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Original Research Article

A comprehensive randomized controlled trial investigating the effectiveness of oxygene® gel in accelerating wound healing after dental extractions

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Abstract

Background: Proper wound healing after dental extractions is crucial for minimizing complications and enhancing patient wellbeing. Oxygene® gel has been proposed as a potential adjuvant treatment aid to improve wound healing.
Objective: This study aimed to evaluate the effectiveness of Oxygene® gel in accelerating wound healing following tooth extractions through a comprehensive randomized controlled trial.
Materials and Methods: A split-mouth design was conducted on 27 patients who required dental extractions, with a total of 56 extraction sites at the Oral Surgery Clinic, Faculty of Dentistry, SEGi University. After extraction, participants applied Oxygene® gel to the socket site twice daily for two weeks, and wound healing was assessed on the 3rd and 14th days post-extraction using the Wound Healing Index. Statistical analysis was performed using the Wilcoxon Rank Test.
Results: The test group treated with Oxygene® Gel exhibited better wound healing compared to the control group. On the 3rd day, the mean wound healing score for the test group was 3.2963 (SD= 1.13730), while the control group had a mean score of 2.7037 (SD= 1.10296). After two weeks, the mean score for the test group increased to 4.0741 (SD= 0.78082), while the control group had a mean score of 3.5185 (SD= 0.97548).
Conclusion: Oxygene® gel demonstrated promising potential as an effective adjunctive therapy for accelerating wound healing following dental extractions. These findings support the integration of Oxygene® gel into routine post-extraction care protocols. Additional research is warranted to validate these results and explore further applications of Oxygene® gel in clinical dental practice.

Keywords: Oxygene®gel, Extraction socket, Wound healing, Adjunctive oral wound healing aid

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1. Introduction

Wound healing is a complex biological process, and the primary goal of intervention is to facilitate tissue recovery from the wound (Mendonça F et al, 2009).[1] There are numerous causes, such as burns, surgical procedures, arterial conditions, and physical trauma, that lead to the formation of wounds. Wound healing is a dynamic process that can be divided into three distinct phases. The first phase involves inflammation, congestion, and the infiltration of leukocytes. The removal of the necrotic tissue will constitute the second phase, while the third phase of proliferation encompasses tissue regeneration and the formation of fibrous tissue (Lazarus G , 1994, Hekmatpou et al., 2019).[2]

Generally, individuals with robust health exhibit a more rapid wound healing process, typically completing this within a timeframe of 4 to 6 weeks. In contrast, those who are immunocompromised may experience a significantly prolonged healing duration, extending up to 3 months (McDaniel & Browning, 2014; Wallace et al., 2021). Nonetheless, even among healthy individuals, various factors—both local and systemic—can contribute to delays in wound healing (Guo & DiPietro, 2010).[2] Local factors encompass issues such as infections and inadequate oxygenation. Infections occur when microorganisms infiltrate and establish themselves within the wound, leading to prolonged healing due to ongoing inflammation (Guo &

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DiPietro, 2010).[4] Likewise, insufficient tissue oxygenation and vascular disruptions can hinder the healing process (Guo & DiPietro, 2010). Systemic influences, including age, hormonal variations, stress, nutritional deficiencies, and smoking habits, also play a significant role in the wound healing trajectory (Wernick et al., 2021).[5] Following a tooth extraction, the primary goal is to facilitate prompt wound healing to prevent bacterial growth that could result in infections. Additionally, patients may be at an increased risk of inadequate oral hygiene as they tend to avoid cleaning the area around the extraction socket (Bouloux et al., 2007).[6]

Tooth extraction is a standard dental intervention that, despite its commonplace nature, encompasses inherent risks such as the potential for infection and the occurrence of delayed wound healing, both of which can significantly diminish a patient's quality of life. Mitigating these risks and facilitating prompt wound healing are paramount objectives in the realm of post-extraction care. Various adjunctive preparations that enhance extraction wound healing have been studied (Nimma et al., 2017; Vajrabhaya et al., 2022).[7-8] Our study sets out to investigate a topical preparation called Oxygene® gel by examining its properties in augmenting the wound healing process. The principal objectives are to analyse the differential outcomes of wound healing in extraction sites with and without the administration of Oxygene® gel, thereby elucidating the relationship between the treatment modality and healing effectiveness, as well as to conduct a clinical assessment of the efficacy of Oxygene® gel in fostering wound healing subsequent to tooth extraction, thus providing evidence-based insights into its practical advantages.[9-11]

2. Materials and Methods

The study was conducted at the Oral Surgery Clinic, Faculty of Dentistry, SEGi University, with ethical approval acquired from the institutional ethics committee (SEGiEC/SR/FOD/43/2022-2023). Informed consent was obtained from every participant. This randomized controlled trial utilized a split-mouth design to assess the efficacy of Oxygene® gel in facilitating wound healing subsequent to dental extractions.[13-18] The duration of the study spanned from September 2022 to October 2023 and included 27 patients, resulting in a total of 54 extraction sites. All participants exhibited good health, refrained from smoking, and abstained from alcohol consumption. Inclusion criteria included clinically healthy patients, moderate to heavy smokers (defined as 11-19 cigarettes per day and 20 or more cigarettes per day, respectively), moderate to heavy drinkers (females consuming up to one drink per day and males up to two drinks per day), medically compromised individuals (excluding those with hemophilia, undergoing chemotherapy, or with uncontrolled diabetes), aged 20 to 60 years, requiring multiple extractions, with no pathology at the extraction site or adjacent teeth, and undergoing closed extractions. Exclusion criteria encompassed non-consenting patients, pregnant women, and those with specific medical conditions.

The sample size was determined through a one-way ANOVA power analysis, which indicated a necessity for at least 21 participants corresponding to 42 extraction sites. To mitigate the impact of potential participant dropouts, a total of 54 sites were included in the study. Random assignment of test and control sites was executed by operators who were not part of the research team, with the assignments meticulously documented in the patients' folders. Participants were instructed to apply a pea-sized quantity of Oxygene® gel to the designated test site twice daily over a two-week period, with follow-up assessments scheduled for the 3rd and 14th days following the extraction procedure. During these evaluations, clinical assessments and photographic documentation were performed, and adherence to the application protocol was both confirmed and reinforced (**Figure 1**).

Wound healing was evaluated utilizing the Wound Healing Index established by Landry et al. in 1988. The study was conducted in accordance with CONSORT guidelines to promote transparency and reliability in both methodology and reporting. The data collected were subjected to analysis using the Wilcoxon Rank Test within SPSS version.[22]

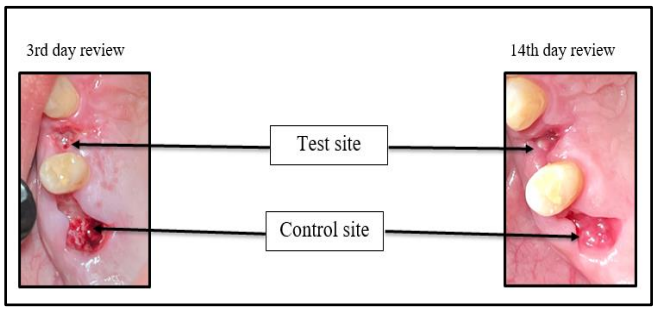

Figure 1:

3. Results

The data obtained were subjected to analysis through the Wilcoxon Ranked Test utilizing SPSS version 22. The results, presented in Tables 1 and 2, illustrate the mean grade, mean rank, and p-value for both the 3rd day and the 2-week review, respectively.

Table 1: Mean value for the wound healing between test tooth and control tooth

	N	Mean	Std. Deviation	Minimum	Maximum
Test - 3days	27	3.2963	1.13730	2.00	5.00
Test - 2 weeks	27	4.0741	0.78082	3.00	5.00
Control - 3days	27	2.7037	1.10296	1.00	4.00
Control - 2 weeks	27	3.5185	0.97548	2.00	5.00

Table 2;

		N	Mean Rank	Sum of Ranks
Control(3days) - Test(3days)	Negative Ranks	21	11.29	237.00
	Positive Ranks	4	22.00	88.00
	Ties	2		
	Total	27		
Control(2 weeks) - Test (2 weeks)	Negative Ranks	19	11.89	226.00
	Positive Ranks	5	14.80	74.00
	Ties	3		
	Total	27		

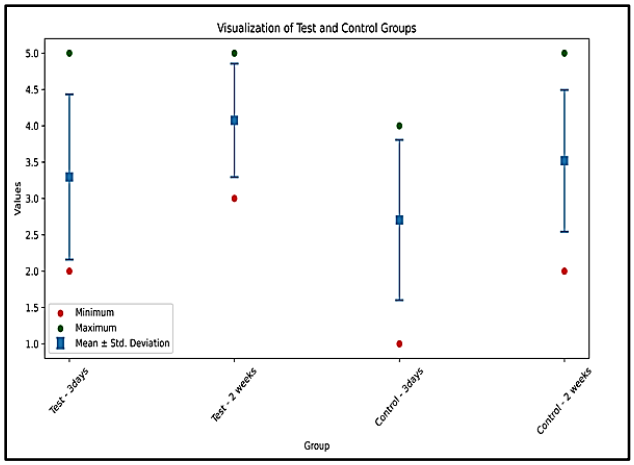

Figure 1: Bar plot illustrating mean values with error bars for each group, representing standard deviation

The analysis of the data reveals that the group receiving treatment with Oxygene® gel exhibited superior wound healing results compared to the control group. On the third day following extraction, the average wound healing score for the treatment group was 3.2963, accompanied by a standard deviation of 1.13730, with scores ranging from 2.00 to 5.00.[19-23] In contrast, the control group recorded an average score of 2.7037, with a standard deviation of 1.10296, and scores ranging from 1.00 to 4.00. After a two-week period, the mean score for the treatment group rose to 4.0741, with a standard deviation of 0.78082, and scores ranging from 3.00 to 5.00. Meanwhile, the control group achieved a mean score of 3.5185, with a standard deviation of 0.97548, and scores ranging from 2.00 to 5.00. These findings indicate that Oxygene® gel plays a significant role in promoting wound healing after dental extractions. **Figure 1** depicts a bar plot illustrating the mean values, with error bars representing the standard deviation for each group. The red and green points signify the minimum and maximum values, respectively. The x-axis represents the different groups, while the y-axis indicates the mean values.

At 3 days post-extraction, the negative ranks for the control group (21a) indicate instances where the control group had lower ranks compared to the test group, resulting in a mean rank of 11.29 and a sum of ranks of 237.00. Conversely, the positive ranks (4b) signify instances where the control group had higher ranks than the test group, yielding a mean rank of 22.00 and a sum of ranks of 88.00. There were also 2 ties (2c) observed in the data. Similarly, at 2 weeks post-extraction, the control group had 19 negative ranks (19d) with a mean rank of 11.89 and a sum of ranks of 226.00, while the positive ranks (5e) resulted in a mean rank of 14.80 and a sum of ranks of 74.00. Additionally, 3 ties (3f) were observed in the data. Notations (a, b, c, d, e, f) clarify the direction of the comparison and the relationship between the control and test groups, providing valuable insights into the distribution of ranks and the balance of positive and negative comparisons for each time point.

4. Discussion

Oxygene® gel, a thixotropic and easily injectable formulation, is manufactured by Oxyfresh Malaysia and comprises a diverse array of components, including sodium chloride, aloe vera, carrageenan, chamomile extract, methylparaben, and propylparaben (Taiyeb Ali et al., 2018). The gel has received approval from the Ministry of Health Malaysia and is specifically designed to promote wound healing and enhance oral health. The formulation includes purified deionized water, NaClO2, carrageenan, chamomile extract, aloe vera, methylparaben, and propylparaben, all of which work in concert to provide therapeutic effects (T.B., Taiyeb, et al., 2009). Aloe vera is renowned for its therapeutic benefits, which encompass antioxidant, anti-inflammatory, and antimicrobial effects against oral pathogens such as Streptococcus mutans and Candida albicans (Vajrabhaya et

al., 2022). Furthermore, aloe vera is effective in promoting wound healing and minimizing plaque formation (Nimma et al., 2017; Vajrabhaya et al., 2022). Chamomile oil is also noted for its potential to enhance wound healing (Anis et al., 2021). The presence of NaClO2 acts as an antimicrobial agent, effectively targeting oral pathogens to mitigate infection risks. Furthermore, the anti-inflammatory properties of carrageenan, chamomile extract, and aloe vera contribute to tissue repair and regeneration (Vajrabhaya L. O et al., 2022). This gel, also referred to as skin and gum care Gel, is designed for easy self-application, offering patients a practical and efficient means to improve post-extraction wound healing and maintain oral hygiene.

In addition, the inclusion of methylparaben and propylparaben enhances the gel's stability and shelf life, ensuring its effectiveness is preserved over time. Oxygene® gel adopts a comprehensive approach to oral care, addressing both immediate wound healing needs and the long-term maintenance of oral health, thereby establishing itself as a significant adjunctive therapy in dental practices. Its adaptability and ease of use render it an appealing choice for patients aiming to enhance their oral health outcomes following dental interventions.

Our study aimed to evaluate the effectiveness of Oxygene® gel in promoting the healing process following dental extractions. Utilizing a split-mouth design within a randomized controlled trial framework, the research compared the clinical outcomes associated with the application of Oxygene® gel against those observed in a control group. The findings, detailed in, offer robust evidence supporting the beneficial effects of Oxygene® gel on wound healing. The experimental group exhibited significantly enhanced wound healing at both the 3-day and 2-week post-extraction intervals when contrasted with the control group. Statistical analysis using the Wilcoxon Signed Ranks Test indicated significant differences between the two groups, with p-values of 0.035 and 0.021, respectively, underscoring a marked improvement in healing outcomes linked to the use of Oxygene® gel. At the 3-day mark, 21 out of 27 participants showed superior healing at the site treated with Oxygene® gel compared to the control site, demonstrating the gel's immediate efficacy in facilitating the early stages of wound recovery. Likewise, at the 2-week follow-up, 19 out of 27 participants reported enhanced healing at the test site, reinforcing the prolonged effectiveness of Oxygene® gel in supporting tissue regeneration and repair over time. These results carry important clinical implications for dental practice, as effective wound healing post-extraction is crucial for reducing postoperative complications and improving patient comfort and satisfaction. By decreasing the likelihood of infection and accelerating tissue repair, Oxygene® gel presents itself as a valuable adjunctive treatment for optimizing post-extraction recovery outcomes.

The therapeutic effects of Oxygene® gel can be ascribed to its distinctive formulation, which incorporates essential ingredients such as purified deionized water, NaClO2, carrageenan, chamomile extract, aloe vera, methylparaben, and propylparaben. These components function in concert to provide antimicrobial, anti-inflammatory, and wound-healing effects. The antimicrobial properties of NaClO2 are effective in eradicating pathogens within the oral cavity, thereby diminishing the likelihood of infection at the site of extraction. Additionally, carrageenan, chamomile extract, and aloe vera contribute anti-inflammatory effects, facilitating the reduction of inflammation and the promotion of tissue regeneration. The presence of methylparaben and propylparaben serves to improve the stability and longevity of the gel formulation, ensuring its sustained efficacy. Furthermore, the ease of application of Oxygene® gel enhances patient compliance and convenience, allowing them to self-administer the gel and actively engage in their own postoperative recovery.

Moreover, research conducted by Vajrabhaya, L. O et al. in 2022 investigated the anti-inflammatory properties of the components found in Oxygene® gel, including chamomile extract and aloe vera. The findings indicated that these ingredients can diminish inflammation and facilitate tissue regeneration (Vajrabhaya, L. O et al., 2022). Such mechanistic understanding underpins the clinical advantages of Oxygene® gel and reinforces its application in improving wound healing results post-dental extraction. Similarly, Nimma et al, 2017 found enhanced tooth socket healing following extractions while using aloe vera as an adjective aid for healing.

While the findings of this study are encouraging, it is also important to address the limitations. The small sample size and the brief follow-up period may restrict the applicability of the results to broader populations. To bridge this gap, future research implementing larger studies with extended follow-up times to evaluate the long-term efficacy and safety of Oxygene® gel is advocated. Also, additional investigation is necessary to investigate the potential synergistic effects of Oxygene® gel when used alongside other therapeutic options, such as antibiotics or analgesics, to enhance outcomes following dental extractions. Long-term comparative analyses assessing the cost-effectiveness of Oxygene® gel in relation to traditional treatments will also provide valuable information for healthcare professionals.

5. Conclusion

In summary, the findings of this research offer significant evidence for the clinical utility of Oxygene® gel as an effective adjunctive treatment to enhance wound healing following dental extractions. Its ability to reduce the risk of infection, alleviate inflammation, and promote tissue repair positions Oxygene® gel as a valuable option for improving post-extraction results and increasing patient satisfaction. Further research and investigation in this area is essential to

validate these findings and broaden our understanding of the therapeutic potential of Oxygene® gel in clinical dental practice.

6. Source of Funding

None.

7. Conflict of Interest

None.

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