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Comparative Evaluation Of Axiostat Vs . Gelfoam For Post-Extraction Hemostasis And Healing In Patients On Antiplatelet Therapy: A Clinical Study

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Abstract
Objectives: *To evaluate the effectiveness of Axiostat Hemostatic Dental (AHD) dressing compared to Gelfoam in achieving hemostasis and promoting healing following mandibular tooth extractions in patients on antiplatelet therapy.*
Materials and Methods: *A split-mouth study was conducted on 12 patients requiring bilateral mandibular molar extractions. AHD was applied to the Site A (Study group), and Gelfoam was applied to the site B (Control group). Hemostasis time was recorded, and healing was assessed on the 7th, 14th, and 21st day using the Landry, Turnbull, and Howley index.*
Results: *AHD demonstrated a significantly faster hemostasis time (1 minute 36 seconds) compared to Gelfoam (10 minutes 45 seconds). Enhanced epithelialization and reduced granulation tissue were observed in the AHD group on the 7th day, with consistent superiority in healing outcomes noted on the 21st day.*
Conclusion: *Axiostat demonstrated superior hemostatic efficacy and healing outcomes compared to Gelfoam, suggesting its potential as a preferred local hemostatic agent in dental extractions for patients on antiplatelet therapy.*
Key Words: *Antiplatelet therapy, Axiostat, Gelfoam, Hemostasis, Wound healing*

INTRODUCTION

Achieving effective hemostasis following dental extractions in patients on oral antiplatelet therapy (OAT) is a critical challenge due to an increased risk of postoperative bleeding. Antiplatelet agents play a pivotal role in preventing thrombotic events in patients with cardiovascular diseases, including ischemic heart disease, stroke, and peripheral artery disease. While these medications significantly reduce the risk of life-threatening thrombotic complications, they also interfere with normal platelet aggregation, potentially leading to prolonged bleeding during and after surgical procedures. The reasoning behind platelet inhibition is to prevent their unintended adhesion, activation, and aggregation at the site of a ruptured atherosclerotic plaque. Managing hemostasis in such patients requires a delicate balance between minimizing bleeding risks and avoiding thrombotic complications associated with discontinuing antiplatelet therapy.[1,2]

Traditional methods for controlling bleeding in dental and surgical procedures have primarily relied on mechanical techniques such as direct pressure, suturing, and cauterization, as well as chemical hemostatic agents like ferric sulfate or aluminum chloride. However, these methods may not be sufficient for patients on OAT, where platelet function is impaired.[10,11,14]

Advances in hemostatic materials have led to the development of specialized dressings that enhance clot formation and wound healing. Among these, chitosan-based hemostatic agents have gained attention due to their unique ability to induce hemostasis independently of the coagulation cascade.[9,10,11,12] It is a naturally derived biomaterial and a deacetylated form of chitin. Its structure primarily consists of glucosamine and N-acetyl glucosamine residues linked by 1,4-β bonds.[19,20] Due to the presence of primary amine (-NH_2) groups, chitosan exhibits a polycationic nature, giving it a net positive charge. [7,20] It also possesses antimicrobial properties along with notable biocompatibility and biodegradability.

The Axiostat Hemostatic Dental (AHD) (Axiostat Bio-solutions, Gujarat, India) dressing, a chitosan-based hemostatic agent, offers a novel approach to managing post-extraction bleeding. It has been introduced as a novel method for achieving hemostasis.[3] This electropositive, sponge-like biomaterial, derived from crustaceans, exhibits strong hemostatic properties. Unlike conventional methods, it works by drawing in negatively charged red blood cells (RBCs) and platelets, creating a firm seal over the extraction site. [2] The following study compares the hemostatic efficacy and healing outcomes of AHD and Gelfoam dressings in patients on oral antiplatelet therapy.

MATERIALS AND METHODS

Study Design: A split-mouth retrospective study was carried out in the Dept of Oral and Maxillofacial Surgery, at Dr. DY Patil Dental College Pune from (November 2023-October 2024) in patients on oral antiplatelet therapy (included aspirin or clopidogrel or both) with INR values between 1 and 2 requiring bilateral extraction of mandibular teeth with similar difficulty index were included in the study. The patient age ranged from 35-65 years were included. Patients with a history of genetic bleeding disorders, seafood allergies, and anticoagulant use were excluded from the study.

Sampling technique: The sample size calculated was N= 24. A total 24 extraction sites were included. It was divided into Study group(n=12) - AHD dressing was placed immediately after extraction and Control group (n=12) - Gelfoam was placed in the extraction socket.

METHODOLOGY:

The study was approved by the institutional research review committee . Informed consent was obtained from all participants.

Preoperative assessment: Blood investigations, including CBC, clotting time, bleeding time, ESR, INR, and platelet count, were performed in all patients.

1. **Extraction and dressing**: Bilateral extractions of mandibular teeth was performed atraumatically under local anesthesia. Custom-cut AHD or Gelfoam dressings were placed into the extraction sockets.
2. **Postoperative care**: Patients were prescribed amoxicillin (500 mg) and diclofenac (TDS) for 5 days. Follow-ups occurred on the 7th, 14th, and 21st days to evaluate healing.

Outcome Measures

1. **Hemostasis time**: Measured using a stopwatch.
2. **Healing**: Assessed on postoperative Day 7^{th}, 14^{th} 21^{st} using the Landry, Turnbull, and Howley index.

Results - Total of 12 patients on antiplatelet therapy, requiring bilateral extraction of mandibular teeth were included in the study. evenly divided between the study group and control groups, with each group comprising 66.7% males and 33.3% females **.** Total of 24 extraction sites were included, with AHD applied to Site A (Study group) and Gelfoam to Site B (Control group). The age of patient ranged from 35–65 years (mean age 35 years).

FIG-1 – PLACEMENT OF BOTH AXIOSTAT AND GELFOAM PRODUCTS

Healing Assessment in the Axiostat Group

Healing in the Axiostat group demonstrated significant improvement over time. On day 21, 50% of patients exhibited excellent tissue color, and 66.7% showed no bleeding**.**

The Friedman test revealed statistically significant differences in tissue color, bleeding, granulation tissue, incision margin, and suppuration between different time points ($p<0.05$).

Post hoc analysis indicated significant improvements between day 7 and day 21 and day 14 and day 21 for all parameters, except between day 7 and day 14, where no significant differences were observed.

Healing Assessment in the Gelfoam Group

In the Gelfoam group, 100% of patients demonstrated good tissue color by day 21**.** Statistically significant improvements were noted in tissue color, bleeding, granulation tissue, incision margin, and suppuration over time ($p<0.05$). Post hoc analysis confirmed significant differences between day 7 and day 21, while no significant changes were observed between day 14 and day 21 for certain parameters**.**

1. **Day 7**: The AHD group showed superior epithelialization and reduced granulation tissue compared to the Gelfoam group.
2. **Day 14**: Healing outcomes between the groups were comparable.
3. **Day 21**: The AHD group demonstrated significantly better tissue quality, incision margin, and granulation tissue than the Gelfoam group.

Comparison Between Axiostat and Gelfoam

On day 7, significant differences were noted in granulation tissue and suppuration, with Axiostat outperforming Gelfoam ($p<0.05$), while tissue color, bleeding, and incision margin showed no significant differences .

On day 14, the tissue color significantly differed between the two groups ($p=0.009$), with Gelfoam showing better outcomes. No significant differences were observed in bleeding, granulation tissue, incision margin, or suppuration.

By day 21, all parameters, including tissue color, bleeding, granulation tissue, incision margin, and suppuration, exhibited significant differences, favoring Axiostat over Gelfoam ($p<0.05$) **.**

The Axiostat group showed superior outcomes in long-term healing, with significant improvements in all assessed parameters by day 21 compared to the Gelfoam group.

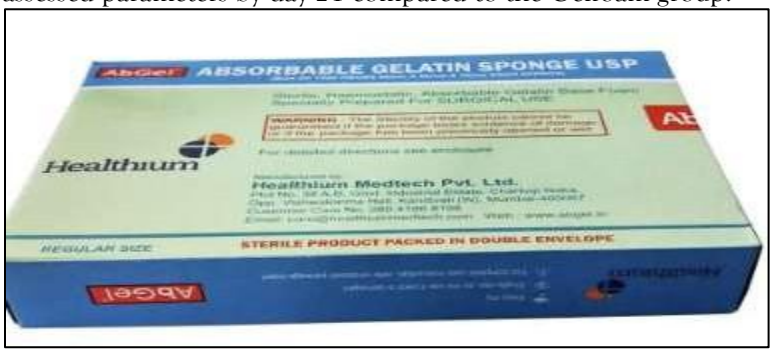

FIG -2 HEALING ON DAY -14

FIG -3 – HEALING ON DAY 21

Hemostasis Time

- **AHD group**: Mean hemostasis time was 1 minute 36 seconds.
- **Gelfoam group**: Mean hemostasis time was 10 minutes 45 seconds.

Healing Assessment

4. **Day 7**: The AHD group showed superior epithelialization and reduced granulation tissue compared to the Gelfoam group.
5. **Day 14**: Healing outcomes between the groups were comparable.
6. **Day 21**: The AHD group demonstrated significantly better tissue quality, incision margin, and granulation tissue than the Gelfoam group.

Healing assessment of the patients in Axiostat group

Parameter	Healing status	Day 7		Day 14		Day 21	
		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Tissue color	Very poor	0	0	0	0	0	0
	Poor	4	33.3	7	58.3	0	0
	Good	7	58.3	5	41.7	1	8.3
	Very good	1	8.3	0	0	5	41.7
	Excellent	0	0	0	0	6	50.0
Bleeding	Very poor	0	0	0	0	0	0

	Poor	4	33.3	5	41.7	0	0
	Good	8	66.7	6	50.0	1	8.3
	Very good	0	0	1	8.3	3	25.0
	Excellent	0	0	0	0	8	66.7
Granulation tissue	Very poor	0	0	0	0	0	0
	Poor	2	16.7	2	16.7	0	0
	Good	9	75.0	10	83.3	0	0
	Very good	1	8.3	0	0	5	41.7
	Excellent	0	0	0	0	7	58.3
Incision margin	Very poor	0	0	0	0	0	0
	Poor	3	25.0	7	58.3	0	0
	Good	9	75.0	5	41.7	0	0
	Very good	0	0	0	0	6	50.0
	Excellent	0	0	0	0	6	50.0
Suppuration	Very poor	0	0	0	0	0	0
	Poor	0	0	2	16.7	0	0
	Good	0	0	4	33.3	0	0
	Very good	0	0	3	25.0	0	0
	Excellent	12	100.0	3	25.0	12	100.0

Healing assessment of the patients in Gelfoam group

Parameter	**Healing status**	**Day 7**		**Day 14**		**Day 21**	
		Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Tissue color	Very poor	2	16.7	0	0	0	0
	Poor	7	58.3	1	8.3	0	0
	Good	3	25.0	11	91.7	12	100.0
	Very good	0	0	0	0	0	0
	Excellent	0	0	0	0	0	0
Bleeding	Very poor	0	0	0	0	0	0
	Poor	4	33.3	1	8.3	0	0
	Good	8	66.7	8	66.7	8	66.7
	Very good	0	0	3	25.0	4	33.3
	Excellent	0	0	0	0	0	0
Granulation tissue	Very poor	2	16.7	0	0	0	0
	Poor	9	75.0	2	16.7	0	0
	Good	1	8.3	8	66.7	9	75.0
	Very good	0	0	2	16.7	3	25.0
	Excellent	0	0	0	0	0	0
Incision margin	Very poor	0	0	0	0	0	0
	Poor	6	50.0	2	16.7	0	0
	Good	6	50.0	8	66.7	8	66.7
	Very good	0	0	2	16.7	4	33.3
	Excellent	0	0	0	0	0	0
Suppuration	Very poor	0	0	0	0	0	0
	Poor	2	16.7	0	0	0	0

	Good	9	75.0	4	33.3	2	16.7
	Very good	1	8.3	4	33.3	6	50.0
	Excellent	0	0	4	33.3	4	33.3

Difference in the healing status between Axiostat and Gelfoam group at different time points

Parameter	Time point	Chi-square	Significance (p)
Tissue color	On Day 7	5.418	0.144
	On Day 14	6.750	**0.009***
	On Day 21	20.308	**0.0001***
Bleeding	On Day 7	0.000	1.000
	On Day 14	3.952	0.139
	On Day 21	13.587	**0.001***
Granulation tissue	On Day 7	13.855	**0.003***
	On Day 14	2.222	0.329
	On Day 21	16.500	**0.0001***
Incision margin	On Day 7	1.600	0.206
	On Day 14	5.470	0.065
	On Day 21	14.400	**0.001***
Suppuration	On Day 7	24.000	**0.0001***
	On Day 14	2.286	0.515
	On Day 21	12.000	**0.002***

DISCUSSION

This study compared Axiostat Hemostatic Dental (AHD) dressing, a chitosan-based hemostatic agent, with Gelfoam, a gelatin-based hemostatic sponge, in achieving hemostasis and promoting wound healing after mandibular molar extractions in OAT patients.[2] The findings suggest that AHD dressing not only achieves hemostasis significantly faster than Gelfoam but also enhances wound healing, making it a superior alternative in this high-risk population.

Hemostatic Efficacy of Axiostat vs. Gelfoam

The results of this study demonstrated a **significant reduction in hemostasis time** with AHD (1 minute 36 seconds) compared to Gelfoam (10 minutes 45 seconds). This difference can be attributed to the electrostatic interaction of chitosan with negatively charged platelets and red blood cells, leading to rapid clot formation independent of the coagulation cascade. A similar mechanism has been reported in previous studies, highlighting chitosan's ability in treating extraction socket shows better healing and also in achieving faster hemostasis , reducing post operative pain , improving and accelerating wound healing and reducing inflammation. (Asawar Mohammad et al.) [4] In contrast, Gelfoam functions as a passive matrix that supports clot formation, relying on the body's intrinsic coagulation pathways, which may be compromised in patients on antiplatelet therapy. (Armin Mohammadi et al.)

Chitosan-based hemostatic dressings have gained attention due to their broad clinical applications, particularly in trauma care and surgical settings. Studies by Xingyu Zhang (2024)[5] have demonstrated that chitosan-based self-healing hydrogel contributes antibacterial abilities, conductivity, anti-oxidation, anti-inflammation, stimulus-response, adhesion and hemostasis, and controlled release abilities.

The present study aligns with these findings, reinforcing that **chitosan-based dressings are a reliable hemostatic option for dental procedures in OAT patients**.

Wound Healing and Tissue Regeneration

In addition to hemostasis, Axiostat demonstrated superior wound healing outcomes compared to Gelfoam. By Day 7, the AHD group showed enhanced epithelialization and reduced granulation tissue formation, while the Gelfoam group exhibited more pronounced inflammation. By Day 21, patients treated with AHD had significantly better tissue color, incision margin integrity, and granulation tissue organization, suggesting faster and more structured wound healing.

The enhanced healing observed with AHD may be attributed to chitosan's inherent antimicrobial properties and biocompatibility, which create a favorable wound environment, reducing the risk of infection and promoting tissue regeneration (Armin Mohammadi et al.)[6] Chitosan has also been shown to stimulate wound healing in debilitating systemic diseases such as diabetic skin wounds, chitosan-based tissue scaffold helps in collagen deposition, crucial for soft tissue repair (Hong cai 2020)[7]. Conversely, Gelfoam, while effective in clot stabilization, lacks antimicrobial activity and degrades more slowly, which may contribute to prolonged inflammatory response and delayed healing (Kim et al., 2020).[10]

Clinical Implications and Future Perspectives

The findings of this study have important clinical implications for managing post-extraction bleeding in antiplatelet therapy patients. AHD dressing not only ensures rapid and reliable hemostasis but also promotes better wound healing, reducing the likelihood of postoperative complications such as delayed healing, infection, or prolonged bleeding.[1,2,3] Given its **non-**reliance on the coagulation cascade, AHD can be particularly beneficial in patients with higher bleeding risks, including those with elevated INR values or concurrent anticoagulant therapy.[9,14,15]

Despite these promising results, **certain limitations** of this study should be acknowledged. The **small sample size (n=12) limits the statistical power**, and further research with **a larger cohort is necessary to validate these findings**. Additionally, **long-term follow-up** could provide insights into the potential impact of AHD on bone healing and overall periodontal health. Future studies comparing AHD with other next-generation hemostatic agents, such as oxidized cellulose or fibrin-based dressings, may further expand the understanding of its clinical advantages.[11,18]

Limitation of the study:

Despite these promising findings, the study has certain limitations. The small sample size of 12 patients limits the generalizability of the results. In addition, exclusion of patients with genetic bleeding disorders or seafood allergies further restricts the applicability of AHD dressing to a larger population of Further studies are needed with a larger, more diverse cohort of patients to confirm these findings and assess long-term efficacy and cost-effectiveness of AHD Studies directly comparing the activity of AHD with other next-generation hemostaticagents may also advance the understanding about itsclinical applications.[3]

CONCLUSION:

Axiostat Hemostatic Dental Dressing showed better hemostatic efficiency and favorable healing outcomes compared to Gelfoam in patients on oral antiplatelet therapy.[3] Its unique mechanism of action, antimicrobial properties, and long-term healing benefits make it a valuable tool for managing post-extraction bleeding in high-risk patients. These findings support its potential as a standard-of-care option in dental practices, pending further research to validate and expand upon the current results.

Small sample size (n=12) limits statistical power.

Exclusion criteria (e.g., seafood allergies) restrict broader applicability.

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Conflict of Interest The authors declare no conflicts of interest.

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Ethical Considerations: The study protocol was approved by the Institutional Research Review Committee. All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments. Informed consent was obtained from all individual participants included in the study.

Declarations

Ethics approval and consent to participate: The study protocol was approved by the Institutional Research Review Committee. All procedures were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments. Informed consent was obtained from all individual participants included in the study.

Consent for publication: Not applicable.

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: Dr. Sushree Mahapatra: Conceptualization, Data Collection, Manuscript Writing. Dr. Shilpa Bawane: Supervision, Study Design, Manuscript Review. Dr. Damini Goel: Data Analysis, Literature Review, Editing.

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