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COMPARATIVE STUDY

The Effect of Alloplastic Bone Graft and Absorbable Gelatin Sponge in Prevention of Periodontal Defects on the Distal Aspect of Mandibular Second Molars, After Surgical Removal of Impacted Mandibular Third Molar: A Comparative Prospective Study

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Abstract
Aim Recent studies claim that haemostatic agents can be used as bone graft substitutes. The aim of this study was to compare the efficacy of alloplastic bone graft with absorbable gelatin sponge in prevention of periodontal defects distal to mandibular second molar after the surgical removal of impacted mandibular third molars.
Materials and methods A prospective, randomized, single-blind split-mouth study was designed. The study consisted of 25 patients requiring surgical removal of bilateral impacted mandibular 3rd molars. The surgical sites were randomly divided into 2 groups: group I: G-graft (hydroxyapatite + collagen, study group) and group II: Abgel (absorbable gelatin sponge, control group). Patients were recalled on lst and 7th postoperative days and 3rd and 6th postoperative months. Probing depth, alveolar bone levels and soft tissue wound healing were evaluated. Paired t test was used to compare pre and post-operative alveolar bone levels and probing depth (PD). Wilcoxon signed ranks test was used to compare the wound healing.
Results The soft tissue wound healing, PD and the distance between the cemento–enamel junction on the distal aspect of mandibular second molar (point A) and the alveolar crest on the distal aspect of the same tooth (point B) were significantly higher in group I as compared to group II.
Conclusion This study reveals an increase in the alveolar bone level, improvement of PD and better wound healing in group I. Group II subjects required longer healing time than the normal. The authors disagree the claim that the haemostatic agents can be used as bone graft substitutes. However, long-term, multicenter, randomized controlled clinical trials are required.

Keywords Impacted teeth · Hydroxyapatite-beta tricalcium phosphate · Collagen · Hemostatics

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Introduction

Surgical extraction of impacted third molars is the most commonly performed procedure in oral and maxillofacial surgical practice [1]. Studies have shown that surgical removal of impacted mandibular third molars results in intra-bony defects distal to the mandibular second molars [2–4].Various studies with numerous materials have been reported for prevention and management of this complication [5–7].

Bone grafting done immediately after surgical removal of impacted mandibular third molars maintains the periodontal health by maintaining alveolar height. Hydroxyapatite is a widely used non-resorbable bone graft. It is stable, non-toxic and inert with osteoconductive properties [8]. However, it is brittle and prone to fractures. Hydroxyapatite in combination with bovine collagen has been shown to be effective in bone repair [9]. In collagen treated defects, bone formation is more rapid than in untreated cases [9, 10]. Bone graft materials are quite expensive, thus, various alternatives to bone grafts have been studied.

Table 1 Angulations of impacted mandibular third molars in each group

Type of Impaction	Total number of cases	
	Group 1	Group 2
Mesioangular	9	9
Horizontal	4	4
Vertical	7	7
Distoangular	5	5

In this context, the use of numerous hemostatic agents with dual role of producing hemostasis and allowing bone regeneration has been reported [11]. Some studies suggest that *surgicel* (Haemostatic agent) allows good bone regeneration [11], while others were less emphatic about its results [12]. Studies evaluating the effect of *gelfoam* have also provided diverse results [11, 13–16].

Consequently, this study is designed to compare the efficacy of collagen containing alloplastic bone graft with absorbable gelatin sponge in prevention of periodontal defects occurring distal to mandibular second molar after the surgical removal of impacted mandibular third molar.

Materials and Methods

In this prospective, randomized, single blinded, split-mouth study, 25 (age range 18–50 years) subjects based on the power of the study (2 sided at 90 % power, with an error of 5 %) requiring surgical removal of bilateral impacted mandibular 3rd molars were selected from outpatient section of Department of Oral and Maxillofacial Surgery, Dr. DY Patil Dental College and Hospital, Pune, India. The research protocol was initially submitted to the Institutional Ethics committee and Review Board. After ethical approval, all individuals were verbally informed and a written informed consent was obtained from each for participation in the study. Individuals with known systemic diseases, known or suspected allergy to local anesthetic groups, study sites having periodontal pockets $\geq$5 mm, use of tobacco in any form, alcoholics, subjects with antibiotic therapy within previous 3 months, immune-compromised individuals, pregnant or lactating females were excluded from the study.

Split Mouth Design

Each patient underwent surgical removal of bilateral impacted mandibular 3rd molars, Impacted teeth (38/48) quadrants were randomly allotted into either test or control sides. Degree of angulations of impaction was considered and care was taken to ensure that the study and the control group received equal number of teeth with similar degree of angulations [17–19] (Table 1). Although, we were not been able to standardize the degree of angulations within the same patient, we made sure that the difficulty index (Table 2) laid within 5–6 in each patient and a minimal mesial ostectomy technique was used to reduce the disparity between groups.

Preoperative Preparations

A detailed case history and preoperative investigations such as—routine hemogram, intraoral periapical (IOPA) radiographs using the 1 × 1 mm grid were performed. Because of positioning of the third molar 'Paralleling-cone technique' of radiograph was not possible. We took due care to calibrate the radiographs maintaining it as perpendicular as possible to the axis of the teeth.

Preoperative Assessment

Preoperative assessment of the alveolar bone level, distal to mandibular second molar was recorded. Two points were identified in the intraoral periapical radiographs.

- Point A: Cemento–enamel junction (CEJ) at the distal aspect of the mandibular second molar.
- Point B: The alveolar crest height on the distal aspect of the mandibular second molar.

The distance between these two points gave the initial alveolar bone level. The surgical sites were randomly

Table 2 Difficulty index for the removal of impacted mandibular 3rd molars, as described by Pederson

Classification	Value
Spatial relationship	
Mesioangular	1
Horizontal/transverse	2
Vertical	3
Distoangular	4
Depth	
Level A: high occlusal level	1
Level B: medium occlusal level	2
Level C: deep occlusal level	3
Ramus relationship/space available	
Class 1: sufficient space	1
Class 2: reduced space	2
Class 3: no space	3
Difficulty index	
Very difficult	7–10
Moderately difficult	4–6*
Slightly difficult	3–6

* In the original index, moderately difficult was graded as 5–7

divided into 2 groups: group I: G-graft (hydroxyapatite + collagen). Group II: Abgel.

G–Graft[1] (Hydroxyapatite with Collagen)

Hydroxyapatite is apatite calcium phosphate $[Ca_2(PO_4)_6(OH)_2]$. It is stable, non-toxic and inert. The porous form increases its osteoconduction. However, hydroxyapatite is unfortunately brittle and prone to fracture when placed in load bearing areas.

Bovine collagen is effective in bone repair. No foreign body reaction or inflammatory cells are reported with its use. In collagen treated defects, bone formation is more rapid than in untreated cases.

G-graft is made of natural low crystalline hydroxyapatite with collagen derived from bovine origin. It is available in the form of granules, dowels and blocks. It does not cause any foreign body reaction because there are no cellular components involved. Soft tissue grows faster into the G-graft, since it is porous and mingles with natural tissues. It can be re-sterilized by autoclaving and by dry heat.

As G-graft is similar to human bone, it revitalizes new blood vessels because of its natural porous and trabecular structure. Its complications include collapse of the block, fracture of site and lack of integration.

Abgel (Absorbable Gelatin Sponge)

It is a water-insoluble, off white, non-elastic, porous, pliable product prepared from purified pork-skin gelatin granules. Abgel has haemostatic properties. The hemostatic effect of Abgel appears to be more physical than altering the blood clotting mechanism. It is absorbed within 4–6 weeks. Abgel is used in abdominal, anorectal, orthopedic, gynecological, otolaryngeal, genital, urinary and neurosurgeries to control bleeding. Similarly, it is also used in oral and maxillofacial surgeries. However, Abgel should not be used in closure of skin incision and in the intravascular compartments.

Abgel is supplied in a sterile envelop enclosed in an outer envelope that can be peeled off. It is available in the following sizes: Regular Size: 80 mm × 50 mm × 10 mm, Dental Size: 20 mm × 20 mm × 7 mm, Nasal Size: 80 mm × 15 mm × 7 mm. Abgel should be stored at 25 °C. The gel foam is contraindicated in the presence of infection, within the bony cavities, as a primary treatment of coagulation disorders. There have been reports of fever, infection, giant cell granuloma, foreign body reactions and toxic shock syndrome associated with use of Abgel.

[1] G–Graft: Surgiwear Limited, Shahjahanpur—242001, India.

Surgical Procedure

Surgery was performed under standard aseptic conditions. Bilateral pterygomandibular and long buccal nerve blocks were administered using 2 % lignocaine hydrochloride with 1: 200,000 adrenaline. Ward's incision was given and full thickness mucoperiosteal flap was reflected. Buccal and distal bone guttering was done using No. 8 round and No. 702 tapered fissure burs with copious irrigation of normal saline, to expose the crown of the impacted third molar. The tooth was luxated with straight elevator and then slowly delivered out.

In some cases, sectioning of the tooth had to be done to deliver it. The extraction socket was curetted and irrigated with normal saline. Similar surgical procedure was carried out on the other side. G-graft was placed in one extraction socket and Abgel in the other. The wound was closed with 3–0 black silk interrupted sutures and pressure pack was given. The routine postoperative instructions were given to all the patients. Cap. Amoxicillin 500 mg TDS, Tab. Combiflam TDS and Tab. Rantac 150 mg BD for 5 days PO were prescribed for all the patients.

To ensure adequate intra-clinician reproducibility, a previously trained clinician (MS) provided treatment to both groups, and all pre and post-treatment clinical parameters and analysis were recorded by another examiner (SSN) who was masked to the type of material received by the subjects. The examiner was considered calibrated once statistically significant correlation and statistically non-significant difference between duplicate measurements were obtained.

Patient Recall

The patients were recalled on the next day of surgery and after 7th day for suture removal. Drug compliance was determined by verbally asking the patients whether they consumed all tablets as directed. During these visits, all patients were assessed for wound healing.

Wound Healing Score [20]

0: No wound breakdown.
1: Slight wound breakdown, explorable with blunt instrument.
2: Moderate wound breakdown, socket exposed.
3: Severe wound breakdown, socket exposed and non-vital bone visible.

Thereafter, patients were recalled at 3rd and 6th month post-operatively for measuring the probing depth and to measure alveolar bone level distal to mandibular second molar. The values were tabulated and were subjected to statistical analysis.

Table 3 Wound healing between group I and group II

Groups (n = 25)	Mean ± SD	Z	*P*
Wound healing score 1 day Post-op			
Group I	0.00 ± 0.000	4.359	<0.001**
Group II	0.76 ± 0.436		
Wound healing score 7 day Post-op			
Group I	0.08 ± 0.277	4.379	<0.001 **
Group II	0.92 ± 0.400		

** Statistically highly significant

Statistical Analysis

The results were averaged (mean ± standard deviation) for each parameter. Paired t test was used to compare the pre- and post- operative alveolar bone levels and PD at 3 and 6 month. Wilcoxon signed ranks test was used to compare the wound healing between the two groups.

Results

A total number of 25 patients with mean age of 25.4 yrs ± 5.50 were included in this study. Majority of these patients were between 18-27 years (68 %). Out of 25 patients, 13 were males (52 %) and 12 were females (48 %).

Soft Tissue Wound Healing

The mean soft tissue wound healing score on 1st post-operative day for group I was 0 and for group II was 0.76 ± 0.436. The score on 7th post-operative day showed a mean value of 0.08 ± 0.277 for group I and 0.92 + 0.40 for group II. Group I showed superior wound healing. There was highly significant difference between group I and group II ($P < 0.001$) (Table 3).

PD

At the end of 3rd month, group I showed mean probing depth of 2.16 mm ± 0.374 and group II showed 2.64 mm ± 0.638. At the end of 6th month, group I showed a mean probing depth of 2 mm and group II showed 2.56 mm ± 0.583. The results at 3rd month and 6th month showed statistically significant ($P < 0.005$) and highly significant ($P < 0.001$) differences respectively (Table 4).

Alveolar Bone Height

There was highly significant reduction in the mean distance between point A and point B in group I. The mean distance between point A and point B at 3rd and 6th months in group I was 1.40 mm ± 0.645 and 1.00 mm ± 0.408 respectively. However, the corresponding distance in group II at 3rd and 6th months were 2.48 mm ± 0.918 and 2.12 mm ± 0.666 respectively. The radiographic reduction in the distance between point A and point B suggests that

Table 4 Mean probing depth between group I and group II

Groups (n = 25)	Mean ± SD	Paired t	*P*
PD at 3-months			
Group I	2.16 ± 0.374	3.361	0.003*
Group II	2.64 ± 0.638		
PD at 6-months			
Group I	2.00 ± 0.000	4.802	<0.001**
Group II	2.56 ± 0.583		

* Statistically significant

** Statistically highly significant

Table 5 Mean radiographic distance between point A and point B between group I and group II

Groups (n = 25)	Mean ± SD	Paired t	*P*
Bone height at Pre-op			
Group I	2.36 ± 1.221	0.310	0.759 NS
Group II	2.44 ± 1.083		
Bone height at 3-month			
Group I	1.40 ± 0.645	6.263	<0.001**
Group II	2.48 ± 0.918		
Bone height at 6-month			
Group I	1.00 ± 0.408	8.411	<0.001**
Group II	2.12 ± 0.666		

Point A: Cemento–enamel junction of the distal aspect of the mandibular second molar; Point B: The alveolar crest height on the distal aspect of the mandibular second molar

** Statistically highly significant

Table 6 Difference between pre- and post-operative mean radiographic distance from point A to B in groups I and II

	Mean ± SD	Paired t	*P*
Group I (n = 25)			
Pre	2.36 ± 1.221	–	–
3-Month	1.40 ± 0.645	4.529	<0.001**
6-Month	1.00 ± 0.408	5.155	<0.001**
Group II (n = 25)			
Pre	2.44 ± 1.083	–	–
3-Month	2.48 ± 0.918	0.214	0.832 NS
6-Month	2.12 ± 0.666	1.995	0.058 **NS**

** Statistically highly significant

there was increase in the alveolar bone level in group I as compared to group II (Table 5).

Intra group analysis in group I between these points at 3rd and 6th months postoperatively showed highly statistical significance (Table 6). However, the intra group analysis in group II between points A and B at 3rd and 6th months postoperatively were not significant statistically (Table 6).

Discussion

Periodontal pocket formation in the second molar is a usual postoperative complication in third molar surgery. Several explanations for this have been advocated. In a follow- up study 4 years after third molar extraction, Kugelberg [21] showed that 44.4 % of subjects aged 26 years or older had intra-bony defects exceeding 4 mm. Risk factors associated with bone loss after lower third molar extraction included age, direction of eruption, preoperative bony defects and resorption of second molar [21].

The study subjects had an age range of 18–50 years with no systemic disease involvement, ensuring no difference in healing potential between the study groups. Moreover, this being a split mouth study we ensured similar intra-group healing. The wound healing following placement of G- graft and Abgel, compared on lst and 7th postoperative days, showed wound dehiscence in almost all cases in the presence of Abgel. This was in accordance with the results obtained by Ibarrola et al. [22] Nappi and Lehman [12] and Olson et al. [23]. However, it was in contrast to the results obtained by Petersen et al. [14], Finn et al. [11] and Guralnick and Berg [24]. This may be attributed to the presence of gelfoam alone. The packing of gelfoam would neither promote fibroblast growth and mitosis nor provide a support for epithelial overgrowth. The G-graft contains bovine collagen, which acts as a scaffold for the growing cells. It is known to cause aggregation of platelets and provide a matrix to strengthen the clot. Therefore group I subjects showed little or no wound dehiscence. The results of this study are in concurrence with that of el Deeb et al. [25]. The lack of wound dehiscence in group I may be due to the use of granular form of G-graft rather than the blocks [25].

The mean PD at 3rd month in group I and group II were 2.16 mm $\pm$ 0.374 and 2.64 mm $\pm$ 0.638 respectively. By 6th month subjects in group I showed near normal values in terms of PD. This was mainly due to the denser bone regenerate provided by the G-graft and gain in the attachment level. This result was similar to the results of Throndson and Sexton [26]. However, the subjects in group II did not show much change in the mean PD. This may be attributed to the degeneration of residual periodontal fibres caused by gelfoam resulting in the further delay in periodontal healing. The result of our study was in accordance with that of de Carvalho et al. [27].

The distance between cemento–enamel junction and alveolar crest on the distal aspect of the mandibular second molar gives changes in the bone level. In this study the subjects in group I showed gradual increase in the bone level on the distal aspect of the mandibular second molar at 3rd and 6th months postoperatively. This was in accordance to the study by Coceancig [7] and Throndson and Sexton [26]. The increase in the bone level on the distal aspect of the mandibular second molar may be attributed to the presence of G-graft and its osteoconductive properties. This was in contrast with subjects in group II who showed little or no increase in the bone level. The result of this study was similar to that of Ibarrola et al. [22]. The lack of bone formation in group II may be attributed to the fact that gelfoam usually blocks the cancellous bone replacement.

We failed to standardize the degree of angulations of impacted teeth within groups, this being the only drawback of the study. The results clearly indicate an increase in the alveolar bone level, improvement of probing depth and better wound healing in group I (G-graft) rather than in group II (Abgel). This improvement in the bone regeneration signifies and highlights the use of G-graft as a valid method in the healing of bony defects. We disagree the claim that the haemostatic agents can be used as bone graft substitutes. However, a long-term, multicenter, randomized controlled clinical trials standardizing the angulations of the impacted teeth are warranted.

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Conflict of interest None.

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