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Research Protocol

Dentistry Section

Comparing the Effect of Gelatamp and Simvastatin-impregnated Gelfoam on Postoperative Outcomes in Patients Undergoing Surgical Removal of Mandibular Third Molars: A Randomised Controlled Trial Research Protocol

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ABSTRACT

Introduction: Surgical removal of impacted mandibular third molars is common in oral surgery but often leads to pain, swelling, trismus, and delayed healing. To improve recovery, materials like Gelatamp, a silver-impregnated gelatin sponge and simvastatin, a drug with anti-inflammatory and bone-healing effects, have been used. Comparing their effects may help identify the better option for enhancing postoperative outcomes.

Need of the study: The role of Gelatamp and simvastatin-impregnated gelfoam in improving postoperative outcomes after mandibular third molar surgery remains under-explored and requires further research. Comparative evaluation of these agents is essential to better understand their effectiveness in controlling postoperative complications like pain, swelling, and healing, which are key aspects of patient recovery.

Aim: To compare the efficacy of Gelatamp and simvastatin-impregnated gelfoam in enhancing postoperative outcomes in patients undergoing surgical removal of impacted mandibular third molars.

Materials and Methods: This single-masked protocol for randomised controlled trial will be conducted in the Department of Oral and Maxillofacial Surgery of Sharad Pawar Dental College associated with Datta Meghe Institute of Higher Education and Research, a tertiary care centre situated in the state of Maharashtra, India from May 2025 to January 2027. The minimum sample size required was calculated as 39, which was rounded up to 40 to improve statistical power. Therefore, a total of 40 patients will be included in the study. These patients will be randomly allocated into two equal groups using a computer-generated randomisation list: Group A (n=20): Gelatamp will be placed in the extraction socket. Group B (n=20): Simvastatin-impregnated Gelfoam will be placed in the extraction socket. Patients aged 16-50 years attending the Outpatient Department (OPD) and indicated for surgical extraction of a mandibular third molar will be included. Following extraction, the surgical site will be filled with either Gelatamp or simvastatin-impregnated Gelfoam and sutured appropriately, after considering all applicable exclusion criteria. A fixed dose of either material will be administered by the investigators, as decided by the principal investigator and the secondary investigator to track the patient's effects and primary outcomes, including pain, soft-tissue healing, and bone regeneration, as well as secondary outcomes, including haemostasis and postoperative swelling. Various demographic, clinical, and outcome variables will be compared using the Chi-square test, Fischer's-exact test for categorical data, and independent t-test for continuous data with a normal distribution. The following parameters will be evaluated: immediately postoperatively, pain, bleeding, and bone density; on postoperative Days 1 and 2, pain, soft tissue healing, swelling, and secondary bleeding; on Day 7, swelling and haemostasis (along with suture removal); and at three months, final assessment of bone regeneration. The p-value <0.05 will be considered significant.

Keywords: Bone regeneration, Haemostasis, Surgical extraction, Swelling

INTRODUCTION

The surgical removal of impacted mandibular third molars is among the most frequently performed procedures in oral and maxillofacial surgery. It is indicated for reasons such as pericoronitis, dental caries in adjacent teeth, and pathologies like cyst formation. Despite being a routine minor surgical intervention, it is commonly associated with several postoperative complications, including pain, oedema, trismus, delayed wound healing, and localised infection. These complications can significantly compromise patient comfort, delay return to normal function, and, in some cases, result in further intervention [1,2].

Over the years, several adjunctive strategies have been introduced to minimise these postoperative issues and enhance tissue healing. Among them, local drug delivery systems using bioactive materials have shown promising results. One such agent is Gelatamp, asterile, absorbable gelatin sponge embedded with colloidal silver. Gelatamp is primarily used for haemostasis and localised antimicrobial action. The silver component exhibits broad-spectrum bactericidal activity against common oral pathogens, thereby reducing the risk of infection and inflammation. Additionally, the gelatin matrix supports clot formation and stabilises the extraction socket, which is essential in the early phases of healing [3].

Another material gaining attention in oral surgery is Simvastatin, traditionally used as a 3-Hydroxy-3-Methylglutaryl-Coenzyme A reductase inhibitor for managing hyperlipidaemia. Beyond its systemic effects, simvastatin has been shown to possess pleiotropic properties, including anti-inflammatory, angiogenic, and osteopromotive effects. When applied locally to bone or soft-tissue defects, simvastatin stimulates the production of Bone Morphogenetic Proteins (BMPs), particularly BMP-2, enhancing osteoblastic differentiation and accelerating bone regeneration. It also modulates inflammatory cytokines and promotes neovascularisation, both of which are critical for optimal postoperative healing [4-6].

While both Gelatamp and simvastatin have individually demonstrated beneficial outcomes in enhancing healing and reducing complications in oral surgical settings, there is a notable lack of direct comparative studies assessing their efficacy. Most available literature focuses on their independent roles, with limited data exploring how they perform against each other when applied under similar clinical conditions. This gap in knowledge presents an important opportunity to evaluate which of these materials provides superior control over postoperative pain, oedema, wound healing, and complication rates. Given the widespread nature of third molar surgeries and the emphasis on minimising patient morbidity, it is imperative to explore and establish evidence-based protocols that incorporate effective local therapeutic agents. A comparative analysis of Gelatamp and simvastatin-impregnated gelfoam may not only help refine clinical practices but also guide future developments in socket preservation and minimally invasive postoperative management strategies.

Hence, the present study aims to compare the effects of Gelatamp and simvastatin-impregnated gelfoam on the postoperative outcomes in patients undergoing surgical extraction of impacted mandibular third molars, with a focus on pain, swelling, trismus, and wound healing.

The primary objective of the study will be to study the effects of the above-mentioned material on pain, soft-tissue healing and bone regeneration. The secondary objective is to assess the postoperative swelling and haemostasis in patients treated with either of the above two materials.

The null hypothesis is that, there is no significant difference in postoperative outcomes between the use of Gelatamp and simvastatin- impregnated gelfoam in patients undergoing surgical removal of mandibular third molars.

The alternate hypothesis is that, there is significant difference in postoperative outcomes between the use of Gelatamp and simvastatin- impregnated gelfoam in patients undergoing surgical removal of mandibular third molars.

REVIEW OF LITERATURE

Surgical extraction of impacted mandibular third molars is a common procedure in oral and maxillofacial surgery, often accompanied by postoperative complications such as pain, swelling, trismus, and delayed wound healing. Various adjunctive materials have been explored to mitigate these sequelae and enhance patient recovery.

Gelatamp, a colloidal silver-impregnated gelatin sponge, has been investigated for its haemostatic and antimicrobial properties. Colloidal silver acts by releasing silver ions at the wound site, providing a sustained antimicrobial effect without promoting bacterial resistance. It is especially effective against antibiotic-resistant strains, making it a valuable alternative in cases where systemic antibiotics are contraindicated or overused. A study by Thuruthel MJ et al., (2023) demonstrated that Gelatamp significantly improved soft-tissue healing scores on the third and seventh postoperative days when compared to controls. The Landry Healing Index showed statistically significant improvements in the Gelatamp group. Additionally, postoperative bleeding was markedly reduced at five minutes, 30 minutes, and two hours postsurgery, indicating strong haemostatic properties. However, pain and swelling did not show significant intergroup differences, suggesting that Gelatamp's primary advantage lies in tissue healing and bleeding control. Previous investigations have validated the effectiveness of Gelatamp in reducing dry socket incidence, enhancing clot stability, and promoting a clean healing environment. Its sponge structure supports platelet aggregation, while the slow resorption releases silver ions consistently at the site [7].

In a preclinical study, Dong Y et al., (2017) explored the impact of colloidal silver-infused gelatin sponges on bone repair in Methicillin-Resistant Staphylococcus aureus (MRSA)-infected cranial defects. The results showed that this material effectively decreased local bacterial infection and inflammatory markers such as Interleukin-6 (IL-6) and Tumour Necrosis Factor (TNF)-α. Advanced imaging and tissue analysis revealed that the treated sites exhibited enhanced bone formation and more rapid healing when compared to sites treated with plain gelatin sponges. These outcomes suggest that gelatin sponges containing colloidal silver offer both antimicrobial and bone-regenerative benefits, making them a valuable option for managing infected bone defects in surgical settings [8].

Simvastatin, a widely used lipid-lowering agent, has demonstrated significant potential in promoting bone regeneration when applied locally in dental extraction sockets. As described by Aminov A et al., (2025), simvastatin exerts osteopromotive effects by upregulating BMP-2, enhancing osteoblast differentiation and activity. When impregnated into biodegradable carriers such as gelfoam, simvastatin enables sustained drug release directly into the socket, creating a localised regenerative microenvironment. The study reported notable improvements in bone density and trabecular architecture in simvastatin-treated sockets compared to controls, as measured via radiographic and histological analysis. Additionally, simvastatin exhibits anti-inflammatory and angiogenic properties, reducing postoperative discomfort and supporting early tissue remodelling. Its cost-effectiveness, availability, and dual mechanism- promoting bone formation while modulating inflammation- make it an attractive adjunct for enhancing socket healing. These findings suggest that local simvastatin application can effectively accelerate both hard and soft-tissue healing following third molar surgery [9].

Recent studies have highlighted the role of simvastatin not only in bone formation but also in modulating the immune microenvironment during bone repair. Zhu S et al., (2025) reported that simvastatin influences macrophage polarisation, favouring the M2 phenotype which is associated with anti-inflammatory and pro-healing effects. This immunomodulatory action plays a vital role in the early stages of bone regeneration, reducing excessive inflammation that could delay healing. Furthermore, the study demonstrated that simvastatin enhances the expression of Vascular Endothelial Growth Factor (VEGF), contributing to improved neovascularisation at the site of bone injury. Importantly, the research emphasised the dose-dependent nature of simvastatin's effects, with optimal regenerative outcomes achieved at controlled low concentrations. Overdosing may impair cell viability and function. These findings provide insight into the complex biological mechanisms by which simvastatin supports bone healing, suggesting that its local application requires careful dose adjustment for maximal therapeutic benefit [10].

Despite the individual benefits of Gelatamp and simvastatin in improving postoperative healing, there is a paucity of comparative studies evaluating their relative efficacy in the context of mandibular third molar extractions. This gap underscores the need for research directly comparing these two agents to establish evidence-based recommendations for clinical practice.

MATERIALS AND METHODS

This single masked randomised control trial (CTRI NO. CTRI/2025/06/088124) will be held in the Sharad Pawar Dental College of Datta Meghe Institute of Higher Education and Research, a tertiary care centre situated in the state of Maharashtra in India, between the time frame of May 2025 to January 2027. The study will be conducted after taking consent from patients who came to the OPD with a treatment plan of surgical mandibular third molar extraction. The Institutional Ethical Clearance (IEC) has been obtained prior to the study DMIMS (DU)/IEC/2025/688.

Inclusion criteria:

1) Patients indicated for surgical extraction of mandibular third molars;
2) Patients aged between 16-50 years;
3) Patients with American Society of Anesthesiologists (ASA) Grade I status [11].

Exclusion criteria:

1) Patients with systemic diseases such as hypertension, diabetes mellitus, blood dyscrasias, immunocompromised status;
2) Patients with poor oral hygiene and chronic smokers and chronic alcoholism;
3) Pregnant or nursing women, female patients taking oral contraceptive pills;
4) Patient on oral or intravenous bisphosphonate treatment;
5) Associated pathology like cyst and tumour;
6) Patients presenting with acute pericoronitis, active infection, or severe trismus/swelling requiring antibiotic therapy prior to surgery;
7) Infected teeth;
8) Patients lost to follow-up;
9) Patients with ASA Grade II, III, and IV status.

Sample size calculation:

Sample size was calculated using the following formula with reference [7]

$$N = \left(\frac{Z_{\alpha/2} + Z_{\beta/2}}{E}\right)^2 \cdot \frac{S^2}{q_1 \cdot q_2}$$

- $Z_{\alpha/2}$ is the critical value corresponding to $\alpha/2$ for a two-tailed test.
- Z_{β} is the critical value corresponding to β for power.
- S is the standard deviation of the outcome in the population.
- *E* is the effect size.
- q_1 and q_2 are the proportions of subjects in Groups 1 and 2, respectively.

Substituted values:

- $\alpha=0.05 \Rightarrow Z_{\alpha/2}=1.96$
- $\beta=0.20 \Rightarrow Z\beta=0.84$
- $q_1=0.5$, $q_2=0.5$
- E=0.9
- S=1

$$N = \left(\frac{1.96 + 0.84}{0.9}\right)^2 \cdot \frac{1^2}{0.5 \cdot 0.5} = 39 \cong 40$$

Rounded to N=40, thus 20 participants in each group

A sample size of 39 was determined through statistical calculation and subsequently rounded to 40 to enhance the reliability and power of the study. Accordingly, a total of 40 patients will be recruited. Participants will be randomly divided into two equal groups using a computer-generated randomisation method:

Group-A (n=20): Gelatamp will be applied to the extraction site.

Group-B (n=20): Simvastatin-impregnated Gelfoam will be placed in the socket.

All participants will undergo surgical extraction of a single impacted mandibular third molar, with the procedure standardised across all cases. The use of random allocation ensures minimisation of selection bias and promotes comparability between the two groups.

Primary outcomes:

1. Pain Assessment (Visual Analogue Scale: VAS):

   Postoperative pain will be assessed first immediately after surgery then on Day 1, and Day 2 using the Visual Analogue VAS. Patients will rate their pain on a 10-point scale ranging from 0 (no pain) to 10 (worst imaginable pain). Scores will be recorded in the respective time slots for each patient and statistically compared between groups [12].

2. Soft-tissue healing (Landry's Healing Index):

   Wound healing will be evaluated on postoperative Days 1 and 2 using the Landry et al. index, which grades tissue healing from 1 (very poor) to 5 (excellent) based on clinical parameters including tissue colour, bleeding on palpation, granulation tissue, epithelialisation, and the presence of suppuration. The detailed clinical criteria will be followed as per the standard index. Sutures will be removed on Day 7 following the final assessment [13].

3. Bone regeneration (Hounsfield Scale - CBCT):

   Radiographic assessment of bone density will be carried out using Cone-Beam Computed Tomography (CBCT). Measurements will be taken immediately postoperatively and again at three months postoperative. Bone density will be quantified using Hounsfield Units (HU) in the region of interest, and changes over time will be analysed between groups.

Secondary outcomes:

1. Postoperative swelling (Souza and Consone Scale):

   Facial swelling will be measured preoperatively, on Day 1, and on Day 7 using the method proposed by Souza and Consone, which calculates swelling based on linear facial measurements. The percentage increase in swelling compared to baseline will be recorded and compared for anti-inflammatory evaluation [14].

2. Haemostasis (Bleeding score):

   Bleeding will be evaluated at five minutes, 30 minutes, and one hour postsurgery (primary bleeding), and again on Day 1, Day 2, and Day 7 (secondary bleeding).

   The classification of bleeding was undertaken using a predefined five-level ordinal scale, patients were asked a series of structured questions regarding bleeding episodes, including the timing, duration, and any interventions applied. Intraoral examination was used to confirm the presence of residual signs of bleeding, including the presence of a clot, discolouration, and fibrin coverage. The five levels comprised

   Grade 0: No bleeding

   Grade 1: Excess clot formation in the socket, no treatment required

   Grade 2-1: Haemostasis achieved by compressing the wound longer than 30 min

   Grade 2-2: Oozing haemorrhage observed on or after the next day of the procedure, with haemostasis being achieved by simple compression

   Grade 3: Haemorrhage requiring treatment other than wound compression, such as application of compression brace and/or electrocoagulation [15].

Study Procedure

Demographic details including age, gender, relevant medical history, reason for extraction, and check if any co-existing systemic conditions exist will be recorded for all participants. Each patient will undergo a comprehensive preoperative examination that includes both intraoral clinical evaluation and baseline CBCT imaging patients indicated for extraction due to recurrent infections (e.g., pericoronitis), dental caries, or periodontal issues related to mandibular third molars will be selected for the study.

Before the surgical procedure, patients will rinse their oral cavity with povidone-iodine solution. Aseptic technique will be ensured by disinfecting the perioral skin using 7.5% povidone-iodine. An experienced oral and maxillofacial surgeon will administer the inferior alveolar nerve block using the Fischer 123 approach. Nerve block efficacy will be assessed subjectively (patient-reported numbness) and objectively using a traumatic probing technique along the course of the nerve.

The tooth extraction will be performed with minimal trauma, avoiding extensive soft-tissue manipulation and ensuring preservation of the alveolar bone. Haemostasis will be established by compressing the extraction site with sterile gauze, followed by irrigation with normal saline to remove any residual blood and debris. Patients will be randomly allocated into one of the two intervention arms:

Group-A (Gelatamp Group):

Gelatamp will be aseptically transferred from its packaging into a sterile container and immediately inserted into the prepared extraction socket. The site will then be closed with 3-0 silk sutures to maintain the material in position.

Group-B (Simvastatin Group):

A sterile 10 mg Simvastatin tablet will be crushed and combined with 2-3 drops of sterile saline to form a smooth paste. Gelfoam will be used as a carrier, soaked in the simvastatin paste, and then placed into the socket. The site will be secured with 3-0 silk sutures to retain the impregnated material.

All participants will be prescribed postoperative medications, including amoxicillin–clavulanic acid 625 mg, to be taken twice daily for three days, and a fixed-dose combination of paracetamol, aceclofenac, and serratiopeptidase, to be taken twice daily for three days. Immediate postoperative clinical photographs and CBCT imaging will be performed.

Follow-up evaluations will be conducted immediate post operatively, postoperative Day 1, Day 2, Day 7.

Pain intensity will be assessed using the VAS at immediate postoperative Days 1, 2, and 7.

Soft-tissue healing will be evaluated on Day 1 and Day 2 using the Landry et al., healing index.

Bone regeneration will be assessed using HU via CBCT imaging taken immediately postoperatively and at three months postsurgery. As secondary outcomes, postoperative swelling will be measured using the Souza and Consone scale preoperatively, and on Day 1 and Day 7. Haemostasis will be evaluated using a predefined five-level ordinal scale, recording primary bleeding at five minutes and 30 minutes, one hour postsurgery, and secondary bleeding on Day 1, Day 2, and Day 7. Sutures will be removed on postoperative Day 7.

The primary outcomes of the study will include levels of postoperative pain, soft-tissue healing status, extent and quality of bone regeneration as seen on CBCT at the three-month mark and secondary outcome will be postoperative swelling and haemostasis, the all clinical and radiographic findings will be systematically recorded in the designated case record form for subsequent evaluation.

STATISTICAL ANALYSIS

Microsoft Excel will be used to enter the data, and Statistics and Data (STATA) 10 software will be used to perform the statistical analysis. The association between various demographic, clinical, and outcome variables will be evaluated using the independent t-test for continuous data with a normal distribution, the Chi-square test, and Fischer's-exact test for categorical data. The parameters that will be compared are pain, bone density immediately postoperatively, along with these, soft-tissue healing, swelling, and haemostasis will be assessed during follow-up visits. The p-value <0.05 will be considered significant.

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