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Case Report

Evaluation of xenograft collagen membrane as a biodegradable dressing for soft tissue wounds in oral and maxillofacial surgery

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Abstract

Introduction: Wound healing is a complex process affected by both internal and external factors, especially in the oral and maxillofacial area. This study examines how well the Xenograft collagen membrane, a biodegradable dressing, works for soft tissue wounds.
Materials and Methods: We conducted a single-center, randomized controlled trial with 30 patients divided into two groups: Study (n=15) and Control (n=15). The study group received the collagen membrane dressing, while the control group did not receive any dressing. We assessed key factors such as bleeding control, granulation, skin cell development, and scarring after the surgery.
Results: The collagen membranes improved bleeding control, granulation, and skin cell development, which led to better wound healing and less scarring. There were no major complications or infections in the study group.
Conclusion: Xenograft collagen membranes are effective for managing soft tissue wounds in oral and maxillofacial surgery. They offer a good alternative to autologous grafts.

Keywords: Biodegradable Dressing, Epithelialization, Hemostasis, Oral and Maxillofacial Surgery, Soft Tissue Wounds, Wound Healing, Xenograft Collagen Membrane

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1. Introduction

Wound healing is a vital biological process that restores tissue integrity. It involves various cellular and biochemical activities that promote tissue repair and regeneration.[1] The oral and maxillofacial area often experiences soft tissue injuries and is more susceptible to conditions like oral submucous fibrosis, squamous cell carcinoma, and traumatic wounds. Effective wound management is critical to prevent complications such as infection, excessive scarring, and contractures.[2]

In the past, soft tissue wounds in this area were treated with autologous grafts. While these grafts are effective, they come with challenges like donor site pain, longer surgical times, and limited tissue availability.[3] Consequently, biological dressings, including Xenograft collagen membranes, have gained popularity. They offer benefits such as easy application, compatibility with the body, and support for the healing process.[4]

Xenograft collagen membrane made from bovine collagen, and it shows promise as a biodegradable dressing material.[5] Its use has been found to improve tissue repair by encouraging blood clotting, supporting the growth of granulation tissue, and helping with epithelialization.[6] This study aims to assess how effective Xenograft collagen is in managing soft tissue wounds in the oral and maxillofacial area.[7]

2. Aims and Objectives

The main goal of this study was to determine how suitable the Xenograft collagen membrane is as a biodegradable dressing for soft tissue wounds in the oral and maxillofacial

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area. The secondary goals were to evaluate how well the membrane handles, adheres, and is accepted by patients. The study also looked into complications like allergic reactions, infections, or rejections. Additionally, it aimed to compare clinical outcomes such as blood clotting, granulation, epithelialization, and scarring between wounds treated with the collagen dressing and untreated wounds.

3. Materials and Methods

This study followed the CONSORT guidelines for reporting randomized controlled trials (RCTs). It was a single-center, randomized controlled trial done at a tertiary care center that focuses on oral and maxillofacial surgery. The institutional ethics committee approved the study (Approval No: KVG/267/27718), and all participants gave written informed consent before taking part.

3.1. Participants

The trial included 30 healthy patients aged 18 to 70 years with similar types of soft tissue wounds in the oral and maxillofacial area to ensure consistency. Patients were randomly assigned to either the Study Group, which received a collagen membrane dressing, or the Control Group, which received no dressing. Inclusion criteria were healthy patients classified as ASA I and II. Those with chronic diseases, active infections, poor oral hygiene, or allergies to collagen were not included (**Figure 1**). Wound types were limited to surgical excision defects caused by oral submucous fibrosis or leukoplakia for consistent comparisons(**Figure 2**).

3.2. Randomization and blinding

Participants were randomized using a computer-generated sequence. Opaque, sealed envelopes were used to conceal the allocation. Outcome assessors were blinded to reduce bias.

3.3. Interventions

Preoperative preparation included sedation and local anesthesia. Surgical excision was performed, followed by standard postoperative care, which included prescribed antibiotics and pain relievers. The Study Group received the collagen membrane dressing, while the Control Group had no dressing(**Figure 3**).

3.4. Sample size calculation

The sample size was based on previous studies that looked at the effectiveness of collagen membrane dressings in wound healing. Assuming a clinically significant difference of 20% in wound healing outcomes between the groups, a power of 80%, and a two-sided alpha level of 0.05, at least 15 patients were needed in each group (**Figure 4**).

3.5. Outcome measures

Primary outcomes were hemostasis, granulation tissue formation, epithelialization, wound contracture, pain relief (measured with a Visual Analog Scale, VAS), and infection rates. Follow-up visits occurred weekly for four weeks to monitor wound healing. Secondary outcomes included patient satisfaction and any adverse reactions.

3.6. Statistical analysis

Data were analyzed using SPSS software (verson XX). Continuous variables were reported as mean ± standard deviation (SD) and compared using independent t-tests. Categorical variables were compared using the chi-square test or Fisher's exact test. A p-value of less than 0.05 was regarded as statistically significant.

4. Results

3.1. Patient demographics

Thirty patients were enrolled and evenly divided into the Study Group (n=15) and the Control Group (n=15). The average age in the Study Group was 53.67 ± 12.19 years, while in the Control Group, it was 52.47 ± 9.49 years. The gender distribution was similar ($p = 0.624$). All wounds resulted from surgical excision of oral submucous fibrosis (60%) or leukoplakia (40%), with no significant differences in baseline characteristics ($p > 0.05$).

3.2. Wound characteristics

Most wounds were located in the buccal mucosa (70%) and the floor of the mouth (30%). Wound sizes ranged from 2 to 4 cm to keep consistency across the groups.

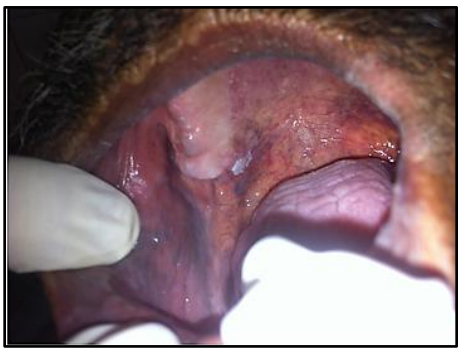

Figure 1: Lesion of soft tissues of oral cavity

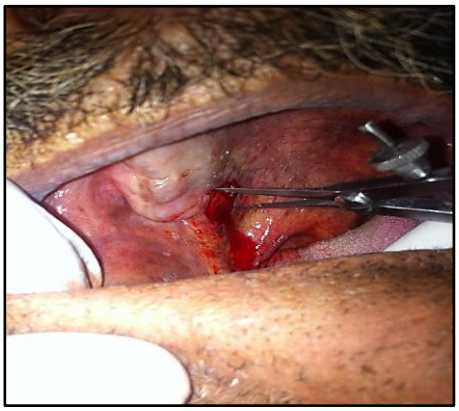

Figure 2: Excision of the wound

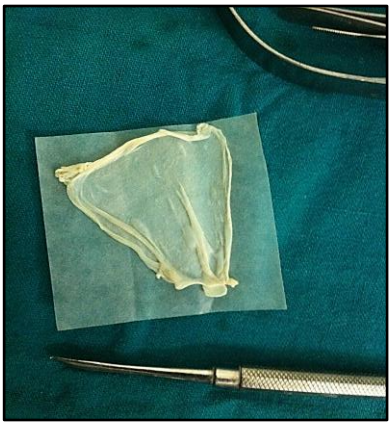

Figure 3: Collagen membrane used after excision

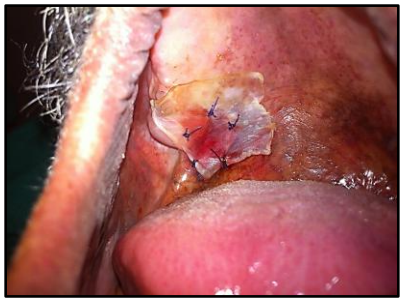

Figure 4: placement of collagen membrane

3.3. Clinical outcomes

1. Hemostasis: Study Group: 80% achieved satisfactory hemostasis. Control Group: 100% achieved satisfactory hemostasis. Statistical significance: p = 0.02.
2. Pain Relief: No significant difference between groups (p = 0.30).
3. Granulation Tissue Formation: Study Group: 70% showed substantial granulation tissue formation by week 2. Control Group: 40% showed substantial granulation tissue formation by week 2. Statistical significance: p = 0.04.
4. Epithelialization: Study Group: 73.3% achieved good epithelialization at one month. Control Group: 60% achieved good epithelialization at one month. Statistical significance: p = 0.07 (trend observed).
5. Contracture: Similar results in both groups (66.7% with good contracture, p > 0.05).
6. Infection and Reactivity: No infections in the Study Group. 10% of Control Group patients reported mild reactions (erythema and irritation).
7. Patient Satisfaction: Study Group: 93.3% rated treatment as very effective. Control Group: 72.4% rated treatment as very effective. Statistical significance: p = 0.03.

5. Discussion

Wound healing is a complex process that involves hemostasis, inflammation, proliferation, and remodelling.[7] Collagen, an important part of the extracellular matrix, plays a key role in repairing tissue. This is especially true in the oral and maxillofacial area, where wounds are at risk for infection, scarring, and slow healing due to constant movement, moisture, and bacteria (Velnar et al., 2009).[8] Biological dressings like collagen membranes, which come from bovine sources, are increasingly popular because they are compatible with the body, easy to use, and effective in helping tissue grow back.[9]

This study reveals significant findings about using Xenograft collagen membrane in soft tissue wounds related to oral and maxillofacial surgery.[10] The Study group showed noticeable improvements in stopping bleeding and forming granulation tissue. This indicates that collagen membranes can effectively manage bleeding and support the early stages of healing.[11] These findings match previous studies that found collagen membranes create a favorable environment for cell movement, fibroblast activity, and blood vessel formation, which facilitates tissue repair (Sowjanya et al., 2016; Lee et al., 2001).[12]

The lack of significant differences in pain relief between the two groups suggests that the collagen membrane mainly aids in wound healing, not pain relief.[13] Similar pain scores imply that healing may gradually reduce pain over time. The use of antibiotics and painkillers in both groups probably helped manage pain during recovery.[13]

Epithelialization was slightly better in the Study group (73.3% compared to 60% in the Control group), but this difference was not statistically meaningful. This could be due to the relatively short follow-up period, which may not have fully shown the benefits of collagen membranes for long-term wound closure. Previous studies have indicated that collagen membranes can help speed up epithelial movement and tissue closure by acting as a scaffold for epithelial cells, suggesting that there may be improved epithelialization over longer periods (Rastogi et al., 2009)[13]

Interestingly, there was no significant difference in contraction between the two groups, even though improvements were noted in other areas for the Study group. This outcome could result from factors that influence wound contraction, such as tension, scar tissue quality, and patient movement. While collagen membranes may reduce excessive scarring in some situations, they might not significantly affect contraction in all wound types (Pruitt & Levine, 1984).[13]

Concerning complications, the absence of infections or allergic reactions in the Study group strongly supports the safety and compatibility of collagen membranes. No negative effects or rejections were observed, showing that Xenograft collagenis well-accepted in oral and maxillofacial areas. In

contrast, mild irritation was noted in the Control group, likely due to the raw tissue being exposed to the outside, which collagen membrane dressings could have minimized (Khan et al., 2011).[14]

In terms of patient satisfaction, a higher percentage of patients in the Study group reported positive outcomes, which reflects the objective clinical improvements in healing. Collagen membrane dressings have been shown to enhance both the speed and quality of wound healing, likely leading to greater overall satisfaction (Vastani et al., 2016).

Although the results are encouraging, there are some limitations. The small sample size and brief follow-up period limit how widely these findings can be applied. A larger group with a longer follow-up would yield stronger data about the long-term effects of collagen membranes on healing and scarring. Additionally, comparative studies with other biodegradable membranes or advanced wound care methods are necessary to better understand the advantages of Xenograft collagen in managing soft tissue injuries in oral and maxillofacial surgery.

6. Conclusion

The findings of this study highlight how effective and safe Xenograft collagen membrane is for promoting wound healing in oral and maxillofacial surgery. The study group showed significant improvements in controlling bleeding, forming granulation tissue, and overall patient satisfaction when compared to the control group. There were minimal complications, and no infections were reported. While the outcomes for epithelialization and contracture were similar between the groups, the improved wound healing with Xenograft collagen shows its value as a biological dressing. The lack of adverse reactions further supports its compatibility with the body. However, larger studies with longer follow-up are necessary to fully assess its long-term benefits and compare its effectiveness with other wound care options.

7. Ethical Clearance

The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the institutional ethics committee. Informed consent was obtained from all participants before enrollment in the trial. Participants were made aware of the study's aims, procedures, potential risks, and benefits. Their confidentiality and privacy were maintained throughout the research.

8. Conflict of Interest

The authors declare that there are no conflicts of interest associated with this study. The research was conducted independently, without any financial or professional influence from external parties.

9. Source of Funding

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