10.5005/JP-Journals-10012-1090

CASE SERIES

Synergy between 3D Models and Tissue Engineering to Optimize Sinus Lift, Implant Placement and Immediate Loading in Partially Edentulous Patients

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ABSTRACT

Tissue engineering is a clinical approach toward the development of dynamic molecular delivery that can restore and improve regeneration. The 3D models and regenerative principles applied during implant guided dental surgery open new approaches for tissue constructs favoring sinus lift and implant placement.

Purpose: The aim of the present clinical study was to determine evidence that synergy between 3D models and bone regeneration utilizing autologous fibroblast growth factor (FGF) and growth factors matrices mixed with demineralized freeze-dried bone allograft (DFDBA) particles optimize tissue engineering for immediate dental implant placement and loading during sinus lift procedure.

Materials and methods: Twelve endo-osseous implants were placed into residual crestal bone (5.0 ± 0.15 mm). A minimal invasive osteotome Summer's technique was performed in combination with autologous FGF matrices mixed with FDBA particles. Soft tissue height and width were measured at baseline, 1, 3 and 6 months. Engineered bone surrounding implants was analyzed through 3D metric models for volume and contact interface from baseline to 6 months.

Results: Healing was uneventful. The surgical guide and the osteotome technique significantly contribute to the initial implant stability. Gingival soft tissue improves in color and contour. Soft tissue height and width both increased from baseline to 6 months. At 1 month, soft tissue height (STH) increase was 2.55 ± 0.30 mm (CI 95%—p = 0.001), and soft tissue width (STW) gain was 1.50 ± 0.50 mm (p = 0.001—CI 95%). At 3 months, STH increased to 3.12 ± 0.50 mm and STW gain was 2.40 ± 0.40 mm (p = 0.001—CI 95%). At 6 months, these values remained stable. Implant sites receiving autologous FGF matrices mixed with DFDBA exhibited a BV gain of 0.47 ± 0.10 cm^3—bone fill averaging 100% at 6 months (p = 0.001).

Conclusion: The osteotome Summer`s technique was a predictable technique to increase bone volume. Autologous FGF matrices mixed with DFDBA favors 3D scaffold enhancing bioguided soft tissue gain and bone engineering at implant interface. Sinus membrane perforations were favorable controlled. Guided dental surgery and three-dimensional metric applications improve surgical placement, mechanical support, clinical performance and patient cost/benefit satisfaction. Further studies with a larger sample are needed to enhance the statistical significance of our clinical findings.

Keywords: Tissue engineering, Growth factors, Sinus lifting procedure, 3D models, Implant placement.

How to cite this article: Mahesh L, Restrepo E, Restrepo MA. Synergy between 3D Models and Tissue Engineering to Optimize Sinus Lift, Implant Placement and Immediate Loading in Partially Edentulous Patients. Int J Oral Implantol Clin Res 2013;4(1):36-43.

Source of support: Nil

Conflict of interest: None declared

INTRODUCTION

Dental surgeons are frequently faced with defects in bone resulting from disease or trauma.[1-3] Bioguided tissue engineering is a novel concept of cell intelligence toward the development of biological, cellular and molecular deliveries that restore and improve biomimetic processes.[4-6] The bioengineering of tissues and organs, sometimes called regenerative medicine, is emerging as a science, as a technology, and as an industry.[7,8]

Tissue engineering is a term used to describe tissue produced in culture by cells seeded grown in various porous absorbable matrices.[9-11] Autologous fibrin matrices and growth factors grafts applied during guided dental surgery open new approaches for soft tissue repair and bone regeneration.[8,12-20] Normal healing is controlled by growth factors made in the body. The first growth factor application were described by Rita Leevy more than 50 years ago, but only in the last 15 years have scientist been able to clone and manufacture them in quantity. Researchers theorize that applying larger doses of these potent molecular constructs should speed the whole healing process.[21-23] Growth factors also play an important role in local regulation of periodontal repair and bone regeneration favoring angiogenesis, chemiotaxis and cellular proliferation and differentiation.[24,25]

A variety of materials and surgical techniques are available for tissue and bone engineering.[26-34] Bone substitutes may replace autogenous bone for sinus lift procedures and also can be used to augment bone vertically in extremely atrophic posterior maxilla.[35-40] It remains unclear whether augmentation procedures are needed at immediate single implants placed in fresh extraction sockets; however, sites treated with bone morphogenetic proteins may enhance bone formation around implants grafted, but there is not enough evidence that support the efficacy of other molecular constructs, such as growth factors grafts in conjunction with implant treatment.[41,42]

Sinus lift surgery has been used by the dental profession to increase bone volume in the posterior maxilla and currently, the treatment of choice for posterior dental implant anchorage.[43-47] Density of host bone is crucial for implant placement and stability. For some patients, implant treatment would not be an option without bone augmentation. However, the amount of alveolar bone preoperatively available for implant placement in an ideal position is often inaccurate. In most cases, the surgeon cannot tell with any certainty what structural bone quality will be available before preparing the implant site.[48,49] Bone cannot be fully understood unless conceived and analyzed in three dimensional (3D) terms. Commonly used referents may include soft tissue changes, bone volume, bone surface and bone width.[50-54]

Guided dental surgery is a concept whereby the planning and installation of an implant is controlled to achieve precise results.[55-61] A number of guided surgery possibilities exist utilizing either analogue or digital technologies.[62-65] These protocols offer a controlled treatment, reduce clinical time and provide greater safety with respect to damage involving adjacent anatomical structures.[60,66-68] The evolution in sophisticated diagnostic imaging modalities and associated software applications began in the late 1980s. As computing power increased, the ability to move from 2D to 3D data marked the beginning of a new challenge and exciting area.[69-71] Cone beam computed tomography (CBCT) data display four primary views: The axial, the panoramic, the 3D reconstructed and the cross-sectional. The standard for digital computed tomographic images is called DICOM, digital imaging and communications in medicine. Various third-party interactive treatment planning software can also manipulate the CBCT data in an ever-expanding array of capabilities to facilitate the diagnosis, treatment planning and surgical interventions.[68,72-77]

From a clinical point of view, many questions are still opened: Is there sufficient soft bone tissue to achieve an optimal result during implant placement? Is reasonable the simultaneous placement of an implant with or without hard tissue grafting? Should the hard tissue grafting be done simultaneously? What will be the best option for presurgical measurement information? What about metric accuracy? Will it be cost-effective?

The applicability of metric techniques may provide a favorable conceptualization of bone volume as well as vertical dimensions of the ridge. The aim of the present clinical study was to determine evidence that synergy between 3D models and bone regeneration utilizing autologous fibroblast growth factor (FGF) and growth factors matrices mixed with demineralized freeze-dried bone allograt (DFDBA) particles optimize tissue engineering for immediate dental implant placement and loading during sinus lift procedure.

MATERIALS AND METHODS

Twelve endo-osseous implants were placed into residual crestal bone (5.0 ± 0.15 mm). All patients were systemically healthy and have no contraindications for any surgical procedure (total of 6, 4 female and 2 male). Patients with periodontal disease, or that received any antibiotic therapy 6 months before surgery and pregnant women were excluded. Prior surgical procedure a written informed consent and voluntary acceptance was obtained according to the Helsinki, 1983 protocol.

In all cases initial periodontal therapy was performed, consisting in plaque control, oral hygiene motivation, scaling, root planning and coronal polishing. Elimination of decay and handling the occlusal trauma was included when necessary.

Integration of Visible Image, X-rays and CBCT

The 3D metric values were obtained from images models, periapical and panoramic X-rays to elaborate the surgical guide. 3D submilimetric measurements were also evaluated for soft tissue height (STH) and width (STW) from baseline, 1, 3 and 6 months (Figs 1A, C and G).

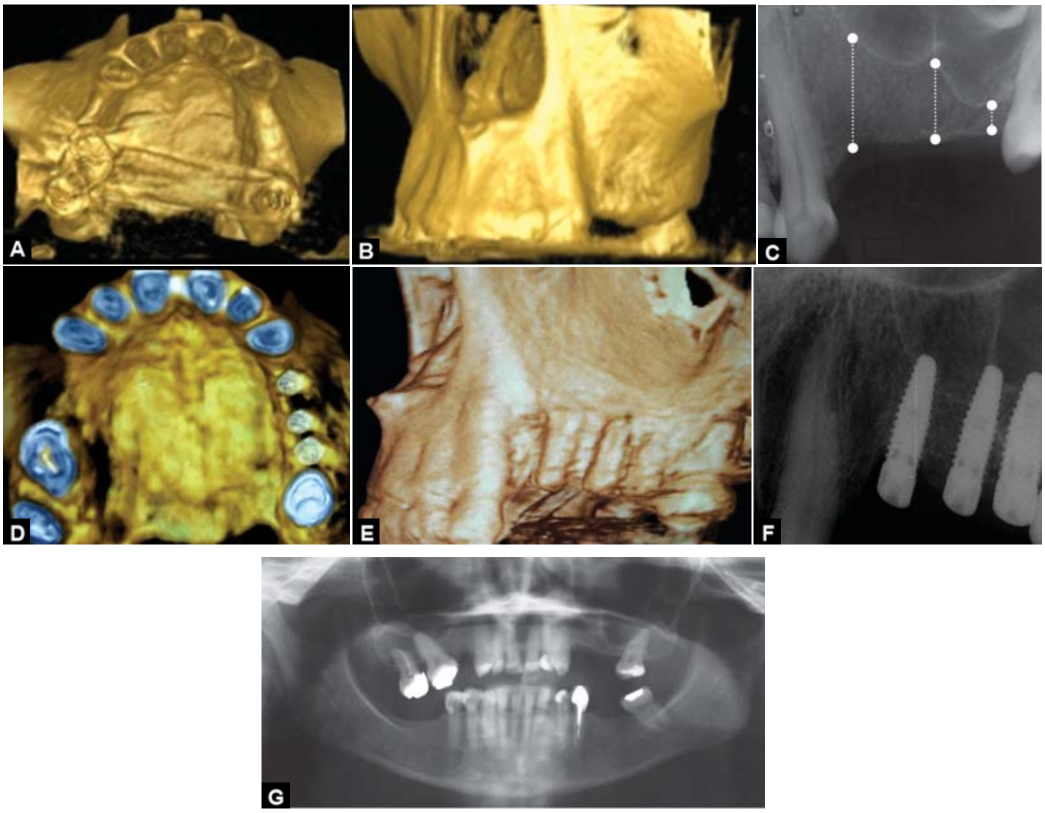
Engineered bone was measured to evaluate bone volume gain (mm) and fill (%) and, to determine surrounding bone apposition by bone contact interface (BC) during healing from baseline to 6 months.

Growth Factors Bioguided Molecular Process

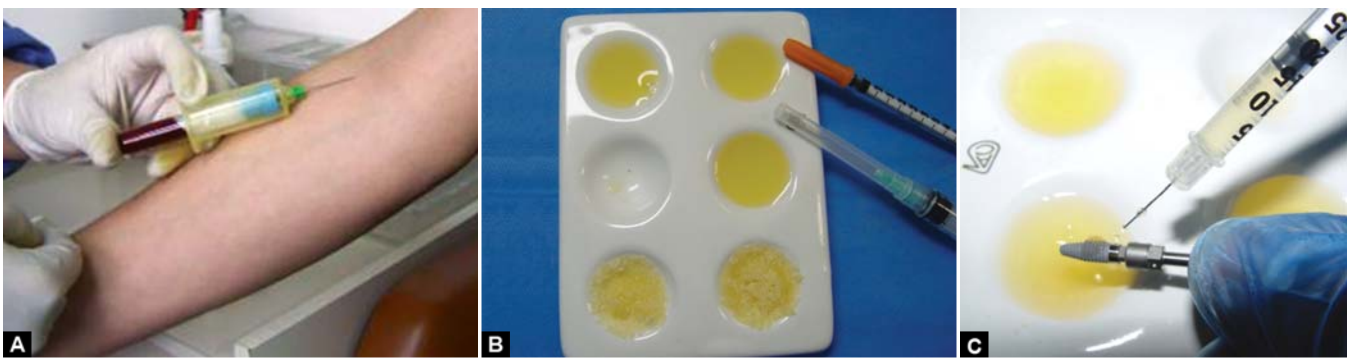
Autologous fibrin and growth factors matrices were obtained prior the surgical procedure using a vacuum collection system. A 20 ml of blood drawn from the most common point, median cubital vein which is pushed by means of a double-pointed needle into a vacuum tube (Fig. 2A). After labeling, the sample became mixed and blended for 5 minutes over a blood roller mixer. A cellular sweeping of the plasma concentration was carefully manipulated to obtain selective molecular fraction preserving platelet integrity. The jellification process begins immediately after adding 5 units volume of the ionic fraction using an insulin syringe (ionic content Mg^{++}, Zn^{++}, Na^{+}, K^{+}, Ca^{++} and Cl^{-}). Once a consistent gel texture was obtained (appx. 30 min/ room temperature) autologous FGF matrices were mixed with demineralized freeze dry bone allograft particles (1,000 microns diameter) (Fig. 2B).

Guided Dental Surgery

Twelve endo-osseous implants (4.3 × 13 mm) were placed into residual crestal bone (5.0 ± 0.15 mm) utilizing a custom fabricated cast-based surgical guide made of polymerized



Figs 1A to G: Metric models integration and image models to evaluate bone volume gain and surrounding bone apposition during healing: (A) Baseline occlusal CBCT view, (B) baseline lateral CBCT view, (C) preoperative X-ray metric analyzes to evaluate bone and soft tissue height and width, (D) postoperative occlusal CBCT view, (E) lateral CBCT view of engineered bone surrounding endosseous implants and soft tissue at 6 months, (F) postsurgical X-ray metric analyzes to evaluate endosseous implant placement, (G) initial panoramic X-ray



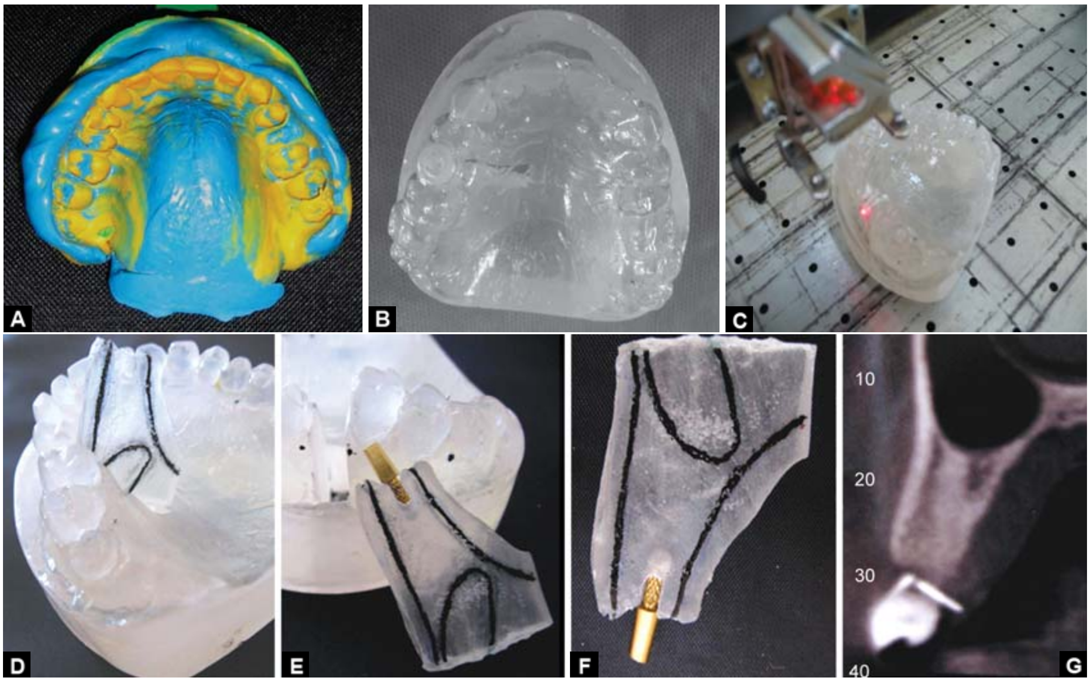
Figs 2A to C: Growth factors bioguided molecular process: (A) Autologous fibrin and growth factor matrices were obtained prior the surgical procedure using a vacuum collection system. A 20 ml of blood drawn pushed by means of a double-pointed needle into a vacuum tube, (B) autologous FGF matrices were mixed with demineralized freeze dry bone allograft particles during jellification state (C) autologous FGF in liquid state configuration were used to irrigate implant surface before implant placement

resin. Acrylic sleeves were attached to the guides for accurate implant placement in a prosthetically driven position (Figs 3A to G).

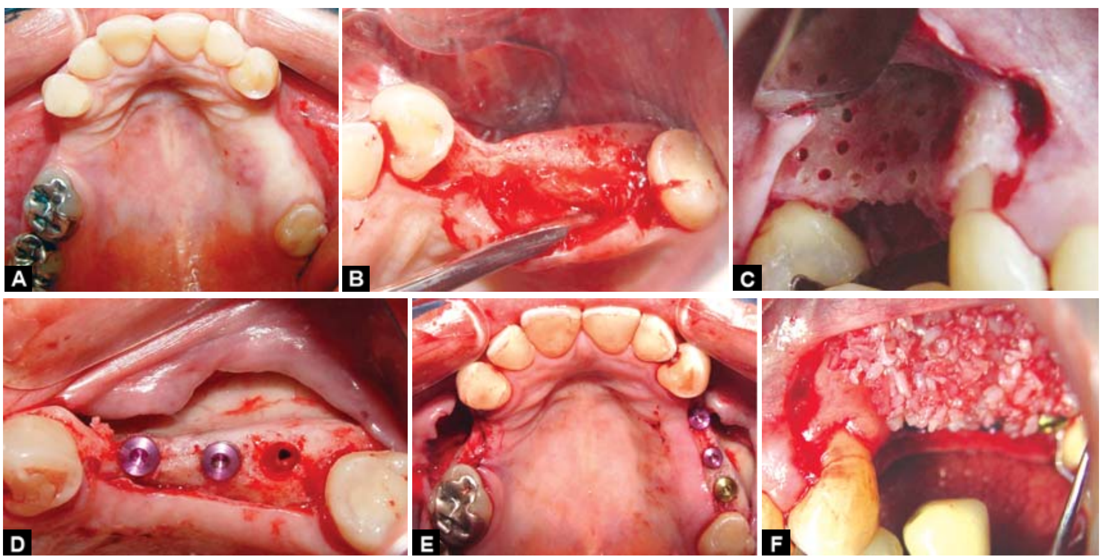
A minimal invasive osteotome Summer's technique was performed for lifting up to 5 mm from original floor height sinus. Once the osteotomy was accomplished autogenous FGF matrices were inserted and pushed inside utilizing a filler flat instrument to lift up the sinus membrane and to minimize damage to the Schneiderian membrane. Simultaneously, autologous FGF matrices mixed with DFDBA particles were applied to treat inadequate ridge morphology and/or alveolar deficiencies. Immediate loading was considered at the same surgical appointment. Implants were restored with crowns or short fixed partial dentures at 6 months (Figs 4C and F).

Statistical Analysis

All analysis was made by means of the averages estimation and its respective intervals of confidence. In addition, a statistical t-test was used to identify differences between



Figs 3A to G: Integration of visible image, X-rays and CBCT for custom cast-based surgical guide fabrication and accurate implant placement in a prosthetically driven position: (A) Silicone impression, (B) acrylic high melting model-design, (C) laser cutting and obtention of a manufacturing die, (D) die mapping based in 3D submillimetric osseous measurements, (E) pin indicator for implant position, (F) pin accurate position for implant placement, (G) soft tissues submillimetric 3D measurements



Figs 4A to F: Guided surgery for sinus lifting and implant placement: (A) Occlusal image of initial clinical overview, (B) residual bone architecture prior surgical procedure, (C) bone conditioning and bleeding to improve tissue regeneration and soft tissue adaptation (D) minimally invasive osteotome Summer's technique and sinus lifting. The sinus floor is elevated and augmented with autologous growth factor and fibrin matrices following a conservative opening created on the residual bone, (E) guided surgery and implant placement, (F) guided bone plate regeneration utilizing particulated bone allograft and autogenous growth factors and fibrin

groups and differences over time within groups. The level of significance was set at $p = 0.001$ value.

RESULTS

Sinus lift floor was a predictable technique to increase bone volume and consequently, immediate implant placement. The 12 endo-osseous implants were successfully placed into residual crestal bone (5.0 ± 0.15 mm) and the osteotome Summer's approach made a significant contribution to the initial stability of implant during placement surgery (see Fig. 4F).

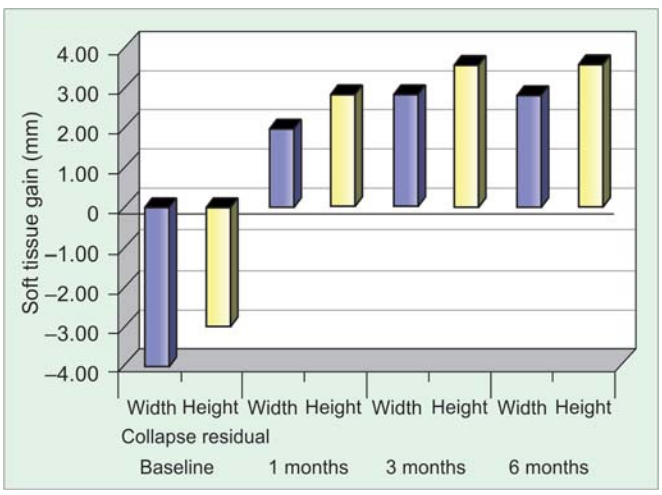
Guided dental surgery remarkable offered precise clinical results for accurate implant placement in a prosthetically driven position. The use of a well-designed clinical surgical guide improved clinical mechanical support; reduce clinical time, patient cost/benefit satisfaction and safety-respect damage involving adjacent anatomical structures (Figs 4A, B and E).

The nanostructured third-generation bioactive autologous fibrin and growth factors matrices due to is high porosity structure and plasticity properties provided suitable microenvironments for optimal recovery of bone architecture and tissue topography (Fig. 2C).

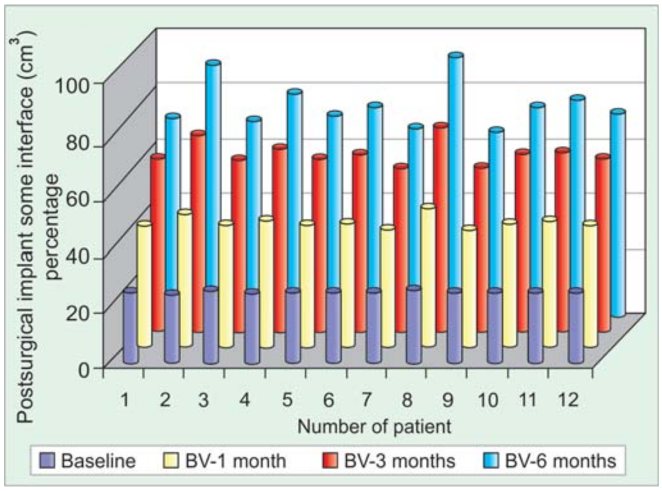
The use of autologous FGF matrices mixed with DFDBA promoted 3D scaffold enhancing bioguided soft tissue gain and bone engineering. Additionally, there were no complications related to the sinus lift surgery and sinus membrane perforations were favorable controlled (Figs 1F and 4D).

Realistic goals of submilimetric measurements highly integrate visible image models with the 3D applications and measurements. Healthy peri-implant gingival contour significantly improved esthetic results in tissue-regenerated sites. Gingival STH and STW showed a significant gain from baseline to 6 months (Figs 1A to D and F). At 1 month, STH increased 2.55 ± 0.30 mm (CI 95%—p = 0.001), and STW gain was 1.50 ± 0.50 mm (p = 0.001—CI 95%). At 3 months, STH gain increases to 3.12 ± 0.50 mm and STW gain was 2.40 ± 0.40 mm (p = 0.001—CI 95%). At 6 months, these values remained stable (Graph 1).

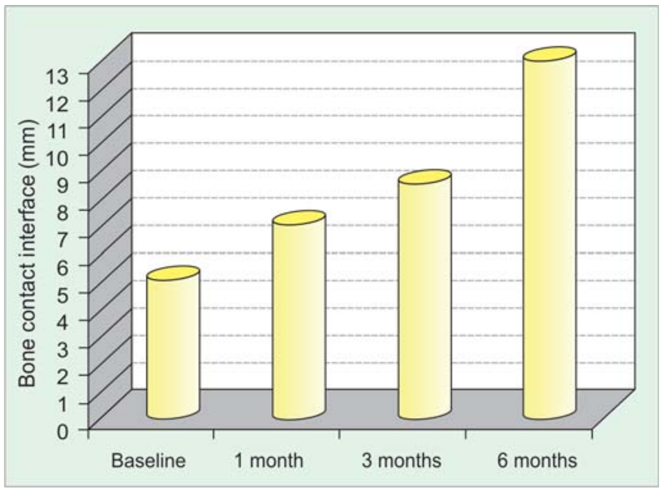
Engineered bone was determined by visualizing periapical, panoramic radiographs and CBCT readings (Fig. 1E). Implant sites receiving autologous FGF matrices mixed with DFDBA exhibited a bone volume gain of 0.47 ± 0.10 cm^3 and bone fill averaging to 100% at 6 months (p = 0.001) (Graph 2). Similar findings were found for increasing bone contact interface (baseline 5.0 ± 0.10 mm—30-40%) increased at 1 month to 5.45 ± 1.55 mm (20-40%), at 3 months 7.75 ± 0.75 mm (40-70%) and 10.75 ± 2.25 mm (70-100%) at 6 months respectively (Graph 3).



Graph 1: Soft tissue measurements: Gingival soft tissue height (STH) and width (STW) showed a significant increase from baseline to 6 months. At 1 month, soft tissue height increases to 2.55 ± 0.30 mm (CI 95%, p = 0.001), and soft tissue width gain was 1.50 mm ± 0.50 mm (p = 0.001, CI 95%). At 3 months, height increases to 3.12 mm ± 0.50 mm and width gain was 2.40 ± 0.40 mm (p = 0.001, CI 95%)



Graph 2: Bone volume: Implant sites receiving autologous FGF matrices mixed with DFDBA exhibited a BV gain of 0.47 ± 0.10 cm^3—bone fill averaging 100% at 6 months (p = 0.001)



Graph 3: Bone contact interface: At baseline, BC interface surrounding implant was 5.0 ± 0.10 mm (30-40%) engineered bone increased at 1 month to 5.45 ± 1.55 mm (20-40%), at 3 months to 7.75 ± 0.75 mm (40-70%) and to 10.75 ± 2.25 mm (70-100%) at 6 months respectively

CONCLUSION

The osteotome Summer's technique was a predictable technique to increase bone volume and consequently, for immediate implants placement. Autologous FGF matrices mixed with DFDBA favors 3D scaffold enhancing bioguided soft tissue gain and bone engineering at implant interface. Additionally, there were no complications related to the sinus lift surgery and sinus membrane perforations were favorably controlled. Guided surgery improves surgical placement, mechanical support, clinical performance and patient cost/benefit satisfaction. Further studies with a larger sample are needed to enhance the statistical significance of our clinical findings.

ACKNOWLEDGMENT

We would like to thank to individuals who contributed to the research and/or the manuscript preparation.

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