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Role of Polylactic-Polyglycolic Acid (Plga Co-Polymer) In Maintaining Alveolar Height and Width Following Extraction of Teeth.

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ABSTRACT

Background: This study was undertaken to consider the successful use of biodegradable osteosynthetic graft material polylactic- polyglycolic acid sponge as biodegradable root replicas which is placed as immediate implants in extraction socket to preserve the dimensions of alveolar process. **Methods**: A split mouth study was conducted on 20 patients who were selecte for orthodontic extraction of 1st and 2nd premolar teeth in the outpatient department of Oral and Maxillofacial Surgery, Peoples College of Dental Sciences and Research Centre, Bhopal from 1st January 2010 to 31st December 2010. One socket in each patient was randomly selected as test site (T) in which polylactic-polyglycolic acid sponge (Alvelac®) was inserted and the contralateral socket was taken as control site (C), which was allowed to heal naturally. **Results**: The test and control sites were evaluated preoperatively and postoperatively. Measurements recorded with regards to clinical (bucco-palatal width and height of the alveolus) and radiologically (mesio-buccal, mid buccal, disto-buccal). Clinical and radiological measurements shows there is a statistically significant decrease in bucco-palatal width and height of the alveolus on the control site as compared to that of the test site. Analysis of CT SCAN shows greater bone density on test site. **Conclusion**: The use of PLGA scaffolds (Alvelac®) significantly reduces the bone resorption both in height and width of the extracted socket. The quality of bone preserved when PLGA scaffolds is used, is of good quality to retain implants.

Keywords: PLGA scaffolds (Alvelac®), tooth extraction socket, alveolar socket preservation.

INTRODUCTION

Alveolar bone is a specialized part of mandibular and maxillary bone that forms the primary support for teeth. It is composed of bundles of bone, which is built up in layers in a parallel orientation to the coronal apical direction of the tooth. Alveolar ridge defects and deformities can be the result of trauma, periodontal disease, surgical treatment or congenital maldevelopment. Alveolar bone is resorbed after tooth extraction or avulsion most rapidly during the first year.[1]

The use of osseointegrated prosthesis has become an important treatment mode in edentulous patients. The prerequisite for an expected long-term prognosis of such implant surgery is the presence of sufficient volume of healthy bone at the implant recipient site, a requirement that depends on the nature of post extraction healing and rehabilitation of the alveolar process.[3] The remolded alveolar process cannot properly accommodate cylindrical implants, thereby causing functional and esthetic problems of implant restoration. Therefore it is essential to maintain or achieve the original dimensions of the alveolar process for successful long- term outcome of the treatment.[2]

In order to preserve the alveolar width, height and contour of the alveolar process, various prophylactic and post extraction therapeutic measures have been attempted with varying outcomes. The post extraction therapeutic measures include (a) physiologic preservation of alveolar process by retention of the natural roots (b) application of prefabricated semianalogus root form implants, and (c) modified version of guided

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tissue regeneration (GTR) techniques. In the latter alloplastic bone substitute and bone or bone derivatives of isogenic, allogenic and xenogenic have been used as osteoinductive and or osteoconductive materials.[2]

Based on the successful use of biodegradable osteosynthesis devices in the internal fracture fixation in maxillofacial and orthopaedic surgeries. Suhonen et al hypothesized that custom made biodegradable root replicas placed as immediate implants in extraction socket could preserve the dimensions of alveolar process.[2]

Considering the successful use of biodegradable osteosynthetic graft material polylactic-polyglycolic acid sponge, this study was undertaken.

Aims and objective

This study aims to examine the utility of PLGA (Alvelac®) root replica for alveolar preservation in extraction socket.

The objective of this study is to assess the following

1. Study the role of PLGA in the preservation of alveolar width.
2. Study the preservation of alveolar height.
3. Assess the quality of bone formed radiologically when PLGA is used.
4. To assess the adverse effects of PLGA when used for alveolar preservation

MATERIALS AND METHODS

This study was undertaken in the outpatient department of Oral and Maxillofacial Surgery, Peoples College of Dental Sciences and Research Centre, Bhanpur, Bhopal, on patients who reported for extraction of teeth from 1st January 2010 to 31st December 2010.

All patients enlisted were educated regarding the procedure and explained that they were part of a clinical trial. The ethical clearance for the study was provided by an institutionally approved ethical committee.

Sample Selection

The study comprised of split mouth study on 20 patients who were selected from patients referred for bilateral orthodontic 1st and 2nd maxillary premolar tooth extraction to the outpatients department of Oral &Maxillofacial Surgery, People's College of Dental Sciences &Research Centre, Bhopal. The selected patients aged between 15-30 years. One socket was randomly selected as test site (T) in which polylactic-polyglycolic acid sponge (Alvelac®) was inserted and the contra lateral socket was taken as control site (C), which was allowed to heal naturally.

Case Selection Criteria

Inclusion criteria

1. Maxillary 1st and 2nd premolar teeth, indicated for orthodontic extraction.
2. Teeth removed atraumatically.
3. Absence of infection.
4. Patients aged between 15 to 30 years.
5. Systemically healthy patients.

Exclusion criteria

1. Transalveolar extraction.
2. Periodontitis.
3. Tooth avulsion due to trauma.
4. Patients suffering from immunocompromising diseases like Diabetes, osteoporosis, AIDS, Leukemia etc.
5. Patients on any medication which could potentially interfere with bone healing .

Materials

Bioscaff Alvelac®: 100% biodegradable and osteoconductive copolymer made of polylactic co-glycolic acid (PLGA) manufactured by BSI (Bio-scaffold International) was used at the test site [Figure 1 & 2].

Surgical Procedures

Tooth extraction was done carefully, preserving the alveolar bone around the teeth. The socket was then gently flushed with sterile saline. Haemostasis was achieved.

The socket was measured with measuring devices (supplied by the manufacturer) to ensure snug fit of the gauge at the crestal level of alveolar bone. Correct size of Alvelac®. Alvelac® was gently pushed into the socket till it engaged the socket at the crestal level of the socket with the help of applicator end of the measuring device. Horizontal mattress suture was placed over the wound with 4-0 Vicryl® suture without tension. Patients were instructed to apply gentle pressure on the gauze pack over the operated site for a period of 30 minutes. The patients were recalled on the second and tenth days following surgery. Subsequently, patient was seen every 4 weeks to examine the soft tissue status and it was followed up to next 3 months.

Methods of colllection of data

Clinical measurement Width: Pre-operatively bucco-palatal width was measured with the help of Castroveijo calliper at the level of alveolar crest.

Height measurement (Distance between alveolar crest and gingival margin):

1. For measurement of height, pre-operatively an acrylic splint was fabricated over both sides of jaw in the region of teeth to be extracted, which rested on the occlusal surface of the adjacent teeth.
2. The acrylic splint was trimmed to exactly the gingival margin of the tooth to be extracted preoperatively. All measurement were obtained from the lower edge of splint to the height of the healing alveolar crest.

Radiological measurement

Pre-operative intra oral periapical (I.O.P.A) radiograph of the area was obtained. The radiograph were obtained using the paralleling technique to eliminate bias due to radiographic elongation or foreshortening.

The radiograph obtained was traced. This tracing was used to record the measurement of height of the alveolar socket. A standard line was drawn by joining 10 mm above the deepest part of alveolar crest of two adjacent teeth (i.e. from one mesial and one distal teeth adjacent to extracted tooth). 3 perpendicular lines were drawn from this standard line to (a) mid-buccal region (b) mesial region (c) distal margin of the alveolar crest of the extracted tooth. The length of these lines were the radiographic (a) mid buccal (b) mesio-buccal (c) disto-buccal height of the alveolar crest

All measurements were recorded preoperatively, immediate preoperatively, 10th day, 1st month, 2nd month and 3rd month. The preoperative, postoperative (10th day, 1st month, 2nd month and 3rd month) measurements were compared and the differences were statistically analysed.

A CT denta scan was performed on one patient to check the results for accuracy.

The results were compared using a Student's unpaired 't' test.

RESULTS

A split mouth study was conducted on 20 patients who were selected from patients referred for bilateral orthodontic 1st and 2nd maxillary premolar tooth extraction to the outpatient department of Oral & Maxillofacial Surgery, People's College of Dental Sciences & Research Centre, Bhopal. One socket in each patient was randomly selected as test site (T) in which polylactic-polyglycolic acid sponge (Alvelac®) was inserted and the contralateral socket was taken as control site (C), which was allowed to heal naturally.

The test and control sites were evaluated preoperatively and measurements recorded with regards to width (bucco-palatal, clinical) and height of the alveolus (clinical and radiographic). The procedure conducted was similar for both the sites and similar postoperative regimen followed. Postoperatively the same measurements were recorded at intervals of 10 days, 1 month, 2 month and 3 months. The results obtained was compared and the following observations were made.

Clinical bucco-palatal (B-P) width measuements outcome

The results of the measurements obtained with regards to the clinical bucco-palatal width of the extracted sockets are shown in [Graph 1]. This data reveals that there was no statistically significant difference between the the test site and the control site in the immediate postoperative period and after 10 days following the procedure. However, 1 month following the procedure, there is a statistically significant decrease in bucco-palatal width of the alveolus on the control site as compared to that of the test site. This difference indicates that there is higher preservation of bone in the bucco-palatal width in the test site as compared to that of the study site.

Clinical height measuements outcome

The results of the measurements obtained with regards to the clinical height of the extracted sockets are shown in [Graph 2]. This data reveals that there was no statistically significant difference between the test site and the control site in the immediate postoperative period and 10 days following the procedure. However, 1 month following the procedure, there is a statistically significant decrease in distance between original alveolar crest and healing gingival margin, on the study side as compared to that of the control. This decreases shows that there was significantly lower loss of bone in the test site as compared to that of control site.

Radiological height measuements outcome

Mesio-buccal (M-B) height measurement outcome

The results of the measurements obtained with regards to the Radiological height of the extracted sockets are shown in [Graph 3]. This data reveals that there is no statistically significant difference between the the test site and the control site in the immediate postoperative period, after 10 days and 1 month following the procedure. However, 2 month following the procedure, there was a statistically significant differences seen between the test and control site. This data reveals that bone height increased in the test site from its initial measurement and bone height decreased in the control site as compared to its initial measurement.

Radiological disto-buccal (D-B) height measurements outcome

The results of the measurements obtained with regards to the Radiological height of the extracted sockets are shown in [Graph 4]. This data reveals that there was no statistically significant difference between the the test site and the control site in the immediate postoperative period, after 10 days and 1 month following the procedure. However, 2 month following the procedure, there was a statistically significant differences seen between the test and control site. This data reveals that bone height increased in test site from its initial measurement and bone height decreased in control site as compared to its initial measurement.

Radiological mid-buccal height measurement

The results of the measurements obtained with regards to the Radiological height of the extracted sockets are shown in [Graph 5]. This data reveals

that there was no statistically significant difference between the the test site and the control site in the immediate postoperative period , after 10 days and 1 month following the procedure. However, 2 month following the procedure, there was a statistically significant differences seen between the test and control site. This data reveals that bone height increased in test site from its initial measurement and bone height decreased in control site as compared to its initial measurement.

CT Scan Analysis

CT scan was done to verify the study findings in only one patient at different time interval preoperative, 10 days after extraction of teeth, after 1 month, 2 months & 3 months. Preoperatively CT analysis revealed slightly higher bone density on left side as compared to right Side. It was decided to place Alvelac® on right side. 10 days after extraction of teeth, we found slightly greater bone density on test site as compared to control site. After 1 month and 2 months, the same was observed. After 3 months slightly more bone density was found on test site as compared to control site, but the differences was not much appreciable.

Both clinical, radiological measurements revealed that polylactic-polyglycolic acid (PLGA - copolymer) (Alvelac®) helps in maintaining/preventing alveolar bone loss after extraction of teeth. CT denta scan also confirmed the above findings.

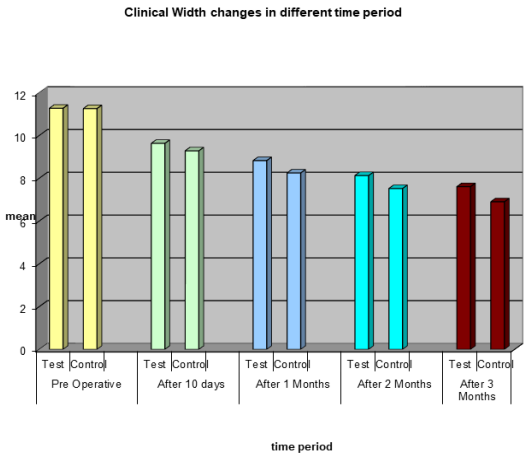
Figure 1: Alvelac® (Polylactic co glycolic acid copolymer scaffold).

Figure 2: Correct size alvelac® placed at the level of alveolar crest.

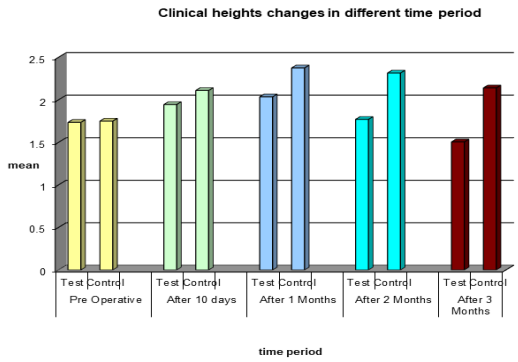
Fig 3: Alvelac®.

Figure 4: Measuring device.

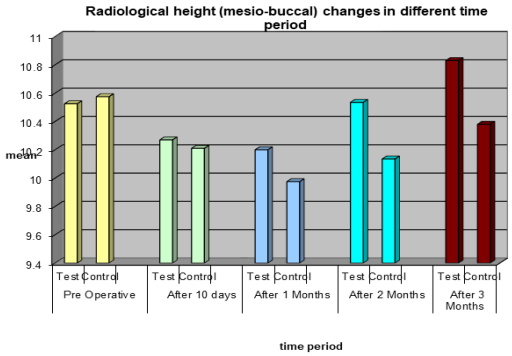
Figure 5: Axial view ct denta scan (Rt: test side, Lt: control side).



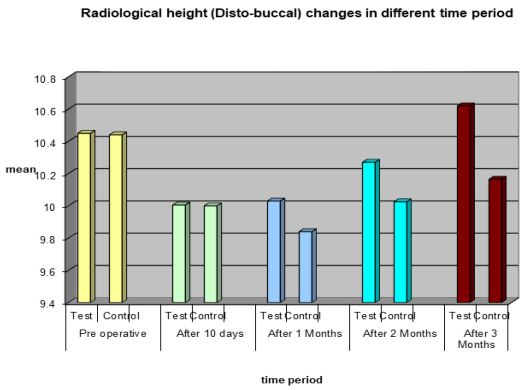
Graph 1: Clinical Width changes in different time period



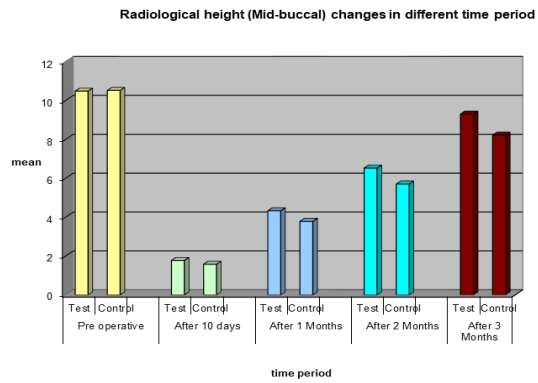
Graph 2: Clinical heights changes in different time period



Graph 3: Radiological height (mesio-buccal) changes in different time period



Graph 4: Radiological height (Disto-buccal) changes in different time period



Graph 5: Radiological height (Mid-buccal) changes in different time period

DISCUSSION

With the advent of Implant dentistry, bone maintenance or augmentation in alveolar sockets prior to the placement of dental implants is a frequent goal in current restorative dentistry. Bone tissue engineering methods have used several synthetic materials as grafting materials into defects of several bones. Although the ideal bone graft should be osteoinductive and nonantigenic, the majority of the available biomaterials have questionable osteoinductive properties. For this reason, a number of osteoconductive materials have been tested both in animal and human studies.[3]

Grafts materials include autogenous bone, allografts, xenografts, and synthetic materials.[4] Bioceramic materials including calcium phosphates such as tricalcium phosphate and hydroxyapatite, as well as calcium carbonate, are widely used for synthetic bone grafting.[3] Synthetic polymers of resorbable polylactic (PLA) and polyglycolic (PGA) acids, each alone or both combined in different proportions, are applied as mini-screws, membranes, mini-plates, and as bone substitutes.[3]

Poly (lactic) and poly (glycolic) acid copolymers are bioabsorbable material and they overcome some of the limitations of non-resorbable membranes, such as the need for a second surgical procedure for their removal. The bioresorption process, resulting in total elimination of the material, comprises an in vivo degradation by a hydrolytic reaction, resulting lactic and glycolic acids, eliminated through physiological mechanisms.[5]

Lekovic et al. (1998),[6] reported that healing of extraction sites seems to occur with different degrees of bone resorption, which can be partly prevented by the use of resorbable membranes made of glycolide and lactide polymers. However, the use of the membrane technique may present some clinical disadvantages such as (1) difficulty in obtaining the complete coverage of the membrane, which may eventually be exposed to the oral environment and consequently be colonized by bacteria.

For this reason in our study we used PLGA copolymer in the form of scaffolds for socket grafting after extraction of teeth and sutured the socket with vicryl® suture material. In spite of not giving any type of coverage, we did not encounter infection in any of our cases.

Serino G et al (2003),[6] had done a study to (1) evaluate whether alveolar ridge resorption following tooth extraction could be prevented or reduced by the application of a bioabsorbable polylactide-polyglycolide sponge used as a space filler, compared to natural healing by clot formation, and (2) evaluate histologically the amount and quality of bone tissue formed in the sockets, 6 months after the use of the bioabsorbable

material. The biopsies harvested from the test sites revealed that the new bone formed at 6 months was mineralized, mature and well structured. Particles of the grafted material could not be identified. The results of this study indicate that alveolar bone resorption following tooth extraction may be prevented or reduced by the use of a bioabsorbable synthetic sponge of polylactide-polyglycolide acid.

The same was observed in our study, we observed both clinical and radiological gain in bone height in test site and loss of bone in control site. Although there was reduction in bucco-palatal width after extraction in both sites i.e. test and control site, but the degree of reduction in width was less in the test site as compared to that of the control site. CT scan in one case also revealed greater bone density in the test site as compared to that of control site.

Ana Vitoria Imbronito et al (2004),[7] evaluated ultra structurally the healing pattern of bone defects filled with a copolymer of polylactic/polyglycolic acid (Fisiograft®), with the purpose to ultra structurally analyze how the bone forms around the graft material. They concluded that the copolymer of PLA/PGA studied appeared to be an osteoconductive material when it is used to fill bone defects.

P.N. Ramchandran Nair et al (2004),[8] conducted a clinical, radiographic and histologic follow up of alveolar socket healing in 8 human cases in which the extraction sockets of the involved teeth were treated with biodegradable root replicas. They found that 2 forms of root replicas were biocompatble and biodegradable, but the compact solid form may cause an initial temporary lactic acid induced decalcifiation of the alveolar process, which makes it unsuitable for regular clinical application as compared to the granular porous form.

From the results of our study, we performed clinical and radiographic study of PLGA in extraction socket and during this study we did not encounter any complications. This demonstrates that it is biocompatible, biodegradable and osteoconductive material. Clinically, we found statistically significant differences in measurements of height and width between test and control site in only after 1 month. Radiologically, we found the statistical differences in measurements of height between test and control site after 2 month. Results showed greater gain in height and lower width resorption in test site as compared to control site. CT SCAN confirmed greater bone density in the test site as compared to the control site after 3 month.

R. Gunaseelan et al (2010),[9] conducted a study which focused on comparing the healing and bone quality after using two different approaches to ridge preservation in the mandibular arch. Bioscaff Alvelac®, a resorbable PLGA scaffold was evaluated clinically in comparison to Xenograft. The results indicate better bone density in sockets with the scaffold compared to those sockets which were grafted using a Xenograft. In order to confirm the observation, the bone microarchitecture was evaluated using a micro CT. We also found the similar findings in CT scan after 3 months.

The results of this study indicate that loss of alveolar bone height and width following tooth extraction was lower in the sockets where a bioabsorbable synthetic sponge made of polylactide and polyglycolide acid was inserted compared to what was observed in the tooth extraction socket where natural healing by clot formation was permitted

CONCLUSION

The following conclusions may be drawn

1. Without placement of any support material, a significant degree of alveolar resorption will occur. This could cause difficulty in the future placement of implants.
2. The use of PLGA scaffolds (Alvelac®) significantly reduces the bone resorption both in height and width of the extracted socket. There by providing adequate bone for the placement of wider implants.
3. The quality of bone preserved when PLGA scaffolds is used, is of good quality to retain implants.
4. The placement of PLGA scaffolds is very simple and can be easily mastered and performed in a dental setup. The use of measuring device will greatly assist in measurement and placement of the scaffolds, though it can be performed without it also.

However, it should be noted that PLGA scaffolds adding significantly to the cost of treatment.

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