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VASCULARIZED INTER-POSITIONAL PERIOSTEAL CONNECTIVE TISSUE FLAP VERSUS COLLAGEN MEMBRANE IN GUIDED BONE REGENERATION IN HORIZONTAL RIDGE AUGMENTATION IN AESTHETIC ZONE (RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

Aim: This study aimed to evaluate the efficacy of the collagen membrane versus Vascularized inter-positional Periosteal connective tissue flap (VIP-CT) in Guided bone regeneration in horizontal ridge augmentation in the aesthetic zone in terms of radiographic outcome

Methodology: Twenty-four patients with horizontal bone defect were randomly allocated equally into two groups; the control group: (group I) underwent bone graft augmentation (autograft and xenograft) with collagen membrane fixed with suture or tacks, whereas the other group underwent bone graft augmentation, VIP-CT flap was performed and fixed over graft with sutures. Each patient was assessed pre operatively and 6 months post operatively radiographically using cone beam computed tomography (CBCT) to asses horizontal bone gain

Results: The post operative recovery and healing phase was uneventful in all patients except in one patient in group II, where infection was observed 3 days post operatively. The horizontal bone gain was significantly higher in the control group (1.82± 0.62) than the intervention group (1.12 ± 0.59), consequently there was a significant statistical difference (P= 0.01).

Conclusion: The vascularized inter-positional periosteal connective tissue flap has promising results in soft tissue and bone augmentation in the aesthetic zone as it offers a solution for type II sockets with thin soft tissue biotype in a single step.

KEYWORDS: Guided bone regeneration, vascularized pedicle flap, Collagen membrane, Horizontal ridge augmentation, connective tissue graft.

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INTRODUCTION

Extraction sockets with missing labial bone have a high tendency for volume loss, subsequently restoration of them represent a challenge particularly in the aesthetic zone. Therefore, many techniques were introduced to solve the problem of alveolar bone defects including Guided bone regeneration, ridge splitting, distraction osteogenesis, growth factors and stem cells incorporation by bone tissue engineering (BTE) [1]

Accordingly, Guided bone regeneration is specifically suitable for horizontal defects within a contained ridge defect. GBR is a surgical procedure that uses a barrier to direct growth of new bone at defect areas. Barrier membranes are an integral part of the GBR procedure. The role of membranes in GBR is prevention of soft tissue infiltration into the grafted defect. The desired characteristics of barrier membranes include; (1) bio-compatibility,(2) space maintenance, (3) ease of handling and (4) cell occlusion property. [2]

Therefore, Defects can be grafted by autograft (Intraoral or extraoral sources), xenograft (derived from animals), allograft can be taken from living donors or cadaveric bone sources [3], so ideal bone graft is to do mechanical support and motivate osteo-regeneration. [4]

Ideal aesthetic requirements for implant placement with Guided bone regeneration is often elusive. However, GBR using collagen membranes and bone substitutes do not provide sufficient volume maintenance for esthetic outcomes after implant placement in the anterior zone. Therefore, application of Vascularized flaps tends to show a higher percentage of volume maintenance during healing period compared to grafts alone. Vascularized inter-positional periosteal connective tissue flap offers several advantages over conventional collagen membranes, including enhanced vascularity, reduced cost (as it can serve as a membrane substitute), and improved soft tissue thickness.[5]**.**

So a new technique known as VIP-CT flap is alternative to other techniques because it has many advantages as minimally invasive technique, decreases treatment time, provides primary closure of donor site (palate), excellent aesthetic outcomes and maintenance of vascular supply**.(Mehta et al., 2014)**

Since VIP-CTF functioning as a replacement of collagen membranes would provide both soft tissue and bone augmentation, it is essential to assess the success of the technique using both soft tissue and bony assessment tools. Assessment of success or failure of GBR VIP-CT flap is best done after 6 months, for enough time for bone maturation. [7]

To the best of our knowledge, there is no enough evidence about VIP-CT flap and its efficiency as a barrier membrane in GBR, consequently this study aims to compare the efficacy of the collagen membrane versus Vascularized inter-positional Periosteal connective tissue flap (VIP-CT) in Guided bone regeneration in horizontal ridge augmentation in the aesthetic zone in terms of radiographic outcome.

SUBJECTS AND METHODS

This study included twenty-four patients with horizontal alveolar defects in the aesthetic zone (maxillary anterior and premolar areas) resulting from missing one or two teeth. The study was conducted between March 2023 and January 2025 at Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University, Egypt. This study was approved by the research ethics committee of faculty of dentistry with the Reference number 20123.

The patients were randomly assigned into two groups (group 1: collagen membrane fixed over bone graft) and (group 2: VIP-CT flap fixed over bone graft). The patients included in the present study had the following inclusion criteria; Patients with horizontal defect in anterior and premolar

areas of maxilla (aesthetic zone), Both genders & age (20 to 35 years), whereas the exclusion criteria; Local criteria (poor oral hygiene, radiation therapy of the head and neck cancer, intraoral soft and hard tissue lesions), Systemic criteria (Heavy smoking, Bone pathology)

This randomized study was elected to ensure that patients were randomly allocated without bias. In this study, a computer-generated sequence was used to randomly allocate the participants with 1:1 allocation ratio. Allocation concealment was implemented with sequentially numbered, opaque sealed envelopes (SNOSE). Following preoperative assessment, the envelope containing the predetermined generated sequence was opened, and the patient was randomly assigned to one of two groups; Group I comprised 12 patients with collagen membrane fixed over bone graft while Group II comprised 12 patients with VIP-CT flap fixed over bone graft. Throughout this study, both patients and outcome assessors were blinded.

Planning and surgical technique:

Cone beam computed tomography (CBCT) was ordered from all patients, then planning for bone augmentation was performed on an implant planning software*

Surgical intervention:

In Group I:

Local anesthesia was given to patients, Crestal and intrasulcular incision (around adjacent teeth), and a vertical incision were made, to achieve tension-free flap advancement, a periosteal-releasing incision was carried out internally at the apical portion of the mucogingival junction. A vestibular incision was made in the chin area. Autograft was harvested by auto chip maker bur** and mixed with xenograft with (1:1) ratio. Packing of bone graft in the deficient area and fixation of collagen membrane over graft with vicryl sutures was done(**fig1**), then the recipient and donor site (chin) were sutured by interrupted vicryl suture.

In group II:

Split thickness (sub-epithelial) dissection was made toward the palate **(fig2)**, A vertical incision was made through the connective tissue and periosteum, followed by elevation of the flap from the underlying bone (Fig. 3). Using the labial gingival flap as a base, an internal periosteal-releasing incision was performed at the apical portion of the mucogingival junction. The pedicle flap was then rotated and positioned over the bone graft material.

Fig. (1) Photograph showing packing of bone graft in deficient area and fixation of collagen membrane over it.

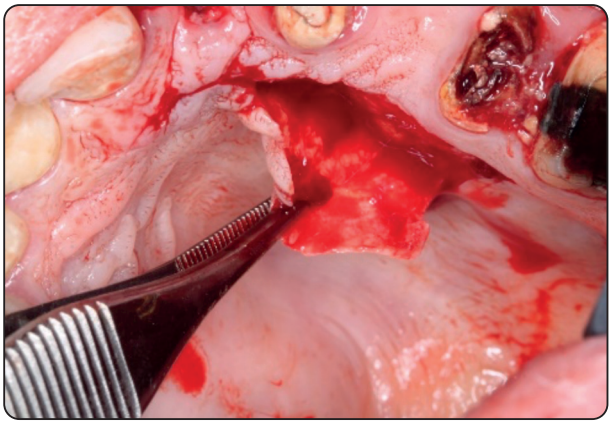

Fig. (2) Photograph showing split thickness flap reflecting epithelium.

* Blue sky plan 4, blue sky bio, U.S.A.

** ACM, Neobiotech, U.S.A.

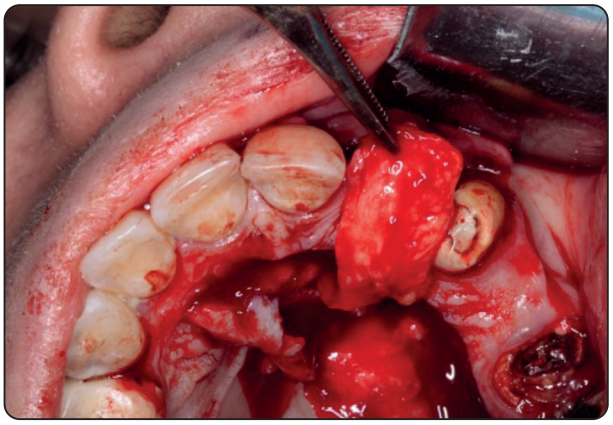

Fig. (3) Release of (VIP-CT) flap.

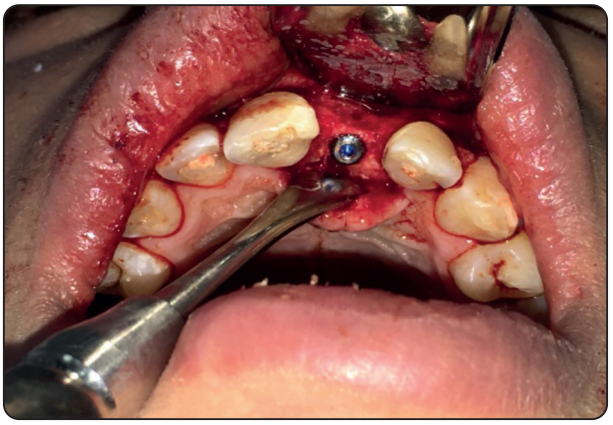

Fig. (4) Photographs showing implant placement after 6months.

Finally, the pedicle flap was sutured at the mucogingival junction by interrupted absorbable vicryl suture, and the donor site (palatal) was sutured by interrupted vicryl suture.

Second stage surgery

After 6 months, Re-entry was performed for dental implant placement in both groups**(fig4)**.

Radiographic assessment

In both groups, 6 months post operative CBCT was done to get the final bone gain horizontally and plan it for implant placement

Finally, horizontal bone gain assessment was carried by superimposition of the preoperative CBCT on 6 months postoperative CBCT by using implant planning software * **(fig5)**.

Anterior nasal spine, infra-orbital foramen and incisive canal served as anatomical landmark for alignment.

Statistical analysis

All data was explored for normality, using Kolmogorov-Smirnov and Shapiro-Wilk tests, all normal data were presented as means and standard deviation, while non-parametric data presented as minimum, maximum, median and range, all tests were two-tailed and $p < 0.05$ was considered statistically significant.

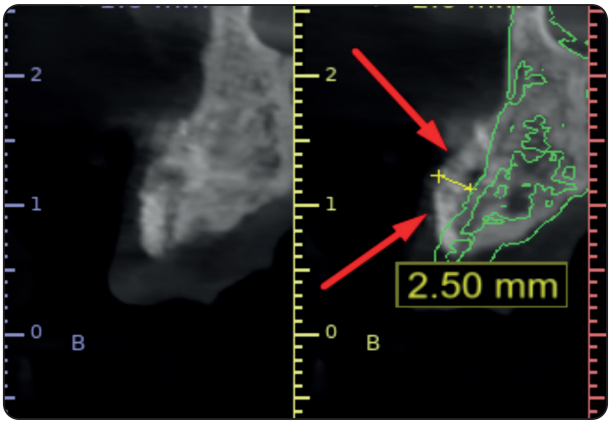

Fig. (5) Photo-radiograph showing Preoperative CBCT was superimposed on 6 months postoperative CBCT.

RESULTS

The age in control and intervention groups were presented in **Fig6**. Comparison between age in both groups was performed by using independent t test which revealed that there was insignificant difference between them (P=0.36) as control group (29.75± 5.63) was insignificantly lower than intervention group (31.75 ± 4.81) with mean difference (2.00).

* Blue sky plan 4, blue sky bio, U.S.A.

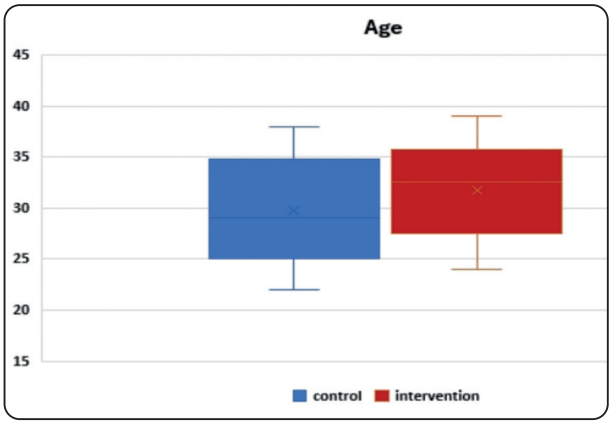

Fig. (6) Box-plot representing age in control and intervention groups.

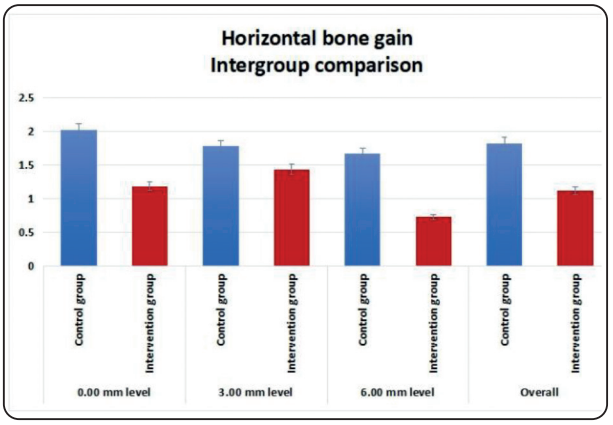

Fig. (7) Bar chart representing comparison between control and intervention groups regarding horizontal bone gain at 0.00 mm, 3.00 mm, 6.00 mm level, and overall.

Radiographic result (horizontal bone gain)

Intergroup comparison:

Descriptive results of horizontal bone gain at 0.00 mm, 3.00 mm, 6.00mm from a point drawn at the most coronal part of the crest of the augmented alveolar ridge, in control and intervention groups were presented in **Fig7:** Comparison between control and intervention groups was performed by using Mann Whitney test which revealed:

At 0.00 mm level: there was a significant difference between groups (P=0.01), as control (2.02 ± 0.85) was significantly higher than intervention groups (1.19 ± 0.63).

At 3.00 mm level: there was insignificant difference between groups (P=0.19), as control (1.78± 0.85) was insignificantly higher than intervention groups (1.44 ± 1.11)

At 6.00 mm level: there was a significant difference between groups (P<0.0001), as control (1.67 ± 0.66) was significantly higher than intervention groups (0.73 ± 0.56).

Regarding overall: there was a significant difference between groups (P= 0.01), as control (1.82± 0.62) was significantly higher than intervention groups (1.12 ± 0.59).

DISCUSSION

Implant placement in aesthetic zone is challenging, especially in the presence of alveolar ridge deficiencies which complicates the implant placement in prosthetically driven position. So, many techniques were introduced for alveolar ridge augmentation of aesthetic area; however, they have some drawbacks such as high cost and several complications. This study compared collagen membranes in GBR versus vascularized inter-positional periosteal connective tissue flap (soft tissue flap from the palate) regarding horizontal ridge augmentation; this current study aiming to decrease the cost and improve the quality of soft tissue surrounding the defect preparing the ridge for implant placement. [8]

The VIP-CT flap, first described by Sclar in 2003, is an anteriorly based pedicled flap derived from the palatal submucosa (highly vascular). It consists of connective tissue and periosteum. This flap has a random-pattern blood supply, with its rotation point located near the incisive papilla.[5]

The mucosa of palate is rich in blood supply. This blood supply is provided mainly by the descending palatine artery (greater palatine and lesser palatine). There are two branches of ascending palatine artery in soft palate and many branches of greater palatine artery in hard palate, The random pattern design

of the flap enables its rotation to cover the anterior region. Its blood supply comes from a vascular plexus formed by branches of the greater palatine artery as it approaches the incisive foramen. **(Zhong et al ., 2001)**

This study used vascularized inter-positional periosteal connective tissue flap as membrane resembling collagen membrane in guided bone regeneration as stated by Rahpeyma and could be used in socket preservation. [5]

The main advantage of this flap is the simultaneous soft tissue augmentation with bone augmentation in a single procedure during peri-implant ridge preparation as stated by Chang-Sung Kim**.** [10]

The flap is covered by the buccal flap (tension free closure), which helps preservation of the natural color and texture of the tissue, minimizing the need for additional surgical interventions. The donor site is located close to the area of surgery and typically results in minimal complications.[11]

Free soft tissue grafts require two surgical sites, their vascularity depends on the recipient bed so the chance for necrosis is increased, Free gingival or subepithelial connective tissue grafts do not improve the marginal gingiva around an exposed implant. In contrast, a pedunculated connective tissue design provides better blood supply, helping to correct ridge deficiencies and promote thickening of the marginal gingiva. **(Mehta et al., 2014)**

The collagen membrane is chosen as a resorbable material with a single-step surgical procedure, low patient morbidity good tissue integration, and low incidence of membrane exposure, The primary role of the collagen membrane is to serve as a barrier, preventing the invasion of soft tissue into the graft material. [12]

The patients were recruited for the study according to several criteria, First, the age range was from 18 to 35 years, young adult patients were preferred for their better cooperation, more aesthetics demands with higher motivation for treatment, better healing and better oral hygiene.

CBCT was imaging modality of choice for preoperative planning of the ridge augmentation procedure and for assessment of horizontal bone gain after 6 months of the augmentation due to several reasons including reduced radiation dose with clinically acceptable quality , lower cost with less scanning time compared to conventional CT.[13]**.**

As stated by Ankit Desai The chin presented several benefits as a donor site, including easy access, straightforward harvesting—even with local anesthesia—low risk of complications, and no visible scarring.[14], this was consistent with the present study, Bone augmentation using chin graft, 5-7ml corticocancellous particulate graft was obtained from this area using ACM bur . This bur was chosen because it can collect up to 1cc of autogenous bone within 10 seconds, Bone volume can be modified using various diameters. Additionally, it features a unique non-slip tip design, delivers strong cutting performance, and operates without causing vibration on any surface.[15]

The use of a three-arm trapezoidal full-thickness mucoperiosteal flap permit better exposure for the augmented area and better release of the flap to permit tension-free closure and fixation of membrane or pedicle flap with suturing.

In the past studies, the enhanced connective tissue exhibited minimal shrinkage within 2 to 3 months. Postoperative discomfort was comparable to that experienced after harvesting a free subepithelial connective tissue graft from the palate. By two months after surgery, the soft tissues had fully and satisfactorily healed, in this study, the post operative recovery and healing phase was uneventful in all patients except for one patient in group II where infection occurred in recipient site after 3 days, which was managed by administration of antibiotics and resolved after one week, **.** [11]

In the past studies, a combination of particulate autogenous and xenogenous bone graft materials,

bound together with injectable platelet-rich fibrin (I-PRF), used for the regeneration of both horizontal and vertical bone defects **(Amaral et al., 2020)**, The effectiveness of a surgical protocol for vertical and lateral alveolar ridge augmentation using a slowly resorbable bilayer collagen membrane, in combination with either a mixture of bovine graft and autograft or bovine graft alone.**(Bassetti et al., 2013)**.This result was consistent with the present study; accordingly There was radiographic evidence of bone formation after 6 months with a significant difference in the mean bone value between groups (P= 0.01), as the horizontal bone gain in control group was significantly higher than intervention group .

Our speculation for the limited horizontal bone gain in the VIP CT flap group compared to collagen membrane GBR group might be due to the nature of the flap, being pedicled, leading to limited packing of bone graft material in the bony defect beneath it

This VIP CT flap had some limitations such as inability to correct mucogingival problems, lack of long term clinical studies for graft stability assessment, soft tissue volume gain is dependent on graft size, and potential for Postoperative Shrinkage.[11 18]

In summary, hard and soft tissue augmentation is possible with the VIP-CT technique as it can protect and nourish bone grafts [5] compared with a collagen membrane used in bone augmentation only, VIP-CT improves esthetics and predictability as good blood supply, surgical skills and execution are crucial .

Finally, further studies with large sample size are recommended to asses long term stability of this technique.

CONCLUSION

The Vascularized inter-positional periosteal connective tissue flap technique results in an aesthetic prosthesis in the anterior aesthetic area; it provides the solution for type II sockets with thin soft tissue biotype in a single step (soft tissue and bone augmentation).

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Conflict of interest

The authors declare no conflict of interest.

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Ethics

This study protocol was approved by the ethical committee of the faculty of Dentistry-Cairo university on: 31.01.2023 approval number: 20-1-23

Data availability

Data will be available upon request

Clinical trial registration

The protocol for this study was registered on clinicaltrials.gov, under ID: NCT05813340

Credit statement:

Author 1:Data curation, manuscript writing and editing, original draft preparation, methodology development, conceptual design, and resource provision.

Author 2: Data curation, Conceptualization, Project administration, Supervision, Methodology, Writing - review & editing, Writing - original draft.

Author 3: data management, conceptual development, project coordination, oversight and supervision, methodological design, drafting of the original manuscript, and reviewing and editing of the written work.

Author 4: Methodology, Writing - original draft, Writing - review & editing, Investigation, Formal analysis, Supervision, Data curation.

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