

Study protocol for comparative evaluation between open flap debridement, osseous resective surgery and autogenous bone graft in treatment of hemiseptal periodontal defect - A clinical and radiographic study.

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Abstract: Background: Osseous resection is established treatment protocol for periodontal hemiseptal defects, however this forces clinician to settle for less than optimal results and leads to undesirable outcomes like unpleasant esthetics, dentinal hypersensitivity, root caries etc. the present treatment protocol is designed to assess defect resolution by autogenous bone pieces in treatment of periodontal hemiseptal defects. **Objectives:** To evaluate the soft and hard tissue response using clinical parameters like probing pocket depth (PPD), clinical attachment level (CAL) and radiographic bone fill in treatment of hemiseptal periodontal defects to Open flap debridement, Osseous resective surgery autogenous bone graft. **Methods:** the study sample will be randomly divided into 3 groups of 12 hemiseptal defects each. Group I to be treated by resective osseous surgery, Group II treated by open flap debridement and Group III treated by Autogenous bone graft. Clinical parameters include gingival index, probing pocket depth and clinical attachment level along with radiographic assessment with radiograph (RVG) and cone beam computed tomography (CBCT). All parameters will be evaluated at baseline, 3, 6 and 9 months interval. The Independent-Samples t Test will be done to compare means for two groups." The Paired-Samples t test to compare means of two variables for a single group. Difference will be considered significant when p value <0.05. **Expected results:** Proposed approach is expected to show improvement in probing pocket depth, clinical attachment level, and gingival index. It is also expected to gain defect fill reduction or resolution of hemiseptal defect. **Conclusion :** By attempting to treat periodontal hemiseptal defects with regenerative method this study is attempting to avoid all undesired effect associated with osseous resection and provide evidence of regeneration in such defects, this can lead to paradigm shift in treatment approach of periodontal hemiseptal defects.

Keywords: osseous, resective, bone grafts, hemiseptal defects, periodontal flap surgery.

Rationale and background:

Periodontium is a distinctive interface where gingival epithelium, soft and mineralized connective tissues namely gingival epithelium, periodontal ligament, cementum and alveolar bone join together to form dentogingival unit. Integrity of this junction is critical for maintenance of periodontal health. “Conversely chronic inflammation associated with periodontal diseases leads to disruption of the junction and results in destruction of periodontal tissues.”¹

“ Conventional periodontal treatment like scaling, root planing, curettage are effective in repairing and arresting the damage caused by periodontitis .However these therapies lead to healing with long junctional epithelium formation between root surface and gingival connective tissue”¹ instead of restoring normal architecture of the periodontium².

Thus the quests to design treatment modalities that can restore lost periodontal structures and predictably promote body’s natural capacity of healing were developed. It began with radical gingivectomy, excisional new attachment procedure (ENAP), open flap debridement (OFD) etc. Open flap debridement resulted in average 2 mm of probing depth reduction and average 1.5mm of bone fill the amount of defect fill depends on various factors such and number of bony walls around defect and angulation of defect with root surface².

Bone grafting, guided tissue regeneration and tissue engineering with biological agents such as platelet rich fibrin have been particularly effective in treatment of two and three walled intrabony defects³.

Due to presence of only one bony wall and non-contained nature, hemiseptal defects were treated by resective osseous surgery which aims at creating new attachment at an apical level to achieve maintainable pocket depth. It also requires intentional destruction of supporting bone of adjacent tooth which often limits osseous resection and forces clinician to settle for less than optimal results⁴.

Over decades autogenous bone grafts harvested from intraoral and extraoral sites have been utilized with great success to achieve regeneration of lost periodontal tissues ³.It is gold standard regenerative material for treatment of osseous defects⁵.

These techniques work by preserving wound space which is particularly difficult in non contained hemiseptal defects as pressure from overlying flap results in collapse of wound space and spillage of bone graft material thereby hampering regeneration^{6, 8-10}.

Autogenous bone chips can help in maintaining wound space by providing support to overlying flap which makes the suitable material to integrate with native host bone in hemiseptal periodontal defects.

Hemiseptal defects provide very little source of osteoblasts and lack of support from bony wall which results in collapse of wound space thereby limiting the amount of regeneration. Because of these reasons hemiseptal defects have less inherent regenerative potential therefore recommended mode of treatment for such defect is resective osseous surgery. Since there are no studies evaluating and comparing the outcome of regenerative procedures in hemiseptal periodontal defects the results of present study can change the preferred treatment method from resective surgeries which often require removal of tooth supporting bone and results in esthetically unpleasant appearance, gingival recession, hypersensitivity, root caries etc., to regenerative procedures which will result in formation of new bone and prevent unfavorable outcomes like recurrence of disease causing increased loss of attachment in involved tooth.

Robert G. Schallhorn, M.S., Denver and Colo(1968)in their case report described used of Autogenous bone and bone marrow obtained from hip marrow biopsy for treatment of inter proximal craters. “A35 year old male having moderately advanced localized periodontitis

interproximal bony crater of 4 to 5 mm from the crests of the labial and lingual cortical plates which were treated with autogenous hip marrow biopsy material. On surgical re-entry after five months the defects were completely resolved. Therefore the authors concluded that autogenous bone and marrow can be used to treat periodontal intraosseous defects¹¹.

Earl Robinson (1969) described a surgical technique using osseous coagulum to fill bone defects. In series of 5 cases the reentry was done after 4 months in 1st case, after 6 months in 2nd case, after 12 months in 3rd case, after 18 months in 4th case and after two years in 5th case. In all cases significant bone fill was seen. Findings of this case series indicate that bone induction from Autogenous osseous coagulum is fairly consistent and can be used to treat periodontal bone defects¹².

William H. Hiatt and Robert G. Schallhorn (1973) treated intrabony periodontal defects with autogenous cancellous bone and marrow. The mean defect fill in radiographic assessment was 3.44mm. The greatest defect fill was observed in defect with more no of bony walls concluding amount of regeneration depends on surface area of bony walls surrounding the defect¹³.

Oscheinbein C in 1958 described a technique to reshape alveolar bone to eliminate infrabony component of periodontal pockets and facilitate maintainable pocket depth¹⁴.

Oscheinbein C and Bohannon HM in 1958 stated that resective type of surgery requires removal of tooth supporting bone hence deep intraosseous defects are not the candidate for this type of surgery⁴.

Kaldahl BW et al in 1998 compared scaling and root planing, modified widman flap and resective osseous surgery with follow up to 7 years and concluded results obtained from resective osseous surgery were more stable when compared to other groups¹⁵.

Hsien Chung Chiu, E Chin Shen and Shu Jiun Lin in 2013 did a study on Beagle dogs bilateral in which bilateral 1-wall periodontal defects were created one quadrant received space preservation by titanium mesh device and opposite quadrant served as sham surgery site after 8 weeks animal were euthanized. Defects treated with titanium mesh demonstrated significantly better bone and cementum. Results of this study show that use of space maintaining device can be promising approach for treatment of non contained periodontal defects¹⁶.

Chang-Kyun Lee et al in 2010 prepared bilateral hemiseptal defects in beagle dogs and treated one side by collagen membrane. Regeneration of all periodontal tissues occurred in both sides but sites treated with collagen membrane had significantly better results¹⁷.

Parthasaradhi Thakkalapati, Chitraa R Chandran and Aravindhan Thiruputkuzhi et al (2015) in his case report treated one walled periodontal defect with combination of DFDBA and PRP at 6 months follow-up resolution of pocket, improvement of clinical attachment level and almost complete resolution of bone defect leading to conclusion that DFDBA and PRF combination hold promising potential for treatment of periodontal hemiseptal defects¹⁸.

Aditi Chopra, Kaartil Shivraman and Tarun Awatarmany (2014) in her case report described a technique to create a contained defect by making buccal and lingual walls with calcium phosphate barrier along with placement of DFDBA demonstrated significant reduction in clinical parameter and bone fill. Results of this case report indicate that calcium phosphate

barrier can be a good alternative to titanium mesh to ensure stable wound system for regeneration¹⁹.

Autogenous bone fragments can result in preservation of wound space as it will not spill and collapse like particulate bone graft. Autogenous bone contains host cells and is Osseo inductive in nature. This lead to our research question, “Whether autogenous bone graft can give better soft and hard tissue response than open flap debridement, osseous resective surgery in treatment of hemiseptal periodontal defect in individuals suffering from chronic periodontitis?”

MATERIAL AND METHODS:

Recruitment of study subjects:

“Study subjects are selected from the Department of Periodontology, Sharad Pawar Dental College, Sawangi (M), Wardha (Maharashtra) and Govt Dental College, Raipur (Chhattisgarh). The study protocol will be approved by the Institutional Ethics Committee and will be in accordance with the Helsinki Declaration for the conduct of biomedical research in humans. It is an interventional study”.

Patients will be examined in good light with an oral mirror, tweezers and a Williams graduated periodontal probe and cotton pads.

“Individuals aged 35 to 55 years in good general health and diagnosed with chronic periodontal having pocket of 5 to 8 mm depth, with radiographic evidence of periodontal hemiseptal defects and no history of systemic disease or medical condition which can influence the outcome of the research.”

Individuals showing poor oral hygiene during presurgical (Phase 1) period. Pregnant women and lactating mothers, history of taking anti-inflammatory drugs or antibiotics within the previous 3 months. And non co-operative individual will be excluded.

Total of 36 hemiseptal defects will be selected and randomly assigned in three groups. Groups are as follows:

- Group I: 12 hemiseptal defects to be treated by resective osseous surgery.
- Group II: 12 hemiseptal defects to be treated by open flap debridement.
- Group III: 12 hemiseptal defects to be treated by Autogenous bone graft.

Randomization

Simple random sampling will be done with help of computer software to divide sample in 3 groups randomly.

Periodontal assessment:

“The Gingival Index (GI) [Loe and Silness]²⁰ will be used to reduce severity and quantify gum inflammation. Bleeding is estimated by running a periodontal probe along the soft tissue wall of the gingival sulcus. Each of the 4 gingival areas of the tooth (face, mesial, distal and lingual) is evaluated and obtains a score ranging from 0 to 3²⁰.”

Final score for tooth will be derived by dividing the sum of scores of individual surfaces by 4²⁰.

Score	Criteria
0	Normal gingival
1	Mild inflammation: Slight change in color, slight edema, no bleeding on probing
2	Moderate inflammation: Redness, edema, glazing and Bleeding on probing
3	Severe inflammation: Marked redness and edema, ulceration, tendency towards spontaneous bleeding

Suggested scale for patient evaluation:

Gingival score	Condition
0.1-1.0	Mild inflammation
1.1-2.0	Moderate inflammation inflammation
2.1-3.0	Severe inflammation

Probing measurements

The probe pocket depth and of clinical attachment level are measured with a custom acrylic stent on the selected teeth by Williams graduated periodontal probe.

A custom acrylic occlusal stent will be fabricated with cold-curing acrylic resin for each patient cast in to be placed on the selected teeth.

A groove is made on the acrylic stent so that the probe can be inserted into the pocket in a standardized access point before surgery and during subsequent appointments after surgery.

Probing pocket depth (PPD)²¹

The depth of the pocket will be evaluated using a William graduated periodontal probe from the tip of the marginal gum to the base of the pocket using the William graduated periodontal probe and the recording will be entered into the customized proforma made for the study.

Custom acrylic stents are held in place in prepared casts to minimize distortion and capture measurement for 3 months, 6 months, and 9 months post operatively²¹.

Clinical Attachment Level (CAL)²²

The customized acrylic stent will be placed on the selected teeth and the probe will be gently inserted along the hole on the acrylic stent and the space from the apicle edge of the acrylic stent to the gingival margin will be measured and recorded. This distance will be added to the probing pocket depth to determin CAL.

RADIOGRAPHIC PARAMETERS

Intraoral periapical radiovisograph (RVG) of individual defect site will be taken using long cone paralleling technique. Exposures will be made at 70KVP, 8ma; 0.6 sec. with inherent filtration of 2 mm AL. radio visual graphs with XCP holder will be used.

The radiographs will be taken by the same radiologist in the entire course of the study to minimize errors.

Criteria for radiographic measurement²³

“The cementoenamel junction, the alveolar ridge and the base of the defect (BD) are marked as reference points on the radiography. BD is defined as the most coronal point where the periodontal ligament has a continuous width. If the periodontal ligament space is not identifiable, the point where the alveolar border intersects the root surface is used. If the two structures cannot be identified in a defect, the reference point defined by the periodontal ligament is taken as the base of the defect and the intersection of the contour of the alveolar ridge with the root surface is defined as the alveolar ridge. If multiple bone contours can be identified, the most apical junction of the root is defined as the base of the defect and the most coronal as the alveolar crest.”

Cone Beam Computed Tomography (CBCT) will be obtained for 3 dimensional assessment of bone fill.

All radiographs will be evaluated at baseline, 6 months and 9 months postoperatively.

Radiographic Evaluation

“Defect fill will be calculated by calculating the difference between the distance between CEJ to base of the defect at baseline and distance from CEJ to base of the defect 6 months and 9 months post surgery.”

Surgical Intervention

Selected individuals will be instructed regarding plaque control measures and full mouth scaling and root planing will be performed. Reevaluation and recording of clinical and radiographic parameters will be done after 4 weeks after initial therapy.

Subjects will be selected randomly and categorized into 3 groups. A total of 36 bone defects samples will be randomly assigned to two groups:

Group I–12 defects will be treated with open flap debridement.

Group II –12 defects will be treated with resective osseous surgery.

Group III – 12 defects will be treated with Autogenous bone graft.

Group I

After administration of local anaesthesia a full thickness flap will be elevated and scaling, root planning and debridement will be performed at recipient site. Osseous recontouring will be done with the help of rotary and hand instruments . The graft will be shaped if needed to fit in to

defect. Flaps and donor site will be closed by interrupted sutures (3-0 silk) and protected by non eugenol periodontal dressing.

Group II

After administration of local anaesthesia a full thickness flap will be elevated and scaling, root planning and debridement of defect will be performed.

Flaps will be closed by interrupted sutures (3-0 silk) and protected by non-eugenol periodontal dressing.

Group III:

After administration of local anaesthesia a full thickness flap will be elevated and scaling, root planning and debridement will be performed at recipient site. A vestibular incision will be given in labial vestibule mandibular symphysis will be adequately exposed and Autogenous bone will be harvested. The graft will be shaped if needed to fit in to defect. Flaps and donor site will be closed by interrupted sutures (3-0 silk) and protected by non eugenic periodontal dressing.

Potential subjects are informed that their participation is voluntary and informed consent is obtained in writing from those who agree to participate.

Benefits and risks of participation:

Participating individual will be investigated and treated for periodontal disease.

Risk involve intraoperative and post operative complications resulting from administration of local anesthesia and periodontal flap surgery and harvesting of autogenous bone including swelling, trismus, pain, hemorrhage from surgical procedure.

Statistical analysis:

“The t-test of independent samples will be used for the intergroup comparison of cases. The subjects are randomly divided into two groups, so that the difference in response is due to treatment (or lack of treatment) and not to other factors.”

The Paired-Samples t test will be applied for intergroup comparison of the two variables. Difference will be considered significant when p value <0.05.

Limitations:

Histological evaluation of treatment outcomes is not possible due to ethical considerations. Further follow up will be required to assess long term stability of results.

Expected Outcome:

Proposed approach can shift the preferred treatment approach of hemiseptal periodontal defect from resective to regenerative procedures.

Implications:

Periodontal hemiseptal defects are treated with resective osseous surgery which lead to complications such as esthetically unpleasant appearance, gingival recession, hypersensitivity, root caries etc. proposed treatment approaches attempt to treat such defects with regenerative approach which will prevent above mentioned complications and enhance long term prognosis.

Discussion:

Regenerative procedures are lately focused on 2 and 3 walled defects³. Initial studies have reported some amount of bone formation in defects with less regenerative potential such as craters and hemiseptal periodontal defects. Hemiseptal defects prove difficult to treat regeneratively because of their non contained nature and less source of regenerative cell to populate the area because of presence of only one boney wall, hence preservation of wound space and repopulation of cells for regeneration is not considered feasible.⁴

To best of our knowledge two case reports have been published reporting successful regeneration on periodontal hemiseptal defects^{18,19} moreover recently it has been used in animal models and to test and efficacy of bone grafts and has reported regeneration²⁴⁻²⁷.

Autogenous bone graft is regarded as gold standard and is osseoinductive in nature. Pieces of autogenous bone shaped according to defect morphology will be non collapsible and along with its osseoinductive property and presence of bone cells, author propose it can compensate for non contained nature and lack of source of regenerative cell due to presence of only one boney wall in periodontal hemiseptal defects.

Gingival index will be used to record soft tissue response. Probing pocket depth and clinical attachment level are standardized by customized acrylic stent for reproducibility of measurement site.

RVG is used for screening and evaluation of bone formation. Cone beam computed tomography which has been reported to be highly accurate when compared to intraoperative measurement of periodontal defects²⁷⁻²⁹ will be used to confirm the diagnosis and record the changes during follow up period.

The authors of this protocol aims to comprehensively investigate possibility of regeneration on periodontal; hemiseptal defects compare the outcome with established treatment modalities such as Open flap debridement and resective osseous surgery.

Trial Status: Post intervention follow of study subjects is being conducted.

Abbreviations: “RVG-radiovisiographCBCT- conebeam computed tomography, PPD-pocket probing depth, CAL-clinical attachment level.”

Competing interests: Authors declare that there are no competing interests.

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