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Comparative Evaluation of Bone Regeneration - With and Without Simvastatin after surgical removal of bilateral impacted third molar-A split mouth randomized clinical trial

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Background:
Third molar extraction is very common procedure performed in oral and maxillofacial surgery. Loss of bone on the second molar is a common concern. Thus, preservation or augmentation of the alveolar bone or ridge after extraction is advantageous. Bone regeneration is a complex process of bone formation similar to normal fracture healing and bone remodelling . Three essential component for bone to successfully repair are osteoinduction , osteogenesis , and the osteoconductive matrix .

Objectives: To assess the efficacy of simvastatin in bone regeneration after the surgical extraction of Bilaterally Impacted Mandibular Third Molar with a series of intraoral periapical radiographs(IOPARS) at different intervals during healing.

Methodology: A randomized controlled parallel-arm study was conducted on 40 patients requiring bilateral mandibular third molar removal. One extraction site (test) received 10 mg of simvastatin with gel foam, while the contralateral site (control) received gel foam alone. Bone regeneration was assessed on postoperative Day 14 and at 1 month using orthopantomogram (OPG) and intraoral periapical radiographs (IOPAR). Pain scores were also evaluated at regular postoperative intervals. Bone density values were analyzed using standardized radiographic methods, and statistical significance was determined using the Chi-square test for categorical variables and the Mann-Whitney U test for ordinal outcomes such as lamina dura and bone density scores.

Results: Radiographic evaluation revealed a statistically significant increase in bone density at the simvastatin-treated sites compared to the control group ($p < 0.05$). The mean bone density was consistently higher on Day 14 and at the 1-month evaluations in the simvastatin group. Additionally, patients in the test group reported lower pain scores at 1st, 3rd, and 7th postoperative days, indicating a secondary anti-inflammatory benefit.

Conclusion: The local application of 10 mg simvastatin combined with gel foam significantly enhances bone regeneration in extraction sockets and reduces postoperative discomfort. This approach may serve as a simple, cost-effective adjunct in socket preservation following third molar surgery.

Keywords: Simvastatin, Bone Regeneration, Mandibular Third Molars, Socket Preservation .

I. Introduction :

Impacted mandibular third molars are among the most commonly encountered conditions in oral and maxillofacial surgery and their surgical removal is one of the most frequently performed procedures worldwide. Third molars often fail to erupt completely due to inadequate arch space, abnormal angulation, or developmental disturbances. Impacted teeth may lead to various pathological conditions such as pericoronitis, dental caries, periodontal disease, root resorption of adjacent teeth, cystic lesions, and odontogenic tumors, thereby necessitating surgical extraction. Despite advances in surgical techniques and instrumentation, postoperative complications such as pain, swelling, trismus, dry socket, infection, and alveolar bone loss remain common concerns following third molar surgery.

Alveolar bone plays a crucial role in maintaining tooth support, periodontal health, and overall oral function. Following tooth extraction, the socket undergoes a complex sequence of healing events involving clot formation, inflammation, angiogenesis, cellular proliferation, and bone remodeling. Successful bone regeneration depends on the coordinated action of osteogenesis, osteoinduction, osteoconduction, and adequate vascularization. Growth factors such as Bone Morphogenetic Protein-2 (BMP-2) and Vascular Endothelial Growth Factor (VEGF) are essential mediators of bone healing, stimulating osteoblastic differentiation and angiogenesis. However, the clinical use of recombinant growth factors is often limited by their high cost and restricted availability.

In recent years, pharmacological agents capable of enhancing bone regeneration have gained considerable attention. Simvastatin, a hydroxymethylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor widely prescribed for the treatment of hypercholesterolemia, has demonstrated significant osteogenic, angiogenic, and anti-inflammatory properties beyond its lipid-lowering effects. Experimental studies have shown that simvastatin stimulates osteoblastic activity, suppresses osteoclastic bone resorption, and increases the expression of BMP-2 and VEGF, thereby promoting new bone formation. Furthermore, local application of simvastatin at surgical sites offers the advantage of achieving higher therapeutic concentrations while minimizing systemic adverse effects.

Therefore, the present randomized controlled parallel-arm clinical trial aims to evaluate the effectiveness of locally applied simvastatin with Gelfoam as a carrier in enhancing bone regeneration at mandibular third molar extraction sites. Clinical and radiographic assessments will be performed to determine its potential role in improving socket healing and reducing postoperative complications, thereby providing a cost-effective and biologically favorable approach for alveolar bone regeneration.

AIM OF THE STUDY: The Aim of the study is to evaluate and compare the clinical outcome with or without the use of simvastatin using local anesthesia technique. Simvastatin promote osteoblastic activity, inhibit osteoclastic activity and support osteoblast differentiation induced by bone morphogenetic protein.

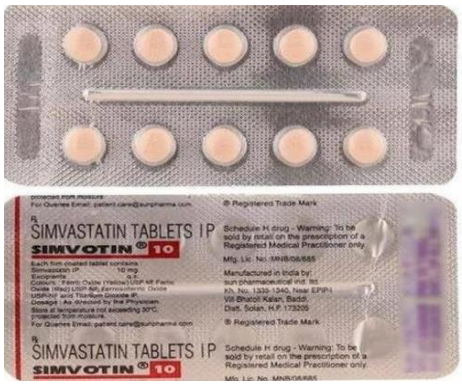
OBJECTIVES : To assess the efficacy of simvastatin in bone regeneration after the surgical extraction of Bilaterally Impacted Mandibular Third Molar with a series of intraoral periapical radiographs(IOPARS) at different intervals during healing .

1. To assess and compare bone density in extraction sockets treated with simvastatin and those without, using OPG/IOPA at 1st day, Day 14 and 1 month postoperatively.
2. To evaluate and compare the clinical healing outcomes in simvastatin-treated and control sites.
3. To determine the effectiveness of simvastatin as a local osteopromotive agent when combined with gel foam in the socket preservation protocol.
4. To evaluate patient-reported postoperative pain levels at various time intervals and assess the anti-inflammatory benefit of simvastatin.

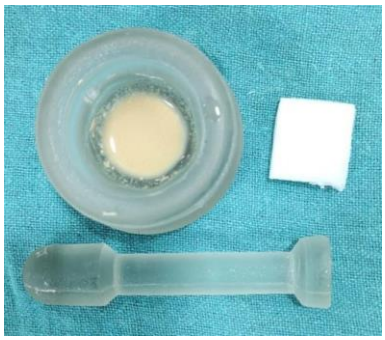
II. Materials and Methods:

This prospective randomized controlled parallel-arm study was conducted in the Department of Oral and Maxillofacial Surgery, Maharana Pratap College of Dentistry and Research Centre, Gwalior, Madhya Pradesh, India, between March 2023 and February 2026.A total of 50 subjects were screened, of which 40 systemically healthy patients requiring mandibular molar extraction fulfilled the inclusion criteria and were enrolled. Patients were randomly allocated into two parallel groups of 20 each: Group A (control, Gelfoam alone) and Group B (study, simvastatin 10 mg with Gelfoam). Patients aged 18–50 years with ASA Grade I status and willing to participate were included. Patients with systemic diseases, pregnancy, smoking or alcohol habits, bisphosphonate therapy, active infection, associated pathology, or known drug allergy were excluded.Participants were randomly allocated into two groups using a computer-generated randomization sequence and sealed opaque envelopes . **Group A (Control):** Gelfoam placed in the extraction socket.**Group B (Study):** Simvastatin (10 mg) impregnated Gelfoam placed in the extraction socket. All extractions were performed under local anesthesia by a single experienced surgeon under aseptic conditions. Following atraumatic extraction and socket irrigation with normal saline, the assigned material was placed in the socket and secured with 3-0 silk sutures using a figure-of-eight technique. Postoperatively, all patients received standard antibiotic and analgesic therapy. Clinical evaluations were performed on postoperative days 1, 3, 7, and 14. Pain was assessed using the Visual Analogue Scale (VAS), while soft tissue healing was evaluated using Landry's Healing Index. Sutures were removed on postoperative day 7. Radiographic assessment of bone regeneration was performed on postoperative Day 14 and at 1 month using intraoral periapical radiographs (IOPA/RVG) and orthopantomography/cone-beam computed tomography (OPG/CBCT).

ARMAMENTARIUM

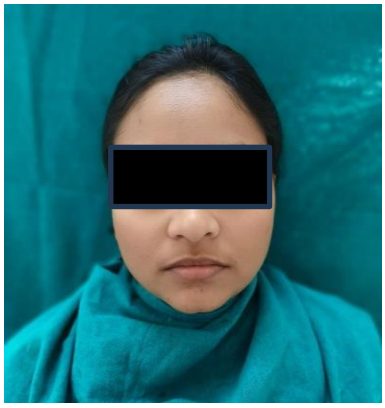


SIMVASTATIN TABLET

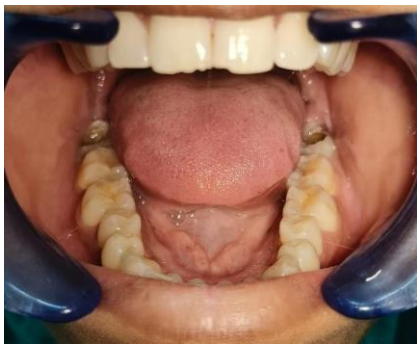


MIXING SIMVASATTIN WITH ABE GEL

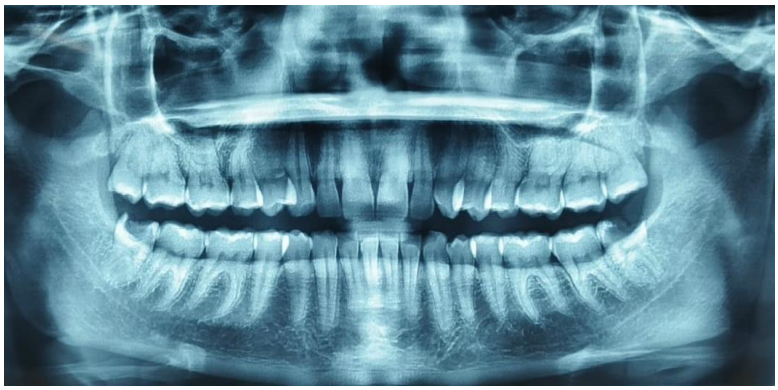
CASE 1 :



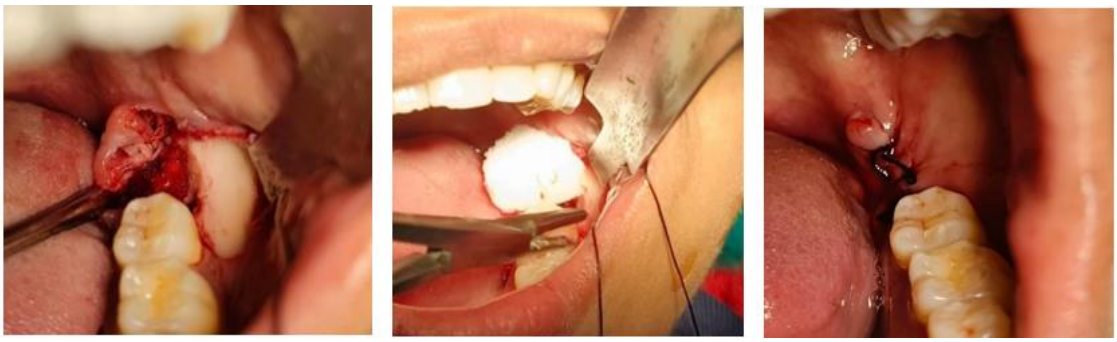
PRECLINICAL PROFILE PICTURE



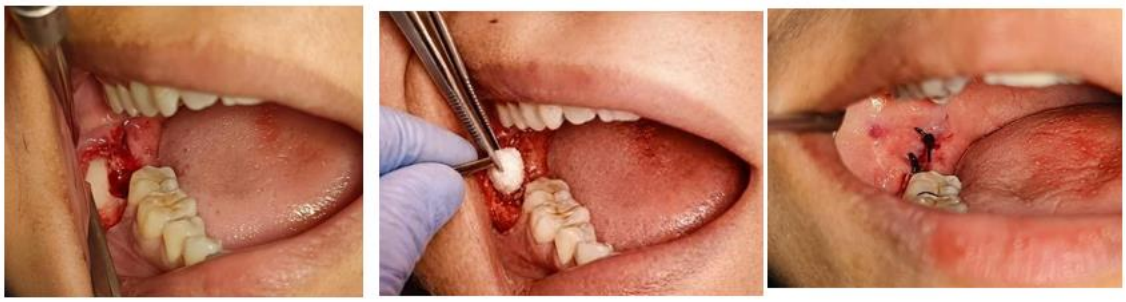
PRECLINICAL INTRAORAL



PREOPERATIVE OPG

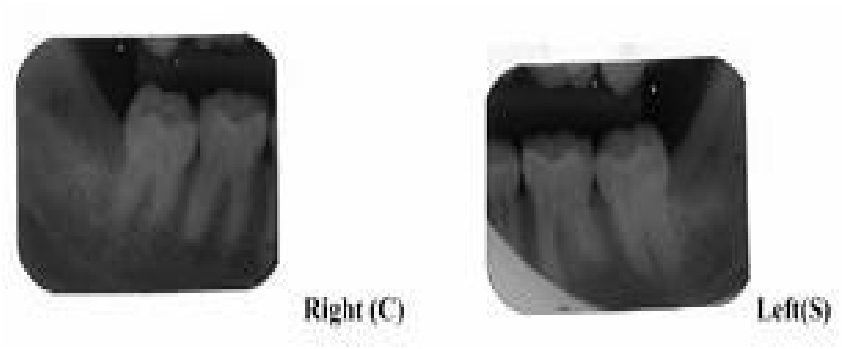


(A)Extraction socket of lower posterior teeth (B) Without Simvastatin Impregnated gel foam placed in extraction socket (C) Socket sutured using 3-0 Silk suture



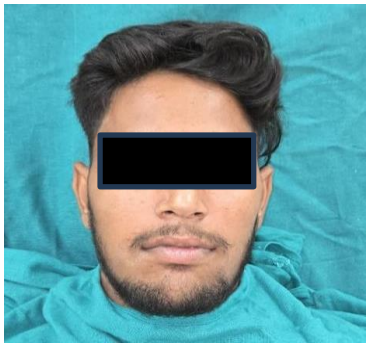
(A)Extraction socket of lower posterior teeth (B) Simvastatin Impregnated gel foam placed in extraction socket (C) Socket sutured using 3-0 Silk suture

POST OP IOPA 14TH DAY IOPAR

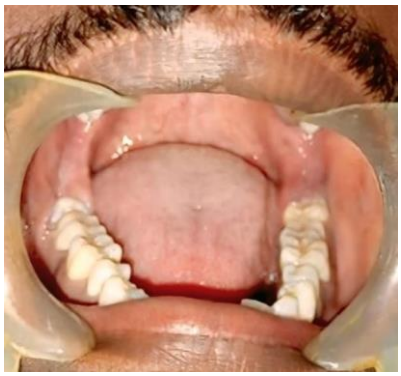


POST OP IOPAR 30TH DAY IOPAR

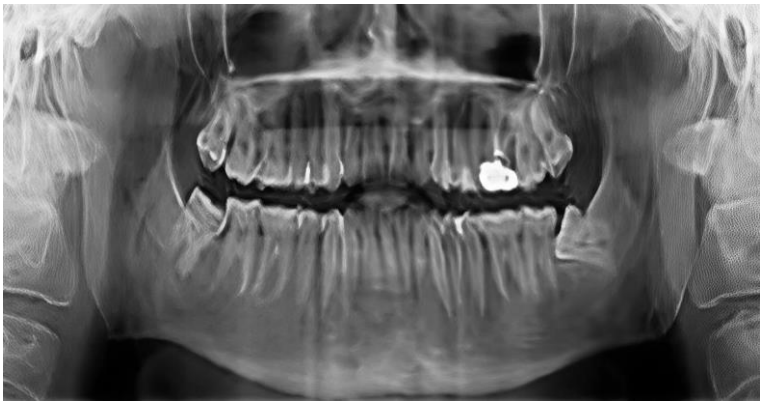
CASE 2



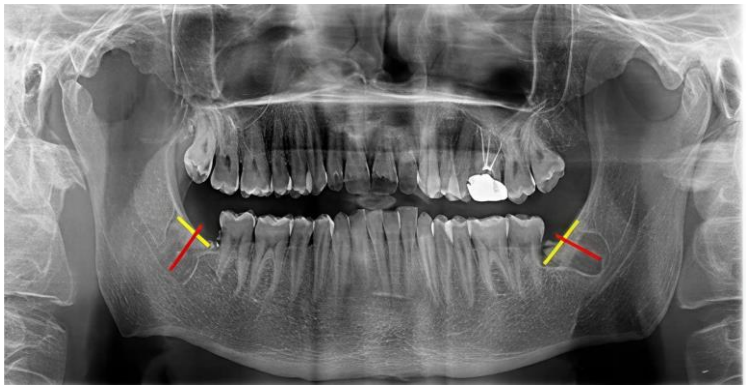
PRECLINICAL PROFILE PHOTO



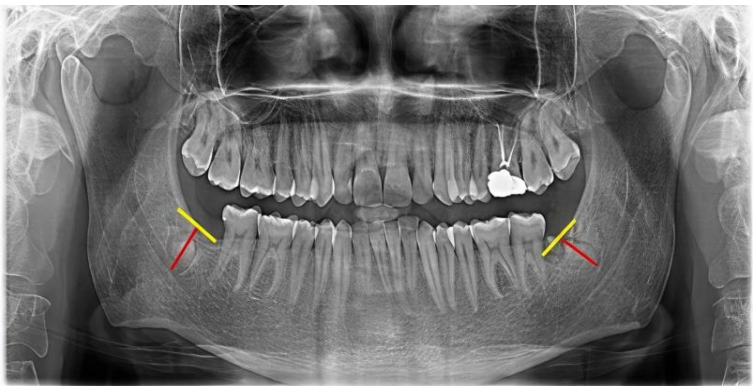
PRECLINICAL INTRAORAL



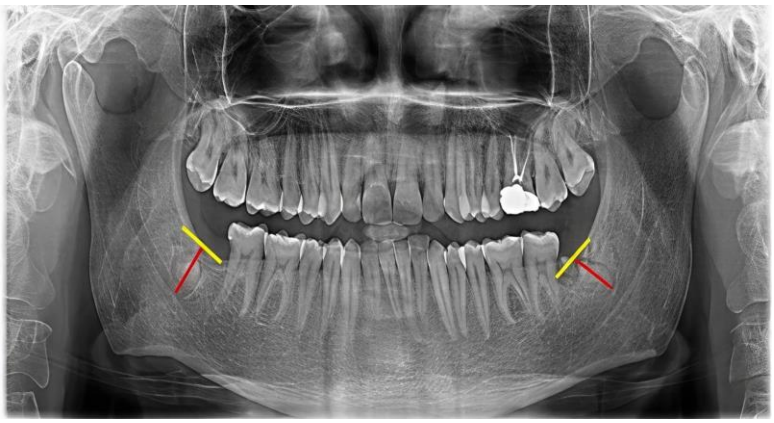
PREOPERATIVE OPG



IMMEDIATE AFTER EXTRACTION



IMMEDIATE AFTER GRAFT PLACEMENT IN 38 TOOTH



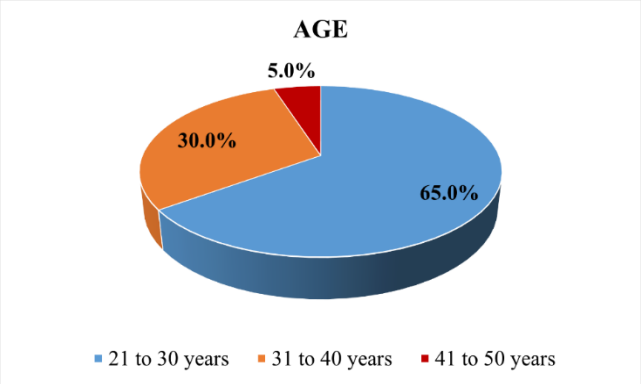
1 MONTH FOLLOW UP

- Red Line Represent – Height of the Socket.
- Yellow Line Represent – Mesio-distal width of the socket

III. RESULTS

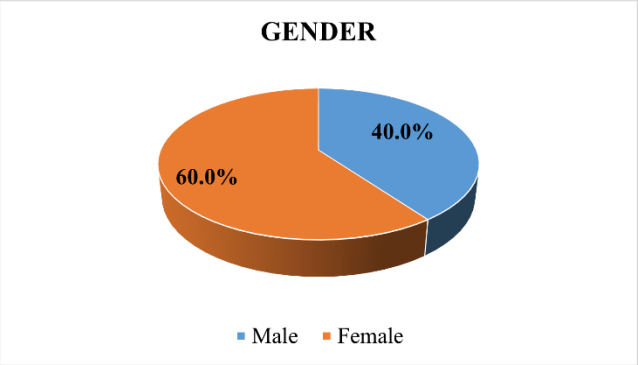
The mean ± standard deviation age of the study subjects was 29.5 ± 6.303 years (minimum= 21 years, maximum= 45 years). The age distribution of the study participants shows that the majority of subjects belonged to the 21–30 years age group, accounting for 13 individuals (65%). This was followed by the 31–40 years age group, comprising 6 subjects (30%). Only 1 participant (5%) was in the 41–50 years age group. Overall, the findings indicate that most of the study population consisted of young adults, with comparatively fewer participants in the older age groups.

Figure 1. Distribution of study subjects according to age.



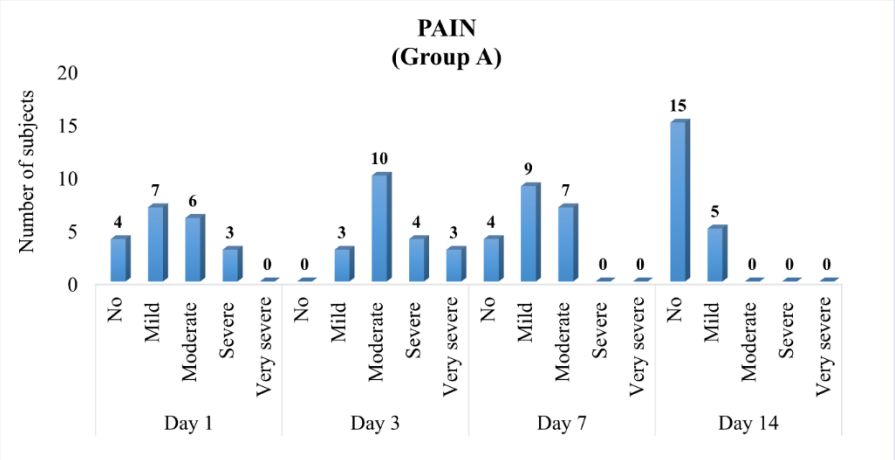
Gender: The gender distribution of the study participants shows that females constituted the majority, with 12 subjects (60%), while males accounted for 8 subjects (40%). This indicates a higher representation of females compared to males in the study population.

Figure 2. Distribution of study subjects according to gender.



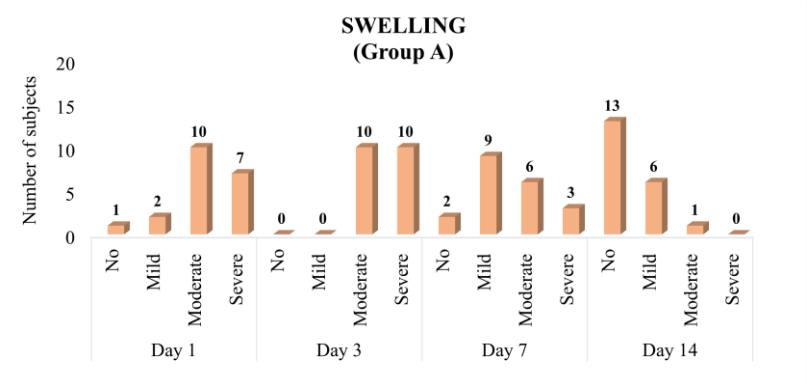
GROUP A: The intragroup comparison of pain severity across different time intervals in Group A revealed a statistically significant change over time ($p < 0.001$). On Day 1, most participants experienced mild (35%) to moderate pain (30%), while 20% reported no pain and 15% had severe pain. By Day 3, pain intensity increased, with 50% reporting moderate pain and 20% severe pain; 15% experienced very severe pain, and none reported absence of pain. On Day 7, a noticeable reduction in pain severity was observed. The majority reported mild pain (45%) or moderate pain (35%), and 20% had no pain. Importantly, no cases of severe or very severe pain were recorded. By Day 14, substantial improvement was evident, with 75% of participants reporting no pain and the remaining 25% experiencing only mild pain. No moderate, severe, or very severe pain was observed at this stage. Overall, pain severity in Group A showed a significant reduction over time, with marked improvement by Day 14.

Figure 3. Severity of pain in Group A.



Swelling: The intragroup comparison of swelling severity across different time intervals in Group A demonstrated a statistically significant change over time ($p < 0.001$). On Day 1, the majority of participants exhibited moderate (50%) to severe swelling (35%), while only 10% had mild swelling and 5% showed no swelling. By Day 3, swelling severity peaked, with 50% experiencing moderate swelling and 50% severe swelling; no participants reported mild or no swelling at this stage. On Day 7, a reduction in swelling was observed. Most participants had mild swelling (45%), followed by moderate (30%) and severe (15%) swelling, while 10% showed no swelling. By Day 14, marked improvement was evident. The majority of participants (65%) had no swelling, 30% had mild swelling, and only 5% had moderate swelling. No cases of severe swelling were recorded. Overall, swelling severity in Group A showed a significant progressive reduction over time, with substantial resolution observed by Day 14.

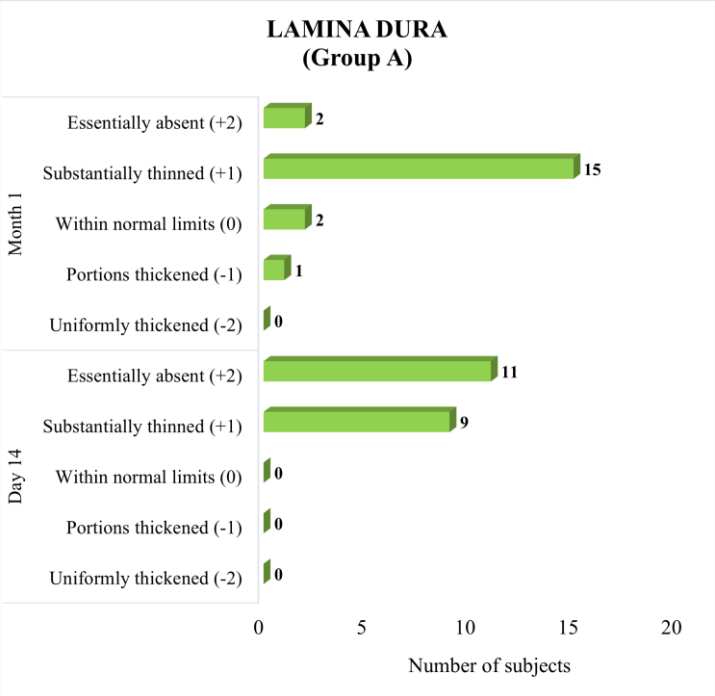
Figure 4. Severity of swelling in Group A.



Lamina dura

The intragroup comparison of lamina dura changes in Group A between Day 14 and 1 month revealed a statistically significant difference ($p = 0.005$), indicating radiographic changes over time. On Day 14, healing appeared limited, as 55% of cases showed the lamina dura to be essentially absent (+2) and 45% were substantially thinned or missing in areas (+1). No cases were within normal limits or showed thickening. By 1 month, some improvement was observed. The proportion of cases with essentially absent lamina dura (+2) decreased to 10%, while 75% remained substantially thinned (+1). Additionally, early signs of healing were evident, with 10% of cases returning to within normal limits (0) and 5% showing portions thickened (−1). However, no cases demonstrated uniformly thickened lamina dura (−2). Overall, although radiographic improvement was noted at 1 month compared to Day 14, the majority of cases in Group A continued to exhibit incomplete lamina dura reformation, suggesting delayed bone healing.

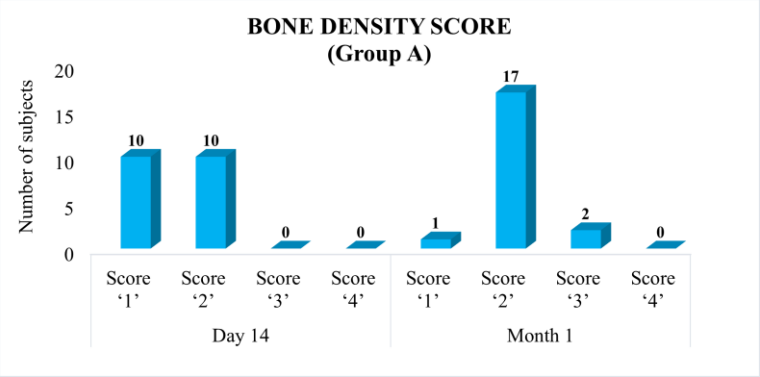
Figure 5. Lamina dura in Group A.



Bone density score

The intragroup comparison of bone density scores in Group A between Day 14 and 1 month showed a statistically significant improvement over time (MH = −3.051, $p < 0.001$). On Day 14, bone density was relatively low, with 50% of cases categorized as Score '1' and the remaining 50% as Score '2'. No cases exhibited higher scores (Score '3' or '4'), indicating early or limited bone mineralization at this stage. By 1 month, a clear shift toward improved bone density was observed. The proportion of Score '1' cases markedly decreased to 5%, while the majority (85%) demonstrated Score '2'. Additionally, 10% of cases progressed to Score '3', reflecting ongoing bone formation. However, no cases reached Score '4' at this time point. Overall, these findings indicate a significant increase in bone density within Group A over the 1-month period, demonstrating progressive but moderate radiographic bone healing.

Figure 6. Bone density score in Group A.

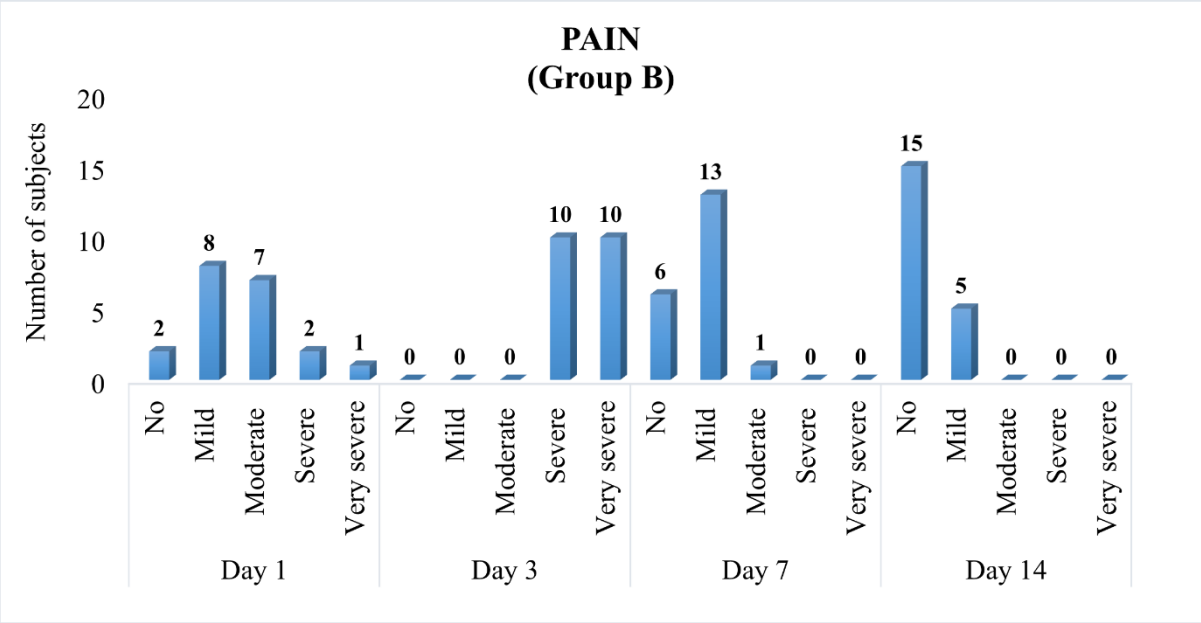


GROUP B

Pain

The intragroup comparison of pain severity across different time intervals in Group B revealed a statistically significant change over time (Chi-square = 50.586, $p < 0.001$). On Day 1, most participants experienced mild (40%) to moderate pain (35%), while 10% reported no pain, 10% had severe pain, and 5% experienced very severe pain. By Day 3, pain intensity increased markedly, with 50% of participants reporting severe pain and the remaining 50% reporting very severe pain. No participants reported mild, moderate, or no pain at this stage. On Day 7, a substantial reduction in pain severity was observed. The majority of participants reported mild pain (65%), followed by 30% with no pain and only 5% with moderate pain. No cases of severe or very severe pain were recorded. By Day 14, significant improvement was evident, with 75% of participants reporting no pain and 25% experiencing only mild pain. Overall, pain severity in Group B showed significant variation over time, with an initial increase by Day 3 followed by marked and progressive reduction, leading to near-complete resolution by Day 14.

Figure 7. Severity of pain in Group B.

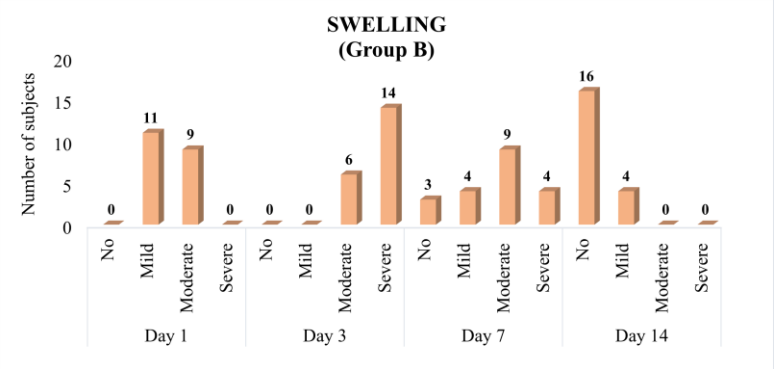


Swelling

The intragroup comparison of swelling severity across different time intervals in Group B demonstrates a progressive change in swelling over time. On Day 1, the majority of participants exhibited mild swelling (55%), while 45% had moderate swelling. By Day 3, swelling severity increased markedly, with 70% of participants experiencing severe swelling and 30% moderate swelling.On Day 7, moderate swelling was most common (45%), followed by mild (20%) and severe (20%) swelling, while 15% of participants showed no swelling. By Day 14,

the majority of participants (80%) had no swelling, and the remaining 20% exhibited only mild swelling. Overall, swelling severity in Group B increased initially up to Day 3, followed by a gradual and marked reduction, with near-complete resolution by Day 14.

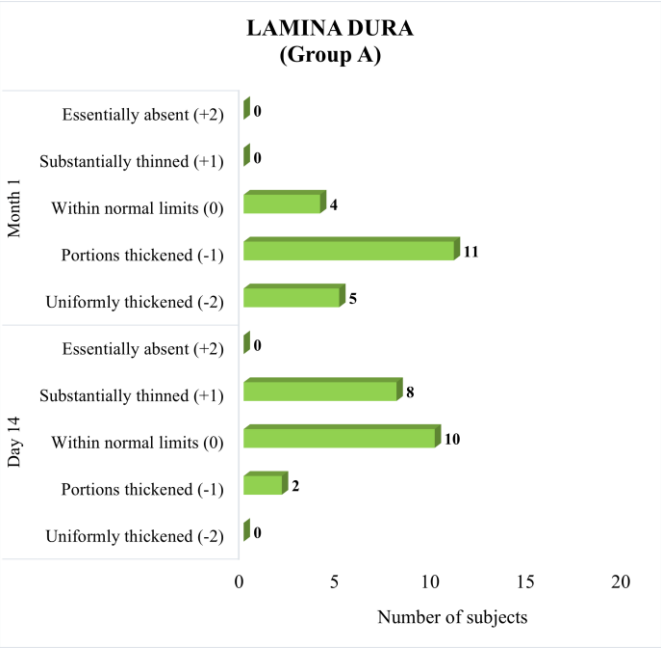
Figure 8. Severity of swelling in Group B.



Lamina dura

The intragroup comparison of lamina dura changes in Group B between Day 14 and 1 month demonstrated a statistically significant improvement over time (MH = 4.117, $p < 0.001$). On Day 14, 50% of cases were within normal limits (0), 10% showed portions thickened (−1), and 40% were substantially thinned or missing in areas (+1). No cases exhibited uniformly thickened (−2) or essentially absent (+2) lamina dura. This indicates partial healing, with a considerable proportion already returning to normal radiographic appearance. By 1 month, marked radiographic improvement was observed. A majority of cases demonstrated thickening of the lamina dura, with 55% showing portions thickened (−1) and 25% uniformly thickened (−2), reflecting enhanced bone deposition and advanced healing. The remaining 20% were within normal limits (0), and no cases showed thinning or absence. Overall, Group B exhibited significant and progressive lamina dura reformation over time, with clear evidence of favorable bone healing by 1 month.

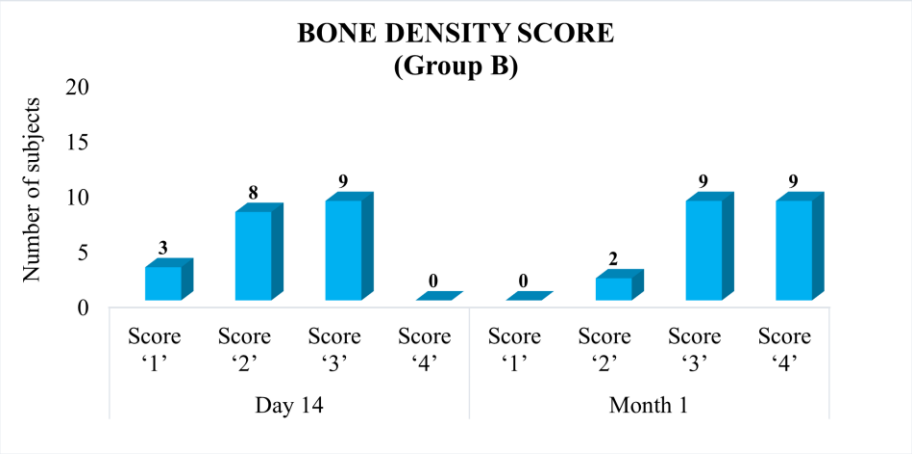
Figure 9. Lamina dura in Group B.



Bone density score

The intragroup comparison of bone density scores in Group B between Day 14 and 1 month demonstrated a statistically significant improvement over time (MH = −3.772, $p < 0.001$). On Day 14, the majority of participants exhibited moderate to good bone density, with 45% categorized as Score '3', 40% as Score '2', and 15% as Score '1'. No cases achieved Score '4', indicating that although healing had progressed, maximal bone density had not yet been attained. By 1 month, marked enhancement in bone density was observed. A substantial proportion of cases reached higher scores, with 45% achieving Score '4' and another 45% maintaining Score '3'. Only 10% remained at Score '2', and no cases were categorized as Score '1'. Overall, these findings indicate significant and progressive bone mineralization in Group B over time, with the majority of cases demonstrating advanced radiographic bone healing by 1 month.

Figure 10. Bone density score in Group B.

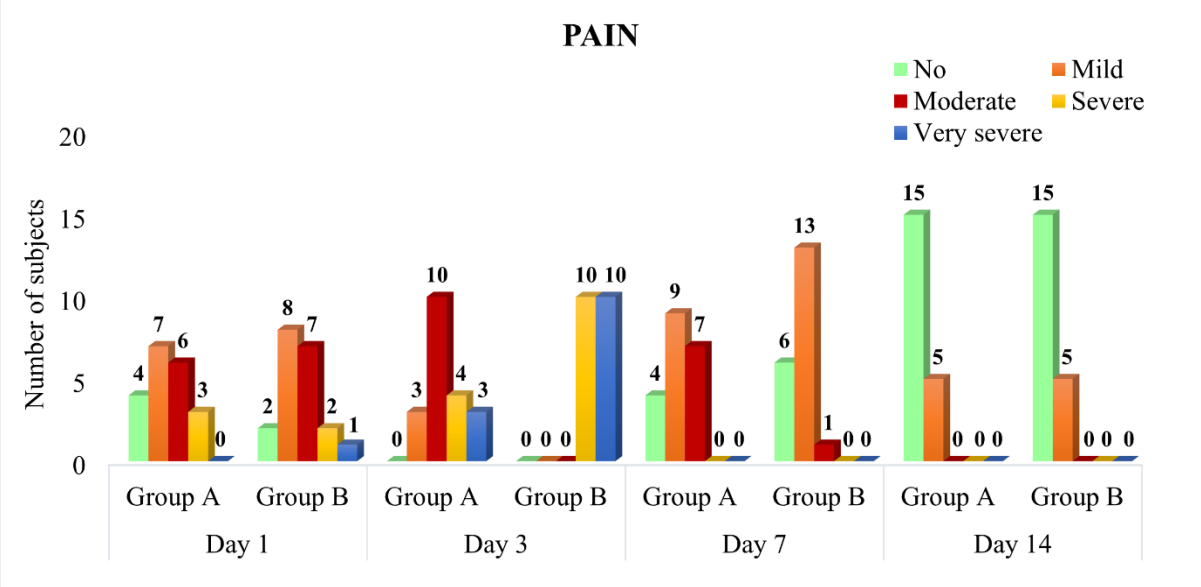


IV. INTER-GROUP COMPARISON

Pain

On Day 1, there was no statistically significant difference in pain severity between Group A and Group B ($p = 0.157$). Both groups showed a comparable distribution of pain levels, with most participants experiencing mild to moderate pain. By Day 3, a statistically significant difference was observed between the groups ($p = 0.001$). In Group A, the majority of participants reported moderate pain (50%), whereas in Group B, 50% reported severe pain and another 50% reported very severe pain, indicating higher pain severity in Group B at this time interval. On Day 7, the difference between the groups remained statistically significant ($p = 0.029$). Group A showed improvement, with most participants experiencing mild (45%) or moderate (35%) pain. In contrast, Group B demonstrated greater reduction in pain severity, with 65% reporting mild pain and 30% reporting no pain, and only 5% experiencing moderate pain. By Day 14, there was no statistically significant difference between the groups ($p = 1.000$). Both groups showed marked improvement, with 75% of participants reporting no pain and 25% reporting mild pain, and no cases of moderate, severe, or very severe pain in either group.

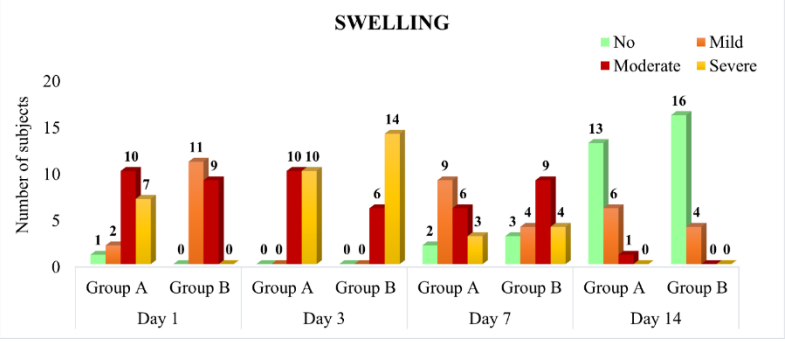
Figure 11. Pain severity in Group A and Group B.



Swelling

On Day 1, there was a statistically significant difference in swelling severity between Group A and Group B ($p = 0.008$). Group A demonstrated more severe swelling, with 35% of participants experiencing severe swelling and 50% moderate swelling. In contrast, Group B showed predominantly mild (55%) and moderate (45%) swelling, with no cases of severe swelling. This indicates greater initial swelling severity in Group A. On Day 3, the difference between the groups was not statistically significant ($p = 0.102$). Both groups exhibited moderate to severe swelling, with a higher proportion of severe cases in Group B (70%) compared to Group A (50%), although this difference was not statistically meaningful. By Day 7, no statistically significant difference was observed between the groups ($p = 0.516$). Swelling severity showed signs of reduction in both groups, with a distribution across mild, moderate, and severe categories. Group A had a higher percentage of mild swelling (45%), whereas Group B had more moderate cases (45%). On Day 14, there was again no statistically significant difference between the groups ($p = 0.157$). The majority of participants in both groups reported no swelling (65% in Group A and 80% in Group B), with only a small proportion experiencing mild swelling and very few moderate cases.

Figure 12. Severity of swelling in Group A and Group B.



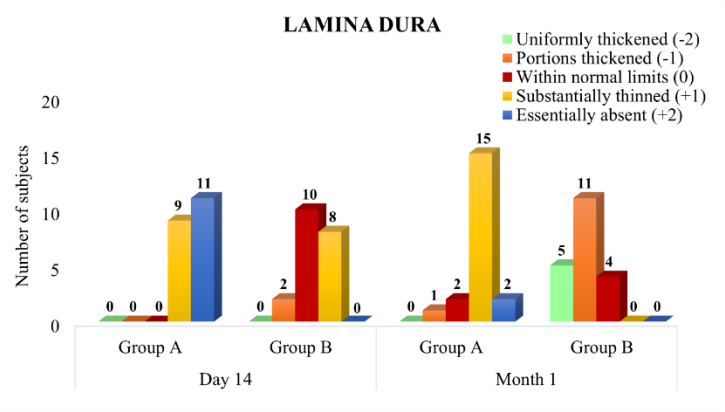
Lamina dura

On Day 14, a statistically significant difference was observed between Group A and Group B in lamina dura status ($MH = 4.003$, $p < 0.001$). In Group A, healing appeared delayed, as 55% of cases showed the lamina dura to be

essentially absent (+2) and 45% were substantially thinned or missing in areas (+1), with no cases within normal limits or showing thickening. In contrast, Group B demonstrated more favorable findings: 50% were within normal limits (0), 10% showed portions thickened (−1), and 40% were substantially thinned (+1), with no cases of complete absence. This indicates better early radiographic healing in Group B compared to Group A.

At 1 month, the difference between the groups remained statistically significant (MH = 4.230, $p < 0.001$). Group B showed marked improvement, with 25% exhibiting uniformly thickened lamina dura (−2), 55% with portions thickened (−1), and 20% within normal limits (0), reflecting advanced bone healing. Conversely, Group A continued to show predominantly delayed healing patterns, with 75% substantially thinned (+1) and 10% essentially absent (+2), while only a small proportion demonstrated normal (10%) or mildly thickened (5%) lamina dura.

Figure 13. Lamina dura in Group A and Group B.

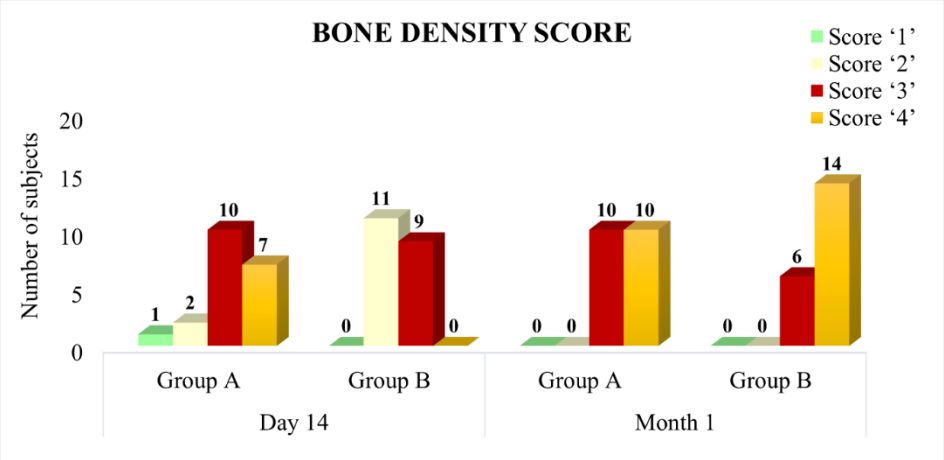


Bone density score

On Day 14, a statistically significant difference was observed between Group A and Group B in bone density scores ($p < 0.001$). In Group A, all cases were distributed between Score '1' (50%) and Score '2' (50%), indicating relatively lower bone density and early stages of healing. In contrast, Group B demonstrated comparatively better bone density, with 45% of cases showing Score '3', 40% Score '2', and only 15% Score '1'. This suggests superior early bone formation and mineralization in Group B.

At 1 month, the intergroup difference remained highly statistically significant ($p < 0.001$). Group B showed marked improvement, with 45% of cases achieving Score '4' and another 45% Score '3', reflecting advanced bone healing and increased density. Only 10% remained at Score '2', and none were at Score '1'. In contrast, Group A predominantly exhibited Score '2' (85%), with only 10% reaching Score '3' and 5% at Score '1', and no cases achieving Score '4'.

Figure 14. Bone density score in Group A and Group B.



V. DISCUSSION:

The surgical extraction of impacted mandibular third molars is frequently associated with postoperative pain, swelling, and alveolar bone loss. Preservation of alveolar bone following extraction has become an important objective in oral and maxillofacial surgery because adequate bone healing is essential for periodontal health, future prosthetic rehabilitation, and implant placement. In recent years, pharmacological agents capable of enhancing bone regeneration have gained considerable attention. Among these agents, simvastatin has emerged as a promising adjunct because of its osteogenic, angiogenic, and anti-inflammatory properties.

The present randomized controlled parallel-arm clinical study evaluated the effect of locally delivered simvastatin (10 mg) with Gelfoam on clinical and radiographic healing following mandibular third molar extraction. Randomized allocation into two independent groups minimized selection bias between groups, thereby improving the reliability of the results.

Pain and swelling showed significant changes over time in both groups. Although pain severity increased during the early postoperative period and peaked on Day 3, a gradual reduction was observed thereafter. By Day 14, most patients in both groups were pain-free or reported only mild discomfort. Similarly, swelling reached its maximum intensity on Day 3 and subsequently resolved during the healing period. These findings are consistent with the normal inflammatory response following third molar surgery and are in agreement with previous studies evaluating postoperative morbidity after impacted tooth removal.

The most significant findings of the present study were related to radiographic bone healing. Evaluation of lamina dura and bone density demonstrated superior healing in the simvastatin-treated sites compared with the control sites. At Day 14, Group B exhibited significantly better lamina dura formation, with several sites showing normal or thickened lamina dura, whereas Group A predominantly demonstrated thinning or absence of lamina dura. At one month, the difference became more pronounced, with most simvastatin-treated sites exhibiting thickened lamina dura suggestive of active bone formation and maturation.

Similarly, bone density scores were significantly greater in the simvastatin group at both Day 14 and one month. By one month, 90% of sites in Group B achieved bone density scores of 3 or 4, indicating advanced mineralization and bone regeneration. In contrast, most sites in Group A remained within lower density categories. These findings suggest that local application of simvastatin accelerates bone formation and mineralization within extraction sockets.

The enhanced healing observed in the simvastatin group may be attributed to its ability to stimulate osteoblastic differentiation and increase the expression of BMP-2 and VEGF. BMP-2 promotes osteogenesis by inducing

mesenchymal stem cell differentiation into osteoblasts, while VEGF enhances angiogenesis, thereby improving blood supply and nutrient delivery to the healing site. Furthermore, simvastatin suppresses osteoclastic activity, resulting in a favorable balance between bone formation and bone resorption.

The findings of the present study are consistent with those reported by Degala and Bathija, Chauhan et al., Deepanjali et al., and Harsha et al., who demonstrated enhanced bone regeneration and increased radiographic bone density following local simvastatin application. Similar observations have also been reported in animal and histological studies, supporting the osteoinductive potential of simvastatin.

No adverse reactions, infections, or delayed healing were observed in the present study, indicating that local application of simvastatin is safe and well tolerated. Despite these encouraging findings, the study was limited by a relatively small sample size and a short follow-up period of one month. Longer follow-up periods and advanced imaging modalities such as CBCT may provide more detailed information regarding long-term bone maturation and volumetric changes.

VI. CONCLUSION:

Within the limitations of the present study, it can be concluded that local application of simvastatin (10 mg) with Gelfoam significantly enhances bone regeneration following surgical extraction of impacted mandibular third molars. Simvastatin-treated sockets demonstrated superior radiographic healing characterized by earlier lamina dura formation and significantly greater bone density compared with control sites.

Although postoperative pain and swelling improved in both groups over time, the radiographic parameters clearly indicated accelerated bone healing in the simvastatin group. The osteogenic effects of simvastatin may be attributed to its ability to stimulate BMP-2 and VEGF expression, enhance osteoblastic activity, promote angiogenesis, and reduce osteoclastic bone resorption.

The results suggest that topical simvastatin is a safe, economical, and effective adjunct for extraction socket preservation and may reduce the need for more expensive regenerative materials. Further studies involving larger sample sizes, longer follow-up periods, histological evaluation, and three-dimensional imaging are recommended to establish standardized clinical protocols for its routine use in oral and maxillofacial surgery.

SUMMARY:

The present randomized controlled parallel-arm clinical trial was conducted to evaluate the effect of locally applied simvastatin on bone regeneration following surgical extraction of impacted mandibular third molars. Forty patients (20 per group) requiring mandibular third molar extraction were included, with one extraction socket receiving simvastatin (10 mg) with Gelfoam and the contralateral socket serving as the control with Gelfoam alone.

Clinical parameters including pain and swelling were evaluated on postoperative Days 1, 3, 7, and 14. Radiographic assessment of lamina dura and bone density was performed on Day 14 and at one month. Both groups exhibited significant improvement in pain and swelling over time. However, radiographic findings demonstrated significantly superior bone healing in the simvastatin-treated sites.

Lamina dura assessment revealed earlier and more complete reformation in the simvastatin group. Bone density scores were significantly higher in Group B at both evaluation intervals, indicating enhanced mineralization and accelerated bone regeneration. By one month, most simvastatin-treated sites demonstrated advanced stages of radiographic healing compared with control sites.

The osteogenic benefits of simvastatin may be attributed to stimulation of BMP-2 production, promotion of angiogenesis through VEGF expression, enhancement of osteoblastic activity, and inhibition of osteoclastic bone resorption. No adverse effects or postoperative complications associated with simvastatin application were observed.

Based on the clinical and radiographic findings, local delivery of simvastatin appears to be a promising, safe, cost-effective, and minimally invasive approach for enhancing extraction socket healing. Its use may contribute to preservation of alveolar bone, maintenance of periodontal health, and improved outcomes for future prosthetic and implant rehabilitation.

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