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ORIGINAL ARTICALE

# IMPACT OF SIMVASTATIN-GEL FOAM COMBINATION ON BONE DENSITY AFTER MANDIBULAR THIRD MOLAR EXTRACTION

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## ABSTRACT

**Aims:** This randomized, prospective comparative study aimed to assess the effectiveness of locally applying 10 mg of simvastatin in promoting bone regeneration within the sockets of surgically extracted mandibular third molars, using CBCT to measure bone density one and three months after the procedure.

**Materials and methods:** The study was carried out over a period of eighteen months, involving 30 patients (14 males and 16 females). These cases were randomly assigned to two groups: 15 in the study group and 15 in the control group. Following the surgical extraction of the mandibular third molars, the study group received a local application of a simvastatin and gel foam combination in the extraction sockets, while the control group was treated with gel foam alone. After a period of one month and three months, bone density in the healing sockets was assessed and compared between the two groups using cone beam computed tomography (CBCT). Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 23.0.

**Results**:Three months after the procedure, CBCT measurements revealed that the mean bone density in the study group (247.772 ± 32.635 Hounsfield Units) was significantly greater than that in the control group (207.622 ± 18.515 Hounsfield Units). The difference in bone density between the two groups was statistically significant (p-value=0.029).

**Conclusion:** Applying a combination of 10 mg simvastatin powder and gel foam locally in the sockets of surgically removed mandibular third molars can enhance bone density and is considered a safe method for preserving the alveolar ridge following tooth extraction.

***Keywords:*** Simvastatain - Gel Foam, Bone Density, Mandibular Third Molar Extraction

## INTRODUCTION

An impacted tooth is one that fails to erupt into the mouth within its expected time frame. The mandibular third molar (wisdom tooth) is classified as impacted when its root development is complete but it lacks functional contact with the opposing tooth. Typically, the mandibular third molars erupt between the ages of 17 and 24.[1,2] However, due to racial and ethnic differences, this timeframe can vary significantly.

Since the third molar is the last tooth to emerge in the oral cavity, it has the highest likelihood of impaction. Kazemian et al. identified that neighbouring teeth, as well as hard and soft tissue obstructions, are the primary causes of third molar impaction. Impacted mandibular third molars can lead to a variety of complications, including

pericoronitis, periodontitis, cysts, tumours, root resorption, and damage to adjacent teeth. These may also cause pain, decay, and infections, which often necessitate surgical removal.[3-5]

Surgical extraction of impacted third molars is a routine procedure in oral and maxillofacial surgery. A common concern following extraction is bone loss at the distal surface of the second molar. Therefore, preserving or enhancing the alveolar bone during or after extraction is advantageous.[7,8]

Following tooth extraction, a reduction in alveolar bone volume and socket structure is expected due to natural bone loss. This bone resorption is physiological response to tooth removal.[9-11] Without proactive measures for bone preservation or regeneration, significant bone loss may occur, requiring invasive and expensive procedures such as bone grafting. The optimal time to begin ridge preservation is at the moment of tooth extraction. Timely bone preservation can prevent 40% to 60% of jawbone atrophy, which typically occurs within the first 2-3 years post-extraction and continues annually at a rate of 15%-25%. Bone healing within the socket involves a complex regenerative process similar to fracture repair and normal bone remodelling.[12,13]

The bone healing process involves three main components: osteoinduction, osteogenesis, and the use of an osteoconductive matrix. Bone Morphogenic Proteins (BMPs) play a crucial role in guiding the differentiation of osteogenic cells during bone repair, prompting multipotent stem cells to transform into osteoblast-like cells. The idea of using affordable, biologically compatible pharmaceutical agents with minimal side effects-such as statins-to stimulate the body's own bone growth factors has shown significant promise.

Statins are commonly prescribed to reduce cholesterol levels. However, Mundy and colleagues were the first to demonstrate that statins could also boost the expression of BMP-2 in bone-forming cells. Statins promote new blood vessel formation, stimulate osteoblast activity, reduce vascular inflammation, exhibit anti-thrombotic properties, and enhance the production of BMP-2 and other bone-stimulating factors.[14]

Several studies, mostly animal-based, have explored the role of statins in bone regeneration, using models such as Wistar rats, New Zealand white rabbits, and mice. These studies consistently showed positive outcomes in booth intraoral and extraoral sites, including cranial defects and femoral fractures. Human clinical trials have also been conducted, focusing on periodontal defects, periapical cysts, extraction sites, and osteoporotic bone conditions in women. In vitro research is ongoing to clarify the precise mechanisms behind these effects.[12,13]

Of all the statins, simvastatin has been the most extensively researched, demonstrating multiple biological effects. It works by inhibiting the enzyme HMG-CoA reductase, a key catalyst in mevalonate pathway that produces cholesterol and other non-steroidal isoprenoids. Blocking this enzyme results in various beneficial effects. Simvastatin is derived through the fermentation of *Aspergillus terreus* and appears as white crystalline powder that is non-hygroscopic and insoluble in water but soluble in chloroform, methanol, and alcohol. When taken orally, its absorption rate ranges from 40% to 75%, with a significant portion metabolized by the liver. Most of the drug is excreted via bile, while 5% to 20% is eliminated through urine. The standard oral dose is 20-40 mg per day, with a toxic dose reported at 160 mg daily.[9,10]

Several delivery systems have been explored for the localized application of statins, including collagen gels, polyglycol, and gelfoam. Notably, bone regeneration has been observed when using fluvastatin embedded in a gelatin hydrogel matrix. Gelfoam is a water-insoluble, flexible, porous material made from purified pork skin gelatin. Initially developed as a haemostatic agent, it can absorb many times its weight in blood and other fluids.[15]

This particular study examined the use of simvastatin combined with gelfoam as carrier for promoting bone regeneration in mandibular third molar extraction sites. A 10 mg dose of raw simvastatin powder was used, based on findings from previous literature.

## MATERIALS AND METHODS

This study was done on patients visiting the Department of oral and maxillofacial surgery and were willing to participate in this prospective, randomized clinical investigation. This research took place in Teerthanker Mahaveer Dental College & Research Centre, Teerthanker Mahaveer University, Moradabad, Uttar Pradesh, India from April 2023 to October 2024.

**Inclusion criteria**

Individuals aged between 18-40 who have a partially or fully impacted mandibular 3rd molar that needed surgical extraction & patients who were interested in the study. All these patients were within ASA-I category.

**Exclusion criteria**

Patients with medical conditions, pregnant women, females on contraceptive medications, individuals under 18 or over 40 years of age, those with poor oral hygiene or widespread chronic destructive periodontitis, individuals with acute pericoronitis, a history of head and neck radiation therapy, those unable to attend follow-up or recall appointments, patients who are on calcium supplements, patients with periapical infections and heavy smokers.

**Consent Form**

All participants were thoroughly informed about the purpose and methodology of the study. They were also made aware of their right to withdraw at any point during the study, and informed consent was obtained from each of them.

**Surgical Procedure**

The operation was performed under local anaesthesia 15-20 mins after the injection. Povidone iodine was used to prepare the surgical site (5% w/v). The patients were draped to achieve asepsis. A standardized surgical procedure using ward's/modified ward's incision was carried out by the operator on each patient. A 2ml syringe containing two percent anesthetising agent and vasoconstrictor in concentration 1:80000 was used to administer a conventional inferior alveolar and long buccal nerve block. The standard surgical technique for extraction of lower third molars were done.

After gaining access to the third tooth from the buccal side, bone was eliminated using a round bur and a straight handpiece while being continuously irrigated. If necessary, both the roots and crowns were sectioned. Following tooth removal, the alveolus was examined, irrigated with sterile solution and curetted to remove granulation tissue. In the control group, saline soaked gel foam pieces were placed in the socket. In the study group, a combination of gel foam and 10 mg of simvastatin was used to fill the socket cavity. Suturing was done using 3-0 silk suture. Post-operatively suture was removed after seven days both groups. The participants were put on medications for five days.

**RESULTS**

**PAIN**

Pain levels were recorded using a visual analog scale ranging from 0 to 10, based on the patients' self-assessment of pain intensity over the seven days following the procedure. The readings were recorded on 1st, 3rd & 7th day post-operatively. The average of two daily pain score readings was used to evaluate and compare pain distribution between the study and control groups. Inter-group comparison (Table 1 & Figure 1) and intra-group comparison (Table 2 & Figure 2) was performed.

**Table 1. Intergroup comparison of mean Visual Analog Scale (VAS) scores**

| | Group | Mean | Std. Deviation | Std. Error Mean | P value |
|---|---|---|---|---|---|
| **Pre-Operative** | Group1 | 5.466 | 1.884 | 0.486 | 0.845 (Non-Sig) |
| | Group 2 | 5.600 | 1.804 | 0.465 | |
| **1st Post-Operative Day** | Group1 | 6.600 | 1.298 | 0.335 | 0.886 (Non-Sig) |
| | Group 2 | 6.666 | 1.234 | 0.318 | |
| **3rd Post-Operative Day** | Group1 | 6.800 | 1.612 | 0.416 | 0.896 (Non-Sig) |
| | Group 2 | 6.866 | 1.125 | 0.290 | |
| **7th Post-Operative Day** | Group1 | 3.133 | 1.505 | 0.388 | 0.157(Non-Sig) |
| | Group 2 | 3.800 | 0.941 | 0.243 | |

Group 1: Simvastatin(10mg) with Gel Foam post-operatively Group 2: Gel Foam post-operatively

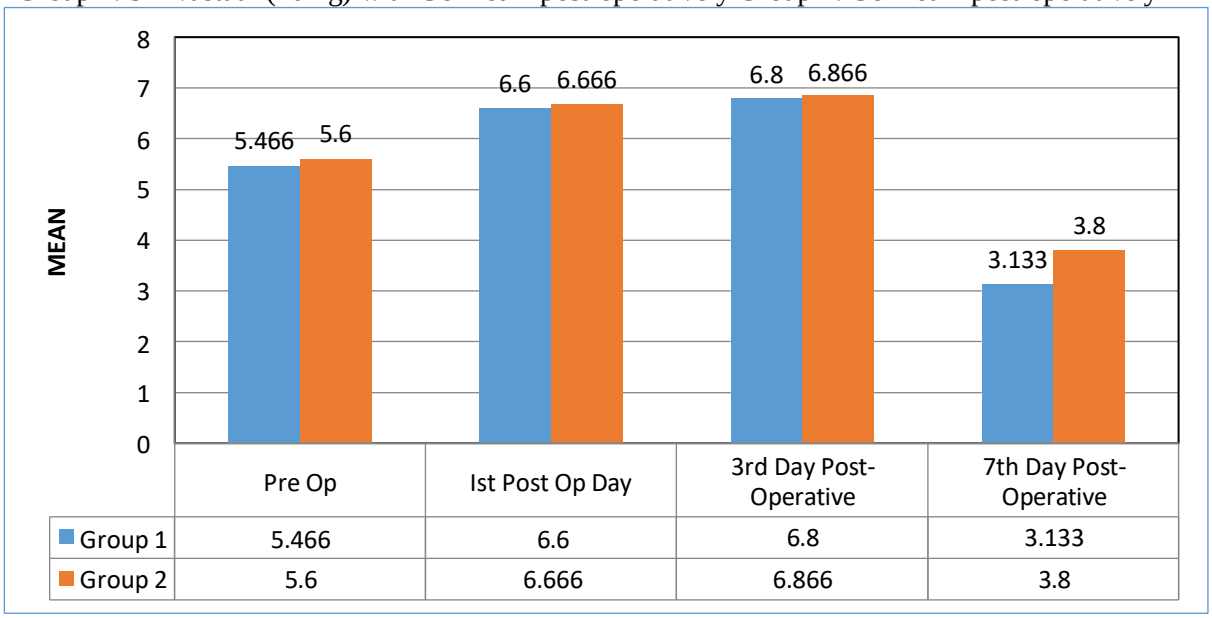


**Figure** 1. Pain distribution between control and study group

**Table 2. Intragroup comparison of mean Visual Analog Scale (VAS) scores**

| | Intragroup Comparison | | Mean Difference | P value |
|---|---|---|---|---|
| **Group 1** | Pre-Operative | 1st Post-Operative Day | -1.134 | 0.001(Sig) |
| | Pre-Operative | 3rd Post-Operative Day | -1.334 | 0.001(Sig) |
| | Pre-Operative | 7th Post-Operative Day | 2.333 | 0.001(Sig) |
| | 1st Post-Operative Day | 3rd Post-Operative Day | -0.2 | 0.321(Non-Sig) |
| | 1st Post-Operative Day | 7th Post-Operative Day | 3.467 | 0.001(Sig) |
| | 3rd Post-Operative Day | 7th Post-Operative Day | 3.667 | 0.001(Sig) |
| **Group 2** | Pre-Operative | 1st Post-Operative Day | -1.066 | 0.001(Sig) |
| | Pre-Operative | 3rd Post-Operative Day | -1.266 | 0.001(Sig) |
| | Pre-Operative | 7th Post-Operative Day | 1.8 | 0.001(Sig) |
| | 1st Post-Operative Day | 3rd Post-Operative Day | -0.2 | 0.321(Non-Sig) |
| | 1st Post-Operative Day | 7th Post-Operative Day | 2.866 | 0.001(Sig) |
| | 3rd Post-Operative Day | 7th Post-Operative Day | 3.066 | 0.001(Sig) |

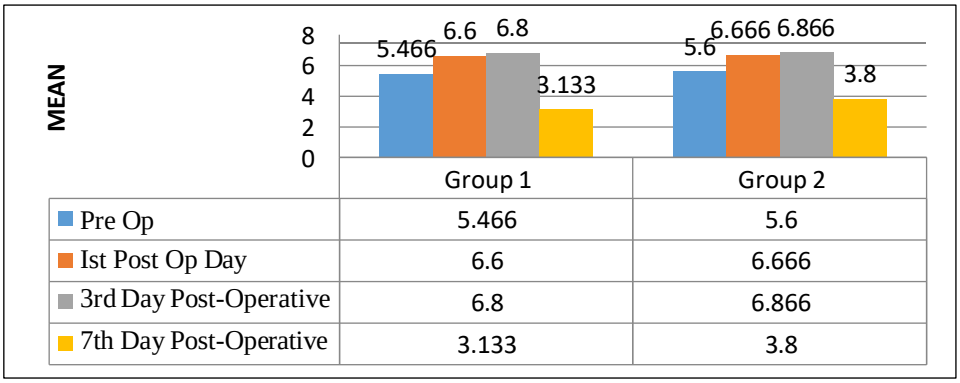


**Figure 2.** Intragroup pain distribution

**SWELLING**

The post operative changes in the dimensions of the face was recorded on the 1st, 3rd & 7th day. Pre-operative dimensions were also recorded and comparison between both the groups was performed (Table 3 & Figure 3). Comparison within the groups were also done and depicted (Table 4 & Figure 4).

**Table 3. Intergroup comparison of mean swelling scores**

| | Group | Mean | Std. Deviation | Std. Error Mean | P value |
|---|---|---|---|---|---|
| **Pre-Operative** | Group1 | 106.712 | 3.012 | 0.777 | 0.515 (Non-Sig) |
| | Group 2 | 107.332 | 2.073 | 0.535 | |
| **1st Post-Operative Day** | Group1 | 111.062 | 3.008 | 0.776 | 0.929 (Non-Sig) |
| | Group 2 | 111.152 | 2.308 | 0.596 | |
| **3rd Post-Operative Day** | Group1 | 113.042 | 4.199 | 1.084 | 0.822 (Non-Sig) |
| | Group 2 | 113.332 | 2.580 | 0.666 | |
| **7th Post-Operative Day** | Group1 | 108.752 | 4.266 | 1.101 | 0.842 (Non-Sig) |
| | Group 2 | 108.512 | 1.947 | 0.502 | |

Group 1: Simvastatin(10mg) with Gel Foam post-operatively Group 2: Gel Foam post-operatively

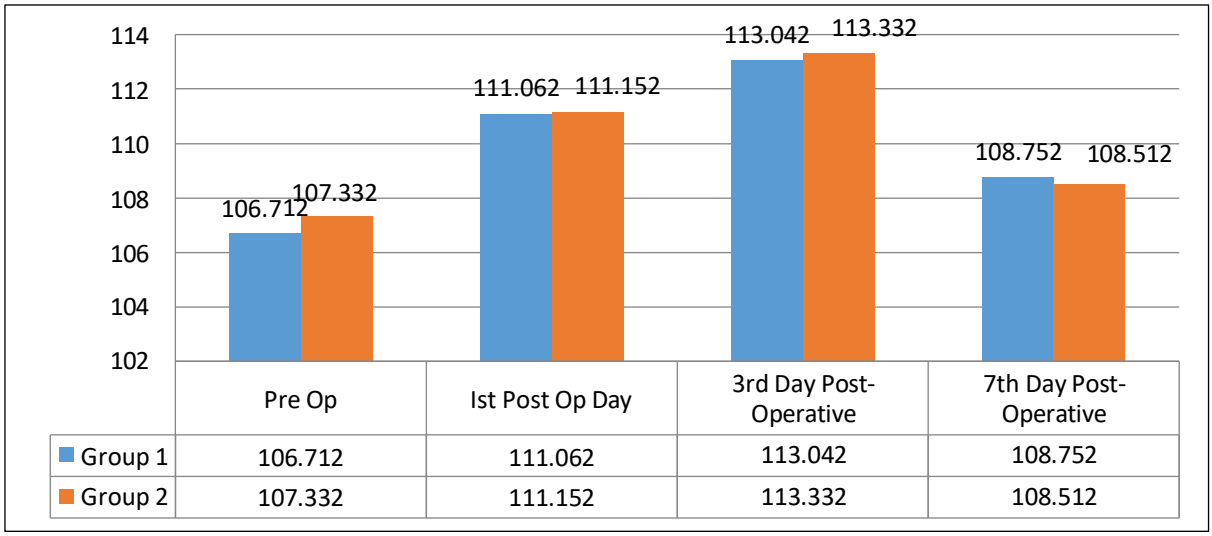


**Figure 3.** Swelling comparison between control and study group

**Table 4. Intragroup comparison of mean swelling scores**

| | Intragroup Comparison | | Mean Difference | P value |
|---|---|---|---|---|
| **Group 1** | Pre-Operative | 1st Post-Operative Day | -4.35 | 0.009(Sig) |
| | Pre-Operative | 3rd Post-Operative Day | -6.33 | 0.011(Sig) |
| | Pre-Operative | 7th Post-Operative Day | -2.04 | 0.021(Sig) |
| | 1st Post-Operative Day | 3rd Post-Operative Day | -1.98 | 0.031(Non-Sig) |
| | 1st Post-Operative Day | 7th Post-Operative Day | 2.31 | 0.021(Sig) |
| | 3rd Post-Operative Day | 7th Post-Operative Day | 4.29 | 0.001(Sig) |
| **Group 2** | Pre-Operative | 1st Post-Operative Day | -3.82 | 0.001(Sig) |
| | Pre-Operative | 3rd Post-Operative Day | -6 | 0.001(Sig) |
| | Pre-Operative | 7th Post-Operative Day | -1.18 | 0.031(Sig) |
| | 1st Post-Operative Day | 3rd Post-Operative Day | -2.18 | 0.021(Non-Sig) |
| | 1st Post-Operative Day | 7th Post-Operative Day | 2.64 | 0.001(Sig) |
| | 3rd Post-Operative Day | 7th Post-Operative Day | 4.82 | 0.008(Sig) |

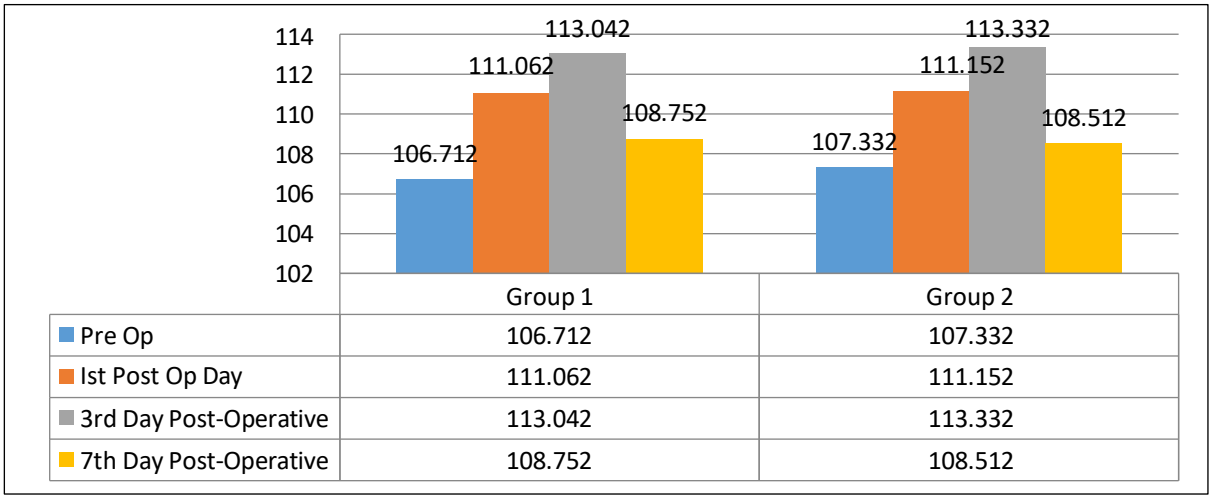


**Figure 4.** Intragroup swelling comparison

**MOUTH OPENING**

The pre operative mouth openning was recorded using metallic scale/vernier calliper. The post operative changes in the extent of mouth opening was also recorded on the 1st, 3rd & 7th day. Comparison was done between the groups was performed (Table 5 & Figure 5). Comparison within the groups were also done and depicted (Table 6 & Figure 6).

**Table 5. Intergroup comparison of mean mouth opening**

| | Group | Mean | Std. Deviation | Std. Error Mean | P value |
|---|---|---|---|---|---|
| **Pre-Operative** | Group1 | 36.600 | 2.971 | 0.767 | 0.515 (Non-Sig) |
| | Group 2 | 35.000 | 3.721 | 0.994 | |
| **1st Post-Operative Day** | Group1 | 31.866 | 4.673 | 1.206 | 0.001 (Sig) |
| | Group 2 | 28.571 | 3.631 | 0.970 | |
| **3rd Post-Operative Day** | Group1 | 30.200 | 4.616 | 1.192 | 0.029 (Sig) |
| | Group 2 | 26.857 | 2.905 | 0.776 | |
| **7th Post-Operative Day** | Group1 | 34.733 | 3.807 | 0.983 | 0.001 (Sig) |
| | Group 2 | 30.571 | 2.737 | 0.731 | |

Group 1: Simvastatin(10mg) with Gel Foam post-operatively Group 2: Gel Foam post-operatively

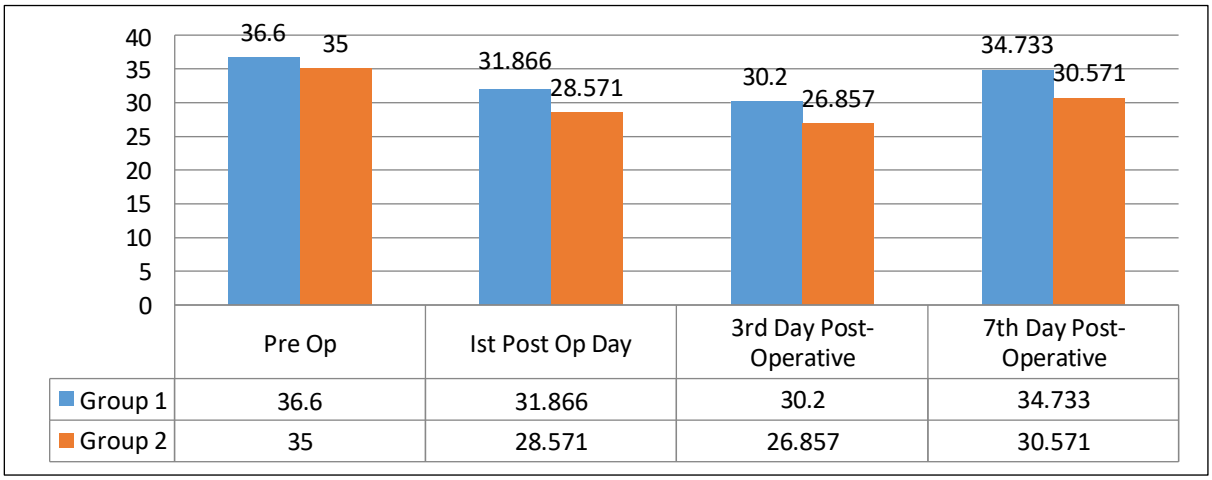


**Figure 5.** Mouth opening comparison between control and study group

**Table 6. Intragroup comparison of mean mouth opening**

| | Intragroup Comparison | | Mean Difference | P value |
|---|---|---|---|---|
| **Group 1** | Pre-Operative | 1st Post-Operative Day | 4.734 | 0.001(Sig) |
| | Pre-Operative | 3rd Post-Operative Day | 6.4 | 0.001(Sig) |
| | Pre-Operative | 7th Post-Operative Day | 1.867 | 0.106(Non-Sig) |
| | 1st Post-Operative Day | 3rd Post-Operative Day | 1.666 | 0.131(Non-Sig) |
| | 1st Post-Operative Day | 7th Post-Operative Day | -2.867 | 0.001(Sig) |
| | 3rd Post-Operative Day | 7th Post-Operative Day | -4.533 | 0.001(Sig) |
| **Group 2** | Pre-Operative | 1st Post-Operative Day | 6.429 | 0.001(Sig) |
| | Pre-Operative | 3rd Post-Operative Day | 8.143 | 0.001(Sig) |
| | Pre-Operative | 7th Post-Operative Day | 4.429 | 0.001(Sig) |
| | 1st Post-Operative Day | 3rd Post-Operative Day | 1.714 | 0.121(Non-Sig) |
| | 1st Post-Operative Day | 7th Post-Operative Day | -2.000 | 0.043(Sig) |
| | 3rd Post-Operative Day | 7th Post-Operative Day | -3.714 | 0.001(Sig) |

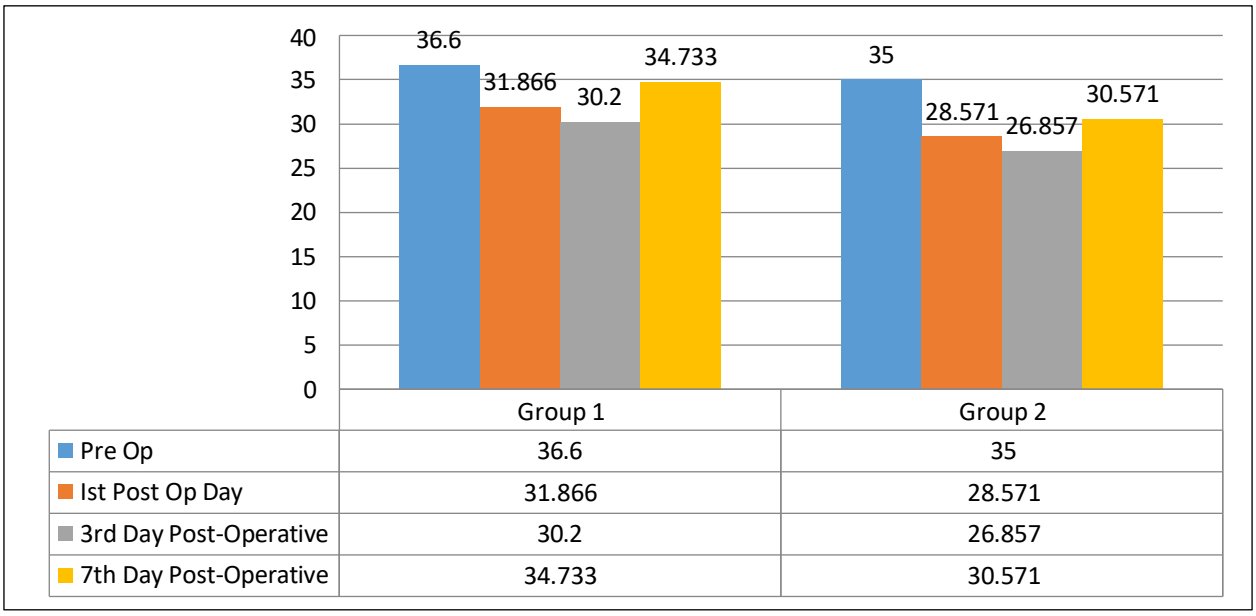


**Figure 6.** Intragroup mouth opening comparison

## POCKET PROBING DEPTH

Pocket probing depth was evaluated pre operatively using a William's probe. Pre operative data was taken along with post operative readings one month and three months post-operatively. Comparison was done between the groups was performed (Table 7 & Figure 7). Comparison within the groups was also done and illustrated graphically (Table 8 & Figure 8).

**Table 7. Intergroup comparison of pocket probing depth**

| | Group | Mean | Std. Deviation | Std. Error Mean | P value |
|---|---|---|---|---|---|
| **Pre-Operative** | Group1 | 2.422 | 0.366 | 0.094 | 0.158(Non-Sig) |
| | Group 2 | 2.644 | 0.462 | 0.119 | |
| **1st Month Post-Operatively** | Group1 | 3.444 | 0.391 | 0.101 | 0.459 (Non-Sig) |
| | Group 2 | 3.555 | 0.482 | 0.124 | |
| **3rd Month Post-operatively** | Group1 | 3.400 | 0.522 | 0.134 | 1.000(Non-Sig) |
| | Group 2 | 3.400 | 0.474 | 0.122 | |

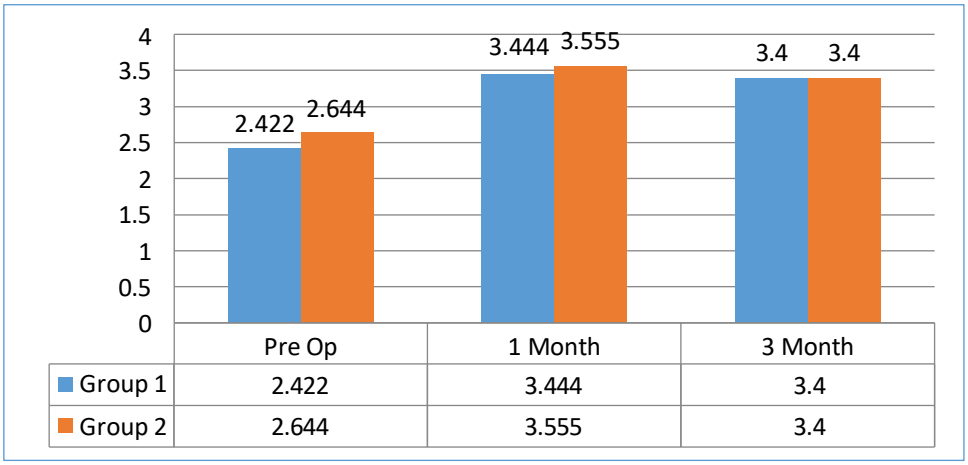


**Figure 7.** Pocket probing depth comparison between control and study group

**Table 8. Intragroup comparison of pocket probing depth**

| | Intragroup Comparison | | Mean Difference | P value |
|---|---|---|---|---|
| **Group 1** | Pre-Operative | 1st Month Post-Operatively | -1.022 | 0.001(Sig) |
| | Pre-Operative | 3rd Month Post-Operatively | -0.978 | 0.001(Sig) |
| | 1st Month Post-Operatively | 3rd Month Post-Operatively | 0.044 | 0.876(Non-Sig) |
| **Group 2** | Pre-Operative | 1st Month Post-Operatively | -0.911 | 0.001(Sig) |
| | Pre-Operative | 3rd Month Post-Operatively | -0.756 | 0.001(Sig) |
| | 1st Month Post-Operatively | 3rd Month Post-Operatively | 0.155 | 0.023(Sig) |

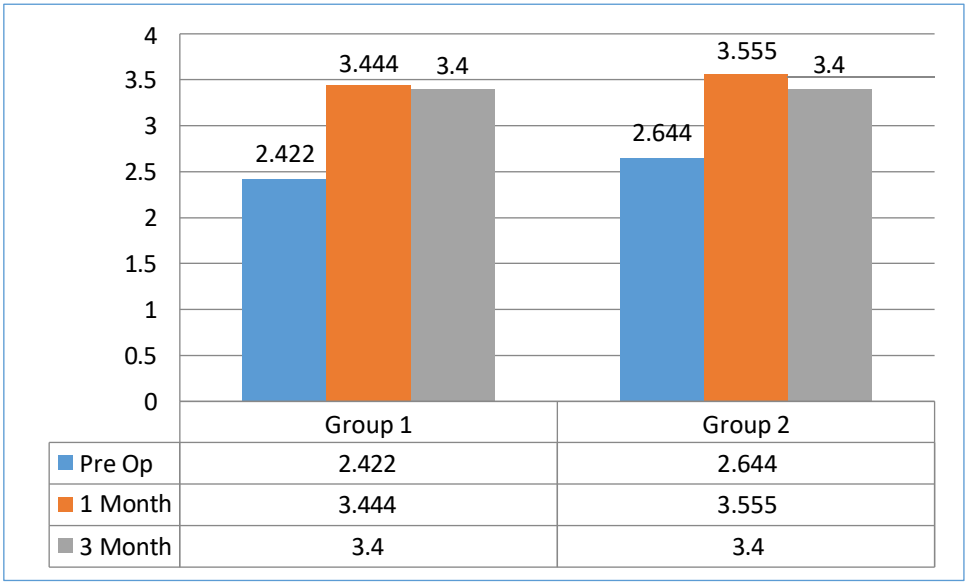


**Figure 8.** Intragroup popcket probing depth comparison

**BONE DENSITY**

Bone density evaluation was based on Cone beam computed tomography (CBCT) scans. Data was obtained using the mean Hounsfield Units (HU) of the third molar socket region and tabulated.[21] Two post operative scans were done at first month and third month respectively. Comparison was done between the two data sets were done (Table 9 & Figure 9). Data comparison within the group were also tabulated and depicted (Table 10 & Figure 10).

**Table 9. Intergroup comparison between the two groups**

| | Group | Mean | Std. Deviation | Std. Error Mean | P value |
|---|---|---|---|---|---|
| **1st Month Post-Operatively** | Group1 | 145.462 | 7.747 | 2.070 | 0.001 (Sig) |
| | Group 2 | 134.522 | 12.092 | 3.122 | |
| **3rd Month Post-Operatively** | Group1 | 247.772 | 32.635 | 8.722 | 0.029 (Sig) |
| | Group 2 | 207.622 | 18.515 | 4.780 | |

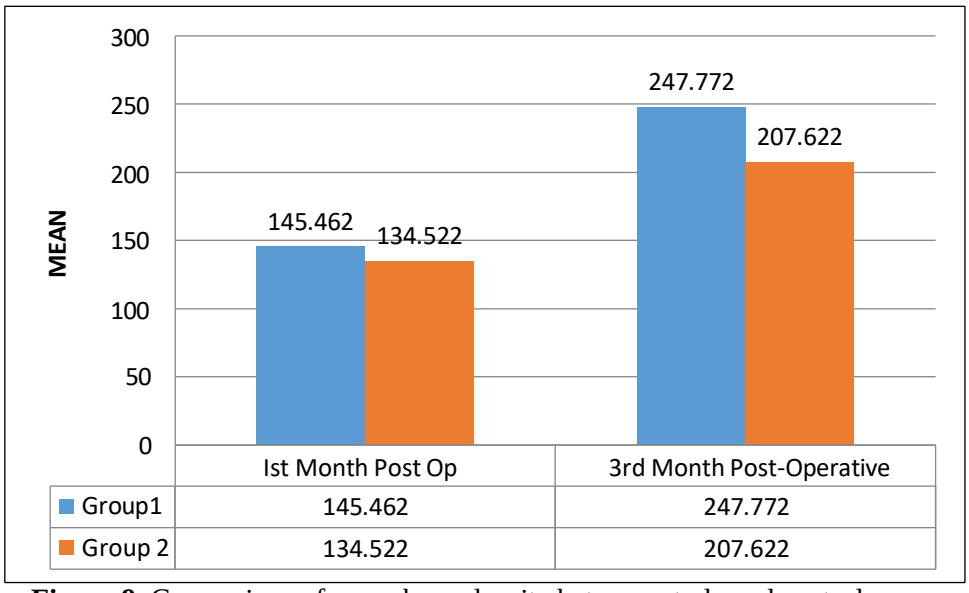


**Figure 9.** Comparison of mean bone density between study and control group

**Table 10. Intragroup comparison of the two groups**

| | Intragroup Comparison | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|
| **Group 1** | 1st Month Post-Operatively | 145.462 | 7.747 | 2.070 |
| | 3rd Month Post-Operatively | 247.772 | 32.635 | 8.722 |
| **Group 2** | 1st Month Post-Operatively | 134.522 | 12.092 | 3.122 |
| | 3rd Month Post-Operatively | 207.622 | 18.515 | 4.780 |

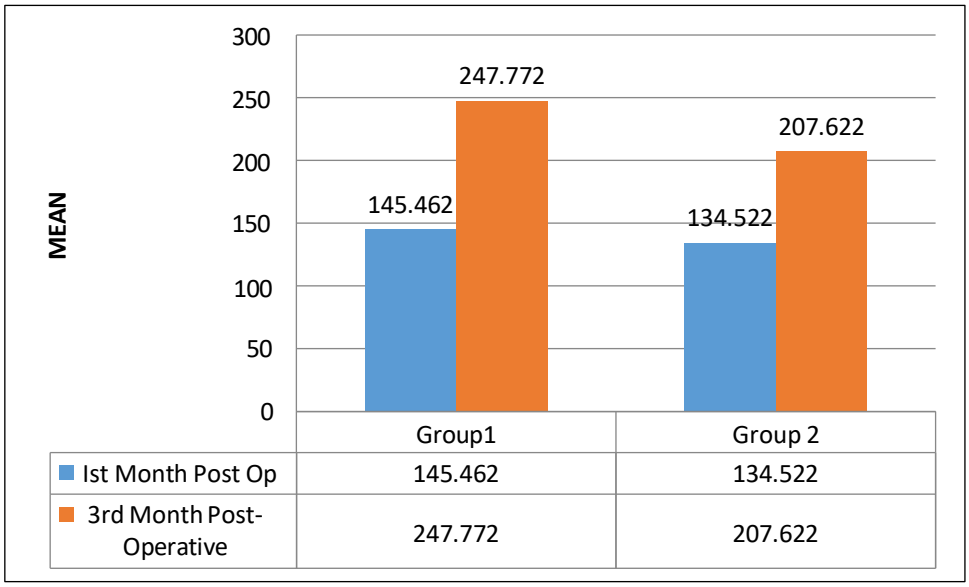


**Figure 10. Intragroup comparison of mean bone density**

## DISCUSSION

The surgical removal of mandibular third molars is amongst the most frequently performed procedures in oral and maxillofacial surgery. Tooth extractioon inevitably leads to bone loss due to physiological changes in the bone structure. The optimal moment to preserve the alveolar ridge is during the extraction itself.[18-20] Implementing bone preservation techniques at this stage can prevent 40% to 60% of the jaw bone resoprtion tpically occurring within 2 to 3 years post extraction, which may further progress at a rate of 15% to 25% annually throughout life.[22,23]

### DISCUSSION ON PAIN

The intergroup comparison of mean Visual Analog Scale (VAS) scores between Group 1 (Simvastatin 10 mg with Gel Foam post-operatively) and Group 2 (Gel Foam post-operatively) showed no statistically significant differences at any time point. At baseline (pre-operative), the mean VAS score was 5.466 ± 1.884 in Group 1 and 5.600 ± 1.804 in Group 2 (p = 0.845, non-significant), indicating similar pain levels before surgery. On the first post-operative day, pain levels increased in both groups, with Group 1 at 6.600 ± 1.298 and Group 2 at 6.666 ± 1.234 (p = 0.886, non-significant). By the third post-operative day, pain levels remained high, with Group 1 at 6.800 ± 1.612 and Group 2 at 6.866 ± 1.125 (p = 0.896, non-significant), showing no significant difference between the two groups. By the seventh post-operative day, pain levels had reduced in both groups, with Group 1 reporting a mean VAS score of 3.133 ± 1.505, while Group 2 had a slightly higher score of 3.800 ± 0.941. However, the difference remained non-significant (p = 0.157). Overall, both treatment groups experienced a similar pain trajectory, with an initial post-operative increase in pain, followed by a gradual decrease by the seventh day. However, there was no statistically significant difference between the two groups at any time point, suggesting that the addition of Simvastatin did not have a significant effect on post-operative pain relief compared to Gel Foam alone.

The intragroup comparison of mean VAS scores over time showed a significant change in pain perception within both groups. In Group 1 (Simvastatin with Gel Foam), the mean pre-operative VAS score was 5.466 ± 1.884. Pain increased significantly on the 1st post-operative day (6.600 ± 1.298, p = 0.001) and remained high on the 3rd post-operative day (6.800 ± 1.612, p = 0.001). However, by the 7th post-operative day, there was a significant reduction in pain to 3.133 ± 1.505 (p = 0.001). The difference between the 1st and 3rd post-operative days was not statistically significant (p = 0.321), but a significant reduction was observed between the 1st and 7th days (p = 0.001) and the 3rd and 7th days (p = 0.001).Similarly, in Group 2 (Gel Foam alone), the pre-operative VAS score was 5.600 ± 1.804, which significantly increased on the 1st post-operative day (6.666 ± 1.234, p = 0.001) and the 3rd post-operative day (6.866 ± 1.125, p = 0.001). By the 7th post-operative day, pain significantly reduced to 3.800 ± 0.941 (p = 0.001). There was no significant difference between the 1st and 3rd post-operative days (p = 0.321), but a significant reduction was observed between the 1st and 7th days (p = 0.001) and the 3rd and 7th days (p = 0.001). Overall, both groups followed a similar pain progression pattern, with an initial increase in pain after surgery, stabilization by the 3rd post-operative day, and a significant reduction in pain by the 7th day. The statistical significance of the results suggests a clear post-operative recovery trend, though the pain relief pattern was comparable between the two groups.

### DISCUSSION ON SWELLING

The intergroup comparison of mean swelling scores revealed no statistically significant differences between Group 1 (Simvastatin with Gel Foam) and Group 2 (Gel Foam alone) at any time interval (p > 0.05 for all comparisons). Pre-operatively, the mean swelling score in Group 1 was 106.712 ± 3.012, while in Group 2, it was 107.332 ± 2.073 (p = 0.515, non-significant). On the 1st post-operative day, swelling increased in both groups, with Group 1 measuring 111.062 ± 3.008 and Group 2 measuring 111.152 ± 2.308 (p = 0.929, non-significant). By the 3rd post-operative day, swelling reached its peak, with Group 1 at 113.042 ± 4.199 and Group 2 at 113.332 ± 2.580 (p = 0.822, non-significant). By the 7th post-operative day, swelling began to subside, with Group 1 measuring 108.752 ± 4.266 and Group 2 at 108.512 ± 1.947 (p = 0.842, non-significant). Overall, both groups followed a similar swelling progression pattern, with a gradual increase in swelling post-operatively, peaking on the 3rd day, and subsiding by the 7th day. The lack of significant intergroup differences suggests that both treatment modalities had a comparable effect on post-operative swelling resolution.

The intragroup comparison of mean swelling scores within both Group 1 (Simvastatin with Gel Foam) and Group 2 (Gel Foam alone) showed significant changes across different time intervals. In Group 1, there was a significant increase in swelling from the pre-operative period (106.712 ± 3.012) to the 1st post-operative day (111.062 ± 3.008, p = 0.009) and further to the 3rd post-operative day (113.042 ± 4.199, p = 0.011). However, by the 7th post-operative day, the swelling significantly decreased (108.752 ± 4.266, p = 0.021). The difference between the 1st and 3rd post-operative days was non-

significant (p = 0.031), but the reduction from the 3rd to the 7th day was highly significant (p = 0.001), indicating a peak in swelling on the 3rd day, followed by a substantial decrease. A similar trend was observed in Group 2, where swelling increased significantly from the pre-operative period (107.332 ± 2.073) to the 1st post-op day (111.152 ± 2.308, p = 0.001) and further to the 3rd post-op day (113.332 ± 2.580, p = 0.001). The swelling then decreased significantly by the 7th post-op day (108.512 ± 1.947, p = 0.031). The difference between the 1st and 3rd post-operative days was non-significant (p = 0.021), while the reduction between the 3rd and 7th days was significant (p = 0.008). Overall, in both groups, swelling followed a characteristic post-operative pattern, peaking on the 3rd day and gradually resolving by the 7th day. The significant reductions observed by the 7th day suggest a natural course of healing, with no major differences in swelling resolution between the two treatment groups.

**DISCUSSION ON MOUTH OPENING**

The comparison of mean mouth opening scores between the two groups revealed significant differences at multiple time points. Pre-operatively, both groups had similar mouth opening values, with Group 1 (Simvastatin with Gel Foam) showing a mean of 36.6 mm, while Group 2 (Gel Foam alone) had 35 mm, and this difference was not statistically significant (p = 0.515). However, a significant reduction in mouth opening was observed post-operatively in both groups, with the 1st post-operative day showing a greater restriction in Group 2 (28.57 mm) compared to Group 1 (31.86 mm), p = 0.001 (significant). By the 3rd post-operative day, mouth opening remained restricted but showed slight improvement, with Group 1 (30.2 mm) demonstrating a significantly better recovery than Group 2 (26.85 mm), p = 0.029. By the 7th post-operative day, both groups showed improvement; however, Group 1 (34.73 mm) had a significantly better recovery than Group 2 (30.57 mm), p = 0.001. These findings suggest that while both groups experienced post-operative trismus, the addition of Simvastatin in Group 1 contributed to a faster recovery and improved functional outcomes, as demonstrated by the significantly better mouth opening scores at all post-operative time points.

The intragroup comparison of mean mouth opening scores over different time intervals showed a significant reduction in mouth opening post-operatively in both groups, followed by gradual improvement in Group 1 (Simvastatin with Gel Foam), there was a significant decrease in mouth opening from the pre-operative measurement (36.6 mm) to the 1st post-operative day (31.86 mm, p = 0.001) and further reduction on the 3rd post-operative day (30.2 mm, p = 0.001). By the 7th day, mouth opening improved to 34.73 mm, and although the difference from the pre-operative value was not statistically significant (p = 0.106), it indicates near-complete recovery. Significant differences were observed when comparing the 3rd day to the 7th day (p = 0.001), showing progressive improvement in mouth opening. Similarly, Group 2 (Gel Foam alone) also showed a significant decline in mouth opening from the pre-operative value (35 mm) to the 1st post-operative day (28.57 mm, p = 0.001) and further reduction on the 3rd post-operative day (26.85 mm, p = 0.001). By the 7th post-operative day, the mouth opening improved to 30.57 mm, but the difference from the pre-operative measurement remained significant (p = 0.001), indicating an incomplete recovery. Notably, a significant improvement was observed from the 3rd to the 7th post-operative day (p = 0.001), suggesting progressive healing. Overall, both groups experienced post-operative trismus, but Group 1 exhibited a faster recovery in mouth opening, with values approaching pre-operative levels by the 7th post-operative day, whereas Group 2 showed a slower recovery with persistent restriction at this time point. These findings suggest that Simvastatin might play a role in promoting early functional recovery after surgery.

**DISCUSSION ON POCKET PROBING DEPTH**

The intergroup comparison of mean pocket probing depth (PPD) scores between Group A (Simvastatin 10 mg with Gel Foam post-operatively) and Group B (Gel Foam post-operatively) at different time intervals showed no statistically significant differences between the two groups. At the pre-operative stage, Group A had a mean PPD score of 2.422 ± 0.366, while Group B had a slightly higher mean of 2.644 ± 0.462 (p = 0.158, non-significant). By the 1st month post-operative period, both groups exhibited an increase in PPD scores, with Group A reaching 3.444 ± 0.391 and Group B reaching 3.555 ± 0.482, but the difference remained non-significant (p = 0.459). At the 3rd month post-operative interval, both groups showed stabilization, with mean PPD scores of 3.400 ± 0.522 for Group A and 3.400 ± 0.474 for Group B (p = 1.000, non-significant). These findings indicate that the use of Simvastatin (10 mg) with Gel Foam post-operatively did not result in a significant difference in PPD scores compared to the use of Gel Foam alone. Both groups followed a similar trend, with an initial increase in PPD at 1 month, followed by stabilization at 3 months.

The intragroup comparison of mean probing pocket depth (PPD) scores across different time intervals for both groups revealed significant changes over time. In Group 1 (Simvastatin 10 mg with Gel Foam post-operatively), the mean PPD increased from 2.422 ± 0.366 at baseline to

3.444 ± 0.391 at 1 month, showing a significant mean difference of -1.022 (p = 0.001). Similarly, the increase from pre-operative to 3 months (3.400 ± 0.522) was also significant, with a mean difference of -0.978 (p = 0.001). However, the change between 1 month and 3 months (mean difference = 0.044, p = 0.876) was not significant, indicating stabilization of PPD after the first month. In Group 2 (Gel Foam post-operatively), a similar pattern was observed. The mean PPD increased from 2.644 ± 0.462 at baseline to 3.555 ± 0.482 at 1 month, with a significant mean difference of -0.911 (p = 0.001). The increase from pre-operative to 3 months (3.400 ± 0.474) was also significant, with a mean difference of -0.756 (p = 0.001). Unlike Group 1, the change between 1 month and 3 months was also significant (mean difference = 0.155, p = 0.023), suggesting a continued but slight reduction in PPD over this period. Overall, both groups experienced a significant increase in PPD from baseline to 1 month and from baseline to 3 months, indicating initial post-operative changes. However, Group 1 exhibited stabilization between 1 and 3 months, whereas Group 2 showed a slight but significant reduction in PPD during this period.

## DISCUSSION ON BONE DENSITY

The intergroup comparison of bone density between the groups at different postoperative time points revealed significant differences. At the first month postoperatively, Group 1 (Simvastatin 10mg with Gel Foam) demonstrated a higher mean bone density (145.462 ± 7.747) compared to Group 2 (Gel Foam alone) with a mean of 134.522 ± 12.092. The difference was statistically significant (p = 0.001). By the third month postoperatively, bone density further increased in both groups, with Group 1 showing a significantly higher mean bone density (247.772 ± 32.635) than Group 2 (207.622 ± 18.515), with a p-value of 0.029. These findings suggest that the addition of Simvastatin (10mg) to Gel Foam postoperatively enhances bone density recovery compared to using Gel Foam alone.

The intragroup comparison of mean bone density between different time intervals revealed a significant increase in both groups from the first to the third month postoperatively. In Group 1 (Simvastatin 10mg with Gel Foam), the mean bone density increased from 145.462 ± 7.747 at the first month to 247.772 ± 32.635 at the third month, indicating substantial bone regeneration over time. Similarly, in Group 2 (Gel Foam alone), the mean bone density improved from 134.522 ± 12.092 at the first month to 207.622 ± 18.515 at the third month, though the increase was relatively lower compared to Group 1. These results suggest that while both groups showed significant bone density improvement over time, Group 1 exhibited a greater increase, reinforcing the potential efficacy of Simvastatin in enhancing bone regeneration.

## CONCLUSION

The localized application of simvastatin promotes bone formation in mandibular third molar extraction sites. It also contributes to better the postoperative functional recovery in the treatment group compared to the control group. Gel foam serves as an effective carrier, facilitating easier handling during local administration. To validate these findings, studies with larger sample sizes, extended follow-up periods, and a split-mouth design are recommended.

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**Ethics approval and consent to participate**
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