gel, formulated to facilitate post-extraction healing while offering antimicrobial benefits. The gel contains glucose oxidase and sodium perborate, which, upon interaction with tissue fluids, produce low concentrations of hydrogen peroxide (0.003–0.15%). Additionally, lactoferrin, a key ingredient, enhances osteoblast proliferation, contributing to bone regeneration. <sup>13</sup>

Blue®M oral gel adheres to fundamental principles of oxygen therapy, offering multiple benefits in oral wound healing; accelerating cellular metabolism, enhancing collagen synthesis, stimulating growth factor release supporting wound regeneration. Additionally, the gel promotes angiogenesis, ensuring optimal blood supply to healing tissues.<sup>13</sup>

With its broad therapeutic potential, the gel also promises to be beneficial for minimizing post-extraction bleeding, expediting soft tissue healing, and preventing bacterial colonization.<sup>13</sup>

The study is an attempt to define the efficacy of this denovo dressing, Blue<sup>®</sup>M oral gel, in comparison to a placebo control group for post-extraction socket healing. By analyzing pain reduction, inflammatory response, and tissue regeneration using validated clinical indices, the study aimed to assess the gel's clinical utility in optimizing oral wound management.

## 2. Materials and Methods

# 2.1. Study design

This study was designed as a prospective randomized controlled trial conducted at the Department of Oral and Maxillofacial Surgery, I.T.S Center for Dental Science and Research (ITS-CDSR), Muradnagar, Ghaziabad. The study included 30 patients who required asymptomatic tooth extractions. Participants were randomly allocated into two groups using a chit-draw method: Group A received Blue®M oral gel, while Group B received KY Jelly. [Figure 1]

## 2.2. Sample size determination

A total of 30 patients were enrolled in the study, with 15 participants in each group. The sample size was determined based on the feasibility of conducting the study within the available timeframe and resources, ensuring adequate representation for comparative analysis.

# 2.3. Blinding

Single-blinded study, wherein only the patients were unaware of the group allocation and the type of gel applied to their extraction sockets. However, the operator performing the extractions and applying the gel was not blinded.

### 2.4. Allocation concealment

Randomization was achieved using a chit-draw method to ensure unbiased allocation of participants into the two groups. The chits ensured that patients had fair chances of falling into any group.

#### 2.4.1. *Groups*

Participants were divided into two groups:

- 1. Group A: Received Blue®M oral gel applied to the extraction socket postoperatively.
- 2. Group B: Received KY Jelly applied to the extraction socket postoperatively.

# 2.5. Method

Inclusion criteria consisted of men and women aged 15–55 years with good oral hygiene requiring elective extractions for reasons such as supernumerary teeth, retained deciduous teeth, orthodontic purposes, or esthetic concerns. Exclusion criteria included patients allergic to any drug, those with cystic or tumorous teeth, chronic smokers or alcoholics, medically compromised individuals (ASA III and above), and those with systemic disorders affecting wound healing. Informed consent was obtained from all participants before their inclusion in the study and for the usage of his/her medical photographs in the study for publication.

The surgical procedure was performed under aseptic conditions. Patients rinsed with 0.2% chlorhexidine gluconate before administration of local anesthesia (2% lignocaine with 1:80,000 adrenaline). Extractions were

carried out using elevators or forceps with minimal trauma to surrounding tissues. Post-extraction, 1.5 ml of Blue®M oral gel or KY Jelly was applied into the socket using a syringe respectively in patients of Group -A and Group-B. Patients were provided with standardized postoperative instructions, including dietary restrictions, avoidance of smoking, and prescribed analgesics (Aceclofenac 100 mg + Paracetamol 325 mg). The patients were followed-up for upto a week. [Figure 2, Figure 3]

# 2.6. Post-operative assessment

Conducted on the 3rd and 7th days, measuring Pain via the Visual Analogue Scale (VAS) [Figure 4] and healing using the Landry Healing Index. The Landry Healing Index (LHI) [Figure 5] provides a standardized, quantitative assessment of extraction socket healing. It evaluates five parameters: bleeding, inflammation, granulation tissue formation, epithelialization, and radiographic evidence of bone healing. Each parameter is assigned a score, generating a total score that reflects the overall healing status.

#### 3. Results

The study demographics included a population comprising of 19 females and 11 males, with patients randomly allocated to either Group A (Blue®M oral gel) or Group B (KY Jelly placebo). The age distribution of the patients ranged from 15 to 55 years, with a mean age of 17.06 years in Group A and 20.93 years in Group B. The age distribution did not show a statistically significant difference between the groups (p=0.4671). Similarly, gender distribution was comparable between the groups, with nine females and six males in Group A and ten females and five males in Group B.

Pain levels were assessed using the Visual Analogue Scale (VAS) preoperatively and on postoperative days 3 and 7. The mean preoperative VAS score was identical in both groups  $(1.53\pm0.52)$ . On postoperative day 3, Group A exhibited a significantly lower mean VAS score  $(4.00\pm0.93)$  compared to Group B  $(5.40\pm0.51)$ , with a p-value of 0.0002, indicating a statistically significant difference. By day 7, pain levels had reduced in both groups, with no statistically significant difference (p=0.3134), confirming that while initial pain reduction was faster in Group A, long-term pain resolution was comparable. [Table 1]

Intra-group comparisons revealed a significant reduction in pain between days 3 and 7 in both groups (p<0.0001 for both), demonstrating effective postoperative pain resolution irrespective of treatment. The study findings aligned with established literature indicating peak pain levels on day 3, followed by gradual decline by day 7. [Table 2, Table 3]

Wound healing was assessed using the Landry Healing Index on days 3 and 7. Group A demonstrated significantly better healing outcomes on both days. On day 3, the mean healing score in Group A was  $3.13\pm0.64$  compared to  $2.47\pm0.64$  in Group B, with a p-value of 0.0124. By day 7,

the mean healing score improved to 4.00±0.53 in Group A, while Group B had a mean score of 2.60±0.74, showing a statistically significant difference (p<0.0001). These results indicated that Blue<sup>®</sup>M oral gel facilitated faster tissue regeneration and enhanced socket healing compared to KY Jelly. [**Table 4**]

The Operative Time was also recorded for both groups. The mean operative time was 30.40±8.87 minutes for Group A and 30.80±9.42 minutes for Group B. The difference was not statistically significant (p=0.9037), confirming that the application of Blue<sup>®</sup>M oral gel did not prolong the surgical procedure. [**Table 5**]

## 3.1. Statistical analysis

The statistical analysis ensured reliability and validity of the results. Normality of data was assessed using the *Shapiro-Wilk test*, confirming that data were normally distributed. The *independent t-test* was applied to compare inter-group differences in pain and healing scores, while the *paired t-test* was used for intra-group comparisons. A p-value of <0.05 was considered statistically significant, validating the superior efficacy of Blue<sup>®</sup>M oral gel in enhancing healing outcomes.



**Figure 1:** Gels used as dressings in post-extraction alveolar socket in group A and B; (For group A - Blue®M oral gel & for group B- KY Jelly)



**Figure 2:** Representative case of blue<sup>®</sup>m oral gel application in the post extraction socket of 14; **A:** Tooth indicated for extraction 14, **B:** Post-extraction (day-0) with gel application, **C:** Post-operative day 3, **D:** Post-operative day 7



**Figure 3:** Representative case of KY Jelly application in the post extraction socket of 24; **A:** Tooth indicated for extraction 24, **B:** Post-extraction (day-0), with gel application, **C:** Post-operative day 3, **D:** Post-operative day 7.

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0		1-3		4	-6	3		7-9		10

**Figure 4:** Visual analogue scale (vas) for pain assessment on 3<sup>rd</sup> and 7<sup>th</sup> day

Very poor	Tissue color: ≥50% of gingiva red
	Response to palpation: Bleeding
	Granulation tissue: Present
	Incision margin: Not epithelialized, with loss of
	epithelium beyond incision margin
	Suppuration: Present
Poor	Tissue color: ≥50% of gingiva red
500000000	Response to palpation: Bleeding
	Granulation tissue: Present
	Incision margin: Not epithelialized, with
	connective tissue exposed
Good	Tissue colour: ≥25% and<50% of gingiva red
	Response to palpation: No bleeding
	Granulation tissue: None
	Incision margin: No connective tissue exposed
Very good	Tissue colour: <25% of gingiva red
20.5	Response to palpation: No bleeding
	Granulation tissue: None
	Incision margin: No connective tissue exposed
Excellent	Tissue color: All tissues pink
700 10 10	Response to palpation: No bleeding
	Granulation tissue: None
	Incision margin: No connective tissue exposed

**Figure 5:** Landry healing index (LHI) for evaluation of wound healing on  $3^{rd}$  and  $7^{th}$  day.

**Table 1:** Inter-group comparison of pain at various intervals for both the groups in terms of mean  $\pm$  SD

VAS	Groups	Mean	SD	p- Value
Prior to extraction	Blue-m gel	1.53	0.52	1.0000
(Day 0)	KY jelly (control group)	1.53	0.52	
Post-op day 3	Blue-m gel	4.00	0.93	0.0002*
	KY jelly (control group)	5.40	0.51	
Post-op day 7	Blue-m gel	1.40	0.51	0.3134
	KY jelly (control group)	1.73	1.03	

Table 2: Intra-group comparison of pain at various intervals for the first group (Blue-M GEL) in terms of mean ± SD

VAS	Groups	Mean	SD	p- Value
Blue® M GEL	Day 0	1.53	0.52	<0.0001*
	Day 3	4.00	0.93	
	Day 0	1.53	0.52	0.4985
Blue ®M GEL	Day 7	1.40	0.51	
Blue ®M GEL	Day 3	4.00	0.93	<0.0001*
	Day 7	1.40	0.51	

**Table 3:** Intra-group comparison of pain at various intervals for the second group (KY Jelly) in terms of mean ± SD

VAS	Groups	Mean	SD	p- Value
KY Jelly	Day 0	1.53	0.52	<0.0001*
	Day 3	5.40	0.51	
KY Jelly	Day 0	1.53	0.52	0.5314
	Day 7	1.73	1.03	
KY Jelly	Day 3	5.40	0.51	<0.0001*
	Day 7	1.73	1.03	

Healing by landry healing index	Groups	Mean	SD	p- Value
Day 3	Blue-m gel	3.13	0.64	0.0124*
	KY Jelly	2.47	0.64	
Day 7	Blue-m gel	4.00	0.53	<0.0001*
	VV Ially	2.60	0.74	

**Table 4:** Inter- group comparison of extraction socket healing using landry wound healing index at various intervals for both the groups in terms of mean  $\pm$  SD

**Table 5:** Inter- group comparison of operating time for both the groups in terms of mean  $\pm$  SD

Groups	Mean (time)	SD	p-Value
Blue-m oral gel	30.40	8.87	0.9037
KY Jelly	30.80	9.42	

#### 4. Discussion

Socket repair after tooth extraction involves a dynamic process of tissue remodelling well guided by nature. However, sometimes a sequential normal healing may not always necessarily happen. As a result premature clot necrosis or loss, accompanied by discomfort and a fetor oris, may occur after early clot formation in the socket. Dry socket, sicca dolorosa, localized alveolar osteitis, or fibrinolytic alveolitis are other names for the typical trio of early extraction socket clot loss/necrosis, pain, and fetor oris. The incidence is most reported between 0.5% and 5%, but some studies have noted it as high as 68%. This is one of the most prevalent post-extraction sequelae which manifest with severe excruciating pain of a prolonged nature manifesting in the initial healing period. This can result in multiple visits for management and symptom relief.

There are very few studies reported in literature that studied different dressings and their complications in fresh extraction sockets. Murat Metin, et al (2006)<sup>14</sup> conducted a study to compare the effect of two chlorhexidine rinse protocols on the incidence of alveolar osteitis and concluded that the use of postoperative chlorhexidine rinse was adequate to reduce alveolar osteitis after impacted third molar surgery. Pilar Hita-Iglesias, et al (2008)<sup>15</sup> conducted a study to compare the effectiveness of chlorhexidine gel versus a chlorhexidine rinse in reducing postoperative alveolar osteitis after the extraction and came to a conclusion that the topical application of bio-adhesive chlorhexidine gel to the surgical wound during the postoperative week may decrease the chances of dry socket all together. Churasia NK, et al (2017)<sup>16</sup> conducted a study which compared the effectiveness of two most commonly used agents (Zinc Oxide Eugenol and Alveogyl TM) for management of dry socket. They concluded that initial and final pain relief on visual analogue scale was better with Zinc Oxide Eugenol. Parveen Akhter Lonea, et al (2018)<sup>17</sup> conducted a study on the therapeutic properties of turmeric and observed significant reduction in pain, inflammation and discomfort after the application of

same. Sanjay Rastogi, et al (2017)<sup>18</sup> conducted a study to assess the efficacy of Platelet Rich Fibrin (PRF) on the pain and healing of extraction socket after removal molars, a significant reduction in pain on 3rd and 7th day along with better wound healing was seen by the end of week 2.

We conducted a prospective randomized controlled study that focused on patients who took treatment for the removal of relatively painless teeth. Especially elective extractions such as ones removed for traditional orthodontic treatment, or teeth that needed to be removed for cosmetic reasons. The main objective was to clinically evaluate and compare the effects of a novel topical oxygen therapy-Blue®M oral gel with a non-intervention group (Placebo – KY jelly) for post extraction healing of alveolar sockets with 3rd and 7th day follow up.

Patients were included with age ranging from 15 years to 45 years with mean age of 17.60 years in Group-A and 20.93 years in Group-B, the age range so selected was conjunction with the work of Amler MH et al, (1977)<sup>19</sup> that investigated the influence of age on extraction wound healing and concluded that around ten days post-extraction, younger individuals exhibited an acceleration in tissue regeneration, while older individuals experienced a lag phase.

The mean operative time was similar for both the groups (30.40 minutes for Group-A and 30.80 minutes for Group-B). A higher operative time in any of the groups would have signified an increase in postoperative morbidity which is also as such stated by several other authors, Baqain ZH et al (2008)<sup>20</sup> and Garcia A et al (1997),<sup>21</sup> in their respective studies.

The mean VAS score at third day was calculated for Blue®M Oral Gel and Control group wherein we found a statistically significant result. Similarly, on seventh day the comparison was done which yielded a statistically insignificant result, accounting for a VAS score of a near normal value by 7th post-operative day. This finding of a peaked score at 3rd day was similar with a recent study by

Andrea Blasi et al (2023)<sup>22</sup> wherein twenty-five patients underwent lower impacted third molar extraction to assess pain onset and severity along with other complications post-surgery. Pain, evaluated using the VAS scale, was reported as mild at 6 hours (44%), 12 hours (48%), 24 hours (68%), and 48 hours (68%) after the procedure.

The mean value for Laundry Healing index at third and seventh post-operative day for Blue®M and Control group was found to be statistically significant. There was discernible resolution in signs of inflammation, marked decrease in bleeding on probing and decreased amount of granulation tissue post-extraction as signified by lower scores on Landry Wound Healing index in the Blue M group. Amler MH et al (1960)<sup>23</sup> conducted a histochemical study that investigated undisturbed alveolar socket healing by analyzing post extraction biopsies from normal human tissues at two to three-day intervals over 50 days and as one of his significant findings was the evidence of epithelization by the fourth day and osteoid at the base of the socket by the seventh day. This landmark study was one of the first works evaluating healing of a socket extraction, Landry Wound Healing comparison on 3rd and 7th day is in coherence with this finding.

Blue®M oral gel as indicated by the results of our study have shown to yield lower pain scores and a better Landry Wound Healing Index. This was in accordance to Habib Juliana et al.'s (2022)<sup>24</sup> split-mouth randomized clinical trial, which examined the effects of BlueM gel and conventional Coe-Pack dressing on gingival healing and pain following surgical depigmentation, Blue M gel has been demonstrated to exhibit significantly lower pain scores at different time points and higher reepithelization index scores.

Based on the outcomes of our study, in comparison to the non-intervention group, Blue®M oral gel had the additional benefit of reducing pain scores and promoting better healing of the socket following extraction yielding a lower spectrum of post-extraction discomfort.

#### 5. Conclusion

This study provided compelling evidence that Blue®M oral gel enhanced post-extraction healing by reducing pain, accelerating tissue regeneration, and minimizing bacterial colonization. Unlike conventional wound dressings, Blue®M oral gel offered a unique mechanism of action through the controlled release of oxygen, which actively promoted angiogenesis and tissue repair. The study differed from previous research by incorporating a direct comparative analysis with a placebo group, ensuring that the observed benefits were specifically attributable to Blue®M oral gel. Additionally, this research emphasized the antibacterial and anti-inflammatory advantages of lactoferrin and oxygen therapy in post-extraction healing, a relatively underexplored area. Further studies with extended follow-up periods and larger sample sizes were warranted to confirm these results

and explore additional clinical applications of Blue<sup>®</sup>M oral gel in dental and maxillofacial procedures.

## 6. Source of Funding

None.

## 7. Conflict of Interest

None.

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