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After tooth extraction, the extraction socket heals by forming a blood clot which leads to the formation of new bone within 3-4 months. Although bone deposition in the socket will continue for several months, it will not reach the crestal level of the neighbouring teeth (Fig. 1). The resulting alveolar bone loss may lead to problems such as poor aesthetic appearance and difficulty in placement of implants or protheses for partially or totally toothless patients (Fig. 2). Various techniques have been proposed to limit alveolar bone loss such as atraumatic extraction, immediate post-extraction removable prosthesis, immediate placement of dental implant and immediate bone-filling of extraction socket. Guided bone regeneration (GBR) and guided tissue regeneration (GTR) has been gaining attention in recent years for repair of bone defects and had been used in patients after tooth extraction with the aim of preserving alveolar bone. However, none of the currently available solutions work on the principle of providing a strong mechanical support that is also bio-inert. The need for such a design gave birth to the development of Alvelac™, a strong, yet porous synthetic polymer-based bio-scaffold which has degradation rates matching that of natural bone healing and bone remodelling process. The bio-scaffold is made of PLGA (Poly lactic co-glycolic acid) material and acts as a mechanical support to hold the blood clot at the crest level (Fig. 03).

To analyze the efficacy of the bio-scaffold for alveolar socket preservation, a multi site clinical trial was initiated and bio-scaffold used in post-extraction sockets of patients analyzed over 12 weeks with dental OPG.
SUMMARY OF CLINICAL TRIAL RESULT

RADIOGRAPHIC ASSESSMENT OF BONE REGENERATION IN ALVEOLAR SOCKETS WITH PLGA BIO-SCAFFOLD (BIOSCAFF™ ALVELACT™) AFTER TEETH EXTRACTION

Clinical trial.gov registration no: NCT00836797

Objective: To assess the effectiveness of ridge height preservation with Alvelac™ after tooth extraction.

Trial Site: A multi-site clinical study at the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, National University Hospital, Singapore, in collaboration with the Saveetha University, Chennai, India.

Procedure: OPGs were taken at 1st week, 8th week and 12th week. Bone height differences were measured between the 1st week and 12th week to determine height gained, lost or neutral.

Sample Size: Final report: seventeen cases and sixteen controls with seven dropouts.

Results: Out of these seventeen cases (Blue bars in Fig. 1), nine cases (53%) show height gain, three cases (18%) shows insignificant height loss (height preservation) and another five cases (29%) shows minimum height loss compared to the controls. All the controls (Red bars in Fig. 1) show height loss after 12 weeks.

Result Analysis:
Statistical analysis by SPSS (statistical analysis software) showed that, the mean difference of bone gain/loss (+/-) between two group is 1.69mm which is significant based on the Mann-Whitney U test conducted (p < 0.0005). The medians of bone loss were 0.06mm (range -1.01 to 1.81) for cases with scaffold and -1.80mm(range -3.09 to -0.18) for controls without scaffold. This confirms the clinical trial hypotheses of bone height preservation with the scaffold in the alveolar socket.

Out of the nine cases that showed bone height gain, we analyzed one patient (random pick) to see how the height gain was achieved.

“This summary clinical report is not for circulation as it has been submitted for international publication”
This case showed a bone gain of 0.84mm after 12 weeks. It was an upper right 1st premolar and an atraumatic extraction was done with forceps. After extraction, socket size was measured with a perio probe and bio-scaffold size was selected. Bio-scaffold was placed buccopalatally at the alveolar crest level and secured in place with two interrupted sutures. This case showed very good healing and after 12 weeks, it showed 0.84mm of bone gain. It demonstrates that proper bio-scaffold placement can help in achieving bone height gain. One explanation for the height gain could be due to the bio-scaffold being placed higher than the alveolar crest level measured at 1st week. This could well be the case to explain those cases where there were height loss, i.e. bio-scaffold was placed lower than crest level at 1st week.

**Conclusions:**
Bio-scaffold successfully preserved height after the tooth extraction. The result shows statistical significance in preserving alveolar bone height with the placement of a rigid bio-scaffold. The bio-scaffold material exhibited excellent biocompatibility with no significant reactions at the placement site. The PLGA bio-scaffold, Alvelac™, demonstrated a high degree of osteoconductive capabilities favouring the regeneration of bone tissue. The placement of the bio-scaffold higher in the socket could explain the height gain of the nine cases. Overall 71% shows good height preservation or better results.

*"This summary clinical report is not for circulation as it has been submitted for international publication"*
Though the clinical trial successfully concluded the efficacy of bio-scaffold in preserving the alveolar bone socket height, however, the density of the bone could not be assessed through the x-ray analysis and a different method of analysis was required. To achieve that goal, bone was harvested from one of the bio-scaffold preserved site and underwent a conventional histopathological examination. To be more assured, a micro CT analysis method was further adopted to show the micro structure of the bone in a 3D model to show the quality and density of the analyzed bone. This was a new testing method of assessing the bone density and we had to be assured of its effectiveness. So a joint collaboration was initiated with Xradia Inc, Concord, CA, USA and the finished project was presented at 3 different international Symposia –

• European Symposium on Calcified Tissues, Barcelona, Spain 2008.
• European Tissue Engineering Symposium, Poland, 2008
• European Symposium on Calcified Tissues, Barcelona Spain 2009.

The project clearly showed the evidence of good bone density and structural quality in a 3D model through the effective use of micro CT. Below are the posters presented at the Symposia -

“BIO-SCAFFOLD YIELDS A GOOD SOCKET BONE DENSITY”
Bone sample was harvested from a bio-scaffold preserved site and assessed through micro CT scan and was compared against the normal histopathological slides. Micro CT successfully confirmed the evidence of good bone density and proved its effectiveness and power of detailing in a 3D model.
**Abstract**

The current study is focused on developing a new rapid non invasive 3D imaging technique for bone quality, bioscaffold, cartilage and its related drug efficacy evaluation. Bone quality evaluation is critical in patients suspected with osteoporosis or those treated with synthetic scaffolds for restoration of bone. Similarity success of synthetic scaffolds depends much on the micro architecture of the scaffold. These evaluation plus those involving cartilage thickness in osteoarthritis are mainly carried out with conventional histology, which requires experienced personnel and time consuming sample preparation techniques. In addition, histology studies can take up to a few weeks, results are often operator dependant, and are only available as individual 2D slices. While in recent years there are several publications on the use of microCT for such evaluation, the biggest deficiency of conventional microCT is the lack of contrast and resolution to detect fine microstructures on bones and low Z (low contrast) bioscaffold materials and soft tissue. It is also not possible to image cartilage without contrast enhancing agents.

In the current work we have used a novel microCT system for rapid virtual histology in 3D for bone quality, cartilage and scaffold microchannel evaluation to submicron pixel resolution, without contrast agents. Examples using human and murine bones will be illustrated, including a clinical study involving a human cancellous bone after bioscaffold implant and its comparison with conventional histology.

**Methods**

Four different samples are used in this study to test the use of the novel microCT as a possible means for rapid 3D imaging technique for bone quality, bioscaffold and microchannel evaluation. These includes:

1. Human Cancellous Bone extracted from a dental alveolar socket after placement of bioscaffold for 4 months in the socket
2. Rat knee joint for cartilage imaging in Osteoarthrosis
3. Resorption Pit Assays for Osteoporosis
4. Bioscaffold microchannel and microporosity evaluation after fabrication and post processing.

The patient had a placement of bioscaffold (fig 4) in the socket after extraction for about 4 months within which sufficient bone volume was achieved in the socket. Patient opted for an implant placement and a bone piece was harvested from the proposed implant site to ensure bone quality and absence of any inflammation. The bone sample was analyzed both using conventional histology and microCT which is shown in the Figures 2&3.

 caractizing 3D Microchannels in Bioscaffolds

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**Results & Discussion**

**Human Cancellous Bone Quality Evaluation**

**Evaluation of the bone sample shows trabecular bone structure with a cortical layer similar to Type III bone structure suited for implant placement.**

**Characterizing Cartilage Thickness without Contrast Agent in Murine Model**

**Evaluation of cartilage degeneration in osteoarthrits using murine model is possible with a microCT (only with contrast agents), with a MRI or conventional histology. The novel high contrast CT can image cartilage structure and its bone interface quickly with no sample preparation agent (fig 5 & 6) [2]. Fig 5 compares the novel CT imaging at low and high resolution and the equivalent images from MRI and conventional histology. MRI are typically very low resolution, while conventional histology generally takes 3 weeks to prepare.**

**Characterizing Bone Resorption pits in Osteoporosis Assays**

**From the above figures and discussion, it is evident that the novel microCT is an effective tool for characterizing any solids with very low attenuation factors including human cancellous bones, murine cartilage and bones and resorbable bio-scaffolds non-invasively. As microCT technique also requires little or no sample preparation thereby minimizing the time required while preserving the integrity of sample and information required. It is therefore envisioned that this technique could supplement conventional histology for these assays in preclinical and possibly clinical applications.**

**References**


RAPID TECHNIQUE FOR BONE QUALITY & OSTEOCYTES LACUNAE EVALUATION USING A NOVEL MICROCT WITH HISTOLOGY RESOLUTION

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1Bio-scaffold International Pte. Ltd, Singapore; 2Xradia Inc, Concord, CA, USA

Abstract

The current study is focused on developing a rapid technique to compare and evaluate bone quality and osteocyte lacunae distribution in human and murine bones in high resolution comparable to histology. We will present results in regenerating human maxillary jaw bone sample comparing a novel resorbable bioscaffolds and those obtained from enograft sources in dental implants. Preliminary results of the 3D distribution of osteocyte lacunae network and its relationship to its canal network will also be shown using the cortical bone of a lactating mouse.

Conventional histology studies can take up to a few weeks, results are often operator dependant, and are only available as indidual 2D slides. While in recent years there are a number of publications on the use of MicroCT for bone quality evaluation, conventional histology is still vastly inadequate compared to histology. It is also not possible to characterize the distribution of osteocyte lacunae sample in laboratory based micro or nanoCTs.

In the current work we have used a novel microCT system for rapid virtual histology in 3D for bone quality, and osteocyte ultrastructural evaluation at submicron resolution and without contrast agents. Results are comparable to some existing studies using micro and nanotomography in synchrotron radiation.

Methods

Bone Quality Evaluation: BioOss vs Bioscaffold

It can be seen from the above pictures that Micro CT is able to clearly identify the osteocytes and the compact bone and even to the extent of remnants of PLGA scaffold with similar resolution if not better than the conventional histopathology. In addition to it, the Micro CT is able to distinguish between type of bone and stages of healing when different grafting materials were used. In addition to this, the power of 3 D Micro CT is its ability to render 3 D image with clear indication of bone density distribution and soft tissue presence across the three dimensions which is not possible wit conventional histology.

Osteocyte lacunae and canal network: cortical bone, lactating mouse

The above image shows the Micro CT of cortical bone of a lactating mouse. It clearly shows the removal of bone in the canal network and absence of osteocytes. The 3 D rendered image shows compact bone (cortical) at the edges while the central region shows the canal network.

Conclusion

From the above figures and discussion, it is evident that the novel microCT is an effective and noninvasive tool for bone quality and osteocyte lacunae-canular matrix evaluation. With this technique the relative effectiveness of the different scaffold materials for bone regeneration can be established quickly. With submicron resolution where osteocytes lacunae can visualized clearly could help us understand how these cells respond to strain and regulate bone remodeling. This is turn will lead to new bone therapeutics to prevent bone loss resulting in fracture.

References

[3] Tiffany Fong, Application Lab, Xradia Inc, Concord, CA, USA

Results & Discussion

Bone Quality Evaluation: BioOss vs Bioscaffold

Bone Quality Evaluation: BioOss vs Bioscaffold

Fig 2 Images on the top rows are CT slices of BioOss implant showing lack of new bone growth while images in the bottom row shows new bone regeneration through evidence of osteocytes, which the lighter regions shows compacted mineralized bones

Human Bone Quality Evaluation: microCT vs Histology

Fig 5 microCT slice of bone sample @ 1 µm resolution, compared with conventional histology.

Fig 6 microCT slice of lactating bone sample @ 0.5 µm

Fig 7 3D rendered image of lactating mouse bone showing osteocyte lacunae and canal network microCT slice of lactating bone sample @ 0.5 µm

Fig 3 3D render image comparing BioOss (left) and Bioscaffold (right). There is greater presence of soft tissues in the bone sample grafted with bioscaffold

Fig 4 MicroCT 3D image of Bioscaffold regenerated bone sample @ 1 µm resolution

Fig 1: Apparatus: schematic of the novel microCT with unique high resolution and high-contrast optics

The apparatus used for this study (Fig 1) is based on the Xradia’s MicroXCT[1], which is capable of submicron detector pixel resolution. Unlike conventional MicroCTs which uses point projection technique where resolution is limited by source spot size and its sample-source distance- resolution of the novel microCT is not dependant on these parameters. Relatively large biological materials of several mm diameter may be imaged to <1 micron resolution. With PhaseEnhanced™ optics, significant increase in contrast is realized, making it possible to image inherently low contrast samples such as cartilage and biomaterials without contrast agents.

For ultrastructural evaluation of Osteocytes lacunae and its canal network using the microCT, a piece of cortical bone about 500 microns in diameter was prepared from a lactating mouse. The sample was scanned with the microCT and preliminary results are shown.
MICRO CT ANALYSIS OF HUMAN BONE

With the confirmation of micro CT usefulness to show bone quality and density, it was used to analyze one case where the bone was harvested during the implant placement after 5 months of scaffold socket preservation (Fig. 01 & Fig. 02). The case is presented below with conventional histopathology (Fig. 03) and novel micro CT analysis (Fig. 04) showing a very healthy, natural and normal bone through bio-scaffold socket preservation.

Histopathological Report:
“L.S sections taken from trephine column of bone removed from the tooth socket grafted with PLGA (Poly lactic Co Glycolic Acid) 6 months back show part cortico-cancellous bone and many interconnecting trabeculae of new bone formed in association with small pieces of PLGA materials which undergoing varying stages of degradation and being replaced by new bone (woven bone) associated with previous cancellous bone. There is also demonstrable conversion of woven bone in to lamellar bone/mature bone with the trabeculae of woven bone. Bony section shows almost no or few inflammatory cells within the marrow spaces. No sign of bony resorption have taken place but rather layers of new bone seen to be forming in some places around the degrading PLGA materials. There is however a foci of PLGA associated with inflammatory infiltrate.”

Micro CT Report:
The upper top left slide (Fig 04: 4a) is taken from the top part of the specimen sent and shows good and compact bony structure. The upper top right slide (Fig 04: 4b) was taken from a side of the specimen and also shows very compact bony that resembles a normal bone. The lower left slide (Fig 04: 4c) was taken from the opposite side of the specimen and also shows the same result. The lower right picture (Fig. 04: 4d) is presenting the 3D view of the specimen itself which shows a cancellus good bony pattern that can be compared with any healthy good quality bone.

After going through all the different level micro CT pictures, we can confidently say that the specimen scan shows good cancellus bony structures of spongy nature that resembles a normal healthy bone. At closer examination we also can identify the spongy characteristics of the bone with its bone marrow space and the havertian system.

So overall the bony specimen proves to have the same consistency and structure as that of a healthy normal bone.
A positive control comparison trial with xenograft

After confirming the bone quality and density, a positive control comparison with other socket preservation procedure with conventional bone grafting materials was arranged. Xenograft granules are the most popular bone grafting product that is used widely in dentistry. In spite of the necessity for a surgical procedure for xenografting, it is being used as a socket preservation option. The efficacy of bio-scaffold over xenograft in terms of bone growth and regeneration capability was compared over the period of 3 month.

A clinical case study is being conducted by Dr R. Gunaseelan of Rajan Dental Institute, Chennai, India involving 10 patients with bilateral extraction in the same patient. 3 patients have already completed the trial and another 7 will be done soon.

One completed case was presented as a poster at the National Oral and Maxillofacial Scientific Conference held at Kochi, India, in November 2009. It was showed and concluded from the analysis of this case that compared to xenograft, synthetic bio-scaffold is able to assist the natural healing process better and provides a better bone quality while preserving the ridge after extractions in the anterior segment.

Materials and method:
Patients who have requirement of removing two teeth in the same ridge (mandible/maxilla) were selected and in one socket PLGA bio-scaffold was used while the other socket was packed with a xenograft widely used for grafting applications which is used as an alternative in socket preservation. The xenograft was filled into the second socket and was closed with a collagen membrane. The OPG radiograph was taken immediately after extraction of the teeth with the bio-scaffold and the xenograft placed in the other socket. In order to get a better picture of healing, a bone sample was extracted from both the socket and was examined using a novel micro CT technique which gives a 3D picture of the bone.

Result:
Bone sample retrieved from socket grafted with xenograft shows a lack of new bone growth while scaffold preserved site demonstrates new bone regeneration through evidence of osteocytes. Sample extracted from the socket preserved using bio-scaffold shows compact mineralized bone. The socket with the bio-scaffold had natural bone with the osteocytes while the bone sample from the socket which had xenograft shows lack of osteocytes.

(1a) Upper left picture showing packed xenograft granules after 3 months.

(1b) Upper right picture showing resorbing bio-scaffold after 3 months.

(1c) Lower left picture is showing granule surface with very few osteocytes.

(1d) Lower right picture showing scaffold surface with osteocytic activity.
Abstract

The current study is focused on comparing the healing and bone quality after using two different approaches to ridge preservation in the mandibular arch. The study also highlights the recent development of rapid techniques to compare bone quality in regenerated human bone using resorbable bio-scaffolds and those obtained from using HAP/TCP or xenograft and allograft sources in dental alveolar sockets. Conventional methods use analysis of healing using a OPG which gives very little information on the bone quality. Despite developments such as Dental C T , it is very difficult to assess the bone quality and most of the implant procedures are done based on assessment of the surgeon. Implant stability is largely dependent on the bone quality and currently most common method of assessment is using histopathological assessment. Conventional histology can take up to a few weeks and the results are often operator dependent. Moreover, the results are only as available as individual 2D planes and so many planes are required from the bone sample before making a decision on the quality of the bone. In the current work, we have used a novel Micro CT with histology resolution and superior contrast as a rapid means to evaluate bone quality in 2D and 3D between bone samples extracted from patients who used a synthetic resorbable bio-scaffold against conventional grafting materials.

Methods

In the current study, patients who were having multiple extractions in the same jaw were selected and after the tooth extraction, the alveolar sockets were treated with two different solutions. One of the sockets was grafted with commercially available xenograft and covered with a membrane while BioScaf® AlveoLift™ (a synthetic scaffold made of polylactic acid) was placed and was closed with a simple interrupted suture. The OPG of the patient was taken immediately after the procedure and was subsequently followed up after 3 months. Figure 1 and 2 shows a typical OPG taken on the patient immediately after placement of scaffold grafting the socket size and after 3 months.

For ultrastructural evaluation of Osteocytes lacunae and its canal network using the Micro CT, a piece of cortical bone about 500 microns in diameter was prepared. The sample was scanned with the Micro CT and the results are shown below.

Results & Discussion

Bone Quality Evaluation: Xenograft vs BioScaffold

It can be seen from the above pictures that Micro CT is able to clearly identify the osteocytes and the compact bone and even to the extent of remnants of PLGA scaffold with similar resolution if not better than the conventional histopathology. In addition to it, the Micro CT is able to distinguish between the type of bone and stages of healing when different grafting materials were used. In addition to this, the power of 3 D Micro CT is its ability to render 3 D images with clear indication of bone density distribution and soft tissue presence across the three dimension which is not possible with conventional histology.

Introduction

After tooth extraction, the extraction socket heals by forming a blood clot which leads to the formation of new bone within 3-4 months. Although bone deposition in the socket will continue for another 3 months, it will not reach the critical level of the neighbouring teeth. The resulting alveolar bone loss may lead to problems such as poor aesthetic appearance and difficulty in placement of implants or prostheses for partially or totally toothless patients. Various techniques have been proposed to limit alveolar bone loss such as autogenous, immediate post-extraction removal, immediate placement of dental implant and immediate bone-filling of extraction socket. Guided bone regeneration (GBR) and guided tissue regeneration (GTR) have been gaining attention in recent years for repair of bone defects and has been used in patients after tooth extraction with the aim of preserving alveolar bone. In the current work, two different methods of ridge preservation techniques is compared for the healing and quality of bone regenerated after grafting.

Conclusion

From the above figures and discussion, it is evident that the synthetic Bio-scaffold is able to better assist the natural healing process and provides a better bone quality while preserving the ridge after extractions in the anterior segment. The posterior segment indicates new bone growth but needs further analysis to yield conclusive evidence. Micro CT provides a good insight in to the bone healing and the bone quality in 3 dimension compared to conventional histopathology.

References

CASE STUDIES

To gather more clinical evidences, case studies are continuously conducted. Dentists who are using bio-scaffold for their patients were welcome to share their cases as a form of case study. Presented below are some of the case studies with bio-scaffold socket preservation.
CASE STUDY 01

A female patient aged 34 came for an extraction of the right lower first molar due to endodontic treatment failure. Extraction was done with forceps. After the extraction, bio-scaffolds were placed horizontally in the extraction site engaging the buccal and lingual walls. Subsequently, the buccal and lingual flaps were sutured using vicryl suture. X-ray was taken at one week follow up and sutures were removed. Healing was good with no complains and patient was advised for the next follow up in two months.

Second and third month follow ups showed normal tissue contour at the extracted site with no scarring effect or tissue defect (Fig. 01).

The patient came back after five months for implant placement at the healed site. At fifth month, the same site showed good bony contour with well maintained height and width with no bony defects (Fig. 02 and Fig. 03).

To assess the bone quality of the healed socket site, a sample of bone was trephine out from the healed socket area for histopathological examination and micro CT (Fig. 04).

The histopathological slides were made in the histopathology laboratory, Faculty of Dentistry, NUH, Singapore and the report was given by A/P Yeo Jin Fei, Head of the OMS Department, NUH, Singapore (Fig. 05). The histopathological report shows cortico-cancellous bone with many interconnecting trabeculae of new bone formed in association with small fragments of PLGA bio-scaffold materials while undergoing varying stages of degradation and being replaced by new bone associated with previous cancellous bone. Section shows almost no or few inflammatory cells within the marrow space.

The micro CT of the trephine bone (Fig. 06) shows normal healthy bony structure similar to that of the normal bone (Fig. 07).

After the bone piece was trephine out, an implant (Fig. 08) was placed at the same prepared site with good initial stability.

Conclusion: Use of bio-scaffolds in the socket after extraction helps to promote good healing. The bio-scaffolds also helped to preserved the height and width of the alveolar ridge after 5 months with very little residue of bio-scaffold material at the site. The quality of bone was good and healthy at the post socket site after 5 months.
CASE STUDY 02

A male patient of age 38 had a fractured 11 which was root canal treated and restored with a post crown. The tooth was fractured transversely and subgingivally. Fractured post crown and remaining tooth was beyond salvage (Fig. 01). There was an existing apical lesion from the failed root canal treatment and could be seen in the OPG. Patient oral hygiene was bad with lots of plaques and calculus.

An OPG was taken before extraction clearly showing the apical lesion (Fig. 02).

Extraction was done and the coronal portion was removed first. The root was extracted atraumatically with periotomes (Fig. 03).

Socket was cleaned of all infected debris (Fig. 04) and bio-scaffold was placed horizontally at the crestal level (Fig. 05). Healing was good after a week and suture was removed. There was no complicacy or complains from the patient.

The patient came back after 10 month for a follow up visit as he was planning to have implant for his missing 11. While the patient’s oral hygiene continues to be bad, it was however clear that the extracted socket showed minimal height loss as seen in the picture (Fig. 06). Width loss was observed to be insignificant and is likely to be due to the patient’s early apical infections and bad periodontal condition.

Due to financial situation, patient is still waiting for a suitable time for his implant restoration.

Conclusion: Bio-scaffolding of this extracted 11 preserved the height of the socket and also prevented severe collapse of width of the socket despite having an apical infection and periodontal conditions.
CASE STUDY 03

A female patient of age 59yrs came to the clinic with periodontically involved two upper central incisor and the teeth were beyond salvation (Fig. 01). An OPG was taken before extraction clearly showing the condition of the teeth and surrounding bone which was not so good (Fig. 02). The bone height is already far below the cervical margin and only half or so socket was remaining. So to preserve the remaining socket bone, socket preservation was done with Alvelac™. An atraumatic extraction was done with periotomes and 21 was removed first followed by 11 (Fig. 03 & Fig. 04).

Sockets were cleaned of all infected debris and bio-scaffolds were placed horizontally at the crestal level (Fig. 05). Two 3.5×4.0mm bio-scaffolds were used which resembles the width of the socket at crest level (Fig. 06).

Healing was good after a week and suture was removed. There was no complicacy or complain from the patient. The patient came back after seven months for a follow up visit (Fig. 07) as she was planning to have implant for her missing 11 and 21. At seventh month re-entry, the alveolar ridge height is almost at the same level as the time of extraction though there was a bit of height loss at the 21 site (Fig. 08). The thickness of the ridge was compromised at the time of extraction and now it is just suitable for a 4×11mm implant (Fig. 09).

As the thickness of the ridge was compromised, there was some labial exposure of implant threads and needed bone grafting. Xenograft was used for grafting and was covered with a resorbable membrane (Fig. 10). Mucoperiosteal flap was replaced and sutured with 3.0 vicryl. An immediate denture was given to restore the aesthetic look of the patient (Fig. 11).

Conclusion: Bio-scaffolding of extracted 11 and 21 preserved the height of the socket and also prevented severe collapse of width of the socket despite having a very bad periodontal condition and bone resorption.
CASE STUDY 04

A female patient of age 70 had a fractured 45 which was grossly carious. The tooth fractured vertically and was beyond salvage, thus extraction were performed (Fig. 01). Other then the fracture, there was an existing apical lesion seen in the OPG (Fig. 02). The patient’s oral hygiene was moderate. OPG was taken before and after extraction (Fig. 03).

Extraction was done and the tooth was extracted atraumatically with periotomes. Socket was healthy with normal bleeding and blood clot. Socket was cleaned of all infected debris (Fig. 04) and bio-scaffold was placed vertically at the crestal level (Fig. 05). Healing was good after a week and suture was removed. After 3 weeks, bio-scaffold was visible with good soft tissue healing (Fig. 06). There was no complicacy or complain from the patient.

The patient came back after four months for a follow up visit (Fig. 07) as she wanted to have implant for her missing 45. Implant was placed at the end of the fourth month with good initial stability (Fig. 08).

Restoration was done at fifth month (Fig. 09) and extracted socket did not show any height loss as seen in the picture (Fig. 10). The soft tissue profile looks normal without any marked deformation and depression.

**Conclusion:** Bio-scaffolding of this extracted 45 preserved the height of the socket, prevented severe collapse of width of the socket and preserved the soft tissue aesthetic nicely for the implant restoration.
CONCLUSION

Amongst the various osteoconductive materials that are widely used, biopolymers occupy a principal position due to their relatively faster degradation and metabolisation rates compared with other synthetic substitutes. The most commonly used material includes PLA and PGA where degradation time and strength are critical. The PLGA bio-scaffold, Alvelac™, developed by Bio-Scaffold International has a typical strength of 6 MPa and a degradation time of 2-6 months. The material is biocompatible to the surrounding tissue and does not induce any inflammatory reaction or damage to the local tissue. Osteogenesis and fibrogenesis were seen in the scaffold preserved sites.

Through a well design multi site clinical trial, the efficacy and effectiveness of the bio-scaffold was proven with a statistical significance. Collaboration with Rajan Dental Institute, Chennai, India, Xradia Inc, CA, USA, has further strengthened evidences of bone quality and density after socket preservation with bio-scaffold and established the fact that Alvelac™ is a better choice for bone regeneration in alveolar socket after extraction.